



Comprehensive Reproductive
Immunology Assessment

IRMA Report

Report ID
DOEJ121685F-IRMA



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TABLE OF CONTENTS

Medical History	3
Report Summary	4
Parental Test Results	
1. Parental Histocompatibility	8
2. Parental Chromosome Analysis	11
Patient Test Results	
3. Thrombophilia	12
4. Blood Count	15
5. Inflammation	16
6. Autoimmunity	19
7. Autoimmunity Predisposition	22
8. Thyroid Function	23
9. Metabolism	24
10. Nutrition	25

IMPORTANT INFORMATION ABOUT THE IRMA REPORT

Pregmune Medical PA ("Pregmune Medical") is pleased to deliver this IRMA report to the patient and their ordering physician consistent with the terms and conditions within the Consent and Agreement previously executed by the patient, which can be found within the Patient Portal. The information presented in this report is complex and should be reviewed by the patient in conjunction with their physician. In connection with this report the patient acknowledges receipt of Pregmune Medical's Notice of Privacy Practices (located in the Patient Portal) which describes how information about the patient is used and disclosed by Pregmune Medical and consulting medical providers who are supported by business associates under contract to deliver services on their behalf consistent with HIPAA and the terms and conditions within the Consent and Agreement.

IMPORTANT INFORMATION ABOUT THE IRMA REPORT

Pregmune strives to promote social change and contribute to achieving gender equality. Because our reports are designed to be used by anyone seeking parenthood, we use the gender-neutral pronouns "they/them" and other language throughout the report to represent the diversity of people who we hope will benefit from this report.

Medical History

Patient

Name _____ JANE DOE
 Patient ID _____ 1002290
 DOB _____ 1985-12-16
 Age _____ 36
 Height (in) _____ 64
 Weight (lbs) _____ 120
 BMI _____ 20.60
 Address _____ 123 Happy Lane
 City _____ GARDEN CITY
 State _____ NY
 Zip _____ 11530
 Email _____ care@pregmune.com
 Phone _____ 2014094100

Partner/sperm donor

Name _____ JOHN DOE
 Patient ID _____ 1002291
 DOB _____ 1985-01-01
 Age _____ 37
 Height (in) _____ 71
 Weight (lbs) _____ 175
 BMI _____ 24.40
 Address _____ 123 Happy Lane
 City _____ Garden City
 State _____ NY
 Zip _____ 11530
 Email _____ care@pregmune.com
 Phone _____ 2014094100

Patient Fertility and Medical History Summary

Type of infertility _____ Primary (never had a full pregnancy)
 Duration of infertility (months) _____ 48
 Number of pregnancies _____ 3
 RPL _____ YES
 Stillbirths _____ 0
 Live births _____ 0
 Miscarriages _____ 3
 Terminations for medical reasons _____ 0
 Terminations for personal reasons _____ 0
 Failed IVF transfers _____ 0
 Any medical/autoimmune conditions? _____ Thyroid problems, anxiety
 Any family medical/autoimmune conditions? _____ Breast cancer, thyroid problems (mother), anxiety (sister), lung cancer (maternal grandmother)
 Is patient on fish oil or any medication? _____ Lexapro (10 mg), Synthroid (50 mcg), prenatal vitamin (1 tablet daily), EPA/DHA (1500 mg), Coenzyme Q10 (300 mg), Folic Acid (1 mg)
 Known allergies to medications _____ None
 Partner/sperm donor medical conditions? _____ High blood pressure
 Embryos currently stored? _____ YES
 Number of embryos (if yes) _____ 2
 Number of genetically tested embryos _____ 2
 Number of genetically normal embryos _____ 2

Report Summary

→ CLICK THE SECTIONS TO NAVIGATE THE REPORT

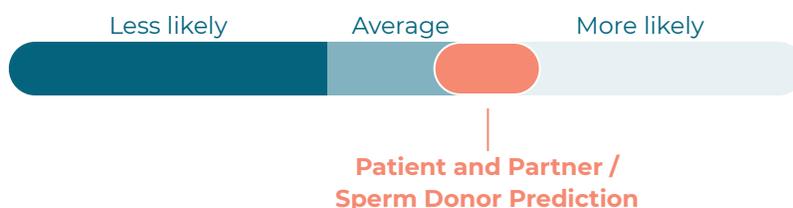
	LOW RISK/ NORMAL	MEDIUM RISK/ BORDERLINE	HIGH RISK/ ABNORMAL
1. Parental Histocompatibility			
Fetal HLA-C and Maternal KIR Interaction			██████████
HLA Mismatches		██████████	
HY Immunity	██████████		
HLA Antibodies	██████████		
2. Parental Chromosome Analysis			
Maternal Chromosomes	██████████		
Paternal Chromosomes	██████████		
3. Thrombophilia			
Prothrombin Factor II Alleles	██████████		
Leiden Factor V Alleles	██████████		
Plasminogen Activator Inhibitor Type I Alleles			██████████
Homocysteine	██████████		
Blood Clotting Measurements	██████████		
4. Blood Count			
Cell Blood Count (CBC)	██████████		
5. Inflammation			
Total Immunoglobulin	██████████		
Complement Activity	██████████		
Th1/Th2 Helper T Cell Ratio	██████████		
Natural Killer Cell Cytotoxic Activity (NKa)	██████████		
Regulatory T Cells	██████████		
6. Autoimmunity			
Antinuclear Antibodies (ANAs)	██████████		
Antiphospholipid Antibodies (APAs)		██████████	
CCP Antibodies and Rheumatoid Factor	██████████		
7. Autoimmunity Predisposition			
HLA Autoimmune Disease Predisposition	██████████		
8. Thyroid Function			
Thyroid Function		██████████	
9. Metabolism			
Insulin Resistance and PCOS Assessment	██████████		
10. Nutrition			
Vitamin D	██████████		
Folic Acid	██████████		
Fatty Acid Profile		██████████	
Leptin Levels			██████████

ABOUT IRMA

IRMA is a holistic examination of different blood markers and genetic traits that have been found in scientific studies to contribute to implantation failure, miscarriage, or pregnancy complications. Some tests (histocompatibility and chromosome analysis) involve both parents when a partner or sperm donor is available for testing. The remaining tests check the patient for signs of an autoimmune condition or high inflammation levels, as well as assess the patient's thyroid, metabolism, thrombophilia risk, nutrition status, and hormones.

IRMA PREDICTION*

LIKELIHOOD OF A SUCCESSFUL BIRTH



ABOUT THIS VALUE

This is an AI-generated estimate of the likelihood that the patient and their partner/sperm donor will have a successful pregnancy and birth using their own eggs and sperm while following our recommendations. It is calculated based on a comparison against data from over 700 fertility clinic patients with an average success rate of 55%. The fertility clinic patients were aged 45 or younger and typically had a history of recurrent pregnancy loss, implantation failure, or infertility. This prediction is based on patient history, genetics, and immunological factors. Because this prediction was created from a database of patients aged 45 or younger, this calculation will be less accurate for patients over the age of 45, and in some cases will not be calculated.

WHAT IMPACTS THIS PREDICTION

The patient history and test results that most impact this prediction are presented on the following page. Not all individual IRMA test results that are high risk or abnormal will impact this prediction as they may not present a significant risk for pregnancy failure. Similarly, some IRMA test results that are normal may impact this prediction but should not be factored into treatment decisions. The IRMA prediction algorithm considers all factors as they relate to one another, which means a factor that is important for one person may not be important for someone else who is, for example, a different age. Because it is an AI-generated model, factor importance may change over time. Treatment decisions should be based on the provider's clinical judgment and unique patient circumstances and should not be solely based on factor importance in the IRMA prediction.

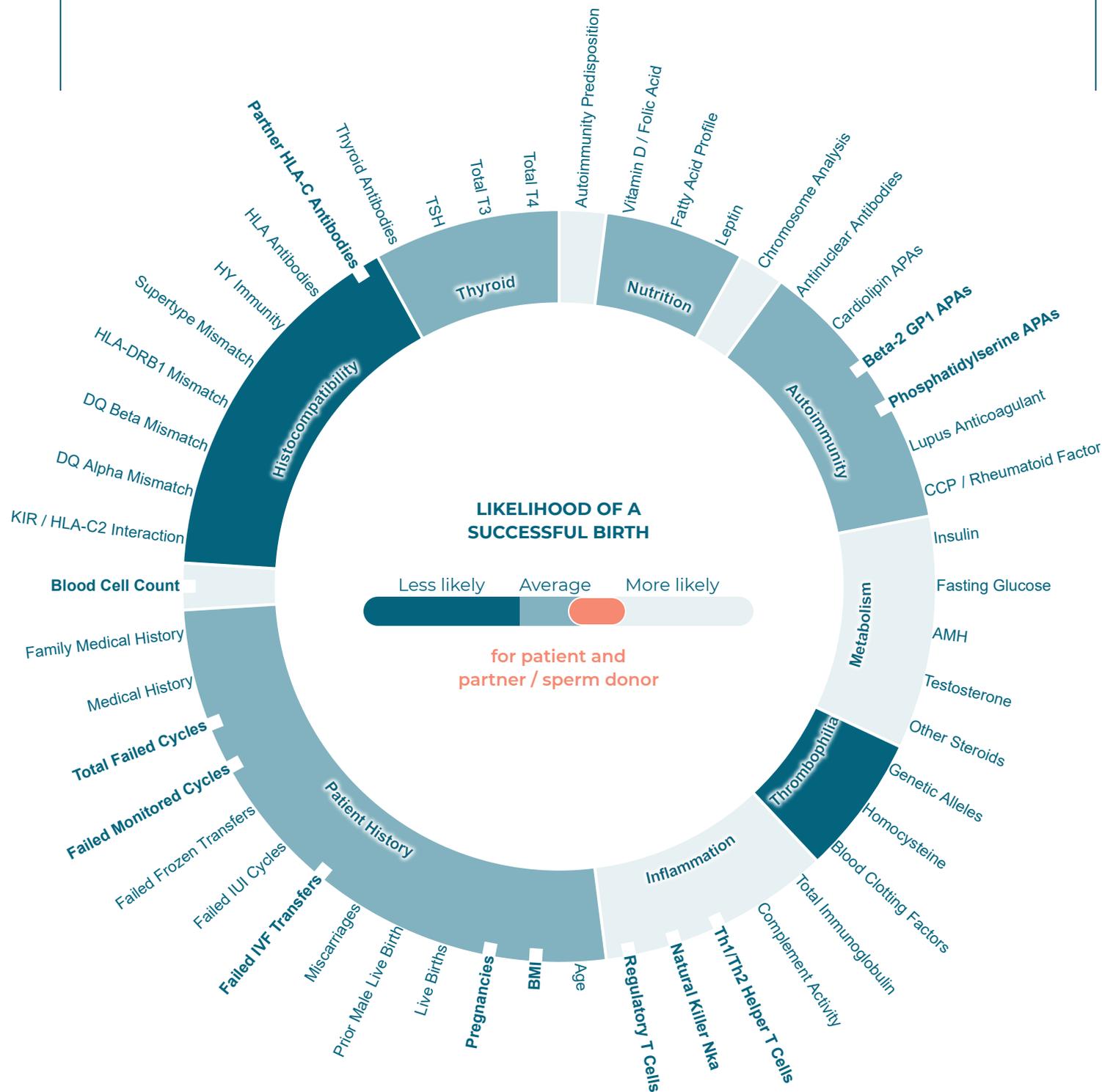
*DISCLAIMER

The IRMA Prediction and other predictions contained in this Report ("Predictions") are for informational purposes only and should not be viewed or relied upon as any form of assurance or guarantee. The Predictions are estimates generated by statistical models and related technology used to analyze the limited data provided to Pregmune. Various factors may impact this analysis including information about the patient that is not included within the data provided to Pregmune and changes to the patient's health status that may cause the Predictions to be incomplete or incorrect. Pregmune does not assume any liability for these Predictions and makes no warranties, nor express or implied representations whatsoever regarding the accuracy, completeness, or timeliness of any of these Predictions.

Color: Risk Level



Cubes: Success Predictors



Recommended Actions

Every drug recommended addresses a specific issue and all recommendations may have to be taken into consideration for full benefit.

Immunological/Fertility Treatment

ACOG/ESHRE standard recommendations

-Based on the patient's PAI-1 genotype, and due to the patient's positivity for antiphospholipid antibodies and history of recurrent pregnancy loss, they may benefit from using low dose aspirin and Lovenox.

Other recommendations (Based on published clinical trials)

-The patient's uterine natural killer cells have a receptor (KIR AA) that may be less compatible with a significant proportion of their potential embryos. In addition, the patient and their partner have a partial lack of HLA class II mismatches which increases the risk for pregnancy failure; the patient may benefit from using G-CSF (Neupogen) to promote immune tolerance.

Hormonal/Metabolic Treatment

-Based on their history of RPL, the patient may benefit from using a progesterone supplement.

Nutritional Recommendations

-The patient's fatty acid profile is medium risk and they may benefit from EPA/DHA (fish oil) supplementation. We recommend starting with 4g per day for 2 weeks, followed by 3g per day as a maintenance dose.
-Because the patient has a history of recurrent pregnancy losses (occurring at 5-6 weeks), the patient may benefit from using antioxidant therapy (resveratrol, pycnogenol, and continue coenzyme Q10) to improve egg quality if they will pursue a natural pregnancy or plan on future egg retrievals.

Further Evaluation

-The patient's bloodwork suggests they have abnormal thyroid function; the patient may want to consult with a thyroid specialist to manage and/or restore thyroid function.
-The patient has elevated levels of antiphospholipid antibodies; this may warrant close monitoring during pregnancy.

Additional Doctor Comments

No further recommendations

DISCLAIMER

Immune therapy recommendations are based on guidelines published by The American Society of Reproductive Medicine (ASRM), The American College of Obstetricians and Gynecologists (ACOG), The European Society of Human Reproduction and Embryology (ESHRE) as well as peer-reviewed published articles including Cochrane studies. Please note that the list of our recommendations is not exhaustive and allows the practitioner to have some flexibility to select the adequate immune therapies. Please note that therapeutic guidelines of individual societies are not always in agreement. Therapeutic recommendations are intended to be part of physician-to-physician communication between the reviewing physician and the ordering physician. Some medications that are recommended fall within "off label" uses of an FDA-approved drug that are permitted at the direction of a physician. Please note that implementation of a therapeutic plan by a treating physician is the result of a complete evaluation of all the factors affecting a patient's condition including but not limited to those presented in the IRMA report.

1. Parental Histocompatibility

This section of the report examines the impact of human leukocyte antigens (HLAs) on pregnancy. HLAs are diverse proteins displayed on human cells like a barcode - unique for everyone. The immune system uses HLAs to differentiate “self” from “non-self.” This

section includes paternal test results because half of a developing embryo's HLAs come from their father. These compatibility tests are designed to determine how the patient's immune system will interact with the developing embryo and affect pregnancy.

Fetal HLA-C and Maternal KIR Interaction

RISK

Higher Risk



LEGEND

- KIR A / KIR A** Poor C2 Compatibility
- KIR A / KIR B -2DS1** Weak C2 Compatibility
- KIR A / KIR B +2DS1** Good C2 Compatibility
- KIR B / KIR B** Good C2 Compatibility

LEGEND

- Higher C2** Fetal C2 > Maternal C2
- Equal C2** Fetal C2 = Maternal C2
- Lower C2** Fetal C2 < Maternal C2

WHY WE TEST THIS

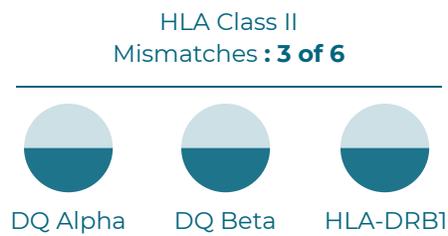
A developing embryo's unique HLAs are recognized by the mother's uterine natural killer cells using receptors called killer immunoglobulin-like receptors (KIRs). Some maternal KIRs respond better than others to embryos displaying HLA-C2, which influences how much oxygen and nutrition is sent through the placenta (through spiral artery remodeling). Additionally, if the embryo has more (or in some cases the same number of) HLA-C2 alleles than the mother, this could also pose a risk. This test examines the patient's HLA-C2 content, the predicted embryo's HLA-C2 content, and whether the maternal KIRs are a good match for HLA-C2. [Learn more →](#)

WHAT THESE RESULTS MEAN

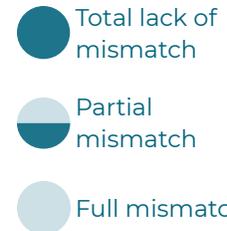
There is a considerable compatibility concern between the patient's KIR genes and fetal HLA-C alleles. This could contribute to a weakened immune tolerance towards the embryo's HLAs and impaired spiral artery remodeling. The patient and their healthcare provider might want to explore the benefit of immune modulating treatments to help promote immune tolerance.

HLA Mismatches

RISK

Medium Risk


LEGEND



WHY WE TEST THIS

A mother's immune system needs to develop tolerance to the embryo to maintain a healthy pregnancy. Part of this process lies in recognizing that the embryo is genetically unique. However, if the embryo inherits paternal HLAs that are too similar to the maternal HLAs, the immune system might not develop a strong tolerance. This test determines if there are enough mismatches between the maternal and paternal HLA Class II alleles. [Learn more →](#)

WHAT THESE RESULTS MEAN

With fewer than 4 mismatches, there is a moderate risk that the similarity of HLA class II alleles could impair the maternal immune system from generating a tolerance towards the embryo. The patient and their healthcare provider might want to explore immune modulating treatments to help promote immune tolerance.

HY Immunity

RISK

Lower Risk

HY Restricting Alleles
0

Previous birth to a boy / XY baby
NO

WHY WE TEST THIS

Embryos with a Y chromosome have proteins called HY antigens (male specific minor histocompatibility antigen) on their cells. Occasionally, when a mother gives birth to a boy / baby with a Y chromosome, the mother's immune system can generate an immune response against these HY antigens and interfere with future pregnancies. The mother's HLAs are responsible for initiating this immune response, and some HLA alleles increase the likelihood of this happening. This test determines if the patient carries these higher-risk HY restricting alleles, which might put the patient at higher risk if they've previously given birth to a boy. (An allele is an alternate version of a gene at a specific location of the chromosome.)

[Learn more →](#)

WHAT THESE RESULTS MEAN

There are no concerns that the patient's HLAs put them at increased risk for generating an immune response against HY antigens.

HLA Antibodies

RISK

Lower Risk

Partner-Specific HLA-C Antibodies

NO

Previous Full-Term Pregnancy

NO

Previous Blood Transfusion(s)

No

Previous Lymphocyte Immunization Therapy

No

HLA Class I Antibodies

Antibodies detected: **2**
 High concentration (>4K MFI): **0**
 Partner-specific antibodies: **1**

AI



HLA Class II Antibodies

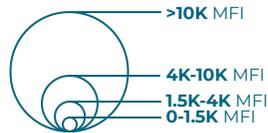
Antibodies detected: **0**
 High concentration (>4K MFI): **0**
 Partner-specific antibodies: **0**



*No partner specific antibodies
 found, including HLA-C*

LEGEND

Circle area: concentration



Circle color



Partner specific



Partner specific and HLA-C

WHY WE TEST THIS

Sometimes, a person's immune system can develop antibodies to HLAs. These antibodies can target "self" HLAs (autoantibodies), they can target "non-self" HLAs from previous full-term pregnancies or blood transfusions, or they can specifically target a partner's HLAs - which the embryo will inherit. HLA antibodies are common and aren't necessarily a problem, but partner-specific HLA-C antibodies (a subtype of Class I antibodies) can pose a considerable risk and are associated with early miscarriages and secondary infertility. This test measures how much and what type of HLA antibodies a patient carries, if any. [Learn more →](#)

WHAT THESE RESULTS MEAN

HLA antibodies were low including a low level of partner-specific antibodies. However, no partner-specific antibodies towards HLA-C were detected which means that HLA antibodies are not a concern.

2. Parental Chromosome Analysis

Although many chromosomal abnormalities are debilitating or fatal, sometimes the only indication of a parent's chromosomal abnormality is reproductive difficulty. Abnormalities can include deletions, duplications, and genetic rearrangements where

sections of chromosomes have been shuffled around. This section of the report uses cytogenetic analysis to visually examine the patient's and their partner's/donor's chromosomes.

Parental Chromosome Analysis		MATERNAL STATUS	PATERNAL STATUS
		Normal	Normal
MATERNAL CHROMOSOME ANALYSIS	PATERNAL CHROMOSOME ANALYSIS		
Total Chromosomes 46	Total Chromosomes 46		
Sex Chromosomes XX	Sex Chromosomes XY		
Findings Normal female karyotype	Findings Normal male karyotype		
WHY WE TEST THIS	WHAT THESE RESULTS MEAN		
Despite being otherwise healthy, parents with chromosomal abnormalities might have trouble producing eggs or sperm with a full set of normal chromosomes. This test visually examines the parents' chromosomes for any major structural anomalies. Please note that the visual nature of this test only detects large chromosomal changes containing multiple genes; it is not a genetic analysis that will detect gene-specific mutations. Learn more →	No chromosomal abnormalities were observed.		

3. Thrombophilia

While pregnant, a person's risk for blood clots in their veins (venous thromboembolism) increases 5- to 6-fold. If they have hereditary thrombophilia, that risk can increase more than 30-fold. Additionally, thrombophilia increases the chance of blood clots in the placenta,

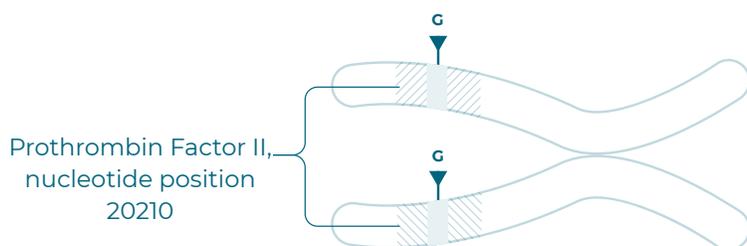
which increases the likelihood of pregnancy loss. These tests examine the patient's risk for thrombophilia to determine if anticoagulants could help improve chances for pregnancy success.

Prothrombin Factor II Alleles

RISK LEVEL

Lower Risk

High risk alleles: **0 out of 2**



WHY WE TEST THIS

Prothrombin (blood coagulation factor II) has an important role in blood clot formation. The "A" allele of prothrombin increases a person's prothrombin levels, which then increases the risk of thrombophilia and pregnancy complications. This test determines if the patient carries the higher risk "A" allele. [Learn more →](#)

WHAT THESE RESULTS MEAN

Prothrombin factor II is not a concern.

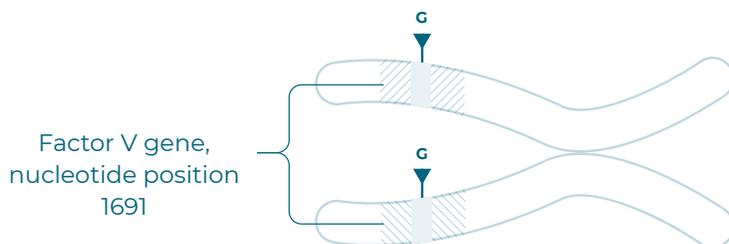
DISCLAIMER

Please note that this is not a complete thrombophilia assessment. Our limited thrombophilia panel is a combination of three genetic tests designed to provide evidence of inherited gene mutations that are associated with an increased risk for developing thromboembolism (blood clot formation) and experiencing recurrent pregnancy losses. Individuals who have inherited a pathogenic variant for one of these genes may have a predisposition to excessive blood clot formation and miscarriages. In addition, we test for both hyperhomocysteinemia as a risk factor for venous thrombosis and for bleeding disorder by assessing the patient's clotting factors.

Leiden Factor V Alleles

RISK LEVEL

Lower Risk

High risk alleles: **0 out of 2**

LEGEND

-  A Allele - mutation
-  G Allele - no mutation

WHY WE TEST THIS

Factor V has an important role in blood clot formation. The Leiden mutation, or "A" allele, causes factor V to remain active longer, which increases the risk of thrombophilia and pregnancy loss. This test determines if the patient carries the higher risk "A" allele. [Learn more →](#)

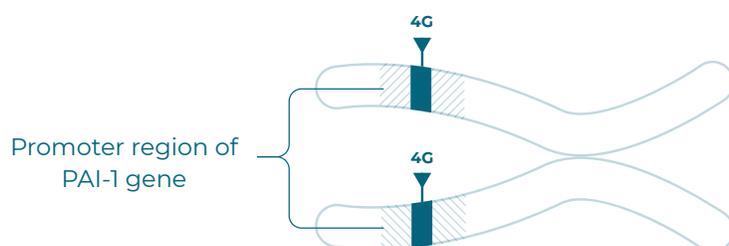
WHAT THESE RESULTS MEAN

Leiden factor V is not a concern.

Plasminogen Activator Inhibitor Type I (PAI-1) Alleles

RISK LEVEL

Higher risk

High risk alleles: **2 out of 2**

LEGEND

-  4G Allele - mutation
-  5G Allele - no mutation

WHY WE TEST THIS

Plasminogen activator inhibitor type 1 (PAI-1) is a protein that inhibits a process that prevents blood clots. In other words, less PAI-1 equals better protection against thrombosis. The high risk 4G allele increases levels of PAI-1 and by doing so can increase a person's risk for blood clot and miscarriage. This test determines if the patient carries the higher risk 4G allele. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient has two high risk alleles for PAI-1 which is associated with a higher risk for thrombosis and miscarriage. The patient and their healthcare provider might discuss blood thinners and other treatment options to help reduce the risk of blood clots.

Homocysteine

STATUS

Normal

normal abnormal

Homocysteine
(umol/L)



WHY WE TEST THIS

Homocysteine is a metabolic by-product. High homocysteine levels (hyperhomocysteinemia) can indicate a vitamin B12, B6, or folate deficiency, and is a risk factor for thrombosis and cardiovascular disease as well as adverse pregnancy outcomes. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient's homocysteine levels are normal and do not pose a risk.

Blood Clotting Measurements

STATUS

Normal

normal abnormal

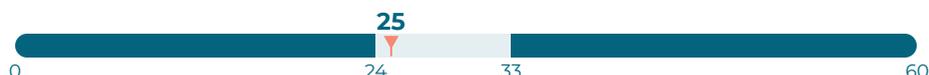
INR



PT
(sec)



aPTT
(sec)



WHY WE TEST THIS

PT (prothrombin time), aPTT (activated partial thromboplastin time), and INR (international normalized ratio) are all different measures of a person's blood clotting reaction. PT measures how quickly a patient's blood clots when exposed to an injury like a cut and INR is simply the ratio of the patient's PT to an average population's PT. aPTT measures how quickly a patient's blood clots when exposed to internal vascular damage. If a patient's blood clots too quickly, it could indicate an increased risk of thrombosis. [Learn more →](#)

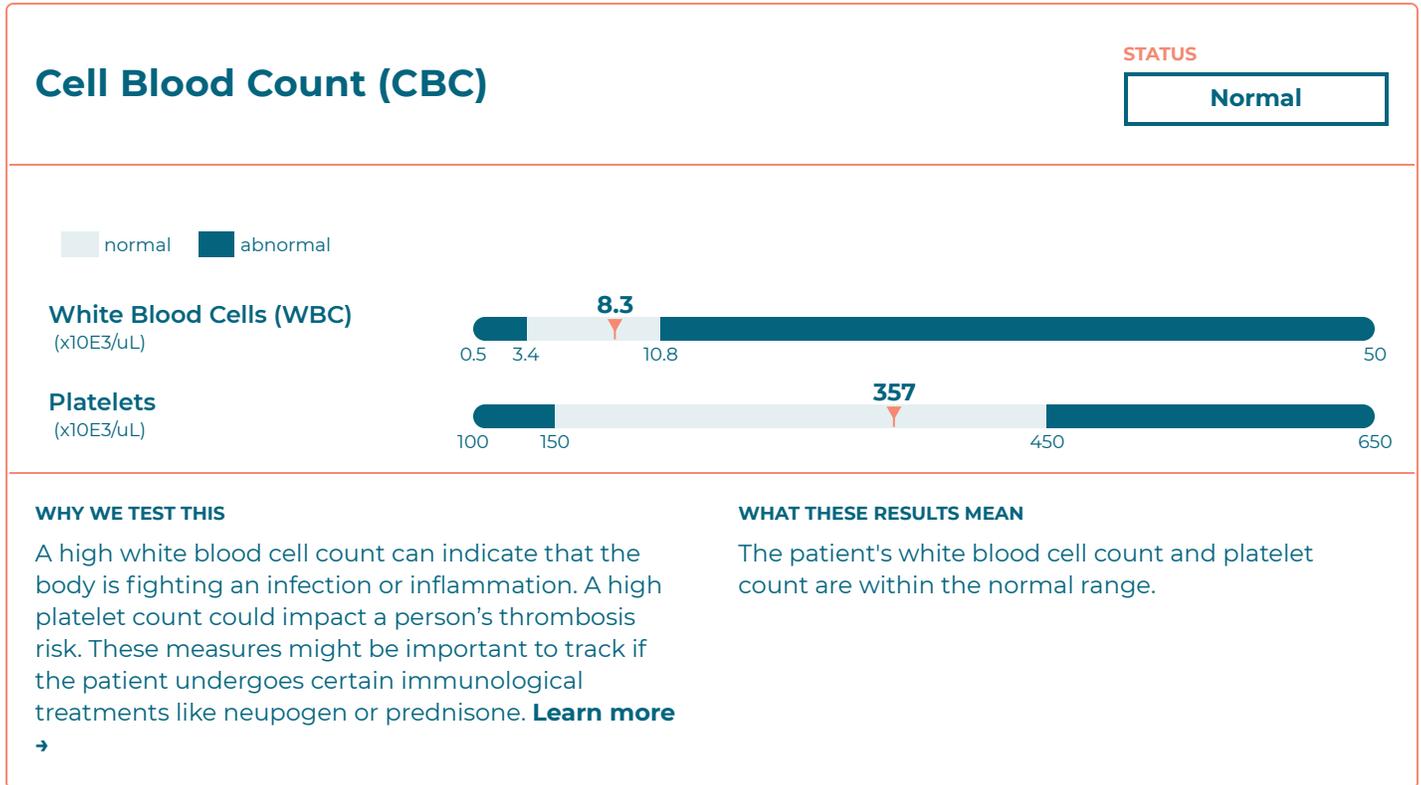
WHAT THESE RESULTS MEAN

The patient's clotting results appear normal.

4. Blood Count

The cells that travel through a person's bloodstream include red blood cells that carry oxygen, white blood cells that belong to the immune system, and platelets that initiate blood clots. Because of the diversity of

blood cell functions, these test results contribute to both a patient's thrombophilia assessment and inflammation assessment.



5. Inflammation

Whether caused by an autoimmune condition, infection, allergies, or another source, different inflammatory markers have been associated with reproductive challenges. During a healthy pregnancy, the body must be able to shift to a relatively anti-inflammatory state to maintain the pregnancy. The

following tests are some of the most established markers of inflammation in reproductive immunology. These results can be used to determine if treatments to reduce inflammation could help improve a patient's chances of reproductive success.

Total Immunoglobulin

STATUS

Normal

normal abnormal

Immunoglobulin G Levels
(mg/dL)



Immunoglobulin A Levels
(mg/dL)



Immunoglobulin M Levels
(mg/dL)



Immunoglobulin E Levels
(IU/mL)



WHY WE TEST THIS

Immunoglobulins, also known as antibodies, are key mediators of the immune system that identify and neutralize pathogens and other targets. Antibody levels can help indicate allergies and other inflammatory reactions. [Learn more →](#)

WHAT THESE RESULTS MEAN

All total Immunoglobulin levels are within the normal range.

Complement Activity

STATUS

Normal

normal abnormal

Complement C4 Activity
(mg/dL)



Complement C3 Activity
(mg/dL)



WHY WE TEST THIS

The complement system is part of the innate immune system and, when activated, is a strong inducer of inflammation. C3 and C4 are two key proteins in the complement system. Complement activation has been linked to pregnancy complications like pre-eclampsia. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient's C3 and C4 complement levels are within the optimal range reflecting a complement activity within the normal range.

Th1/Th2 Helper T Cell Ratio*

STATUS

Normal

normal borderline elevated abnormal

Th1/Th2



WHY WE TEST THIS

Some immune cells, like T helper cells, produce molecules that tell the immune system to either kick into high gear (pro-inflammatory) or calm down (anti-inflammatory). Th1 cells are T helper cells that produce pro-inflammatory molecules, while Th2 cells produce anti-inflammatory molecules. The ratio of Th1 to Th2 can help determine the patient's inflammation levels. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient has a normal Th1/Th2 ratio.

Natural Killer Cell Cytotoxic Activity (NKa)*

STATUS

Normal

normal abnormal

NK Cytotoxic Activity Assay
(%)



WHY WE TEST THIS

Natural killer (NK) cells are immune cells that have a bad reputation as “killers.” However, in addition to killing cells (through cytotoxic activity), NK cells can do many other things like encouraging healthy placental development in the uterus. This test measures how much the patient's NK cells are primed towards killing. High NK cytotoxic activity has been associated with recurrent pregnancy loss. [Learn more](#)

→

WHAT THESE RESULTS MEAN

The patient's NK cytotoxic activity levels are within the normal range.

Regulatory T Cells*

STATUS

Normal

normal abnormal

Regulatory T Cell Levels
(% of Helper T Cells)



WHY WE TEST THIS

Regulatory T cells (Treg cells) are specialized immune cells that suppress inflammation and are essential for preventing the uterus from rejecting the embryo. Low Treg levels in the uterus are linked to infertility, recurrent miscarriage, and pregnancy complications. This test measures the patient's circulating Treg cell levels, which can be used to help estimate recruitment of Treg cells to the uterus during pregnancy. [Learn more](#)

WHAT THESE RESULTS MEAN

The patient's Treg cell levels are within the normal range.

*DISCLAIMER

In the field of reproductive immunology, some functional assays are described which reflect the immune capacity of peripheral blood derived natural killer cells (NK cells) or regulatory T cells. Recent data clearly show that the composition of the immune cells locally in the placenta, where the relevant immune regulation of an ongoing pregnancy takes place, is significantly different from that in the peripheral blood. Nevertheless, data are available showing that increased NK levels in the peripheral blood are associated with pregnancy failure. However, there is no evidence that these peripheral NK cells are directly responsible for the failure. The phenotypic characteristics and function of uterine Natural Killer cells are completely different from those of the peripheral blood derived NK cells. Similarly, scientific literature shows a difference in immune regulation by regulatory T cells in the peripheral blood versus the placenta, in which partner specific regulatory T cells are induced. Thus we don't think there is enough evidence to consider the NK cytotoxic activity or peripheral regulatory T cell function as independent factors to predict failure. Nevertheless, these provide valuable information and are part of the predictive pregnancy success algorithm.

6. Autoimmunity

Many autoimmune diseases can raise a patient's chances for adverse pregnancy outcomes, which is why expectant mothers with antiphospholipid syndrome, lupus, rheumatoid arthritis, and other autoimmune disorders are considered high-risk pregnancies.

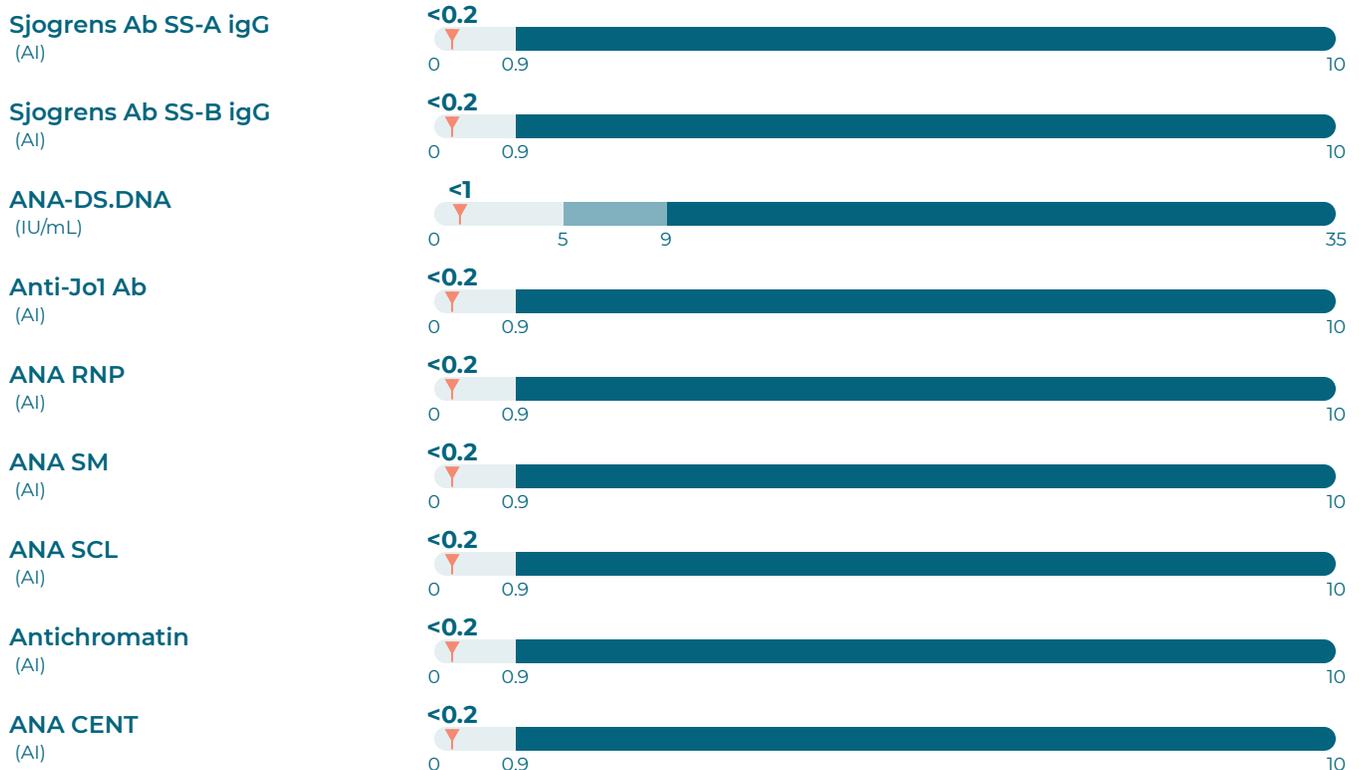
However, many people remain undiagnosed for autoimmune conditions. These tests help determine a patient's risk for various autoimmune conditions, which are each treated accordingly.

Antinuclear Antibodies (ANAs)

STATUS

Normal

negative / normal borderline positive / abnormal



WHY WE TEST THIS

The nucleus of a cell contains DNA and diverse proteins required to keep the cell functioning. Sometimes, a person's immune system will begin to attack proteins in the nucleus by developing antinuclear antibodies (ANAs). When present in high concentrations, ANAs could indicate an autoimmune disease such as lupus. These tests assess the presence of different ANAs. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient is negative for all ANAs tested.

Antiphospholipid Antibodies (APAs)

STATUS

Borderline

negative / normal borderline moderately positive positive / abnormal

Anticardiolipin IgG

(GPL U/mL)



Anticardiolipin IgM

(MPL U/mL)



Anticardiolipin IgA

(APL U/mL)



Anti Beta-2 Glycoprotein I IgG

(GPI IgG units)



Anti Beta-2 Glycoprotein I IgM

(GPI IgM units)



Anti Beta-2 Glycoprotein I IgA

(GPI IgA units)



Antiphosphatidylserine IgG

(Units)



Antiphosphatidylserine IgM

(Units)



Antiphosphatidylserine IgA

(APS Units)



Lupus Anti Coagulant dPT

(sec)



Lupus Anti Coagulant dPT Confirm Ratio

(Ratio)



Lupus Anti Coagulant Thrombin Time

(sec)



Lupus Anti Coagulant PTT-LA

(sec)



Lupus Anti Coagulant DRVVT

(sec)



WHY WE TEST THIS

Phospholipids are integral components of human cell membranes. Sometimes, a person's immune system will begin to attack its own phospholipids by developing antiphospholipid antibodies (APAs). Because blood cells contain phospholipids, APAs can lead to blood clots, miscarriages, or pregnancy complications. These tests assess the presence of different APAs. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient is borderline positive for Anticardiolipin IgM. The patient may benefit from additional APA monitoring during pregnancy.

CCP Antibodies and Rheumatoid Factor

STATUS

Normal

negative / normal
 borderline
 moderately positive
 positive / abnormal

Anti-CCP Antibodies IgG/IgA
(units)



Rheumatoid Factor Levels
(IU/mL)



WHY WE TEST THIS

Cyclic citrullinated protein (CCP) antibodies and rheumatoid factor are antibodies that can indicate rheumatoid arthritis and some other autoimmune diseases. These tests assess the presence of these antibodies. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient is negative for both Rheumatoid Factor and Anti-CCP antibodies.

7. Autoimmunity Predisposition*

Autoimmune diseases are thought to arise from a combination of a person's genetics and environment. Although being genetically predisposed to

autoimmunity might raise a person's chances for developing an autoimmune disease, it is not a guarantee.

HLA Autoimmune Disease Predisposition

RISK LEVEL

Lower Risk

HLA Alleles Associated with Autoimmune Disease

DQB1*05:03, DRB1*14:01

Associated Autoimmune Diseases

Myasthenia gravis, Pemphigus vulgaris

WHY WE TEST THIS

Human Leukocyte Antigen (HLA) genes play an integral role in activating the immune response. Some HLA alleles change the features of a person's HLAs to make them more likely to inappropriately trigger the immune response and develop an autoimmune condition. This genetic test looks at different alleles of the patient's HLA genes which might predispose the patient to autoimmune issues than can interfere with a healthy pregnancy. **Learn more →**

WHAT THESE RESULTS MEAN

The patient harbors some HLA alleles that confer genetic predispositions to some conditions that may affect one's fertility.

8. Thyroid Function

The thyroid is a butterfly-shaped gland located in the neck. It secretes hormones that regulate metabolism, body temperature, the cardiovascular system, and the

digestive system. The thyroid's proper function is crucial when pregnant because the mother's thyroid hormones affect fetal growth and brain development.

Thyroid Function

STATUS

Borderline

normal abnormal

Anti-Thyroglobulin Antibody
(IU/mL)



Thyroid Peroxidase Antibody
(IU/mL)



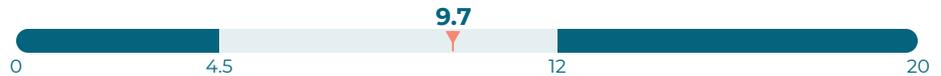
TSH
(IU/L)



TSH Receptor Antibody
(uIU/mL)



Total T4
(ug/dL)



Total T3
(ng/dL)



WHY WE TEST THIS

Thyroid disorders can contribute to pregnancy complications, miscarriage, or a person's ability to get pregnant. Thyroid disorders sometimes arise from autoimmune problems where a person develops antibodies to specific parts of the thyroid. These tests look for thyroid antibodies as well as measure hormone levels related to healthy thyroid functioning.

[Learn more →](#)

WHAT THESE RESULTS MEAN

Some of the patient's hormone levels are out of range but no antibodies were detected. The patient might discuss treatment options to restore healthy thyroid function with their healthcare provider or a thyroid specialist.

9. Metabolism

Metabolic disorders, like diabetes and PCOS, can increase a person's chance for infertility and miscarriage. When these disorders are properly diagnosed, studies indicate that taking metformin

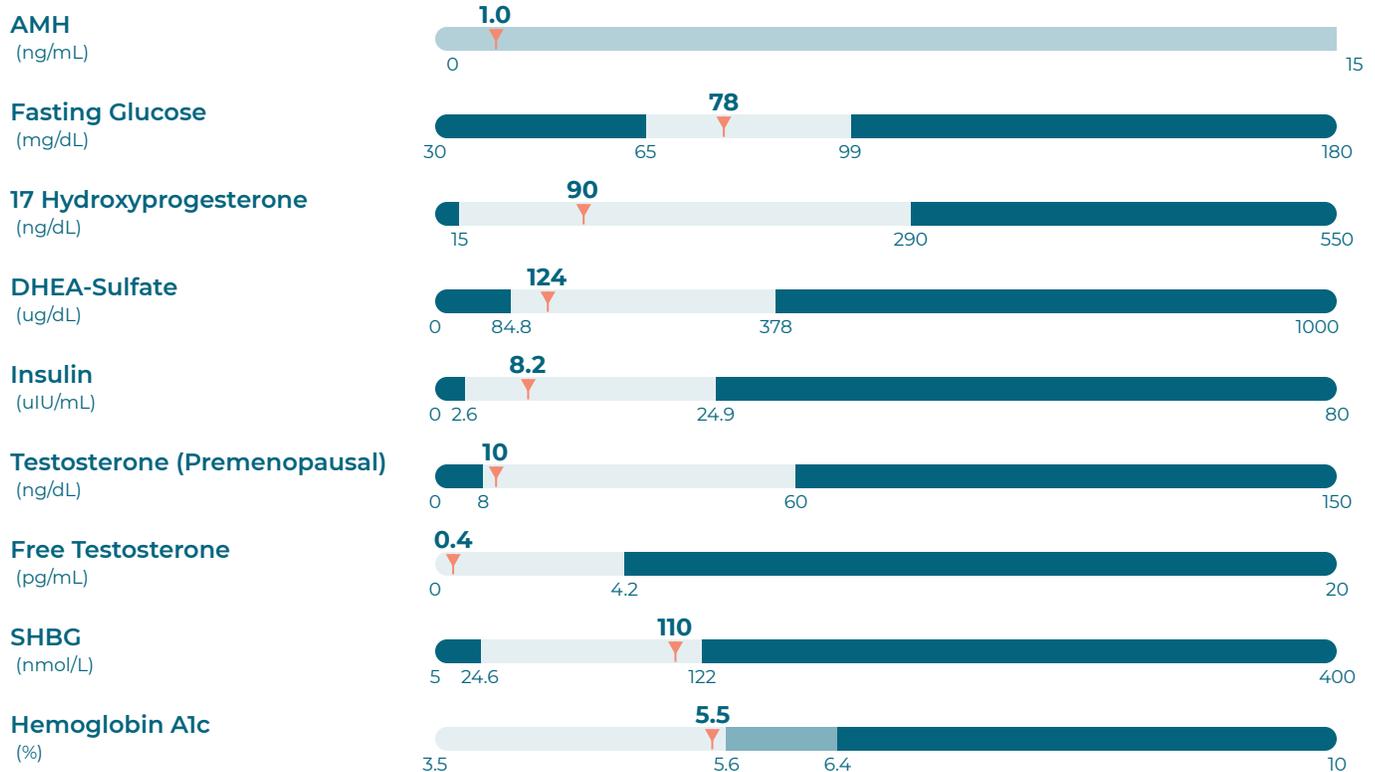
and/or getting blood sugar levels under control could help reduce chances of miscarriage or pregnancy complications. These tests look for signs of metabolic problems.

Insulin Resistance and Polycystic Ovarian Syndrome (PCOS) Assessment

RISK LEVEL

Lower Risk

normal age-based borderline abnormal



WHY WE TEST THIS

Polycystic ovarian syndrome (PCOS) is a common endocrine condition, characterized by high levels of androgens and resistance to insulin. People with PCOS are at an increased risk for infertility and pregnancy complications such as gestational diabetes and hypertension. These tests look for signs of insulin resistance and hormonal dysregulation. [Learn more →](#)

WHAT THESE RESULTS MEAN

Results are normal. There is no indication of insulin resistance or type 2 diabetes. Based on the Rotterdam criteria, the patient is not likely to have PCOS.

10. Nutrition

Diet can impact a person's ability to get pregnant and deliver a healthy baby. Certain dietary deficiencies can increase the risk of pregnancy complications or birth defects, while other dietary imbalances can lead to

increased levels of inflammation. These tests examine a few of the most important nutritional markers for pregnancy to help determine if a dietary supplement or other dietary action could help.

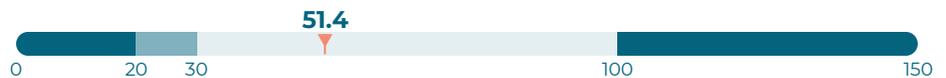
Vitamin D

STATUS

Normal

normal borderline low abnormal

25 Hydroxy Vitamin D levels
(ng/mL)



WHY WE TEST THIS

Vitamin D has an essential role in immune health and calcium absorption. Low levels of vitamin D are linked to recurrent pregnancy loss and numerous pregnancy complications. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient has healthy vitamin D levels and does not require supplementation.

Folic Acid

STATUS

Normal

normal abnormal

Folic Acid levels
(ng/mL)



WHY WE TEST THIS

Folic acid, also known as vitamin B-9, is naturally found in many foods. It is added to prenatal vitamins and many fortified foods such as cereal. Folic acid is a crucial nutrient during early pregnancy and can help reduce the risk of birth defects. [Learn more →](#)

WHAT THESE RESULTS MEAN

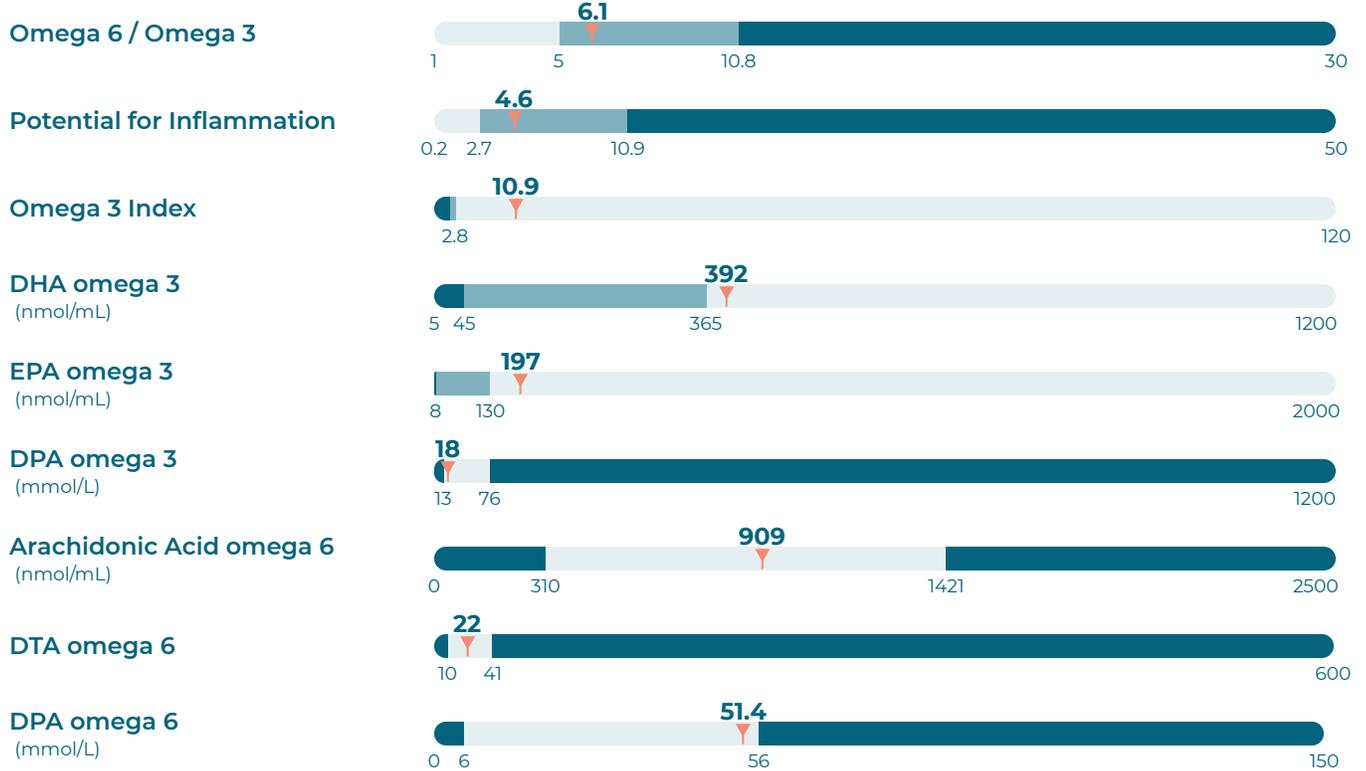
The patient has healthy folic acid levels.

Fatty Acid Profile

RISK LEVEL

Medium Risk

normal borderline abnormal



WHY WE TEST THIS

Omega 3 and omega 6 fatty acids are important classes of dietary fats. Omega 3 fatty acids, like EPA and DHA, are well known for their anti-inflammatory properties and have been found to help lower the risk of pregnancy complications. Omega 6 fatty acids aren't inherently bad, but without a healthy intake of omega 3 fatty acids, could promote inflammation. These tests look at omega 3 levels and determine if they're sufficient to counterbalance omega 6 levels.

[Learn more →](#)

WHAT THESE RESULTS MEAN

The patient's fatty acid levels present a moderate risk, and an EPA/DHA supplement could help restore their omega balance. A good strategy would be to start with 4g per day for 2 weeks, followed by a maintenance dose of 3g per day.

Leptin Levels

STATUS

Abnormal

normal abnormal

Leptin Levels



WHY WE TEST THIS

Leptin is a hormone released by fat cells that regulates hunger and many aspects of pregnancy. High leptin levels are linked to multiple reproductive issues including impaired egg production, pregnancy failures and complications. Low leptin levels might be linked to miscarriage. [Learn more →](#)

WHAT THESE RESULTS MEAN

The patient's leptin levels appear high. The patient and their healthcare provider might discuss the implications of this result, if any other test results could contribute to the patient's high leptin levels, and if dietary or lifestyle modifications could help.

Report Review

Patient Name _____ **JANE DOE**
DOB _____ **1985-12-16**
Partner/Sperm Donor Name _____ **JOHN DOE**
DOB _____ **1985-01-01**

Physician _____ **Dr. Andrea Vidali**
NPI _____ **1265014583**
Report ID _____ **DOEJ121685F-IRMA**

Physician's Signature

Date

DISCLAIMER

Please note that this Assessment is to be considered of high complexity and will be billed accordingly. This Assessment is to be considered complete with the creation of this IRMA report and of the forwarding of this report to the ordering physician.