

\_, request and permit Invitae to analyze the genes indicated on

the test requisition form in my sample.

## I UNDERSTAND THAT:

- 1. More information about the Invitae proactive tests is available from my healthcare provider.
- 2. The results of this DNA test could be:
  - a. Positive, and may:
    - i. alert me to a predisposition or an increased risk for developing a genetic disease in the future.
    - ii. have implications for risk of disease in other family members.
  - b. Negative, and may:
    - i. indicate disease risks close to that of the general population but do not eliminate the risk for developing a genetic disease in the future.
- 3. Molecular genetic tests may or may not provide actionable information or have an implication for my medical management.
- 4. Some types of DNA changes that could cause a specific genetic disorder may not be detected by this test. As with most molecular genetic tests, Invitae's test has technical limitations that may prevent detection of certain changes due to poor DNA quality, inherent DNA sequence properties, or other types of limitations.
- 5. There may be possible sources of error including, but not limited to, trace contamination, rare technical errors in the laboratory, rare DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate reporting of family relationships or clinical diagnosis information.
- 6. Invitae will only interpret the parts of the DNA sequence of the genes indicated on the requisition form by my physician and will not report variants of uncertain significance. No testing apart from that which is ordered will be performed. Additional testing requires my additional, express consent.
- 7. Invitae's clinical reports are released only to the certified healthcare provider(s) listed on the test requisition form. Clinical reports are confidential and will only be released to other medical providers with my explicit written consent. It has been explained to me that my clinical report is available for me to download from within the Invitae patient portal (www.invitae.com/patients/signin) after it has been released by the ordering healthcare provider(s) or upon request in accordance with applicable law.
- 8. It is my responsibility to consider the possible impact of my test results as they relate to insurance rates, obtaining disability or life insurance, implications for family members, and employment.
- 9. The Invitae Proactive tests are screening genetic tests. This means that DNA variants that have implications for my medical management will be reported by this test. I may also receive a result that indicates that I carry a genetic change that does not increase my own risk of developing a specific medical condition, but that may be passed within my family (also known as carrier status).
- 10. I understand that Invitae recommends that I consult with a genetic counselor before consenting to this test and a genetic counselor or my healthcare provider about my results. For a list of medical geneticists and counselors who may be available in my area, I may visit the National Society of Genetic Counselors website at www.nsgc.org. Further testing or additional physician consults may be warranted.
- 11. I understand that my data and personal information will be stored and protected in compliance with applicable regulatory requirements (e.g., HIPAA and equivalent protections), and I acknowledge that I have read and understand Invitae's Privacy Policy and Notice of Privacy Practices (available at www.invitae.com/privacy).
- 12. I understand that knowledge of genetic information will improve over time, that new information may become available in the future that could impact the interpretation of my results, and that Invitae may notify me of clinical updates related to my genetic profile (in consultation with my primary clinician as indicated). I may request additional notifications and resources relevant to my genetic profile by creating an Invitae patient portal account at www.invitae.com/patients/signin.
- 13. Sharing de-identified genetic data can significantly accelerate medical research for both individual patients and society as a whole. Invitae encourages patients to choose to share their genetic variants with the medical and scientific community to help accelerate our understanding of genetic conditions, improve genetic testing, find new therapies, and eventually prevent disease. Invitae will share results after they are de-identified, meaning that Invitae removes any information that identifies or could be used to identify me personally.
  - a. **De-identified genetic information:** I understand Invitae may store and retain indefinitely at its discretion, except as prohibited by law, and use and/or disclose to third parties, including public databases, my de-identified genetic information for quality assurance, test development and/or validation, research, and/or educational purposes.
  - b. **De-identified samples:** I understand Invitae may store and retain indefinitely at its discretion, except as prohibited by law, and use and/or share with third parties my de-identified samples for quality assurance, test development and/or validation, research, and/or educational purposes.
  - c. **Future contact regarding research:** I permit Invitae to contact me in the future about research opportunities that may be related to my condition or my test results.



## **Patient Consent for Proactive Testing**

- FM165-2 (INTERNATIONAL)
- d. Update preferences: I control how Invitae uses my data. I understand that I can log in to the Invitae patient portal (www.invitae.com/patients/signin) and click on Account Settings > Preferences if I would like to change my preferences with respect to how Invitae uses my deidentified data. If I choose to restrict the use of my de-identified genetic information or sample(s): (a) I understand that to the extent that such information has already been used or shared, it cannot be retracted or destroyed, and (b) I understand that my de-identified genetic information and/or sample(s) may still be used for quality assurance, test development and/or validation; shared with public databases; and/or (in connection with de-identified information) used or disclosed to third parties, not on an individual basis but as aggregated information for research or education purposes.
- 14. My sample will be sent for testing to Invitae's laboratory located in the United States, and my data and personal information, including my test results, will be stored in the United States.
- 15. I have a right to receive a copy of this form.

## BY SIGNING BELOW, I ATTEST TO THE FOLLOWING:

- 1. I have read (or had read to me), and that I understand, the information provided in this consent;
- 2. I have all the information I want, and all my questions have been satisfactorily answered; and
- 3. I hereby consent to genetic testing.

Patient signature		Date
Patient name (please print)	Email address	

## HEALTHCARE PROVIDER STATEMENT

By signing below, I attest that:

- 1. I am the referring physician or authorized healthcare provider;
- 2. I have explained the purpose of test described above;
- 3. The patient has had the opportunity to ask questions regarding this test and/or seek genetic counseling; and
- 4. The patient has voluntarily decided to have this test performed by Invitae.

Healthcare provider signature	Date