

Myriad Genetics Prequel[®] Prenatal Screen

Please review this information carefully and then indicate with your signature if you wish to move forward with testing. This is a voluntary test. You may wish to seek genetic counseling prior to signing this form.

Purpose

The Prequel Prenatal Screen is a non-invasive prenatal screen that uses cell-free DNA to assess the risk of a current pregnancy having a chromosome condition, such as Down syndrome, trisomy 18, and trisomy 13. These conditions can lead to health issues including birth defects and intellectual disabilities, and the severity can vary.



- The Prequel Prenatal Screen is intended for women who are at least 10 weeks pregnant with a single fetus or twins.
- A screening test indicates whether there is an increased or decreased chance for a condition while a diagnostic test indicates whether the condition is actually present or not. The Prequel Prenatal Screen is a screening test.
- More information about each of the conditions included in the Prequel Prenatal Screen can be found at myriadwomenshealth.com/prequel. For all of these conditions, severity can vary.

Benefits

- Compared to other screening methods, non-invasive prenatal screening has fewer false positives and false negatives. This can lead to fewer unnecessary invasive tests like chorionic villus sampling (CVS) or amniocentesis. More information is available at myriadwomenshealth.com/prequel. Your results may help you and your healthcare provider make more informed medical management decisions.
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What you might learn

- The Prequel Prenatal Screen evaluates chromosome 13, chromosome 18 and chromosome 21. You and your healthcare provider may select additional studies to be ordered. Please speak with your healthcare provider regarding which version of the test you would like ordered for you.
- The following describes the possible results for the Prequel Prenatal Screen:
 - Positive: An “Aneuploidy Detected” or “Aneuploidy Suspected” result indicates that analysis of cell-free DNA in the mother’s blood is consistent with an increased risk of the current pregnancy having the condition(s) indicated (e.g., Down syndrome). You may receive a positive result for more than one condition.
 - » All “positive” results should be discussed with your healthcare provider to determine next steps, including pursuing diagnostic testing (such as chorionic villus sampling (CVS) and/or amniocentesis) and additional evaluation, as well as genetic counseling. While follow-up testing is recommended according to professional guidelines, the decision of whether to pursue additional testing is entirely yours and should be made in consultation with your healthcare provider.
 - Negative: A “No Aneuploidy Detected” or “No Abnormality Detected” result indicates a reduced risk of your pregnancy being affected by the conditions being screened.

- » This result indicates a significantly reduced likelihood, but does not entirely eliminate the possibility, of your pregnancy being affected by one of these syndromes.
- » In addition, this result does not guarantee that your pregnancy will be healthy. If you wish to further reduce the risk of an affected pregnancy, additional testing may be available.



Procedure

- The Prequel Prenatal Screen can be done 10 weeks into your pregnancy or later.
- A blood sample is taken from your arm and sent to Myriad for screening.
- Except in rare cases, your sample will be kept a maximum of 180 days.*

Risks

- Non-invasive prenatal screening may reveal sensitive information about the health of your pregnancy or, rarely, your own health.
- Your results may lead to your healthcare provider recommending additional testing and evaluation of your pregnancy, or otherwise impact your medical decisions.
- This test may provide information that can have an impact on your medical decisions.

Instructions for healthcare providers:

- This document is provided for your convenience and can be used at your discretion
- Some states may have specific documentation requirements for informed consent

Limitations

- The Prequel Prenatal Screen is designed to detect changes in the chromosomes associated with known syndromes in a current pregnancy. It cannot detect every case, nor does it look for all known genetic diseases or syndromes.
- Only changes in the chromosomes associated with the conditions requested by the ordering healthcare provider will be reported. Your report will indicate which conditions are included.
- Noninvasive prenatal screening results can reduce, but cannot eliminate, the likelihood a pregnancy has any changes in the chromosomes.
- As with all medical screening tests, there is a chance of error, including a false positive or false negative result.
 - A “false positive” refers to identifying an increased risk of changes in the chromosomes when in fact none is present.
 - A “false negative” is the failure to find an increased risk of a change in the chromosomes in a pregnancy that is affected.
- It is important for any relevant personal medical history, family history, and pregnancy history to be communicated to your healthcare provider and Myriad for accurate interpretation of your results.
- The Prequel Prenatal Screen can be performed on singleton or twin pregnancies only. Additional studies are limited in twin pregnancies.
- Additionally, pregnancies that have experienced the demise of one or more fetuses may not receive reliable results. Please check with your healthcare provider.
- If either the patient or the pregnancy has cells with different chromosome contents (called “mosaicism”), the results of the Prequel Prenatal Screen may not be accurate.
- Occasionally it may not be possible to provide a result. A repeat specimen may be requested.

Alternatives

- There are various options available that provide insight into the chromosomal status of a pregnancy and these should be discussed with your healthcare provider. These include screening as well as diagnostic options.
- Diagnostic testing, such as CVS or amniocentesis, is capable of providing definitive information about the chromosomal health of the pregnancy.
- You have the option to decline all such screening and diagnostic tests during pregnancy.

Privacy

- Genetic information is protected under the federal Genetic Information Nondiscrimination Act (GINA), which generally prohibits health insurers and employers from discriminating against you based on your genetic information. However, you should be aware current federal laws do not specifically prohibit genetic discrimination in life insurance, long-term care insurance and disability insurance. More information about GINA and its limitations is available at ginahelp.org.
- Your Prequel Prenatal Screen results will be reported to your healthcare provider or his/her agent.
- By agreeing to testing and signing this consent, you hereby authorize Myriad to share your Prequel Prenatal Screen results with other authorized representatives that you've identified to Myriad or your healthcare provider, or as otherwise allowed by law.
- Myriad may find information that is not included in the original test requested by your healthcare provider and may report these additional results, if clinically relevant. You authorize Myriad to share these results with you and your healthcare provider.

This test is available only to individuals who are at least 18 years old or the Services are being performed during pregnancy. I represent and warrant that I have the right, authority and capacity to consent to testing and am at least 18 years old or am taking this test during pregnancy.

In addition, I represent that (1) all information that I have submitted is complete, accurate and truthful, and (2) in the event that I have allowed a third party to assist me in providing any information, I have reviewed and confirmed that all such information is complete, accurate and truthful prior to its submission to Myriad.

I HAVE READ OR HAVE HAD READ TO ME THIS INFORMATION. I HAVE HAD A DISCUSSION WITH MY HEALTHCARE PROVIDER TO REVIEW THIS INFORMATION AND HAVE HAD AN OPPORTUNITY TO ASK QUESTIONS ABOUT THE PURPOSE, PROCEDURE, RISKS, BENEFITS, AND LIMITATIONS OF TESTING.

I HAVE DECIDED TO PURSUE TESTING and to be bound by the terms of this Consent and any policies referenced herein.

I HAVE DECIDED NOT TO PURSUE TESTING and will discuss next steps with my healthcare provider.

Patient Name

Date of Birth

Patient Signature

Date

Ordering Healthcare Provider Name

Ordering Healthcare Provider Signature

Date

Myriad
genetics

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- You authorize Myriad to contact you about your screen, test or sample, as well as additional products or services offered as part of your Prequel Prenatal Screen (e.g., cost estimates), as well as about additional products and/or offers that may be relevant and/or interesting to you.
- When receiving notifications from Myriad and its affiliates (“Myriad”), email, SMS, and text message may be sent to you to inform you that Myriad has prepared an estimate of your testing costs and to provide you status updates about your test and results. These communications may be unsecure and carry typical risks associated with such transmissions. By agreeing to testing and signing this consent, you agree that (a) you understand the foregoing warning and understand the typical risk of email, SMS, and text message transmissions, and (b) you give Myriad permission to communicate with you by email, SMS, or text message.
- Please refer to Myriad’s Notice of Privacy Policy, available on the Myriad website, for additional information about Myriad’s privacy practices, including how your protected health information (including your samples and genetic information) may be shared with third-party vendors and service providers that we partner with to provide testing services to you.

Research*

- Unless you contact us to tell us otherwise, by agreeing to testing and signing this consent, you authorize Myriad and its partners to use your sample and any information derived from your sample or otherwise collected about you for educational and/or research purposes. You will not be compensated for this use.
- Myriad may collect additional information regarding the outcome of your pregnancy from your healthcare provider for purposes of quality assurance and research.
- De-identified information may additionally be submitted to external research databases.
- You authorize Myriad to contact you about potential educational and/or research opportunities.
- Please contact us at prenatalsupport@myriad.com or **+1-888-268-6795** if you wish to opt out of such research or future contact.

Financial responsibility

- By agreeing to testing and signing this consent you authorize Myriad to submit to your insurance carrier any and all of the information, including test results, necessary for processing your insurance claim.
- By agreeing to testing you also authorize Myriad to obtain a consumer credit report on you from a consumer reporting agency selected by Myriad. You understand and agree that Myriad may use your consumer credit report to confirm whether your income qualifies you for financial assistance. You further understand that this is not a credit application and will not impact your credit score.
- If you qualify for financial assistance, you agree to provide Myriad with any additional information or documentation that may be needed to confirm your qualification for the financial assistance program.
- If your insurance carrier does not reimburse Myriad in full or in part because your insurance carrier determines the Prequel Prenatal Screen is not a covered service, is not medically necessary, or for any other reason, you agree to be responsible for payment if you choose to proceed with the screen.

*Samples from residents of New York state will not be retained for more than 60 days after collection and will not be included in research studies. Samples originating from Florida state will be retained and maintained in accordance with applicable laws and regulations.