IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: AQUEOUS FILM-FORMING FOAMS PRODUCTS LIABILITY LITIGATION	:	MDL No. 2:18-mn-2873-RMG
	:	**This Document Relates to:**
	:	**Case No. 2:20-cv-00257-RMG**
	:	**Case No. 2:20-cv-00209-RMG**
	:	**Case No. 2:20-cv-00301-RMG**
	:	**Case No. 2:20-cv-03181-RMG**
	:	**Case No. 2:18-cv-03438-RMG**

PLAINTIFFS' MOTION FOR CONSOLIDATED TRIAL AND TRIAL SELECTIONS

I. INTRODUCTION

Plaintiffs Michael Bien, Brock Donnelly, Alex Field, Clinton Speers and Kevin Voelker, move for a consolidated trial, and, pursuant to Case Management Order No. 26G [ECF No. 6544], request that all five (5) cases move forward for a consolidated trial. Or, in the alternative, that the three (3) kidney cancers be consolidated as the initial bellwether trial followed by a consolidated trial involving the two (2) testicular cancer cases. Plaintiffs have consistently represented that the commonality within these bellwether cases in Trial Group A supports consolidation for trial purposes.

These cases involve many common and overlapping facts regarding liability and general causation, include the *same* medical specialty (urology), are based upon the *same* common facts involving ingestion of contaminated drinking water resulting from use of the *same* aqueous film forming foams ("AFFFs") in the very same community emanating from the very same source, utilizing the *same* law (Pennsylvania), against the *same* defendants,[1] who all have virtually the

[1] While presently there are varying named Defendants in the five (5) bellwether cases, the Defendants whose products have been identified at the relevant military bases (collectively

same defenses, share many of the *same* experts, and the *same* counsel in each case. Moreover, each of these Plaintiffs were heavily exposed to PFAS as a result of residing for decades in a community identified as highly contaminated, with average PFAS blood levels in the community at large far above the national average.[2] These commonalities present good grounds for grouping these actions together for trial purposes to promote the just, speedy, and inexpensive determination of this proceeding.[3]

The multi-plaintiff trial contemplated here will benefit this MDL, which "allow[s] federal courts to 'conserv[e] judicial resources in situations where multiple cases involving common questions of fact [are] filed in different districts.'"[4] Conducting bellwether trials is "beneficial to the MDL process," because they "provide meaningful information, experience, and data to allow

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referred to herein as Willow Grove) include: 3M, Tyco/Chemguard, BASF/Ciba, Clariant, DuPont, and Carrier/National Foam/Kidde (given the bankruptcy proceeding involving Carrier/National Foam/Kidde, these entities will not be present leaving only five primary Defendants at trial all of whom are Defendants in all five bellwether cases). Notably, many of the peripheral Defendants whose products have not been identified in these cases have been served with notices of voluntary dismissal or are soon to be served by Plaintiffs' counsel and thus are also not anticipated to be at the personal injury bellwether trial. Arkema is the sole defendant named only in *Speers*. However, it is well-settled that consolidation of cases for trial despite different defendants in different cases is permissible. *See, e.g, Johnson v. Celotex Corp*., 899 F.2d 1281, 1283 (2d Cir. 1990) (affirming verdict of consolidated asbestos trial with one plaintiff against three defendants and a second plaintiff against ten defendants). It is of no moment therefore as to whether or not Arkema for example, who has asserted a jurisdictional defense in the Speers case, is successful or not in their stated desire to be dismissed from that case.

Thus, any argument that a joint trial would be too complicated due to varying Defendants clearly rings hollow.

[2] Pennsylvania PFAS Multi-Site Study, "PA PFAS Health Study Update," available at: https://papfas.rti.org/PA_PFAS_MSS_Newsletter_March_2024.pdf.

[3] *See* Fed. R. Civ. P. 1.

[4] *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Prac. & Prods. Liab. Litig. (NO II) MDL 2502*, 892 F.3d 624, 648 (4th Cir. 2018)) (citations omitted).

the parties to make an intelligent and informed decision as to the future course of the litigation."[5] Plaintiffs propose consolidation "of less than ten cases" for bellwether trial because it is recognized to be "an extremely effective tool in resolving disputes."[6] The parties, witnesses, community, and judicial system benefit from the "substantial savings of time and money that consolidation offers."[7] Moreover, Plaintiffs further propose that *Bien*, *Donnelly*, *Field*, *Speers* and *Voelker* be consolidated for trial because they are representative bellwether trial selections. Or, in the alternative, and for the reasons discussed below, Plaintiffs propose that the three (3) representative kidney cancer cases be consolidated as the initial trial.

Indeed, there is no reason that the same principles that were utilized to establish an efficient bellwether discovery process should not be applied here, and a joint trial be held. As noted in prior briefing, the bellwether discovery process was established in part to allow for a potential pathway to conduct multi-plaintiff trials by including plaintiffs with common factual and legal issues decided using only one state's law. Having a uniform choice of law removes one of the DCC's likely objections to a multi-plaintiff trial, and would also make it less burdensome and complex for the Court to instruct the jury.[8] The concept of dividing the bellwether process into two groups, *i.e.*, the Pennsylvania bellwether cases limited to cancer injuries from one exposure source under Pennsylvania law, and the Colorado cases limited to two additional *Leach* injuries (ulcerative colitis and thyroid disease), again, from one exposure source (Peterson Airforce Base) under Colorado law, created efficiency for the *discovery process*. That same concept can now provide

[5] Eldon E. Fallon, *Bellwether Trials*, UMKC Law Review,: Vol. 89: No. 4, Article 15 at 1 (2021).

[6] Francis E. McGovern, *Resolving Mature Mass Tort Litigation*, 69 B.U. L. Rev. 659, 688 (1989).

[7] *Campbell v. Boston Scientific Corp.*, 882 F.3d 70, 76 (4th Cir. 2018).

[8] Plaintiff Executive Committee's letter-brief in support of its Group A and Group B Tier 2 personal injury bellwether selections [ECF No. 5333], at 3.

the Court with the opportunity for efficiency during the *trial process* as well by conducting a joint trial involving a single state's laws, and plaintiffs that share a plethora of common facts.

Fed. R. Civ. P. 42(a) provides courts with broad authority to consolidate actions for a joint trial, including in one MDL involving PFAS chemicals, namely, *In re E. I. du Pont & Co. C-8 Personal Injury Litig.*, MDL No. 2433, before the Honorable Edmund A. Sargus in the Southern District of Ohio where two plaintiffs with different PFAS-related injuries (testicular and kidney cancer) were consolidated and proceeded in a joint trial.[9] Despite claims by Defendants of jury confusion, the jury was able to parse out the issues rendering a verdict in favor of one plaintiff, but not the other. Plaintiffs submit that exercising the Court's discretion in favor of a multi-plaintiff trial will effectuate the purpose of this MDL to efficiently conduct this litigation while minimizing the expenditure of legal and judicial resources.

For the reasons set forth below, Plaintiffs' motion should be granted.

II. FACTUAL BACKGROUND

MDL 2873 was centralized on December 7, 2018, because numerous cases asserted that AFFF had contaminated local ground water and drinking water supplies around the United States.[10] Adjunct to the mandate of 28 U.S.C. 1407, the JPML held that the actions subject to transfer shared common issues of fact:

> These actions thus share factual questions concerning the toxicity of PFOA and PFOS and their effects on human health; the chemical properties of these substances and their propensity to migrate in groundwater supplies; the knowledge of the AFFF manufacturers regarding the dangers of PFOA and PFOS; their warnings, if any, regarding proper use and storage of AFFFs; and to what extent, if any, defendants

[9] *In re E.I. du Pont de Nemours and Co. C-8 Personal Injury Litig.*, MDL 2433, Pretrial Order No. 51-A (consolidating the Swartz and Abbott trials), attached as Ex. A.

[10] *See In re Aqueous Film-Forming Foams Prods. Liab. Litig.*, 357 F. Supp. 3d 1391, 1394 (JPML 2018).

conspired or cooperated to conceal the dangers of PFOA and PFOS in their products.[11]

Similarly, the common issues of law and fact presented by these five (5) cases favor consolidation for trial:

- These cases only involve Pennsylvania law.
- The same strict liability and negligence-type claims are asserted in each case.
- The same AFFF products and their component parts are at issue in each case.
- The trial of these cases will involve the presentation of evidence from the same witnesses – i.e., testimony from the same general causation experts for the Plaintiffs, the same specific causation expert, testimony from the same corporate witnesses, the same product identification witnesses who testified to their personal use of each product at each of the military bases from which it is alleged the contamination emanated, the same fate and transport expert whose fate and transport analysis would be virtually identical for each case.
- The evidence establishing liability and punitive damages significantly overlaps as between each defendant.

All five (5) Plaintiffs reside or have resided in the vicinity of the former Naval Air Station Joint Reserve Base Willow Grove in Horsham, Pennsylvania and adjacent Warminster Naval Air Weapons Center in Warminster, Pennsylvania (collectively "Willow Grove"). The activities on those facilities regularly involved the use and disposal of AFFF for fire suppression and training. No one disputes that these AFFF products contained fluorosurfactants. These fluorosurfactants made their way into the groundwater and were transported over time to various private and public drinking water wells. Ultimately, the contaminants were distributed in a 360-degree radius to the surrounding communities, thereby contaminating multiple public water systems, including the

[11] *Id.*

three that provided drinking water to each of the Plaintiffs[12] who regularly used this water for every purpose -- from drinking water to bathing, and other household uses. Their ingestion of the contaminated drinking water is alleged to have caused their injuries. In short, this exposure to Defendants' carcinogenic products puts each Plaintiff on a similar path to injury. Thus, their individual medical histories are a distinction relevant only to their damages, not to the commonality of defect or general causation.

Specifically, Plaintiffs Donnelly, Speers, and Voelker intend to prove their respective kidney cancers were caused by exposure to Defendants' products. Plaintiffs Bien and Field also intend to prove their respective testicular cancers were caused by exposure to Defendants' products.[13] Mr. Donnelly was exposed exclusively through the Warminster Municipal Authority ("WMA"); while Mr. Voelker was exposed primarily through WMA with some exposure from Horsham Water & Sewer Authority ("Horsham") and Borough of Ambler ("Ambler"). Mr. Speers' drinking water was provided by Ambler. Mssrs. Bien and Field were exposed to Defendants' products via drinking water obtained from Horsham. To prove their exposures, each Plaintiff relies on the same experts (*i.e.*, Christopher P. Higgins, Ph.D. and Anthony Brown) to establish the fate

[12] Accordingly, the evidence regarding fate and transport would be virtually identical whether one case is tried or five (or any number in between). The hydrogeology of the area surrounding the military bases and hydrogeological pathways to drinking water sources are all interrelated. In this regard, it is important to note that Defendants may argue that trials involving multiple water districts would complicate matters. In fact, the opposite is true. It would be to a jury's *detriment* and to Plaintiffs' prejudice if the jury were to hear of and see only a partial picture of the surrounding hydrogeology. Even if it were only one Plaintiff at issue, the jurors in such a case would necessarily have to hear of the evidence of the contamination and the hydrogeology for the entire area in order to best be able to judge the evidence. Moreover, the scope of the contamination is part of the proverbial story that speaks to the conduct and potential evidence supporting Plaintiffs' punitive damages claims. Thus, an argument that a trial involving multiple water districts would *complicate* rather than maximize efficiency rings hollow.

[13] It should be noted that Plaintiff's counsel for Rodney Hartman did not submit expert reports since it was recognized following case-specific discovery that Mr. Hartman's testicular cancer claim does not qualify as an AFFF exposure case as required under CMO 26 [ECF No. 3080].

and transport of Defendants' products from their source to Plaintiffs' homes, which, as Plaintiffs note, in footnote 13, *supra*, requires discussion of the overall hydrogeological pathways in the area surrounding the military bases for a jury to best understand the underlying science. Moreover, Defendants have presented experts (*e.g.*, Russell Abell, P.G., LSP and Tiffany Thomas, PhD) to evaluate the fate and transport and distribution of PFAS within drinking water to each Plaintiff's residence and places of work in vicinages supplied by all these municipal water authorities, which importantly, puts all three (3) water suppliers at issue whether these actions were to be tried individually or jointly.

Plaintiffs anticipate that Defendants will argue that these cases are not appropriate for consolidation for a host of reasons, which may include the Plaintiffs' different medical histories, care, and treatment. These individual differences are neither surprising nor do they make the cases inappropriate for consolidation. If these arguments were to be accepted, there is no circumstance under which individual product liability personal injury cases could ever be consolidated. But that is clearly not the case. In the context of litigations involving numerous plaintiffs alleging personal injuries caused by defective products or toxic exposures, consolidated trials are an accepted procedure to conserve judicial resources, the resources of the parties, and ensure that individual cases are tried in a timely manner.[14]

[14] *See, e.g.*, *Campbell*, 882 F.3d at 76 (finding it "inconceivable" that district court abused its discretion by consolidating four plaintiffs' product liability cases for trial); *Laughlin v. Biomet Inc.*, No. ELH-14-1645, 2020 WL 1307397, at *7 (D. Md. Mar. 18, 2020) ("the existence of facts unique to each plaintiff does not preclude consolidation. Were it otherwise, consolidation would never occur in products liability litigation.") (citing *Blount v. Bos. Sci. Corp.*, No. 1:19-CV-0578 AWI SAB, 2019 WL 394387, at *4 (E.D. Cal. Aug. 21, 2019) (consolidating four transvaginal mesh cases)); *Neal v. Carey Canadians Mines, Ltd.*, 548 F. Supp. 357, 365 (E.D. Pa. 1982), aff'd, 760 F.2d 481 (3d Cir. 1985) (consolidated trial of 15 asbestos plaintiffs decided under Pennsylvania law).

As *Campbell* instructs, when causes of action involve common witnesses, identical evidence, and similar issues, judicial economy will generally favor consolidation.[15] Earlier in these bellwether proceedings, the Court pondered whether "[t]o have maybe 5 plaintiffs with fairly similar claims from a common alleged contamination source," consolidated for trial, provided it is "digestible to the jury."[16] And more recently, it has weighed having just a one plaintiff trial where defendants would "try to make that person a unicorn," against a consolidated multi-plaintiff trial, which "really focuses more on the science of whether there's causation here."[17] Plaintiffs submit that a consolidated multi-plaintiff trial of the five bellwether Plaintiffs better serves the purposes of this MDL and can be accomplished with minimal jury confusion and maximal benefit to all stakeholders.

III. ARGUMENT

A. Consolidation of the Bellwether Plaintiffs for Trial Is Appropriate

Rule 42(a) governs consolidated proceedings, and it provides:

> If actions before the court involve a common question of law or fact, the court may:
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> (1) join for hearing or trial any or all matters at issue in the actions;
> (2) consolidate the actions; or
> (3) issue any other orders to avoid unnecessary cost or delay.[18]

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[15] *Campbell*, 882 F.3d at 75-76. *See also Pariseau v. Anodyne Healthcare Mgmt*., Inc., No. 3:04cv630, 2006 WL 325379, at *1 (W.D.N.C. Feb. 9, 2006) (citing *Arnold v. E. Air Lines*, 681 F .2d 186, 193 (4th Cir.1982)).

[16] *See* Oct. 21, 2022 Status Conf. Hrg. Trans. at 6. *See also* Sept. 23, 2022 Status Conf. Hrg. Trans. at 29 ("But I wouldn't do multiple plaintiffs without having a lot of commonality on the disease processes and location. *** But it might be persuasive if there's enough differences on some of these that the jury verdicts could be very instructive.").

[17] Apr. 4, 2025 Status Conf. Hrg. Trans. at 23.

[18] Fed. R. Civ. P. 42(a).

Under controlling Fourth Circuit precedent, when considering whether to consolidate several actions for trial, this Court must consider "whether the specific risks of prejudice and possible confusion" from consolidation "were overborne by the risk of inconsistent adjudications ..., the burden on parties, witnesses, and available judicial resources posed by multiple lawsuits, the length of time required to conclude multiple suits as against a single one, and the relative expense to all concerned of the single-trial, multiple-trial alternatives."[19]

1. A Consolidated Trial Limited to the Five Bellwether Plaintiffs Will Not Prejudice the Defendants, Nor will it Confuse the Jury

All of the claims to be presented by the Bellwether Plaintiffs at trial are derived from the same conduct by the Defendants. The use of their products at Willow Grove resulted in groundwater contamination. Plaintiffs' exposures to these contaminants allegedly caused them to develop kidney or testicular cancer. Instead of five juries hearing the same evidence, Plaintiffs submit that one jury can more efficiently hear the evidence and make individual determinations of causation and damages to the benefit of all. Multiple procedural safeguards can be employed during the proceedings to avoid prejudice against the defendants and jury confusion, *e.g.*, proper *voir dire*, limiting instructions, jury instructions, special interrogatories, and verdict sheets. Several of these safeguards -- principally jury instructions[20] -- were recognized as being effective to eliminate these concerns in *Campbell* while ensuring a fair trial:

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[19] *Campbell*, 882 F.3d at 74 (quoting *Arnold v. Eastern Air Lines, Inc.*, 681 F.3d 186, 193 (4th Cir. 1982)), *rev'd on other grounds*, 712 F.2d 899 (4th Cir. 1983) (en banc).

[20] Articulating unfounded speculation about jury confusion runs counter to controlling authority. *See Opper v. United States*, 348 U.S. 84, 95 (1954) ("To say that the jury might have been confused amounts to nothing more than an unfounded speculation that the jurors disregarded clear instructions of the court in arriving at their verdict. Our theory of trial relies upon the ability of a jury to follow instructions."). Should Defendants so speculate, any inferential argument is invalid; each must be demonstrated with evidence. *Campbell*, 882 F.3d at 75.

> Of course, regardless of efficiency concerns, consolidation is not appropriate if it would deny a party a fair trial. Alert to this risk, the district court endeavored throughout the trial to limit any potential jury confusion or prejudice resulting from the consolidation. At the outset of trial, the district court instructed the jury that the trial concerned four separate claims and informed them that they must treat each as "as if each have been tried by itself." J.A. 1705–06. During the trial, BSC had the opportunity to address each plaintiff's claims independently, and in fact pursued a comparative negligence defense as to one plaintiff that it did not pursue as to the other plaintiffs. Following trial and prior to jury deliberations, the district court emphasized that the jurors were not to "even consider that more than one claim was brought" in weighing the evidence and that they must consider each case separately. J.A. 1084. To promote independent review of each case, the district court made use of special interrogatories on separate verdict forms for each plaintiff.[21]

Courts have recognized that the consolidation of cases involving personal injuries for trial is an extremely useful procedural tool with any potential prejudice overcome by consistent adjudications of common factual and legal issues and the judicial efficiencies achieved.[22]

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[21] *Campbell*, 882 F.3d at 74-75. Other courts have employed similar measures. *See, e.g.*, *Neal*, 548 F. Supp. at 383 (noting the use photographs and individual summary sheets for each plaintiff); *Blount*, 2019 WL 3943872 at *4 ("The Court concludes that any danger [of jury confusion or prejudice] that is present can be sufficiently alleviated through jury instructions and the trial process."); *Suhn v. Breg, Inc*., No. 08-4190-KES, 2011 WL 1527263, at *2 (D.S.D. Apr. 20, 2011) (noting the use of "proper questioning techniques and identification of exhibits").

[22] *See, e.g., In re Dow Corning Corp*., 211 B.R. 545, 581-89 (Bankr. E.D. Mich. 1997) (consolidating cases of 588 breast implant plaintiffs), *Suhn*, 2011 WL 1527263, at *2 (consolidation of 2 shoulder pain pump cases for trial); *McClellan v. I-Flow Corp*., No. 6:07-cv-1309, 2010 WL 11595942, at *3 (D. Or. July 23, 2010) (consolidating two sets of multiple plaintiffs' cases alleging chondrolysis caused by a shoulder pain pump). Courts have regularly consolidated for trial product liability actions involving multiple plaintiffs alleging similar injuries caused by the same products, including: "popcorn lung" arising out of inhalation of diacetyl, e.g., *Blood v. Givaudan Flavors Corp*., 2009 WL 982022 (N.D. Iowa Apr. 10, 2009); multi-defendant actions involving defective paint product, *Cruickshank v. Clean Seas Co*., 402 F.Supp.2d 328 (D. Mass. 2005); and pharmaceutical product liability actions, *Kershaw v. Sterling Drug, Inc*., 415 F.2d 1009 (5th Cir. 1969). There are also many examples of the effective use of Rule 42 consolidation in cases involving exposure to asbestos. *See, e.g., Cimino v. Raymark Industries, Inc*., 151 F.3d 297 (5th Cir. 1998); *In re: Asbestos Litig.*, 173 F.R.D. 81 (S.D.N.Y.1997); *Carpenter v. GAF Corp*., 1994 WL 47781 (6th Cir. 1994) (unpublished); *Johnson, supra*; *Neal, supra*.

Other MDL Courts have also ordered the consolidation of multiple cases specifically for purposes of "bellwether" trials in the context of MDL product liability proceedings. In *In re: Welding Fume Prods. Liab. Litig.*, MDL 1535, 2006 WL 2869548 (N.D. Ohio Oct. 5, 2006), the court concluded that the benefits of a consolidated bellwether trial of two MDL plaintiffs claiming injury under the same state law outweighed any potential risk of confusion of the jury or prejudice to the defendant. In *In re Stand 'N Seal Prods. Liab. Litig.*, MDL 1804, 2009 WL 2224185, *2 (N.D. Ga. July 21, 2009), the Court denied the defendant's motion to order separate trials for seven MDL plaintiffs who asserted similar claims involving a common product. The court there observed that based on the similarity of the plaintiffs' claims, "separate trials would require redundant testimony that is not in the interest of judicial economy." *Id*. While the court acknowledged "some risk of jury confusion and prejudice [to the defendant manufacturer]," it concluded "that risk is minimized by the straightforward nature of the Plaintiffs' claims and the appropriate use of jury instructions." *Id*.[23]

State court consolidated proceedings have likewise found joint trials appropriate. For example, in *In the Dalkon Shield Litigation* where women developed pelvic inflammatory disease ("PID") from use of the defendant's intrauterine device ("IUD"), the court of appeals in California upheld consolidation of three plaintiffs' actions based on the fact that "a large portion of the trial

[23] In ordering consolidation in *Stand n' Seal*, the court relied on *Hanley v. First Investors Corp*., 151 F.R.D. 76, 80 (E.D. Tex.1993), wherein the district court rejected the defendants' arguments of undue prejudice and potential for confusion in opposition to consolidation of nineteen plaintiffs for trial, and observed "[b]ased on the court's experience, it seems well within the jury's abilities to distinguish between the idiosyncrasies of each case." *See also Avance v. Kerr-McGee Chemical, LLC*, 241 F.R.D. 585, 587 (E.D. Tex. 2006) (denying defense motion for separate trials of five plaintiffs, each of whom resided in same residence and were thereby exposed to defendant's product – creosote and pentachlorophenol – even though exposure occurred at different times over time span of several decades and although each plaintiff suffered different injuries ranging from cancer to birth defects).

would be devoted to issues common to the three cases," and thus consolidation would avoid repetition of presentation of such evidence. *Todd-Stenberg v. Dalkon Shield Claimants Trust,* 48 Cal.App.4th 976, 980 (Cal. App. 1 Dist. 1996). Based on similar reasoning, the court in *Batson v. Lederle Laboratories*, 290 N.J. Super. 49, 55 (N.J. Super. App. 1996), found no reason to conduct two trials on the same issues. Finally, in the New Jersey state court Levaquin litigation, *In re Levaquin Litig*., Case No. 286 (N.J. Super. Law Division May 3.2011), Judge Higbee consolidated the first two bellwether cases for a joint trial.[24] Thus, examples of joint trials being permitted are plentiful, including serving as the first bellwether trial in a state court litigation.

The rationale behind these cases applies here. As the parties in these bellwether cases have all waived *Lexecon* rights, this Court has the opportunity to resolve five cases in one proceeding. While any consolidated trial harbors some risk, as these authorities show, the benefit from proceeding with one consolidated trial versus five separate trials outweighs these risks.

B. Consolidation Will Reduce the Burden on the Court, the Witnesses and the Parties

The advantages of consolidating similar cases for trial, including avoidance of repetitious presentation of facts and the consequent reduction of the burden and expense for all parties inherent in trying cases separately that involve common facts, are amplified when the number of cases exceeds the number that could reasonably be tried individually. For example, in his concurrence in *In re: Tobacco Litigation*, 218 W.Va. 301, 307-08 (2005), former Justice Starcher of the West Virginia Supreme Court observed the following with reference to the evolution of consolidated asbestos trials in West Virginia:

> Circuit courts started to try the cases one at a time, but quickly abandoned that route; trying each case would have required hundreds of years. The same lawyers

[24] *In Re Levaquin Litigation*, Case No. 286, Amended Order Consolidating Cases for Trial, attached as Ex. B.

> and the same witnesses were employed, using the same documents and evidentiary exhibits, on a full-time basis in counties throughout the State. Every trial involved weeks of testimony to try the same issues about the same defendants again and again and again. Virtually everything pertaining to the defendants remained the same. The only issue that changed concerned the plaintiffs….

The lessons learned from asbestos litigation and similar large scale mass torts are instructive and applicable here. As Justice Starcher recognized, Rule 42 consolidation is available specifically to eliminate the sort of redundancy and resulting onerous expense and backlog that would result from trying the same liability in these cases over and over.[25]

As noted above, the liability and general causation witnesses for both plaintiffs and defense are the same. Consolidation will reduce the burden on the witnesses. Regarding Plaintiffs' causation experts, Joseph M. Braun, RN, MSPH, PhD (epidemiology), David H. Sherman, PhD (mechanism of action), Ronald J. Kendall, Ph.D. (toxicology), and David L. MacIntosh, ScD, CIH, DABT (exposure) are slated to testify on behalf of all Plaintiffs. In addition, Plaintiffs' specific causation expert, Dr. Robert Bahnson, would testify to many matters of medicine and science regarding PFAS and its association with kidney and testicular cancer that are *identical* for each, including the differential diagnosis or methodology by which Dr. Bahnson reached his specific causation conclusions for each Plaintiff. These professionals have busy practices, teaching schedules, or other professional responsibilities. The reduction in the expenditure of their time if the cases were consolidated would substantially reduce the burden placed on Plaintiffs as the cost of expert witnesses is one of the major expenditures of trying a product liability case. The reduction

[25] *Id*. at 308; *see also, Wilson v. Johns-Manville Sales Corp.*, 107 F.R.D. 250, 252 (S.D. Tex. 1985) ("The Court's consolidation will save these defendants the expense of litigating the [common] issues of product defectiveness and punitive damages in 50 separate trials."); *In re Joint Eastern and Southern Dists. Asbestos Litig.*, 125 F.R.D. 60, 63 (E.D.N.Y. 1989) ("Consolidation will result in substantial time-savings….When six to eight claims are consolidated for trial, [common evidence] can be presented once rather than six to eight times in individual trials.").

in cost of having these experts prepare and testify once, rather than five times, will be a significant savings to the Plaintiffs, and likely to the Defendants as well.

Accordingly, the standards of Rule 42(a) are satisfied, and this Court should consolidate these actions for a unitary bellwether trial. Alternatively, this Court should consider consolidating the actions according to their cancers, *i.e.*, a unitary trial for the three (3) kidney cancer Plaintiffs (Donnelly, Speers, and Voelker) and a unitary trial for the two (2) testicular cancer Plaintiffs (Bien and Field). In that regard, it is Plaintiffs' understanding that both the DCC and PEC agree that the *Voelker* case, which involves kidney cancer, should be a trial selection.[26] Therefore, it would seem prudent, should the Court alternatively consider a unitary trial according to a specific cancer, that we proceed first with the three (3) kidney cancer Plaintiffs, as it is clear that the DCC is agreeable to kidney cancer as a first bellwether. Finally, it is worth noting that the third-party vendor assessing the Plaintiff Fact Sheet responses has determined there are far more kidney cancer cases filed than testicular cancer cases, and thus underscoring why kidney cancer should get priority.

C. The Five Bellwether Cases are Representative and Therefore Appropriate Bellwether Trial Selections

All five (5) of these bellwether cases are appropriate bellwether trial selections because they are representative of the overall docket, which is the cornerstone of an appropriate bellwether trial selection.[27]

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[26] As noted below, the *Voelker* case requires discussion of all three (3) districts at issue in these five (5) cases because Mr. Voelker was exposed to AFFF-contaminated drinking water from Ambler, WMA, and Horsham. Given this, selection of the *Voelker* case alone will require discussion of all three (3) relevant water authorities.

[27] For any bellwether process to be successful, the cases that populate the bellwether pool must be representative of the overall docket. *See In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, 2010 U.S. Dist. LEXIS 108107, at *4, *6-7 (S.D. Ill. Oct. 8, 2010) (it is "critical to a successful bellwether plan that an honest representative sampling of cases be achieved" because "[l]ittle credibility will be attached to this process, and it will be a waste of everyone's time and resources, if cases are selected which do not accurately reflect the

1. **Kidney Cancer Trial Selections:**

- *Speers*: Mr. Speers alleges kidney cancer resulting from drinking AFFF-contaminated drinking water from Ambler for approximately twenty-four (24) years prior to his kidney cancer diagnosis. The fact that Mr. Speers is male renders his case representative as kidney cancer is more likely to occur in men than in women. Additionally, Mr. Speers' kidney cancer treatment and follow-up was typical of most kidney cancers. In particular, he underwent a surgical procedure to remove the cancer (partial nephrectomy) and received neither chemotherapy nor radiation as part of his treatment course, which is a very typical kidney cancer course. Finally, like most kidney cancer cases, Mr. Speers was required to follow a post-surgical surveillance plan with regular imaging. In addition, Mr. Speers underwent genetic testing, which identified a rare gene mutation, FH, that, according to scientific and medical literature, is not established as having an association with kidney cancer.[28]

- *Donnelly*: Mr. Donnelly alleges kidney cancer resulting from drinking AFFF-contaminated water from WMA for approximately twenty-four (24) years prior to his kidney cancer diagnosis. Again, simply by being male, Mr. Donnelly's case is typical as kidney cancer is more likely to occur in males than females. Mr. Donnelly also underwent a surgical procedure to treat his kidney cancer (radical nephrectomy) but received neither chemotherapy nor radiation, again rendering his case typical for kidney cancer. Finally, like Mr. Speers, Mr. Donnelly was required to follow a post-surgical surveillance plan with regular imaging, again underscoring the representativeness of his case. Mr. Donnelly also underwent genetic testing, which was negative. In addition to his two-plus decades of exposure to high levels of PFAS, Mr. Donnelly had the common risk factor of an elevated BMI of 32.7 (obesity class 1 of 3) at the time of his diagnosis. Mr. Donnelly has no additional risk factors.

- *Voelker*: Mr. Voelker alleges kidney cancer resulting from drinking AFFF-contaminated water from residences serviced by WMA, and workplaces serviced by WMA, Ambler, and Horsham over the course of nearly thirty (30) years prior to

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run-of-the-mill case"); *see also*, Guidelines & Best Practices for Large & Mass-Tort MDLs, Bolch Judicial Institute, Duke Law School 18-19 (2d ed 2018)("[T]he bellwether process will be valuable only if the cases selected for trial are truly representative of the whole (or of one or more distinct categories of cases that comprise the whole.")).

[28] Regarding the FH gene mutation, the genetic testing report indicates as follows: "This variant has been reported in *rare* cases of isolated renal cancer but is *absent* from other large studies of patients with renal cancer. In addition to this *equivocal clinical evidence,* the common frequency in the general population provides *insufficient evidence* to demonstrate that the [variant] causes Hereditary Leiomyomatosis and Renal Cell Carcinoma syndrome (HLRCC). Taken together, *this variant is not expected to be associated with HLRCC* and screening for cancers associated with HLRCC is not indicated." [emphasis added; internal citations removed]. MyRisk Genetic Result for Mr. Speers, dated Jan. 29, 2025, at 1, attached as Ex. C.

> his kidney cancer diagnosis. Like most kidney cancer cases, Mr. Voelker is male, rendering his case typical. Moreover, Mr. Voelker underwent a surgical procedure to treat his kidney cancer (partial nephrectomy), but also, typically, received neither radiation nor chemotherapy. Also, as is customary, after his surgery Mr. Voelker was required to follow an imaging protocol, further rendering his case representative. Mr. Voelker has several additional claimed risk factors or "background noise,"[29] including very common conditions such as an elevated BMI of 36.9 at time of diagnosis (obesity class 2 of 3) and hypertension. Mr. Voelker has likewise been identified as having a rare gene mutation (CHEK2) that has not been generally established as a risk factor for kidney cancer.[30]

These three kidney cancer cases together are a representative sample of the typical array of kidney cancer cases more broadly, with varying degrees of exposure and varying common potential risk factors. There is simply no single case that is representative of the entire population of kidney cancer patients with a history of PFAS exposure, and, trying these three together would give the parties the most informative result, thereby best serving the very purpose of the bellwether process.

2. <u>Testicular Cancer Trial Selections</u>:

- *<u>Bien</u>*: Mr. Bien alleges testicular cancer resulting from drinking AFFF-contaminated water from Horsham for approximately five (5) years prior to his testicular cancer diagnosis. Following his diagnosis, like most testicular cancer cases, Mr. Bien had a surgical procedure to remove the cancer (left radical inguinal orchiectomy). As is typical with testicular cancer cases, Mr. Bien underwent chemotherapy following his surgical procedure, which further renders his case representative. Finally, and, again, as is unfortunately typical with testicular cancer cases, Mr. Bien experienced post-diagnosis infertility. In addition to his exposure

[29] Of the three kidney cancer bellwethers, Mr. Voelker's case presents a more complicated medical history, albeit with conditions common in the general population and among kidney cancer patients generally. The Court has indicated in the past that, "I want as little background noise as possible, cases selected that answer that basic question [of general and specific causation]." July 19, 2024 Status Conf. Hrg. Trans. at 7. While Mr. Voelker's case does contain some "background noise," such as an elevated BMI and hypertension, these are not uncommon in the overall docket and/or the general population and therefore remains representative, albeit with more risk factors than Donnelly or Speers.

[30] Regarding the CHEK2 gene mutation, the genetic testing report indicates as follows: "Some studies have described a *possible* increased risk for a wide range of cancers in patients with CHEK2 mutations, including prostate, gastric, thyroid, renal, hematological malignancies, testicular germ cell tumors, and other malignancies. *However, these studies are not conclusive and there are currently no medical management guidelines to address these possible risks*." [emphasis added]. MyRisk Genetic Result for Mr. Voelker, dated Jan. 29, 2025, at 7, attached as Ex. D.

to high levels of PFAS, the fact that Mr. Bien was a 30-year-old white male at diagnosis renders his case representative as testicular cancer is more likely to occur in white men between the ages of 20 and 34. Given the presence of these common facts, Mr. Bien's case is clearly representative.

- *Field*: Mr. Field alleges testicular cancer resulting from drinking AFFF-contaminated water for approximately twenty-four (24) years prior to his testicular cancer diagnosis. Similar to Mr. Bien, Mr. Field underwent a surgical procedure to remove his testicular cancer (left inguinal radical orchiectomy). Further, as is typical, Mr. Field underwent adjuvant chemotherapy following his orchiectomy. Sadly, as is common, Mr. Field also experienced post-diagnosis infertility further underscoring the representative nature of his case. In addition to his two-plus decades of exposure to high levels of PFAS, the fact that Mr. Field was a 27-year-old white male at diagnosis renders his case representative as testicular cancer is more likely to occur in white men between the ages of 20 and 34.

Plaintiffs submit that the above slate of five representative bellwether trial cases should be consolidated for the first personal injury bellwether trial. Given the commonality of facts and law across the five cases and the representative nature of the proposed trial selections, consolidation of these cases would promote the efficient nature of this phase of the MDL and serve the underlying purpose of a bellwether trial for addressing *Leach* cancer claims, *i.e.*, provide valuable information and insight into the strengths and weaknesses of Plaintiffs' personal injury cases that can be extrapolated to the overall MDL docket.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' motion should be granted and this Court should consolidate these actions for a unitary bellwether trial. Alternatively, Plaintiffs request the Court consolidate the actions according to their cancers, *i.e.*, a unitary trial for the three (3) kidney cancer Plaintiffs (Donnelly, Speers, and Voelker) and a unitary trial for the two (2) testicular cancer Plaintiffs (Bien and Field), in addition to such other and further relief this court deems just and proper under the circumstances.

Dated: May 6, 2025 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was electronically filed with this Court's CM/ECF on this 6th day of May 2025 and was thus served electronically upon counsel of record.

/s/ Fred Thompson, III
Fred Thompson

EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: E. I. DU PONT DE NEMOURS AND COMPANY C-8 PERSONAL INJURY LITIGATION,

Civil Action 2:13-md-2433
CHIEF JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Elizabeth Preston Deavers

This document relates to:

***Angela Swartz and Teddy Swartz v. E. I. du Pont de Nemours and Company*, Case No. 2:18-cv-00136**

and

***Travis and Julie Abbott v. E. I. du Pont de Nemours and Company*, Case No. 2:17-cv-00998**

PRETRIAL ORDR NO. 51-A

Consolidation of Cases for Trial

For the same reasons set forth in Pretrial Order No. 51, the Court hereby consolidates the *Swartz* and the *Abbott* trials. Therefore, the Court **VACATES** the Final Pretrial Conference scheduled for Monday, October 21, 2019 and **SCHEDULES** the *Swartz* trial for January 21, 2020 at 9:00 a.m. The issues that would have been addressed at the vacated conference will be addressed at the Final Pretrial Conferences already scheduled in the *Abbott* case, *i.e.*, January 6, 2020, the First Final Pretrial Conference and January 15, 2020, the Second Final Pretrial Conference. Both conferences will be held at 9:00 a.m.

The Court will endeavor to promptly issue decisions on all pending motions related to these trials, including the issue of whether issue preclusion applies. While Plaintiffs have raised

issue preclusion formally twice, this is the first time the issue will be fully briefed for decision by this Court.[1]

IT IS SO ORDERED.

10-18-2019
DATE

EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE

[1] On January 27, 2017, a similar motion was filed on behalf of the Group 1 Plaintiffs in this MDL. (Pls.' Mot. for Summ. J. on Pls.' Negligence Claims Pursuant to the Doctrine of Issue Preclusion/Collateral Estoppel, ECF No. 5056.) DuPont did not file a response to Plaintiffs' motion because a global resolution was reached before DuPont's brief was due. (*See* Feb. 13, 2017 Order, ECF No. 5086) (vacating all then current scheduling orders). Plaintiffs' filed a second collateral estoppel motion on April 19, 2019 (ECF No. 5202) and Defendants' filed their response on May 19, 2019 (ECF No. 5208). Plaintiffs withdrew their motion on May 23, 2019 after Pretrial Order No. 51 was issued, "reserving the right to re-file in the future, should circumstances warrant." (Pls.' Mot to Withdraw Mot for Summ. J. on Issue Preclusion at 2, (ECF No. 5220).

EXHIBIT B

DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
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Florham Park, NJ 07932-1047
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Attorneys for Defendants
Johnson & Johnson, Johnson & Johnson Research & Development, L.L.C. and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

IN RE LEVAQUIN® LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

Case No. 286

CIVIL ACTION

AMENDED ORDER CONSOLIDATING CASES FOR TRIAL

THIS COURT having considered the respective submissions of the parties, and oral argument having been heard on February 16, 2011, and for good cause shown,

IT IS on this 3 day of May, **2011**;

1. **ORDERED** that the cases of: Robert George Beare and Judith Beare v. Johnson & Johnson, et al., Docket No. ATL-L-196-10 MT; and Paul Gaffney v. Johnson & Johnson, et al., Docket No. ATL-L-4551-09 MT, be and hereby are consolidated, with jury selection to commence on August 29, 2011.

2. **IT IS FURTHER ORDERED** that the cases of Chantal Mastrioanni v. Johnson & Johnson, et al., Docket No. ATL-L-1647 10 MT; and Michael Gilmore v. Johnson & Johnson, et al., Docket No. ATL-L-2672-09 MT, are to be consolidated for trial to commence on a date to be determined.

HON. CAROL E. HIGBEE, P.J.Cv.

FP01/ 6468029.1

EXHIBIT C

56322166

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

MyRisk Genetic Result

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER
Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

SPECIMEN
Specimen Type: Blood
Draw Date: Jan 14, 2025
Accession Date: Jan 15, 2025
Report Date: Jan 29, 2025

PATIENT
Legal Name: Speers, Clinton
Date of Birth: [redacted]
Patient ID:
Sex at Birth: M
Accession #: 05257804-BLD
Requisition #: 11829189

GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION

CLINICAL HISTORY ANALYSIS: BASED ON THE CLINICAL HISTORY PROVIDED, MODIFIED MEDICAL MANAGEMENT GUIDELINES IDENTIFIED

Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	INTERPRETATION
FH	c.1431_1433dup (p.Lys477dup) Heterozygous	Carrier

DETAILS ABOUT: *FH* c.1431_1433dup (p.Lys477dup): NM_000143.3

Functional Significance: Suspected Deleterious - Abnormal Protein Production and/or Function

The heterozygous germline *FH* variant c.1431_1433dup is predicted to result in the duplication of lysine at amino acid position 477 of the *FH* protein (p.Lys477dup). This variant has been reported in rare cases of isolated renal cancer but is absent from other large studies of patients with renal cancer (Forde et al. Eur Urol Oncol 3:764-772, 2020; Gupta et al. Hum Mutat 42:1362-1364, 2021; Zhang et al. Hum Mutat 41:103-109, 2020). In addition to this equivocal clinical evidence, the common frequency in the general population (http://gnomad.broadinstitute.org) provides insufficient evidence to demonstrate that the p.Lys477dup variant causes Hereditary Leiomyomatosis and Renal Cell Carcinoma syndrome (HLRCC). Taken together, this variant is not expected to be associated with HLRCC and screening for cancers associated with HLRCC is not indicated.

Clinical Significance: Carrier

Although this variant has not been shown to cause HLRCC, it has been detected in patients with clinical features of the recessive condition, fumarate hydratase deficiency (FHD) when a second pathogenic variant in the *FH* gene is also present (Coughlin et al. Mol Genet Metab 63:254-262, 1998; Pollard et al. Hum Mol Genet 14:2231-2239, 2005; Deschauer et al. Mol Genet Metab 88:146-52, 2006). Therefore, this patient is considered a carrier of FHD. FHD is characterized by severe neonatal and early infantile encephalopathy usually leading to death in childhood. Two mutations within the *FH* gene, one inherited from each parent, are required for an individual to have symptoms of FHD. There are no known risks of FHD in individuals carrying a single gene mutation. The biological children of this patient are at risk for FHD if the other parent is also a carrier of a pathogenic *FH* variant. Screening the other biological parent of any children for *FH* variants and genetic counseling to discuss reproductive risks may be appropriate.

Myriad genetics

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MyRisk Genetic Result

Name: **Speers, Clinton** DOB: [redacted] Accession #: **05257804-BLD** Report Date: **Jan 29, 2025**

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

Details About Non-Clinically Significant Variants: All individuals carry DNA changes (i.e., variants), and most variants do not increase an individual's risk of cancer or other diseases. When identified, variants of uncertain significance (VUS) are reported. Likely benign variants (Favor Polymorphisms) and benign variants (Polymorphisms) are not reported and available data indicate that these variants most likely do not cause increased cancer risk. Present evidence does not suggest that non-clinically significant variant findings be used to modify patient medical management beyond what is indicated by the personal and family history and any other clinically significant findings.

Variant Classification: Myriad's myVision™ Variant Classification Program performs ongoing evaluations of variant classifications. In certain cases, healthcare providers may be contacted for more clinical information or to arrange family testing to aid in variant classification. When new evidence about a variant is identified and determined to result in clinical significance and management change, that information will automatically be made available to the healthcare provider through an amended report.

ADDITIONAL INFORMATION

Genes Analyzed: Sequencing (seq) and large rearrangement analyses were performed for all coding exons in the following genes, unless otherwise indicated:
APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, CTNNA1, FH, FLCN, HOXB13 (seq only), *MEN1, MET, MLH1, MSH2, MSH3* (excluding repetitive portions of exon 1), *MSH6, MUTYH, NTHL1, PALB2, PMS2, PTEN, RAD51C, RAD51D, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL.*
Limited promoter regions may also be analyzed for large rearrangements.

Sequencing (seq) and/or large rearrangement (LR) analyses were performed only for the gene portions indicated in parenthesis for the following genes:
EGFR (exons 18-21, seq and LR), *EPCAM* (exons 8-9, LR only), *GREM1* (exon 1 and upstream regulatory regions, LR only), *MITF* (c.952, seq only), *POLE* (exonuclease domain, seq only), *POLD1* (exonuclease domain, seq only), *RET* (exons 5, 8, 10, 11, 13-16 seq and LR), *TERT* (promoter region 71 bases upstream of the translation start, c.-71_-1, seq only).

** Other genes not analyzed with this test may also be associated with cancer.

Indication for Testing: It is our understanding that this individual was identified for testing due to a personal or family history suggestive of a hereditary predisposition for cancer.

Patient Information: Sex assigned at birth is a label given to an individual at birth, typically "male" or "female". In this report, the terms "male", "female", "he", "she", "woman", and "man" refer to sex assigned at birth.

Associated Cancer Risks and Clinical Management: The "MyRisk Management Tool" associated with this report provides a summary of cancer risk and professional society medical management guidelines that may be useful in developing a plan for this patient based on any clinically significant test results and/or reported personal/family history. In some cases, a MyRisk Management Tool cannot be provided, such as when the result has a special interpretation or includes a mutation with unusual characteristics.

Analysis Description: The Technical Specifications summary (myriad.com/technical-specifications) describes the analysis, method, performance, nomenclature, and interpretive criteria of this test. Current testing technologies are unable to definitively determine whether a variant is germline or somatic in origin, which may significantly impact risk estimates and medical management; therefore, these results should be correlated with this patient's personal and family history. The interpretation of this test may also be impacted if the patient has a hematologic malignancy or an allogeneic bone marrow transplant.

CLASSIFICATION DISCLAIMER

THE CLASSIFICATION AND INTERPRETATION OF ALL VARIANTS IDENTIFIED IN THIS ASSAY REFLECTS THE CURRENT STATE OF MYRIAD'S SCIENTIFIC UNDERSTANDING AT THE TIME THIS REPORT WAS ISSUED. VARIANT CLASSIFICATION AND INTERPRETATION MAY CHANGE FOR A VARIETY OF REASONS, INCLUDING BUT NOT LIMITED TO, IMPROVEMENTS TO CLASSIFICATION TECHNIQUES, AVAILABILITY OF ADDITIONAL SCIENTIFIC INFORMATION, AND OBSERVATION OF A VARIANT IN MORE PATIENTS.

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MyRisk Genetic Result

Name: **Speers, Clinton** DOB: [redacted] Accession #: **05257804-BLD** Report Date: **Jan 29, 2025**

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. The patient's clinical history and test results should not be disclosed to a third party, unless related to treatment or payment for treatment, without the patient's express written authorization. It is strongly recommended that these results be communicated to the patient in a setting that includes appropriate genetic consultation. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that clearance or approval for laboratory-developed tests is not required.

This **Authorized Signature** pertains to this laboratory report:

Benjamin B. Roa, PhD
Diplomate ABMGG
Laboratory Director

Genetic testing was completed by CLIA and CAP accredited laboratories in the United States located at: 320 Wakara Way, Salt Lake City, UT 84108 and 322 N 2200 W, Salt Lake City, UT 84116 CLIA IDs: 46D0880690, 46D2275645
The following personnel codes and laboratory director signature may reflect remote review of digital data: 1857, 3028

Myriad genetics

56322166

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

Clinical & Cancer Family History Information

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER

Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

SPECIMEN

Specimen Type: Blood
Draw Date: Jan 14, 2025
Accession Date: Jan 15, 2025
Report Date: Jan 29, 2025

PATIENT

Legal Name: Speers, Clinton
Date of Birth: [redacted]
Patient ID:
Sex at Birth: M
Accession #: 05257804-BLD
Requisition #: 11829189

PERSONAL / FAMILY CANCER HISTORY SUMMARY

FAMILY MEMBER	CANCER / CLINICAL DIAGNOSIS	AGE AT DIAGNOSIS
Patient	Other	64
Father	Melanoma	70

The clinical information displayed here was provided by a qualified healthcare provider on the Test Request Form and other documents, and was not verified by Myriad. Female relatives refers to sex assigned at birth, which is a label given to an individual at birth, typically "male" or "female". Family members listed as "other" are not included in a Tyrer-Cuzick breast cancer risk estimate or other personal/family history assessments. For more information see the Specifications for Personal/Family History Analysis at http://myriad.com/technical-specifications.

The accuracy and completeness of the information provided in the Clinical and Cancer Family History Information section of the report (e.g. height and weight, age of menarche) may significantly affect the accuracy of breast cancer risk estimates provided based on either Tyrer-Cuzick or RiskScore. The impact of breast surgeries and hormone therapy (except hormone replacement therapy) have not been assessed or validated for Tyrer-Cuzick and RiskScore.

RiskScore is not valid, and may significantly over- or under-estimate breast cancer risk for individuals who do not meet the eligibility criteria in effect when the testing was performed. The current criteria are: 1) sex assigned at birth is female 2) age is 18 to 84 years, 3) no personal history of breast cancer, LCIS, hyperplasia (with or without atypia), or a breast biopsy with unknown results, 4) there is no mutation detected in a breast cancer risk gene (other than a monoallelic *CHEK2* mutation in a White/Non-Hispanic or Ashkenazi Jewish individual), 5) the individual's relatives have not been found to have a mutation in a high-penetrance breast cancer risk gene (*BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53*, a biallelic mutation in *CHEK2*, or the specific mutation c.7271T>G (p.Val2424Gly) in *ATM*) and 6) the sample was submitted with a current Test Request Form and the ordering healthcare provider has not determined that RiskScore is inappropriate for the patient. If this is an amended report for a patient tested in the past, please refer to the MyRisk Technical Specifications at http://myriad.com/technical-specifications for the eligibility criteria in effect at the time of the original testing.

Myriad genetics

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

MyRisk Management Tool

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER	SPECIMEN	PATIENT
Frederick Dold, MD	Specimen Type: Blood	Legal Name: Speers, Clinton
Alliance Cancer Specialists	Draw Date: Jan 14, 2025	Date of Birth: [redacted]
1311 BRISTOL PIKE STE 100	Accession Date: Jan 15, 2025	Patient ID:
BENSALEM, PA 19020	Report Date: Jan 29, 2025	Sex at Birth: M
		Accession #: 05257804-BLD
		Requisition #: 11829189

GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION

CLINICAL HISTORY ANALYSIS: BASED ON THE CLINICAL HISTORY PROVIDED, MODIFIED MEDICAL MANAGEMENT GUIDELINES IDENTIFIED

Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	THIS GENETIC TEST RESULT IS ASSOCIATED WITH THE FOLLOWING CANCER RISKS:
FH	c.1431_1433dup (p.Lys477dup) Heterozygous	Insufficient data to assess the impact of this finding on cancer risk. See the Genetic Test Result for more information.

Please see the Genetic Test Result for more details on any variant(s) detected in this patient, including variant classification information.

The terms "male", "female", "he", "she", "women", and "men" refer to sex assigned at birth.

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

WHAT ARE THE PATIENT'S CANCER RISKS?

These risk tables show the clinically significant cancer risks identified as part of this patient's testing. Testing for some patients does not include some of the analyses listed:

- GENETIC RESULT: Mutations detected in any of the hereditary cancer genes included on the MyRisk panel.
- BREAST CANCER RISKSCORE: RiskScore estimate of remaining lifetime breast cancer risk if 20% or greater
- CLINICAL HISTORY ANALYSIS for breast cancer risk: Tyrer-Cuzick model estimate of remaining lifetime breast cancer risk of 20% or greater
- CLINICAL HISTORY ANALYSIS for breast, colorectal, pancreatic, prostate and melanoma cancer: Analysis of the patient's personal and family history.

The risks for each of these results are provided separately. If the risk for any individual cancer is affected by more than one of these results, the risk associated with each finding is listed in a separate table. At this time, there is not enough information to estimate risks for cancers affected by more than one gene mutation, or risks based on both gene mutations and personal/family history.

Risks Identified From the Clinical History Analysis for Breast, Colorectal, Prostate, Pancreatic and Melanoma Cancer

The risk(s) below were identified based on information provided by the healthcare provider who ordered this patient's testing. This

information is listed on the Clinical & Cancer Family History Information page of the report.

IMPORTANT NOTE REGARDING THE CLINICAL HISTORY ANALYSIS: If this patient, or any of this patient's relatives, has a gene mutation associated with the risk for any of the cancers listed below, it is likely, but not certain, that the personal/family history is due to that mutation. Therefore, the risks listed here may not apply to this patient. Genetic testing of additional family members may be helpful in these situations.

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION	RELATED TO
MELANOMA			
To age 80	Elevated Risk	1.6%	Family History

WHAT MANAGEMENT FOR CANCER RISKS SHOULD BE CONSIDERED?

This overview of clinical management guidelines is based on the patient's genetic test results and the Clinical History Analysis. Medical management guidelines are summarized from established medical societies, primarily the National Comprehensive Cancer Network (NCCN). If there are overlapping management guidelines for any individual cancer due to more than one of these results, the guidelines associated with each finding are listed in separate tables, even if they are the same. At this time, there are no medical society guidelines for how to adjust management when there are multiple sources of risk, such as from more than one gene mutation, or a mutation and a personal/family history of cancer. In these cases, it may be appropriate to use the most aggressive of the management options provided.

The overview provided below should not be used as the sole source of information to determine medical management. The references cited should always be consulted for more details and updates to the recommendations.

No information is provided related to treatment of a previous or existing cancer or polyps. The recommendation summaries below may require modification due to the patient's personal medical history, past surgeries and other treatments. Patients with a past history of cancer, benign tumors, or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis. Any discussion of medical management options is for general information purposes only and does not constitute a recommendation. While genetic testing and medical society recommendations provide important and useful information, medical management decisions should be made in consultation between each patient and his or her healthcare provider.

Management Options Based on the Clinical History Analysis

The management options below are based on medical society guidelines for individuals with personal/family histories suggesting an increased risk for breast, colorectal, prostate, melanoma and pancreatic cancers.

IMPORTANT NOTE REGARDING RECOMMENDATIONS RELATED TO THE CLINICAL HISTORY ANALYSIS: In most cases, these recommendations will not apply if this patient, or any of this patient's relatives, has a gene mutation association with the risk for any of the cancers listed below.

PROCEDURE	AGE TO BEGIN	FREQUENCY Unless otherwise indicated by findings	RELATED TO
MELANOMA			
Consider available risk-reduction strategies, such as frequent self-examination of the skin, consideration of clinical skin examinations, and minimizing exposure to the sun and other sources of UV radiation. [1,2]	Individualized	NA	Family History

1. Cancer.Net, American Society of Clinical Oncology, Melanoma: Risk Factors and Prevention 12/2021 Available at http://www.cancer.net/cancer-types/melanoma/risk-factors-and-prevention.
2. National Council on Skin Cancer Prevention. At https://skincancerprevention.org/learning/risk-factors/what-causes-melanoma-skin-cancer/ (accessed on 03-24-2023)

MyRisk Management Tool

Name: Speers, Clinton DOB: [redacted] Accession #: 05257804-BLD Report Date: Jan 29, 2025

Notes for Personalized Management:

INFORMATION ON HOW CANCER RISKS AND MANAGEMENT ARE DETERMINED

The MyRisk Management Tool provides cancer risk levels based on analysis of genetic test results (see MyRisk Genetic Result) and a summary of medical society management recommendations based on both the genetic test results and a limited analysis of the patient's clinical history related to the risk for breast, colorectal, prostate, melanoma and pancreatic cancers. Here are some important points to understand as you interpret this test report and decide on the best plan for management:

- Comprehensive patient management. The management recommendations presented in this report are a summary of management options recommended by the National Comprehensive Cancer Network (NCCN) and other established medical societies and are general in nature. The patient's actual management should be modified based on personal medical history, surgeries and other treatments. A comprehensive risk assessment and management plan may take into account this report and other aspects of the patient's personal/family medical history (e.g., all known clinical diagnoses), as well as lifestyle, environmental and other factors.
- Risk estimates based on provider-supplied information. Some of the risk estimates and management recommendation summaries provided in this report are based on our interpretation of information supplied by the ordering health care provider on the test request form (see Specifications for Personal/Family History analysis at myriad.com/technical-specifications). The patient's actual risks and appropriate management may be significantly different if details provided for cancer diagnoses, ages, family relationships or other factors were incorrect, omitted, ambiguous or have since changed. Please review the clinical history listed on the Clinical & Family History Information page of this report to make sure that the information used was provided and interpreted correctly.
- Variability in Tyrer-Cuzick risk estimates. Tyrer-Cuzick estimates of breast cancer risk can vary significantly based on the way in which the model is used, and the estimate provided here may be higher or lower than what would be calculated by other users. For complete details of how Myriad calculates Tyrer-Cuzick risk estimates, including how Myriad handles information provided in a format not compatible with the model, please see the Specifications for Personal/Family History analysis at myriad.com/technical-specifications. These Specifications also include information for recalculating the Tyrer-Cuzick breast cancer risk estimate if desired.
- What is meant by "High Risk" and "Elevated Risk"? In the Genetic Test Result Summary, a gene-associated cancer risk is described as "High Risk" for a cancer type if all of the following conditions are met: the absolute risk of cancer is approximately 5% or higher, the increase in risk over the general population is approximately 2 to 3-fold or higher, and there is significant data from multiple studies supporting the cancer risk estimate. A gene is described as "Elevated Risk" for a cancer type if there is sufficient data to support an increase in cancer risk over the general population risk, but not all criteria for "High Risk" are met.

INFORMATION FOR FAMILY MEMBERS

Family members should talk to their healthcare providers about hereditary cancer testing to help define their own risk and assist in the interpretation of this patient's genetic test result.

- This patient's relatives are at risk for carrying the same mutation(s) and associated cancer risks as this patient. Cancer risks for individuals who have this/these mutation(s) are provided below.
- **Family members should talk to a healthcare provider about genetic testing.** Close relatives such as parents, children, and siblings have the highest chance of having the same mutation(s) as this patient. Other more distant relatives such as cousins, parents siblings, and grandparents also have a chance for carrying the same mutation(s). Testing of at-risk relatives can identify those family members with the same mutation(s) who may benefit from surveillance and early intervention. More resources for family testing are available at MySupport360.com.

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MyRisk Management Tool

Name: Speers, Clinton DOB: [redacted] Accession #: 05257804-BLD Report Date: Jan 29, 2025

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

END OF MANAGEMENT TOOL

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

MyRisk Genetic Result

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER	SPECIMEN		PATIENT	
Frederick Dold, MD	Specimen Type:	Blood	Legal Name:	Speers, Clinton
Alliance Cancer Specialists	Draw Date:	Jan 14, 2025	Date of Birth:	[redacted]
1311 BRISTOL PIKE STE 100	Accession Date:	Jan 15, 2025	Patient ID:	
BENSALEM, PA 19020	Report Date:	Jan 29, 2025	Sex at Birth:	M
			Accession #:	05257804-BLD
			Requisition #:	11829189

GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION

CLINICAL HISTORY ANALYSIS: BASED ON THE CLINICAL HISTORY PROVIDED, MODIFIED MEDICAL MANAGEMENT GUIDELINES IDENTIFIED

Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	INTERPRETATION
FH	c.1431_1433dup (p.Lys477dup) Heterozygous	Carrier

DETAILS ABOUT: *FH* c.1431_1433dup (p.Lys477dup): NM_000143.3

Functional Significance: Suspected Deleterious - Abnormal Protein Production and/or Function

The heterozygous germline *FH* variant c.1431_1433dup is predicted to result in the duplication of lysine at amino acid position 477 of the *FH* protein (p.Lys477dup). This variant has been reported in rare cases of isolated renal cancer but is absent from other large studies of patients with renal cancer (Forde et al. Eur Urol Oncol 3:764-772, 2020; Gupta et al. Hum Mutat 42:1362-1364, 2021; Zhang et al. Hum Mutat 41:103-109, 2020). In addition to this equivocal clinical evidence, the common frequency in the general population (http://gnomad.broadinstitute.org) provides insufficient evidence to demonstrate that the p.Lys477dup variant causes Hereditary Leiomyomatosis and Renal Cell Carcinoma syndrome (HLRCC). Taken together, this variant is not expected to be associated with HLRCC and screening for cancers associated with HLRCC is not indicated.

Clinical Significance: Carrier

Although this variant has not been shown to cause HLRCC, it has been detected in patients with clinical features of the recessive condition, fumarate hydratase deficiency (FHD) when a second pathogenic variant in the *FH* gene is also present (Coughlin et al. Mol Genet Metab 63:254-262, 1998; Pollard et al. Hum Mol Genet 14:2231-2239, 2005; Deschauer et al. Mol Genet Metab 88:146-52, 2006). Therefore, this patient is considered a carrier of FHD. FHD is characterized by severe neonatal and early infantile encephalopathy usually leading to death in childhood. Two mutations within the *FH* gene, one inherited from each parent, are required for an individual to have symptoms of FHD. There are no known risks of FHD in individuals carrying a single gene mutation. The biological children of this patient are at risk for FHD if the other parent is also a carrier of a pathogenic *FH* variant. Screening the other biological parent of any children for *FH* variants and genetic counseling to discuss reproductive risks may be appropriate.

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MyRisk Genetic Result

Name: **Speers, Clinton** DOB: [redacted] Accession #: **05257804-BLD** Report Date: **Jan 29, 2025**

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

Details About Non-Clinically Significant Variants: All individuals carry DNA changes (i.e., variants), and most variants do not increase an individual's risk of cancer or other diseases. When identified, variants of uncertain significance (VUS) are reported. Likely benign variants (Favor Polymorphisms) and benign variants (Polymorphisms) are not reported and available data indicate that these variants most likely do not cause increased cancer risk. Present evidence does not suggest that non-clinically significant variant findings be used to modify patient medical management beyond what is indicated by the personal and family history and any other clinically significant findings.

Variant Classification: Myriad's myVision™ Variant Classification Program performs ongoing evaluations of variant classifications. In certain cases, healthcare providers may be contacted for more clinical information or to arrange family testing to aid in variant classification. When new evidence about a variant is identified and determined to result in clinical significance and management change, that information will automatically be made available to the healthcare provider through an amended report.

ADDITIONAL INFORMATION

Genes Analyzed: Sequencing (seq) and large rearrangement analyses were performed for all coding exons in the following genes, unless otherwise indicated:
APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, CTNNA1, FH, FLCN, HOXB13 (seq only), *MEN1, MET, MLH1, MSH2, MSH3* (excluding repetitive portions of exon 1), *MSH6, MUTYH, NTHL1, PALB2, PMS2, PTEN, RAD51C, RAD51D, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL.*
Limited promoter regions may also be analyzed for large rearrangements.

Sequencing (seq) and/or large rearrangement (LR) analyses were performed only for the gene portions indicated in parenthesis for the following genes:
EGFR (exons 18-21, seq and LR), *EPCAM* (exons 8-9, LR only), *GREM1* (exon 1 and upstream regulatory regions, LR only), *MITF* (c.952, seq only), *POLE* (exonuclease domain, seq only), *POLD1* (exonuclease domain, seq only), *RET* (exons 5, 8, 10, 11, 13-16 seq and LR), *TERT* (promoter region 71 bases upstream of the translation start, c.-71_-1, seq only).

** Other genes not analyzed with this test may also be associated with cancer.

Indication for Testing: It is our understanding that this individual was identified for testing due to a personal or family history suggestive of a hereditary predisposition for cancer.

Patient Information: Sex assigned at birth is a label given to an individual at birth, typically "male" or "female". In this report, the terms "male", "female", "he", "she", "woman", and "man" refer to sex assigned at birth.

Associated Cancer Risks and Clinical Management: The "MyRisk Management Tool" associated with this report provides a summary of cancer risk and professional society medical management guidelines that may be useful in developing a plan for this patient based on any clinically significant test results and/or reported personal/family history. In some cases, a MyRisk Management Tool cannot be provided, such as when the result has a special interpretation or includes a mutation with unusual characteristics.

Analysis Description: The Technical Specifications summary (myriad.com/technical-specifications) describes the analysis, method, performance, nomenclature, and interpretive criteria of this test. Current testing technologies are unable to definitively determine whether a variant is germline or somatic in origin, which may significantly impact risk estimates and medical management; therefore, these results should be correlated with this patient's personal and family history. The interpretation of this test may also be impacted if the patient has a hematologic malignancy or an allogeneic bone marrow transplant.

CLASSIFICATION DISCLAIMER

THE CLASSIFICATION AND INTERPRETATION OF ALL VARIANTS IDENTIFIED IN THIS ASSAY REFLECTS THE CURRENT STATE OF MYRIAD'S SCIENTIFIC UNDERSTANDING AT THE TIME THIS REPORT WAS ISSUED. VARIANT CLASSIFICATION AND INTERPRETATION MAY CHANGE FOR A VARIETY OF REASONS, INCLUDING BUT NOT LIMITED TO, IMPROVEMENTS TO CLASSIFICATION TECHNIQUES, AVAILABILITY OF ADDITIONAL SCIENTIFIC INFORMATION, AND OBSERVATION OF A VARIANT IN MORE PATIENTS.

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MyRisk Genetic Result

Name: **Speers, Clinton** DOB: [redacted] Accession #: **05257804-BLD** Report Date: **Jan 29, 2025**

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. The patient's clinical history and test results should not be disclosed to a third party, unless related to treatment or payment for treatment, without the patient's express written authorization. It is strongly recommended that these results be communicated to the patient in a setting that includes appropriate genetic consultation. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that clearance or approval for laboratory-developed tests is not required.

Genetic testing was completed by CLIA and CAP accredited laboratories in the United States located at: 320 Wakara Way, Salt Lake City, UT 84108 and 322 N 2200 W, Salt Lake City, UT 84116 CLIA IDs: 46D0880690, 46D2275645
The following personnel codes and laboratory director signature may reflect remote review of digital data: 1857, 3028

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

Clinical & Cancer Family History Information

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER
Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

SPECIMEN
Specimen Type: Blood
Draw Date: Jan 14, 2025
Accession Date: Jan 15, 2025
Report Date: Jan 29, 2025

PATIENT
Legal Name: Speers, Clinton
Date of Birth: [redacted]
Patient ID:
Sex at Birth: M
Accession #: 05257804-BLD
Requisition #: 11829189

PERSONAL / FAMILY CANCER HISTORY SUMMARY

FAMILY MEMBER	CANCER / CLINICAL DIAGNOSIS	AGE AT DIAGNOSIS
Patient	Other	64
Father	Melanoma	70

The clinical information displayed here was provided by a qualified healthcare provider on the Test Request Form and other documents, and was not verified by Myriad. Female relatives refers to sex assigned at birth, which is a label given to an individual at birth, typically "male" or "female". Family members listed as "other" are not included in a Tyrer-Cuzick breast cancer risk estimate or other personal/family history assessments. For more information see the Specifications for Personal/Family History Analysis at http://myriad.com/technical-specifications.

The accuracy and completeness of the information provided in the Clinical and Cancer Family History Information section of the report (e.g. height and weight, age of menarche) may significantly affect the accuracy of breast cancer risk estimates provided based on either Tyrer-Cuzick or RiskScore. The impact of breast surgeries and hormone therapy (except hormone replacement therapy) have not been assessed or validated for Tyrer-Cuzick and RiskScore.

RiskScore is not valid, and may significantly over- or under-estimate breast cancer risk for individuals who do not meet the eligibility criteria in effect when the testing was performed. The current criteria are: 1) sex assigned at birth is female 2) age is 18 to 84 years, 3) no personal history of breast cancer, LCIS, hyperplasia (with or without atypia), or a breast biopsy with unknown results, 4) there is no mutation detected in a breast cancer risk gene (other than a monoallelic *CHEK2* mutation in a White/Non-Hispanic or Ashkenazi Jewish individual), 5) the individual's relatives have not been found to have a mutation in a high-penetrance breast cancer risk gene (*BRCA1*, *BRCA2*, *CDH1*, *PALB2*, *PTEN*, *STK11*, *TP53*, a biallelic mutation in *CHEK2*, or the specific mutation c.7271T>G (p.Val2424Gly) in *ATM*) and 6) the sample was submitted with a current Test Request Form and the ordering healthcare provider has not determined that RiskScore is inappropriate for the patient. If this is an amended report for a patient tested in the past, please refer to the MyRisk Technical Specifications at http://myriad.com/technical-specifications for the eligibility criteria in effect at the time of the original testing.

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

MyRisk Management Tool

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER	SPECIMEN		PATIENT	
Frederick Dold, MD	Specimen Type:	Blood	Legal Name:	Speers, Clinton
Alliance Cancer Specialists	Draw Date:	Jan 14, 2025	Date of Birth:	[redacted]
1311 BRISTOL PIKE STE 100	Accession Date:	Jan 15, 2025	Patient ID:	
BENSALEM, PA 19020	Report Date:	Jan 29, 2025	Sex at Birth:	M
			Accession #:	05257804-BLD
			Requisition #:	11829189

GENETIC RESULT: MUTATION IDENTIFIED WITH SPECIAL INTERPRETATION

CLINICAL HISTORY ANALYSIS: BASED ON THE CLINICAL HISTORY PROVIDED, MODIFIED MEDICAL MANAGEMENT GUIDELINES IDENTIFIED

Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	THIS GENETIC TEST RESULT IS ASSOCIATED WITH THE FOLLOWING CANCER RISKS:
FH	c.1431_1433dup (p.Lys477dup) Heterozygous	Insufficient data to assess the impact of this finding on cancer risk. See the Genetic Test Result for more information.

Please see the Genetic Test Result for more details on any variant(s) detected in this patient, including variant classification information.

The terms "male", "female", "he", "she", "women", and "men" refer to sex assigned at birth.

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

WHAT ARE THE PATIENT'S CANCER RISKS?

These risk tables show the clinically significant cancer risks identified as part of this patient's testing. Testing for some patients does not include some of the analyses listed:

- GENETIC RESULT: Mutations detected in any of the hereditary cancer genes included on the MyRisk panel.
- BREAST CANCER RISKSCORE: RiskScore estimate of remaining lifetime breast cancer risk if 20% or greater
- CLINICAL HISTORY ANALYSIS for breast cancer risk: Tyrer-Cuzick model estimate of remaining lifetime breast cancer risk of 20% or greater
- CLINICAL HISTORY ANALYSIS for breast, colorectal, pancreatic, prostate and melanoma cancer: Analysis of the patient's personal and family history.

The risks for each of these results are provided separately. If the risk for any individual cancer is affected by more than one of these results, the risk associated with each finding is listed in a separate table. At this time, there is not enough information to estimate risks for cancers affected by more than one gene mutation, or risks based on both gene mutations and personal/family history.

Risks Identified From the Clinical History Analysis for Breast, Colorectal, Prostate, Pancreatic and Melanoma Cancer

The risk(s) below were identified based on information provided by the healthcare provider who ordered this patient's testing. This

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information is listed on the Clinical & Cancer Family History Information page of the report.

IMPORTANT NOTE REGARDING THE CLINICAL HISTORY ANALYSIS: If this patient, or any of this patient's relatives, has a gene mutation associated with the risk for any of the cancers listed below, it is likely, but not certain, that the personal/family history is due to that mutation. Therefore, the risks listed here may not apply to this patient. Genetic testing of additional family members may be helpful in these situations.

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION	RELATED TO
MELANOMA			
To age 80	Elevated Risk	1.6%	Family History

WHAT MANAGEMENT FOR CANCER RISKS SHOULD BE CONSIDERED?

This overview of clinical management guidelines is based on the patient's genetic test results and the Clinical History Analysis. Medical management guidelines are summarized from established medical societies, primarily the National Comprehensive Cancer Network (NCCN). If there are overlapping management guidelines for any individual cancer due to more than one of these results, the guidelines associated with each finding are listed in separate tables, even if they are the same. At this time, there are no medical society guidelines for how to adjust management when there are multiple sources of risk, such as from more than one gene mutation, or a mutation and a personal/family history of cancer. In these cases, it may be appropriate to use the most aggressive of the management options provided.

The overview provided below should not be used as the sole source of information to determine medical management. The references cited should always be consulted for more details and updates to the recommendations.

No information is provided related to treatment of a previous or existing cancer or polyps. The recommendation summaries below may require modification due to the patient's personal medical history, past surgeries and other treatments. Patients with a past history of cancer, benign tumors, or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis. Any discussion of medical management options is for general information purposes only and does not constitute a recommendation. While genetic testing and medical society recommendations provide important and useful information, medical management decisions should be made in consultation between each patient and his or her healthcare provider.

Management Options Based on the Clinical History Analysis

The management options below are based on medical society guidelines for individuals with personal/family histories suggesting an increased risk for breast, colorectal, prostate, melanoma and pancreatic cancers.

IMPORTANT NOTE REGARDING RECOMMENDATIONS RELATED TO THE CLINICAL HISTORY ANALYSIS: In most cases, these recommendations will not apply if this patient, or any of this patient's relatives, has a gene mutation association with the risk for any of the cancers listed below.

PROCEDURE	AGE TO BEGIN	FREQUENCY Unless otherwise indicated by findings	RELATED TO
MELANOMA			
Consider available risk-reduction strategies, such as frequent self-examination of the skin, consideration of clinical skin examinations, and minimizing exposure to the sun and other sources of UV radiation. [1,2]	Individualized	NA	Family History

1. Cancer.Net, American Society of Clinical Oncology, Melanoma: Risk Factors and Prevention 12/2021 Available at http://www.cancer.net/cancer-types/melanoma/risk-factors-and-prevention.
2. National Council on Skin Cancer Prevention. At https://skincancerprevention.org/learning/risk-factors/what-causes-melanoma-skin-cancer/ (accessed on 03-24-2023)

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MyRisk Management Tool

Name: Speers, Clinton DOB [redacted] Accession #: 05257804-BLD Report Date: Jan 29, 2025

Notes for Personalized Management:

INFORMATION ON HOW CANCER RISKS AND MANAGEMENT ARE DETERMINED

The MyRisk Management Tool provides cancer risk levels based on analysis of genetic test results (see MyRisk Genetic Result) and a summary of medical society management recommendations based on both the genetic test results and a limited analysis of the patient's clinical history related to the risk for breast, colorectal, prostate, melanoma and pancreatic cancers. Here are some important points to understand as you interpret this test report and decide on the best plan for management:

- Comprehensive patient management. The management recommendations presented in this report are a summary of management options recommended by the National Comprehensive Cancer Network (NCCN) and other established medical societies and are general in nature. The patient's actual management should be modified based on personal medical history, surgeries and other treatments. A comprehensive risk assessment and management plan may take into account this report and other aspects of the patient's personal/family medical history (e.g., all known clinical diagnoses), as well as lifestyle, environmental and other factors.
- Risk estimates based on provider-supplied information. Some of the risk estimates and management recommendation summaries provided in this report are based on our interpretation of information supplied by the ordering health care provider on the test request form (see Specifications for Personal/Family History analysis at myriad.com/technical-specifications). The patient's actual risks and appropriate management may be significantly different if details provided for cancer diagnoses, ages, family relationships or other factors were incorrect, omitted, ambiguous or have since changed. Please review the clinical history listed on the Clinical & Family History Information page of this report to make sure that the information used was provided and interpreted correctly.
- Variability in Tyrer-Cuzick risk estimates. Tyrer-Cuzick estimates of breast cancer risk can vary significantly based on the way in which the model is used, and the estimate provided here may be higher or lower than what would be calculated by other users. For complete details of how Myriad calculates Tyrer-Cuzick risk estimates, including how Myriad handles information provided in a format not compatible with the model, please see the Specifications for Personal/Family History analysis at myriad.com/technical-specifications. These Specifications also include information for recalculating the Tyrer-Cuzick breast cancer risk estimate if desired.
- What is meant by "High Risk" and "Elevated Risk"? In the Genetic Test Result Summary, a gene-associated cancer risk is described as "High Risk" for a cancer type if all of the following conditions are met: the absolute risk of cancer is approximately 5% or higher, the increase in risk over the general population is approximately 2 to 3-fold or higher, and there is significant data from multiple studies supporting the cancer risk estimate. A gene is described as "Elevated Risk" for a cancer type if there is sufficient data to support an increase in cancer risk over the general population risk, but not all criteria for "High Risk" are met.

INFORMATION FOR FAMILY MEMBERS

Family members should talk to their healthcare providers about hereditary cancer testing to help define their own risk and assist in the interpretation of this patient's genetic test result.

- This patient's relatives are at risk for carrying the same mutation(s) and associated cancer risks as this patient. Cancer risks for individuals who have this/these mutation(s) are provided below.
- **Family members should talk to a healthcare provider about genetic testing.** Close relatives such as parents, children, and siblings have the highest chance of having the same mutation(s) as this patient. Other more distant relatives such as cousins, parents siblings, and grandparents also have a chance for carrying the same mutation(s). Testing of at-risk relatives can identify those family members with the same mutation(s) who may benefit from surveillance and early intervention. More resources for family testing are available at MySupport360.com.

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MyRisk Management Tool

Name: Speers, Clinton DOB: [redacted] Accession #: 05257804-BLD Report Date: Jan 29, 2025

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

END OF MANAGEMENT TOOL

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EXHIBIT D

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

MyRisk Genetic Result

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER
Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

SPECIMEN
Specimen Type: Blood
Draw Date: Jan 14, 2025
Accession Date: Jan 15, 2025
Report Date: Jan 29, 2025

PATIENT
Legal Name: Voelker, Kevin
Date of Birth: [redacted]
Patient ID:
Sex at Birth: M
Accession #: 05258003-BLD
Requisition #: 11770109

GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

CLINICAL HISTORY ANALYSIS: NO ADDITIONAL MANAGEMENT GUIDELINES IDENTIFIED BASED ON THE CLINICAL HISTORY PROVIDED

Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	INTERPRETATION
CHEK2	c.1100del (p.Thr367Metfs*15) Heterozygous	High Risk This patient has *CHEK2*-associated cancer risk.

DETAILS ABOUT: *CHEK2* c.1100del (p.Thr367Metfs*15): NM_007194.3

Functional Significance: Deleterious - Abnormal Protein Production and/or Function

The heterozygous germline *CHEK2* mutation c.1100del is predicted to result in the premature truncation of the *CHEK2* protein at amino acid position 381 (p.Thr367Metfs*15).

Clinical Significance: High Risk

This mutation is associated with increased cancer risk and should be regarded as clinically significant.

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

Details About Non-Clinically Significant Variants: All individuals carry DNA changes (i.e., variants), and most variants do not increase an individual's risk of cancer or other diseases. When identified, variants of uncertain significance (VUS) are reported. Likely benign variants (Favor Polymorphisms) and benign variants (Polymorphisms) are not reported and available data indicate that these variants most likely do not cause increased cancer risk. Present evidence does not suggest that non-clinically significant variant findings be used to modify patient medical management beyond what is indicated by the personal and family history and any other clinically significant findings.

Variant Classification: Myriad's myVision™ Variant Classification Program performs ongoing evaluations of variant classifications. In certain cases, healthcare providers may be contacted for more clinical information or to arrange family testing to aid in variant classification. When new evidence about a variant is identified and determined to result in clinical significance and management change, that information will automatically be made available to the healthcare provider through an amended report.

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MyRisk Genetic Result

Name: Voelker, Kevin DOB: [redacted] Accession #: 05258003-BLD Report Date: Jan 29, 2025

ADDITIONAL INFORMATION

Genes Analyzed: Sequencing (seq) and large rearrangement analyses were performed for all coding exons in the following genes, unless otherwise indicated:
APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, CTNNA1, FH, FLCN, HOXB13 (seq only), *MEN1, MET, MLH1, MSH2, MSH3* (excluding repetitive portions of exon 1), *MSH6, MUTYH, NTHL1, PALB2, PMS2, PTEN, RAD51C, RAD51D, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL.*
Limited promoter regions may also be analyzed for large rearrangements.

Sequencing (seq) and/or large rearrangement (LR) analyses were performed only for the gene portions indicated in parenthesis for the following genes:
EGFR (exons 18-21, seq and LR), *EPCAM* (exons 8-9, LR only), *GREM1* (exon 1 and upstream regulatory regions, LR only), *MITF* (c.952, seq only), *POLE* (exonuclease domain, seq only), *POLD1* (exonuclease domain, seq only), *RET* (exons 5, 8, 10, 11, 13-16 seq and LR), *TERT* (promoter region 71 bases upstream of the translation start, c.-71_-1, seq only).

** Other genes not analyzed with this test may also be associated with cancer.

Indication for Testing: It is our understanding that this individual was identified for testing due to a personal or family history suggestive of a hereditary predisposition for cancer.

Patient Information: Sex assigned at birth is a label given to an individual at birth, typically "male" or "female". In this report, the terms "male", "female", "he", "she", "woman", and "man" refer to sex assigned at birth.

Associated Cancer Risks and Clinical Management: The "MyRisk Management Tool" associated with this report provides a summary of cancer risk and professional society medical management guidelines that may be useful in developing a plan for this patient based on any clinically significant test results and/or reported personal/family history. In some cases, a MyRisk Management Tool cannot be provided, such as when the result has a special interpretation or includes a mutation with unusual characteristics.

Analysis Description: The Technical Specifications summary (myriad.com/technical-specifications) describes the analysis, method, performance, nomenclature, and interpretive criteria of this test. Current testing technologies are unable to definitively determine whether a variant is germline or somatic in origin, which may significantly impact risk estimates and medical management; therefore, these results should be correlated with this patient's personal and family history. The interpretation of this test may also be impacted if the patient has a hematologic malignancy or an allogeneic bone marrow transplant.

CLASSIFICATION DISCLAIMER

THE CLASSIFICATION AND INTERPRETATION OF ALL VARIANTS IDENTIFIED IN THIS ASSAY REFLECTS THE CURRENT STATE OF MYRIAD'S SCIENTIFIC UNDERSTANDING AT THE TIME THIS REPORT WAS ISSUED. VARIANT CLASSIFICATION AND INTERPRETATION MAY CHANGE FOR A VARIETY OF REASONS, INCLUDING BUT NOT LIMITED TO, IMPROVEMENTS TO CLASSIFICATION TECHNIQUES, AVAILABILITY OF ADDITIONAL SCIENTIFIC INFORMATION, AND OBSERVATION OF A VARIANT IN MORE PATIENTS.

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. The patient's clinical history and test results should not be disclosed to a third party, unless related to treatment or payment for treatment, without the patient's express written authorization. It is strongly recommended that these results be communicated to the patient in a setting that includes appropriate genetic consultation. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that clearance or approval for laboratory-developed tests is not required.

This Authorized Signature pertains to this laboratory report:

Benjamin B. Roa, PhD
Diplomate ABMGG
Laboratory Director

Genetic testing was completed by CLIA and CAP accredited laboratories in the United States located at: 320 Wakara Way, Salt Lake City, UT 84108 and 322 N 2200 W, Salt Lake City, UT 84116 CLIA IDs: 46D0880690, 46D2275645
The following personnel codes and laboratory director signature may reflect remote review of digital data: 572, 3028

Myriad genetics

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

Clinical & Cancer Family History Information

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER
Frederick Dold, MD
Alliance Cancer Specialists
1311 BRISTOL PIKE STE 100
BENSALEM, PA 19020

SPECIMEN
Specimen Type: Blood
Draw Date: Jan 14, 2025
Accession Date: Jan 15, 2025
Report Date: Jan 29, 2025

PATIENT
Legal Name: Voelker, Kevin
Date of Birth: [redacted]
Patient ID:
Sex at Birth: M
Accession #: 05258003-BLD
Requisition #: 11770109

PERSONAL / FAMILY CANCER HISTORY SUMMARY

FAMILY MEMBER	CANCER / CLINICAL DIAGNOSIS	AGE AT DIAGNOSIS
Patient	Kidney/Renal	63
Family History	None	

The clinical information displayed here was provided by a qualified healthcare provider on the Test Request Form and other documents, and was not verified by Myriad. Female relatives refers to sex assigned at birth, which is a label given to an individual at birth, typically "male" or "female". Family members listed as "other" are not included in a Tyrer-Cuzick breast cancer risk estimate or other personal/family history assessments. For more information see the Specifications for Personal/Family History Analysis at http://myriad.com/technical-specifications.

The accuracy and completeness of the information provided in the Clinical and Cancer Family History Information section of the report (e.g. height and weight, age of menarche) may significantly affect the accuracy of breast cancer risk estimates provided based on either Tyrer-Cuzick or RiskScore. The impact of breast surgeries and hormone therapy (except hormone replacement therapy) have not been assessed or validated for Tyrer-Cuzick and RiskScore.

RiskScore is not valid, and may significantly over- or under-estimate breast cancer risk for individuals who do not meet the eligibility criteria in effect when the testing was performed. The current criteria are: 1) sex assigned at birth is female 2) age is 18 to 84 years, 3) no personal history of breast cancer, LCIS, hyperplasia (with or without atypia), or a breast biopsy with unknown results, 4) there is no mutation detected in a breast cancer risk gene (other than a monoallelic *CHEK2* mutation in a White/Non-Hispanic or Ashkenazi Jewish individual), 5) the individual's relatives have not been found to have a mutation in a high-penetrance breast cancer risk gene (*BRCA1*, *BRCA2*, *CDH1*, *PALB2*, *PTEN*, *STK11*, *TP53*, a biallelic mutation in *CHEK2*, or the specific mutation c.7271T>G (p.Val2424Gly) in *ATM*) and 6) the sample was submitted with a current Test Request Form and the ordering healthcare provider has not determined that RiskScore is inappropriate for the patient. If this is an amended report for a patient tested in the past, please refer to the MyRisk Technical Specifications at http://myriad.com/technical-specifications for the eligibility criteria in effect at the time of the original testing.

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

MyRisk Management Tool

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER	SPECIMEN		PATIENT	
Frederick Dold, MD	Specimen Type:	Blood	Legal Name:	Voelker, Kevin
Alliance Cancer Specialists	Draw Date:	Jan 14, 2025	Date of Birth:	[redacted]
1311 BRISTOL PIKE STE 100	Accession Date:	Jan 15, 2025	Patient ID:	
BENSALEM, PA 19020	Report Date:	Jan 29, 2025	Sex at Birth:	M
			Accession #:	05258003-BLD
			Requisition #:	11770109

GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

CLINICAL HISTORY ANALYSIS: NO ADDITIONAL MANAGEMENT GUIDELINES IDENTIFIED BASED ON THE CLINICAL HISTORY PROVIDED

Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	THIS GENETIC TEST RESULT IS ASSOCIATED WITH THE FOLLOWING CANCER RISKS:
CHEK2	c.1100del (p.Thr367Metfs*15) Heterozygous	ELEVATED RISK: Male Breast, Colorectal

Please see the Genetic Test Result for more details on any variant(s) detected in this patient, including variant classification information.

The terms "male", "female", "he", "she", "women", and "men" refer to sex assigned at birth.

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

CLINICAL OVERVIEW OF GENETIC FINDINGS

CHEK2-associated cancer risk

- This patient has been found to have a mutation in the *CHEK2* gene. Most women with *CHEK2* mutations have a risk for breast cancer that is significantly increased over the 12.5% lifetime risk for women in the general population of the United States. Men with *CHEK2* mutations also have an increased risk for breast cancer.
- Estimates of cancer risk for men and women with *CHEK2* mutations vary widely and are strongly influenced by family history. In cases where there is no family history of one of these cancers, the risk for a patient with a *CHEK2* mutation may be lower than in cases where that cancer has been diagnosed in one or more close relatives. Therefore, the family history of a patient should be considered when deciding on the most appropriate strategies to manage cancer risk, with more aggressive strategies targeted to patients with significant family histories of related cancers.
- Individuals with *CHEK2* mutations may have an elevated risk for colorectal cancer, and the National Comprehensive Cancer Network (NCCN) has provided screening recommendations to address this possible risk.
- Some studies have described a possible increased risk for a wide range of cancers in patients with *CHEK2* mutations, including prostate, gastric, thyroid, renal, hematological malignancies, testicular germ cell tumors, and other malignancies. However, these studies are not conclusive and there are currently no medical management guidelines to address these possible risks.

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- Although there are increased risks for cancer in men and women with mutations in *CHEK2*, there are interventions that may reduce these risks. Guidelines from the National Comprehensive Cancer Network (NCCN) that may apply are listed below. Since information about the cancer risks associated with *CHEK2* mutations is relatively new, and there is still some uncertainty about the best ways to reduce these risks, it may be appropriate to interpret these results in consultation with cancer genetics experts in this emerging area of knowledge.

WHAT ARE THE PATIENT'S CANCER RISKS?

These risk tables show the clinically significant cancer risks identified as part of this patient's testing. Testing for some patients does not include some of the analyses listed:

- GENETIC RESULT: Mutations detected in any of the hereditary cancer genes included on the MyRisk panel.
- BREAST CANCER RISKSCORE: RiskScore estimate of remaining lifetime breast cancer risk if 20% or greater
- CLINICAL HISTORY ANALYSIS for breast cancer risk: Tyrer-Cuzick model estimate of remaining lifetime breast cancer risk of 20% or greater
- CLINICAL HISTORY ANALYSIS for breast, colorectal, pancreatic, prostate and melanoma cancer: Analysis of the patient's personal and family history.

The risks for each of these results are provided separately. If the risk for any individual cancer is affected by more than one of these results, the risk associated with each finding is listed in a separate table. At this time, there is not enough information to estimate risks for cancers affected by more than one gene mutation, or risks based on both gene mutations and personal/family history.

Risks Due to *CHEK2*-associated cancer risk

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION	RELATED TO
MALE BREAST			
To age 80	0.4%-1%	0.1%	*CHEK2*
COLORECTAL			
To age 80	Possibly elevated risk	2.8%	*CHEK2*

WHAT MANAGEMENT FOR CANCER RISKS SHOULD BE CONSIDERED?

This overview of clinical management guidelines is based on the patient's genetic test results and the Clinical History Analysis. Medical management guidelines are summarized from established medical societies, primarily the National Comprehensive Cancer Network (NCCN). If there are overlapping management guidelines for any individual cancer due to more than one of these results, the guidelines associated with each finding are listed in separate tables, even if they are the same. At this time, there are no medical society guidelines for how to adjust management when there are multiple sources of risk, such as from more than one gene mutation, or a mutation and a personal/family history of cancer. In these cases, it may be appropriate to use the most aggressive of the management options provided.

The overview provided below should not be used as the sole source of information to determine medical management. The references cited should always be consulted for more details and updates to the recommendations.

No information is provided related to treatment of a previous or existing cancer or polyps. The recommendation summaries below may require modification due to the patient's personal medical history, past surgeries and other treatments. Patients with a past history of cancer, benign tumors, or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis. Any discussion of medical management options is for general information purposes only and does not constitute a recommendation. While genetic testing and medical society recommendations provide important and useful information, medical management decisions should be made in consultation between each patient and his or her healthcare provider.

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MyRisk Management Tool

Name: Voelker, Kevin DOB: [redacted] Accession #: 05258003-BLD Report Date: Jan 29, 2025

Management Options for *CHEK2*-associated cancer risk

PROCEDURE	AGE TO BEGIN	FREQUENCY Unless otherwise indicated by findings	RELATED TO
MALE BREAST			
Currently there are no specific medical management guidelines for male breast cancer risk in mutation carriers. However, the increase in risk warrants consideration of options for male breast cancer screening, such as patient breast awareness education and clinical breast examinations. [1,2]	Individualized	NA	*CHEK2*
COLORECTAL			
Colonoscopy [3]	40 years, or 10 years younger than the age of diagnosis for any first-degree relative with colorectal cancer	Every 5 years	*CHEK2*
FOR PATIENTS WITH A CANCER DIAGNOSIS			
For patients with a gene mutation and a diagnosis of cancer, targeted therapies may be available as a treatment option for certain tumor types (e.g., PARP-inhibitors). [4]	NA	NA	*CHEK2*

1. Bevers TB, et al. NCCN Clinical Practice Guidelines in Oncology®: Breast Cancer Screening and Diagnosis. V 1.2022. Jun 2. Available at https://www.nccn.org.
2. Daly M et al. NCCN Clinical Practice Guidelines in Oncology®: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic. V 3.2023. Feb 13. Available at https://www.nccn.org.
3. Gupta S, et al. NCCN Clinical Practice Guidelines in Oncology® Genetic/Familial High-Risk Assessment: Colorectal. V 1.2023. May 30. Available at https://www.nccn.org.
4. Schaeffer E, et al. NCCN Clinical Practice Guidelines in Oncology®: Prostate Cancer. V 1.2023. Sep 16. Available at https://www.nccn.org.

Notes for Personalized Management:

INFORMATION ON HOW CANCER RISKS AND MANAGEMENT ARE DETERMINED

The MyRisk Management Tool provides cancer risk levels based on analysis of genetic test results (see MyRisk Genetic Result) and a summary of medical society management recommendations based on both the genetic test results and a limited analysis of the patient's clinical history related to the risk for breast, colorectal, prostate, melanoma and pancreatic cancers. Here are some important points to understand as you interpret this test report and decide on the best plan for management:

- Comprehensive patient management. The management recommendations presented in this report are a summary of management options recommended by the National Comprehensive Cancer Network (NCCN) and other established medical societies and are general in nature. The patient's actual management should be modified based on personal medical history, surgeries and other treatments. A comprehensive risk assessment and management plan may take into account this report and other aspects of the patient's personal/family medical history (e.g., all known clinical diagnoses), as well as lifestyle, environmental and other factors.

- Risk estimates based on provider-supplied information. Some of the risk estimates and management recommendation summaries provided in this report are based on our interpretation of information supplied by the ordering health care provider on the test request form (see Specifications for Personal/Family History analysis at myriad.com/technical-specifications). The patient's actual risks and appropriate management may be significantly different if details provided for cancer diagnoses, ages, family relationships or other factors were incorrect, omitted, ambiguous or have since changed. Please review the clinical history listed on the Clinical & Family History Information page of this report to make sure that the information used was provided and interpreted correctly.
- Variability in Tyrer-Cuzick risk estimates. Tyrer-Cuzick estimates of breast cancer risk can vary significantly based on the way in which the model is used, and the estimate provided here may be higher or lower than what would be calculated by other users. For complete details of how Myriad calculates Tyrer-Cuzick risk estimates, including how Myriad handles information provided in a format not compatible with the model, please see the Specifications for Personal/Family History analysis at myriad.com/technical-specifications. These Specifications also include information for recalculating the Tyrer-Cuzick breast cancer risk estimate if desired.
- What is meant by "High Risk" and "Elevated Risk"? In the Genetic Test Result Summary, a gene-associated cancer risk is described as "High Risk" for a cancer type if all of the following conditions are met: the absolute risk of cancer is approximately 5% or higher, the increase in risk over the general population is approximately 2 to 3-fold or higher, and there is significant data from multiple studies supporting the cancer risk estimate. A gene is described as "Elevated Risk" for a cancer type if there is sufficient data to support an increase in cancer risk over the general population risk, but not all criteria for "High Risk" are met.

INFORMATION FOR FAMILY MEMBERS

Family members should talk to their healthcare providers about hereditary cancer testing to help define their own risk and assist in the interpretation of this patient's genetic test result.

- This patient's relatives are at risk for carrying the same mutation(s) and associated cancer risks as this patient. Cancer risks for individuals who have this/these mutation(s) are provided below.
- **Family members should talk to a healthcare provider about genetic testing**. Close relatives such as parents, children, and siblings have the highest chance of having the same mutation(s) as this patient. Other more distant relatives such as cousins, parents siblings, and grandparents also have a chance for carrying the same mutation(s). Testing of at-risk relatives can identify those family members with the same mutation(s) who may benefit from surveillance and early intervention. More resources for family testing are available at MySupport360.com.

Additional Information for *CHEK2*-associated cancer risk

- In rare instances, an individual may inherit mutations in both copies of the *CHEK2* gene, leading to significantly higher breast cancer risks than those in women with a single *CHEK2* mutation. The children of this patient are at risk of inheriting two *CHEK2* mutations only if the other parent is also a carrier of a *CHEK2* mutation. Screening the other biological parent of any children for *CHEK2* mutations may be appropriate. Alternatively, this patient's children may consider genetic testing for any mutations in the entire *CHEK2* gene.

CANCER RISK FOR *CHEK2* CLINICALLY SIGNIFICANT MUTATION

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION
	FEMALES	
FEMALE BREAST		
To age 80	20%-31%	10.7%
Second primary within 10 years of first breast cancer diagnosis	7%-29%	3.5%
	MALES	
MALE BREAST		
To age 80	0.4%-1%	0.1%

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MyRisk Management Tool

Name: Voelker, Kevin DOB [redacted] Accession #: 05258003-BLD Report Date: Jan 29, 2025

CANCER RISK FOR *CHEK2* CLINICALLY SIGNIFICANT MUTATION

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION
	FEMALES AND MALES	
COLORECTAL		
To age 80	Possibly elevated risk	2.8%

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

END OF MANAGEMENT TOOL

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

MyRisk Genetic Result

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER	SPECIMEN	PATIENT
Frederick Dold, MD	Specimen Type: Blood	Legal Name: Voelker, Kevin
Alliance Cancer Specialists	Draw Date: Jan 14, 2025	Date of Birth [redacted]
1311 BRISTOL PIKE STE 100	Accession Date: Jan 15, 2025	Patient ID:
BENSALEM, PA 19020	Report Date: Jan 29, 2025	Sex at Birth: M
		Accession #: 05258003-BLD
		Requisition #: 11770109

GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

CLINICAL HISTORY ANALYSIS: NO ADDITIONAL MANAGEMENT GUIDELINES IDENTIFIED BASED ON THE CLINICAL HISTORY PROVIDED

Other clinical factors may influence individualized management. This analysis may be incomplete if details about cancer diagnoses, ages, family relationships or other factors were omitted or ambiguous. If this patient also has a clinically significant mutation, the recommendations based on the clinical history analysis should be considered in light of the possibility that this mutation explains all or some of the cancer history in the family.

GENE	MUTATION	INTERPRETATION
CHEK2	c.1100del (p.Thr367Metfs*15) Heterozygous	High Risk This patient has *CHEK2*-associated cancer risk.

DETAILS ABOUT: *CHEK2* c.1100del (p.Thr367Metfs*15): NM_007194.3

Functional Significance: Deleterious - Abnormal Protein Production and/or Function

The heterozygous germline *CHEK2* mutation c.1100del is predicted to result in the premature truncation of the *CHEK2* protein at amino acid position 381 (p.Thr367Metfs*15).

Clinical Significance: High Risk

This mutation is associated with increased cancer risk and should be regarded as clinically significant.

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

Details About Non-Clinically Significant Variants: All individuals carry DNA changes (i.e., variants), and most variants do not increase an individual's risk of cancer or other diseases. When identified, variants of uncertain significance (VUS) are reported. Likely benign variants (Favor Polymorphisms) and benign variants (Polymorphisms) are not reported and available data indicate that these variants most likely do not cause increased cancer risk. Present evidence does not suggest that non-clinically significant variant findings be used to modify patient medical management beyond what is indicated by the personal and family history and any other clinically significant findings.

Variant Classification: Myriad's myVision™ Variant Classification Program performs ongoing evaluations of variant classifications. In certain cases, healthcare providers may be contacted for more clinical information or to arrange family testing to aid in variant classification. When new evidence about a variant is identified and determined to result in clinical significance and management change, that information will automatically be made available to the healthcare provider through an amended report.

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MyRisk Genetic Result

Name: Voelker, Kevin DOB: [redacted] Accession #: 05258003-BLD Report Date: Jan 29, 2025

ADDITIONAL INFORMATION

Genes Analyzed: Sequencing (seq) and large rearrangement analyses were performed for all coding exons in the following genes, unless otherwise indicated:
APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, CTNNA1, FH, FLCN, HOXB13 (seq only), *MEN1, MET, MLH1, MSH2, MSH3* (excluding repetitive portions of exon 1), *MSH6, MUTYH, NTHL1, PALB2, PMS2, PTEN, RAD51C, RAD51D, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL.*
Limited promoter regions may also be analyzed for large rearrangements.

Sequencing (seq) and/or large rearrangement (LR) analyses were performed only for the gene portions indicated in parenthesis for the following genes:
EGFR (exons 18-21, seq and LR), *EPCAM* (exons 8-9, LR only), *GREM1* (exon 1 and upstream regulatory regions, LR only), *MITF* (c.952, seq only), *POLE* (exonuclease domain, seq only), *POLD1* (exonuclease domain, seq only), *RET* (exons 5, 8, 10, 11, 13-16 seq and LR), *TERT* (promoter region 71 bases upstream of the translation start, c.-71_-1, seq only).

** Other genes not analyzed with this test may also be associated with cancer.

Indication for Testing: It is our understanding that this individual was identified for testing due to a personal or family history suggestive of a hereditary predisposition for cancer.

Patient Information: Sex assigned at birth is a label given to an individual at birth, typically "male" or "female". In this report, the terms "male", "female", "he", "she", "woman", and "man" refer to sex assigned at birth.

Associated Cancer Risks and Clinical Management: The "MyRisk Management Tool" associated with this report provides a summary of cancer risk and professional society medical management guidelines that may be useful in developing a plan for this patient based on any clinically significant test results and/or reported personal/family history. In some cases, a MyRisk Management Tool cannot be provided, such as when the result has a special interpretation or includes a mutation with unusual characteristics.

Analysis Description: The Technical Specifications summary (myriad.com/technical-specifications) describes the analysis, method, performance, nomenclature, and interpretive criteria of this test. Current testing technologies are unable to definitively determine whether a variant is germline or somatic in origin, which may significantly impact risk estimates and medical management; therefore, these results should be correlated with this patient's personal and family history. The interpretation of this test may also be impacted if the patient has a hematologic malignancy or an allogeneic bone marrow transplant.

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Genetic testing was completed by CLIA and CAP accredited laboratories in the United States located at: 320 Wakara Way, Salt Lake City, UT 84108 and 322 N 2200 W, Salt Lake City, UT 84116 CLIA IDs: 46D0880690, 46D2275645
The following personnel codes and laboratory director signature may reflect remote review of digital data: 572, 3028

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Integrated BRACAnalysis® with MyRisk™ Hereditary Cancer Test

Clinical & Cancer Family History Information

MyRisk™ Hereditary Cancer Test

RECEIVING HEALTHCARE PROVIDER	SPECIMEN	PATIENT
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Alliance Cancer Specialists	Draw Date: Jan 14, 2025	Date of Birth: [redacted]
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PERSONAL / FAMILY CANCER HISTORY SUMMARY

FAMILY MEMBER	CANCER / CLINICAL DIAGNOSIS	AGE AT DIAGNOSIS
Patient	Kidney/Renal	63
Family History	None	

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RiskScore is not valid, and may significantly over- or under-estimate breast cancer risk for individuals who do not meet the eligibility criteria in effect when the testing was performed. The current criteria are: 1) sex assigned at birth is female 2) age is 18 to 84 years, 3) no personal history of breast cancer, LCIS, hyperplasia (with or without atypia), or a breast biopsy with unknown results, 4) there is no mutation detected in a breast cancer risk gene (other than a monoallelic *CHEK2* mutation in a White/Non-Hispanic or Ashkenazi Jewish individual), 5) the individual's relatives have not been found to have a mutation in a high-penetrance breast cancer risk gene (*BRCA1*, *BRCA2*, *CDH1*, *PALB2*, *PTEN*, *STK11*, *TP53*, a biallelic mutation in *CHEK2*, or the specific mutation c.7271T>G (p.Val2424Gly) in *ATM*) and 6) the sample was submitted with a current Test Request Form and the ordering healthcare provider has not determined that RiskScore is inappropriate for the patient. If this is an amended report for a patient tested in the past, please refer to the MyRisk Technical Specifications at http://myriad.com/technical-specifications for the eligibility criteria in effect at the time of the original testing.

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MyRisk Management Tool

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GENE	MUTATION	THIS GENETIC TEST RESULT IS ASSOCIATED WITH THE FOLLOWING CANCER RISKS:
CHEK2	c.1100del (p.Thr367Metfs*15) Heterozygous	ELEVATED RISK: Male Breast, Colorectal

Please see the Genetic Test Result for more details on any variant(s) detected in this patient, including variant classification information.

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CLINICAL OVERVIEW OF GENETIC FINDINGS

CHEK2-associated cancer risk

- This patient has been found to have a mutation in the *CHEK2* gene. Most women with *CHEK2* mutations have a risk for breast cancer that is significantly increased over the 12.5% lifetime risk for women in the general population of the United States. Men with *CHEK2* mutations also have an increased risk for breast cancer.
- Estimates of cancer risk for men and women with *CHEK2* mutations vary widely and are strongly influenced by family history. In cases where there is no family history of one of these cancers, the risk for a patient with a *CHEK2* mutation may be lower than in cases where that cancer has been diagnosed in one or more close relatives. Therefore, the family history of a patient should be considered when deciding on the most appropriate strategies to manage cancer risk, with more aggressive strategies targeted to patients with significant family histories of related cancers.
- Individuals with *CHEK2* mutations may have an elevated risk for colorectal cancer, and the National Comprehensive Cancer Network (NCCN) has provided screening recommendations to address this possible risk.
- Some studies have described a possible increased risk for a wide range of cancers in patients with *CHEK2* mutations, including prostate, gastric, thyroid, renal, hematological malignancies, testicular germ cell tumors, and other malignancies. However, these studies are not conclusive and there are currently no medical management guidelines to address these possible risks.

- Although there are increased risks for cancer in men and women with mutations in *CHEK2*, there are interventions that may reduce these risks. Guidelines from the National Comprehensive Cancer Network (NCCN) that may apply are listed below. Since information about the cancer risks associated with *CHEK2* mutations is relatively new, and there is still some uncertainty about the best ways to reduce these risks, it may be appropriate to interpret these results in consultation with cancer genetics experts in this emerging area of knowledge.

WHAT ARE THE PATIENT'S CANCER RISKS?

These risk tables show the clinically significant cancer risks identified as part of this patient's testing. Testing for some patients does not include some of the analyses listed:

- GENETIC RESULT: Mutations detected in any of the hereditary cancer genes included on the MyRisk panel.
- BREAST CANCER RISKSCORE: RiskScore estimate of remaining lifetime breast cancer risk if 20% or greater
- CLINICAL HISTORY ANALYSIS for breast cancer risk: Tyrer-Cuzick model estimate of remaining lifetime breast cancer risk of 20% or greater
- CLINICAL HISTORY ANALYSIS for breast, colorectal, pancreatic, prostate and melanoma cancer: Analysis of the patient's personal and family history.

The risks for each of these results are provided separately. If the risk for any individual cancer is affected by more than one of these results, the risk associated with each finding is listed in a separate table. At this time, there is not enough information to estimate risks for cancers affected by more than one gene mutation, or risks based on both gene mutations and personal/family history.

Risks Due to *CHEK2*-associated cancer risk

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION	RELATED TO
MALE BREAST			
To age 80	0.4%-1%	0.1%	*CHEK2*
COLORECTAL			
To age 80	Possibly elevated risk	2.8%	*CHEK2*

WHAT MANAGEMENT FOR CANCER RISKS SHOULD BE CONSIDERED?

This overview of clinical management guidelines is based on the patient's genetic test results and the Clinical History Analysis. Medical management guidelines are summarized from established medical societies, primarily the National Comprehensive Cancer Network (NCCN). If there are overlapping management guidelines for any individual cancer due to more than one of these results, the guidelines associated with each finding are listed in separate tables, even if they are the same. At this time, there are no medical society guidelines for how to adjust management when there are multiple sources of risk, such as from more than one gene mutation, or a mutation and a personal/family history of cancer. In these cases, it may be appropriate to use the most aggressive of the management options provided.

The overview provided below should not be used as the sole source of information to determine medical management. The references cited should always be consulted for more details and updates to the recommendations.

No information is provided related to treatment of a previous or existing cancer or polyps. The recommendation summaries below may require modification due to the patient's personal medical history, past surgeries and other treatments. Patients with a past history of cancer, benign tumors, or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis. Any discussion of medical management options is for general information purposes only and does not constitute a recommendation. While genetic testing and medical society recommendations provide important and useful information, medical management decisions should be made in consultation between each patient and his or her healthcare provider.

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MyRisk Management Tool

Name: Voelker, Kevin DOB: [redacted] Accession #: 05258003-BLD Report Date: Jan 29, 2025

Management Options for *CHEK2*-associated cancer risk

PROCEDURE	AGE TO BEGIN	FREQUENCY Unless otherwise indicated by findings	RELATED TO
MALE BREAST			
Currently there are no specific medical management guidelines for male breast cancer risk in mutation carriers. However, the increase in risk warrants consideration of options for male breast cancer screening, such as patient breast awareness education and clinical breast examinations. [1,2]	Individualized	NA	*CHEK2*
COLORECTAL			
Colonoscopy [3]	40 years, or 10 years younger than the age of diagnosis for any first-degree relative with colorectal cancer	Every 5 years	*CHEK2*
FOR PATIENTS WITH A CANCER DIAGNOSIS			
For patients with a gene mutation and a diagnosis of cancer, targeted therapies may be available as a treatment option for certain tumor types (e.g., PARP-inhibitors). [4]	NA	NA	*CHEK2*

1. Bevers TB, et al. NCCN Clinical Practice Guidelines in Oncology®: Breast Cancer Screening and Diagnosis. V 1.2022. Jun 2. Available at https://www.nccn.org.
2. Daly M et al. NCCN Clinical Practice Guidelines in Oncology®: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic. V 3.2023. Feb 13. Available at https://www.nccn.org.
3. Gupta S, et al. NCCN Clinical Practice Guidelines in Oncology® Genetic/Familial High-Risk Assessment: Colorectal. V 1.2023. May 30. Available at https://www.nccn.org.
4. Schaeffer E, et al. NCCN Clinical Practice Guidelines in Oncology®: Prostate Cancer. V 1.2023. Sep 16. Available at https://www.nccn.org.

Notes for Personalized Management:

INFORMATION ON HOW CANCER RISKS AND MANAGEMENT ARE DETERMINED

The MyRisk Management Tool provides cancer risk levels based on analysis of genetic test results (see MyRisk Genetic Result) and a summary of medical society management recommendations based on both the genetic test results and a limited analysis of the patient's clinical history related to the risk for breast, colorectal, prostate, melanoma and pancreatic cancers. Here are some important points to understand as you interpret this test report and decide on the best plan for management:

- Comprehensive patient management. The management recommendations presented in this report are a summary of management options recommended by the National Comprehensive Cancer Network (NCCN) and other established medical societies and are general in nature. The patient's actual management should be modified based on personal medical history, surgeries and other treatments. A comprehensive risk assessment and management plan may take into account this report and other aspects of the patient's personal/family medical history (e.g., all known clinical diagnoses), as well as lifestyle, environmental and other factors.

- Risk estimates based on provider-supplied information. Some of the risk estimates and management recommendation summaries provided in this report are based on our interpretation of information supplied by the ordering health care provider on the test request form (see Specifications for Personal/Family History analysis at myriad.com/technical-specifications). The patient's actual risks and appropriate management may be significantly different if details provided for cancer diagnoses, ages, family relationships or other factors were incorrect, omitted, ambiguous or have since changed. Please review the clinical history listed on the Clinical & Family History Information page of this report to make sure that the information used was provided and interpreted correctly.
- Variability in Tyrer-Cuzick risk estimates. Tyrer-Cuzick estimates of breast cancer risk can vary significantly based on the way in which the model is used, and the estimate provided here may be higher or lower than what would be calculated by other users. For complete details of how Myriad calculates Tyrer-Cuzick risk estimates, including how Myriad handles information provided in a format not compatible with the model, please see the Specifications for Personal/Family History analysis at myriad.com/technical-specifications. These Specifications also include information for recalculating the Tyrer-Cuzick breast cancer risk estimate if desired.
- What is meant by "High Risk" and "Elevated Risk"? In the Genetic Test Result Summary, a gene-associated cancer risk is described as "High Risk" for a cancer type if all of the following conditions are met: the absolute risk of cancer is approximately 5% or higher, the increase in risk over the general population is approximately 2 to 3-fold or higher, and there is significant data from multiple studies supporting the cancer risk estimate. A gene is described as "Elevated Risk" for a cancer type if there is sufficient data to support an increase in cancer risk over the general population risk, but not all criteria for "High Risk" are met.

INFORMATION FOR FAMILY MEMBERS

Family members should talk to their healthcare providers about hereditary cancer testing to help define their own risk and assist in the interpretation of this patient's genetic test result.

- This patient's relatives are at risk for carrying the same mutation(s) and associated cancer risks as this patient. Cancer risks for individuals who have this/these mutation(s) are provided below.
- **Family members should talk to a healthcare provider about genetic testing.** Close relatives such as parents, children, and siblings have the highest chance of having the same mutation(s) as this patient. Other more distant relatives such as cousins, parents siblings, and grandparents also have a chance for carrying the same mutation(s). Testing of at-risk relatives can identify those family members with the same mutation(s) who may benefit from surveillance and early intervention. More resources for family testing are available at MySupport360.com.

Additional Information for *CHEK2*-associated cancer risk

- In rare instances, an individual may inherit mutations in both copies of the *CHEK2* gene, leading to significantly higher breast cancer risks than those in women with a single *CHEK2* mutation. The children of this patient are at risk of inheriting two *CHEK2* mutations only if the other parent is also a carrier of a *CHEK2* mutation. Screening the other biological parent of any children for *CHEK2* mutations may be appropriate. Alternatively, this patient's children may consider genetic testing for any mutations in the entire *CHEK2* gene.

CANCER RISK FOR *CHEK2* CLINICALLY SIGNIFICANT MUTATION

CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION
	FEMALES	
FEMALE BREAST		
To age 80	20%-31%	10.7%
Second primary within 10 years of first breast cancer diagnosis	7%-29%	3.5%
	MALES	
MALE BREAST		
To age 80	0.4%-1%	0.1%

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MyRisk Management Tool

Name: Voelker, Kevin DOB: [redacted] Accession #: 05258003-BLD Report Date: Jan 29, 2025

CANCER RISK FOR *CHEK2* CLINICALLY SIGNIFICANT MUTATION

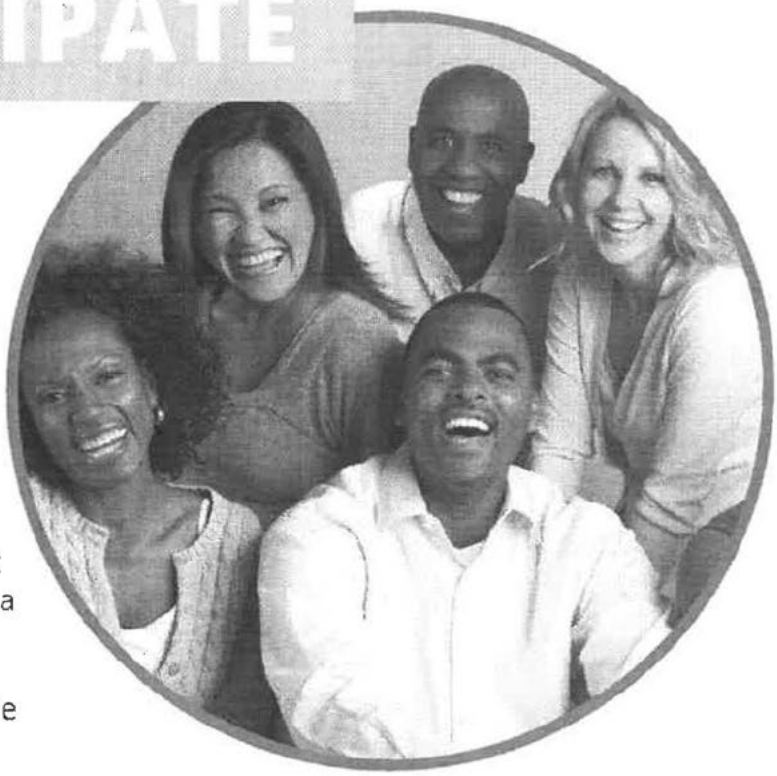
CANCER TYPE	CANCER RISK	RISK FOR GENERAL POPULATION
	FEMALES AND MALES	
COLORECTAL		
To age 80	Possibly elevated risk	2.8%

Please contact Myriad Medical Services at 1-800-469-7423 X 3850 to discuss any questions regarding this result.

END OF MANAGEMENT TOOL

ICARE
Inherited Cancer Registry

WHY PARTICIPATE IN ICARE?



Be a part of new discoveries.

Studies that used information from ICARE participants have...

found that removing the ovaries may not lower breast cancer risk for women with a ***BRCA*** mutation.[1]

improved cancer risk estimates for people with ***PALB2*** mutations.[2]

Get care updates personalized to you.

as new guidelines and other information come out – for example:

ICARE participants with mutations in ***PALB2***, ***CHEK2***, and ***ATM*** were given updates that might affect their care because new National Comprehensive Cancer Network (NCCN) Genetics Guidelines were released in September 2022.

Find out about other studies.

Examples of studies include:

A study providing free resources to help with managing cancer risks and family communication of test results.

A study doing free genomic studies on breast cancers in people with ***BRCA1***, ***BRCA2***, ***PALB2***, ***ATM***, and ***CHEK2*** mutations to learn more about how these tumors develop and how we might best treat them.

Enroll online by visiting
https://redcap.link/ICAREconsent
or **scan the below QR code:**

05258003-BLD

[1] Kotsopoulos J, et al. Bilateral Oophorectomy and the Risk of Breast Cancer in BRCA1 Mutation Carriers: A Reappraisal. Cancer Epidemiol Biomarkers Prev. 2022 Jul 1;31(7):1351-1358. PMID: 35477160; [2] Yang X, et al. Cancer Risks Associated with Germline PALB2 Pathogenic Variants: An International Study of 524 Families. J Clin Oncol. 2020 Mar 1;38(7):674-685. PMID: 31841383.

PROMPT

Prospective Registry Of MultiPlex Testing

Opportunity to Enroll in Hereditary Cancer Research

Genetic testing can help individuals and families by giving them a clearer idea of their cancer risks. Genetic tests (called multi-gene or multiplex panels) look for changes in several different genes, all in a single test. While all of the genes on these panels have been tied to an increased risk of cancer, we understand the risks associated with some of the genes better than we understand others. One way to help improve our understanding is to enroll people with pathogenic mutations or variants of unknown significance in registries. Registries typically follow people over many years to learn more about these alterations and how they impact their health.

How can I find a research registry?

There are several hereditary cancer research registries that are studying individuals who have had multiplex panel testing. One registry that is open to individuals nationwide is PROMPT (or **P**rospective **R**egistry **O**f **M**ulti**P**lex **T**esting). PROMPT is an online registry for patients and families who have had multiplex testing and have been found to have a genetic variation which may be linked to an increased risk of cancer. PROMPT is a joint effort involving several academic medical centers and commercial laboratories, working together to learn more about the genes that are studied on multiplex panels. PROMPT will allow researchers to better understand the cancer risks associated with changes in these genes and thus provide a better understanding of the best way to take care of individuals who have such changes.

What is involved in participation?

Participation in the study simply involves completing online surveys. Additionally, the PROMPT team may reach out to you to talk about ways that you can get more involved with the research effort. Your participation will help researchers learn more and improve the ability of this genetic testing to help people.

How do I enroll?

You can learn more about or register for PROMPT by going to www.promptstudy.info or by scanning the QR code below.

Thank you again for considering taking part in PROMPT!

SCAN ME

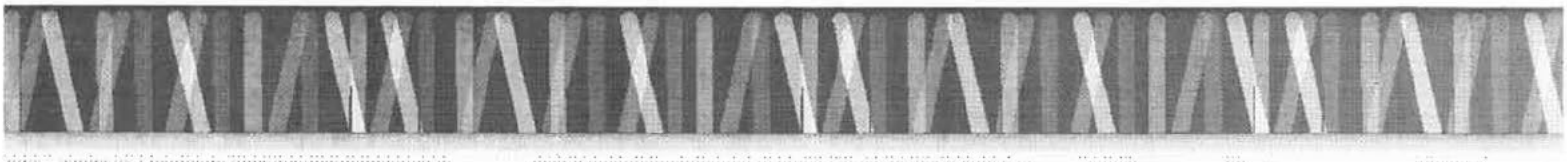
If you would like to read more about multiplex panels, including details about specific genes, please visit our informational website at www.promptstudy.info.

MyRisk™
Hereditary Cancer Test

⊕ Positive result

Understanding a positive result

A guide to understanding risk and taking action



Myriad genetics

Health. Illuminated.

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⊕ Positive result

Understanding your Myriad MyRisk™ hereditary cancer test result

Your Myriad Genetics MyRisk Hereditary Cancer test has three main sections which are summarized in the banner on the first page. Throughout the report, these sections can be identified by the title on the top left of each page of the report.

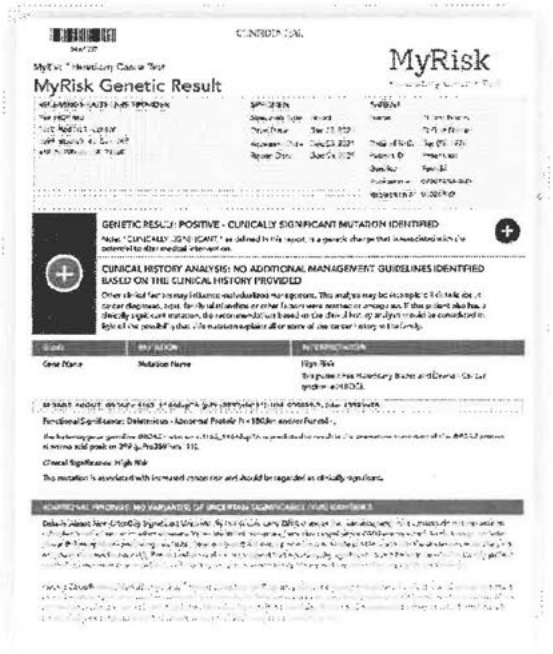
1. Genetic result
2. Clinical & cancer family history information
3. Management tool

1 Genetic result

The MyRisk test looks at multiple genes associated with hereditary cancer risk. When a gene has a clinically significant mutation, or harmful change, there is a higher chance for certain cancers to develop. A list of the genes evaluated on your test can be found in this section of your report. The gene table on our website includes information about each gene and the cancers with which it is associated.

Your genetic result was POSITIVE.
This means that a clinically significant mutation, or harmful genetic change, was found in one or more of the genes analyzed as part of your testing. Since genes are passed down in families, your close relatives, such as your children, brothers and sisters, parents, aunts and uncles, and cousins, are at risk to have the same genetic change that was identified in you. It is important to share your results with your relatives so they can discuss genetic testing with their own healthcare providers.

If a variant of uncertain clinical significance (VUS) was identified, it will also be listed in the genetic result section. A VUS is a genetic change that may or may not be contributing to your cancer risk. A VUS is not considered to be clinically actionable, so medical care decisions should not be made based on a VUS. We are committed to identifying information so that we can better understand these genetic changes. If new information is available about your specific VUS, that information will be shared with your healthcare provider.


MyRisk

MyRisk Genetic Result

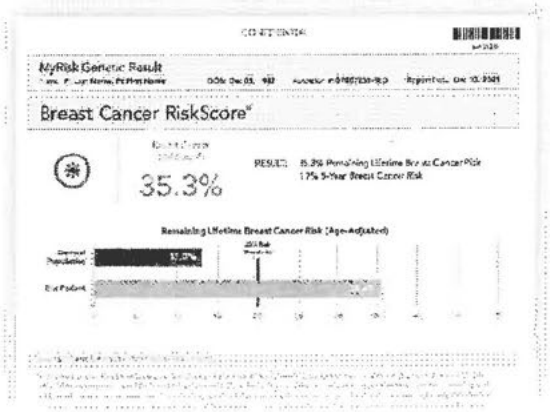
GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

CLINICAL HISTORY ANALYSIS: NO ADDITIONAL MANAGEMENT GUIDELINES IDENTIFIED BASED ON THE CLINICAL HISTORY PROVIDED

Positive results with SINGLE SITE testing: If a member of your family has tested positive for a clinically significant mutation, your provider may have ordered testing for only that specific genetic change. This is known as single site testing. Your positive result means that you DO carry the same harmful genetic change that was found in your family member and you should discuss any changes to your medical management that should be considered with your healthcare provider. Since single site testing does not look for other genetic changes or assess additional risk from family history, this is not a comprehensive risk assessment. Information in the management tool is specific ONLY to the clinically significant mutation listed on your report.

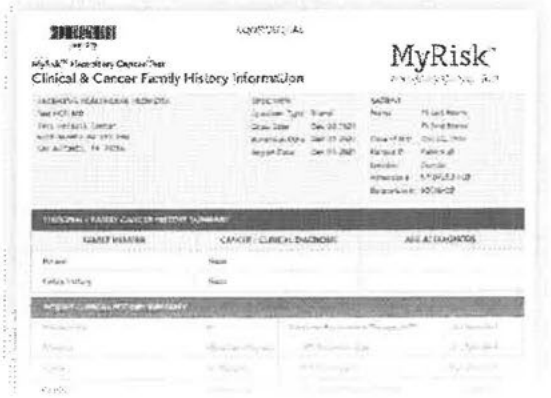
Breast cancer RiskScore™

You may or may not see a breast cancer RiskScore and/or a Tyrer-Cuzick breast cancer risk assessment in this section of the report. These results are calculated for women who meet certain criteria and have never been diagnosed with breast cancer themselves.



❷ Clinical & cancer family history information

The Clinical & Cancer Family History Information section reviews the medical information that your healthcare provider gave us about you and your family. Certain types of cancer in the family or cancers diagnosed at early ages can indicate that someone may have an elevated risk, even if no clinically significant mutations are found.



❸ Management tool

In this section of the result, there will be a table for each gene in which a clinically significant mutation was identified. This table outlines associated cancers and the risk to develop these cancers. In another table, a summary of medical management options from expert medical groups for these cancers and/or a list of other health problems associated with the mutation are included. The medical management options may include changes to screening frequency or recommendations for a specific type of screening, discussions about preventive surgery, consideration of preventive medication, and/or lifestyle changes.

In addition to the genetic result, the presence of certain cancers in the family or certain medical findings in your own health history can also influence your cancer risk. There may be additional recommendations listed in this section due to these personal or family history health factors. If there are recommendations for changes to your breast cancer screening based on your RiskScore™ and/or a Tyrer-Cuzick breast cancer risk assessment, they will be included in this section. Personal and family histories can change over time, so it is important to keep your healthcare providers up to date regarding any changes.

Resources

Your healthcare provider is always your primary resource. You can request a consultation with a genetic counselor at Myriad by going to **my.myriad.com/consults**. During your consultation, the genetic counselor can help you understand your report and the implications of your results.

To view the full list of genes available on the MyRisk™ panel, please visit:
www.myriadmyrisk.com/gene-table/

Next steps

Schedule any follow-up appointments and/or obtain referrals to appropriate specialists

Speak with your relatives about your results and encourage them to see their healthcare provider about cancer prevention and genetic testing

Consider speaking with a **clinical genetic counselor** or other genetics expert in your community about your test result and family history

Myriad genetics

Myriad Genetics, Inc.
320 Wakara Way
Salt Lake City, UT
84108

myriad.com

MGMRHCPOSPET / 02-22

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Notice and Statement Concerning Nondiscrimination and Accessibility

Discrimination is Against the Law

Myriad Genetics, Inc. (Myriad) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Myriad does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Aids and Services

Myriad provides free aids and services to people with disabilities to communicate effectively with us, such as TTY/TDD calls or written information in suitable formats. Myriad will also provide free language services to people whose primary language is not English through qualified interpreters.

If you need these services, contact:

Don Martin
Chief Compliance Officer
320 Wakara Way
Salt Lake City, UT 84108

Telephone: (801) 584-3600
Fax: (801) 584-3640
Email: compliance@myriad.com

Grievances

If you believe that Myriad has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex. You can file a grievance by mail, telephone, fax, or email. If you need help filing a grievance, Mr. Martin is available to help you (see contact information above).

Grievance Procedure

1. Any person who believes someone has been subjected to discrimination by Myriad on the basis of race, color, national origin, sex, age or disability may file a grievance with Myriad. It is against the law for Myriad to retaliate against anyone who opposes discrimination, files a grievance, or participates in the investigation of a grievance.
2. Grievances must be submitted within 60 days of the date the person filing the grievance becomes aware of the alleged discriminatory action.
3. The complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
4. Myriad will conduct an investigation of the complaint. This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. Myriad will maintain the files and records relating to such grievances. To the extent possible, and in accordance with applicable law, Myriad will take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.
5. Myriad will issue a written decision on the grievance, based on a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.
6. The person filing the grievance may appeal Myriad's decision in writing to the Chief Executive Officer (CEO) of Myriad within 15 days of receiving Myriad's initial decision. The CEO will issue a written decision in response to the appeal no later than 30 days after its filing.
7. Individuals seeking access to Section 1557 and its implementing regulations may be facilitated by contacting Mr. Martin (see contact information above).
8. The availability and use of this grievance procedure does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis of race, color, national origin, sex, age or disability in court or with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

   U.S. Department of Health and Human Services
   200 Independence Avenue, SW
   Room 509F, HHH Building
   Washington, D.C. 20201

9. Complaints must be filed within 180 days of the date of the alleged discrimination. Myriad will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this grievance process. Mr. Martin will be responsible for such arrangements.

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Español (Spanish)
Myriad Genetics, Inc. cumple con las leyes federales de derechos civiles aplicables y no discrimina por motivos de raza, color, nacionalidad, edad, discapacidad o sexo.
ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-801-584-3600.

繁體中文 (Chinese)
Myriad Genetics, Inc. 遵守適用的聯邦民權法律規定，不因種族、膚色、民族血統、年齡、殘障或性別而歧視任何人。
注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電1-801-584-3600.。

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Myriad Genetics, Inc.은(는) 관련 연방 공민권법을 준수하며 인종, 피부색, 출신 국가, 연령, 장애 또는 성별을 이유로 차별하지 않습니다.
주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-801-584-3600. 번으로 전화해 주십시오.

Tagalog (Tagalog - Filipino)
Sumusunod ang Myriad Genetics, Inc. sa mga naaangkop na Pederal na batas sa karapatang sibil at hindi nandidiskrimina batay sa lahi, kulay, bansang pinagmulan, edad, kapansanan o kasarian.
PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-801-584-3600.

Updated September 2023

العربية (Arabic)

يلتزم Myriad Genetics, Inc. | بقوانين الحقوق المدنية الفدرالية المعمول بها ولا يميز على أساس العرق أو اللون أو الأصل الوطني أو السن أو الإعاقة أو الجنس.

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1-801-584-3600

Kreyòl Ayisyen (French Creole)
Myriad Genetics, Inc. konfòm ak lwa sou dwa sivil Federal ki aplikab yo e li pa fè diskriminasyon sou baz ras, koulè, peyi orijin, laj, enfimite oswa sèks.
ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-801-584-3600.

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Myriad Genetics, Inc. cumpre as leis de direitos civis federais aplicáveis e não exerce discriminação com base na rtaça, cor, nacionalidade, idade, deficiência ou sexo.
ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 1-801-584-3600.

Italiano (Italian)
Myriad Genetics, Inc. è conforme a tutte le leggi federali vigenti in materia di diritti civili e non pone in essere discriminazioni sulla base di razza, colore, origine nazionale, età, disabilità o sesso.
ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 1-801-584-3600

Polski (Polish)
Myriad Genetics, Inc. postępuje zgodnie z obowiązującymi federalnymi prawami obywatelskimi i nie dopuszcza się dyskryminacji ze względu na rasę, kolor skóry, pochodzenie, wiek, niepełnosprawność bądź płeć.
UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-801-584-3600.

日本語 (Japanese)
Myriad Genetics, Inc. は適用される連邦公民権法を遵守し、人種、肌の色、出身国、年齢、障害または性別に基づく差別をいたしません。注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。1-801-584-3600

Tiếng Việt (Vietnamese)
Myriad Genetics, Inc. tuân thủ luật dân quyền hiện hành của Liên bang và không phân biệt đối xử dựa trên chủng tộc, màu da, nguồn gốc quốc gia, độ tuổi, khuyết tật, hoặc giới tính.
CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-801-584-3600.

Русский (Russian)
Myriad Genetics, Inc. соблюдает применимое федеральное законодательство в области гражданских прав и не допускает дискриминации по признакам расы, цвета кожи, национальной принадлежности, возраста, инвалидности или пола.
ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-801-584-3600.

Français (French)
Myriad Genetics, Inc. respecte les lois fédérales en vigueur relatives aux droits civiques et ne pratique aucune discrimination basée sur la race, la couleur de peau, l'origine nationale, l'âge, le sexe ou un handicap.
ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-801-584-3600.

Deutsch (German)
Myriad Genetics, Inc. erfüllt geltenden bundesstaatliche Menschenrechtsgesetze und lehnt jegliche Diskriminierung aufgrund von Rasse, Hautfarbe, Herkunft, Alter, Behinderung oder Geschlecht ab.
ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-801-584-3600.

فارسی (Farsi)

Myriad Genetics, Inc. | از قوانین حقوق مدنی فدرال مربوطه تبعیت می کند و هیچگونه تبعیضی بر اساس نژاد، رنگ پوست، اصلیت ملیتی، سن، ناتوانی یا جنسیت افراد قایل نمی شود.

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 1-801-584-3600 تماس بگیرید.

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