

Celiac Disease Monitoring Test Report

Date Presented - Apr 23, 2019

Patient Details

Jane Doe
Patient Number: 3
DOB: Feb 1, 1991
Sex: Female
Phone: (234) 234-2343

Specimen Details

Sample ID: 10000815
Sent: Feb 7, 2019
Collected:
Tested:
Source: Capillary Blood

Ordering Doctor

Dr. Jody Smith
UPIN #A999Z9
NPI #9999999999

Welcome To Your Results

Dear Jane Doe

We received your small volume blood sample, and tested it on for the presence of certain biomarkers commonly associated with celiac disease. Celiac disease is an autoimmune reaction in the small intestine to foods containing gluten, a protein found in wheat, rye, and barley.

The testing platform used to produce the results described in this report has been shown to detect these biomarkers to a high level of accuracy when they are present, and to also correctly show a negative result when they are not present.

When shared with your healthcare professional, we are confident this report will provide insight to inform healthcare decisions that may improve your health and quality of life.

You and your healthcare professional can trust the science behind these results, as we have partnered with two leading Medical Doctors who have validated our test processes and reporting.

For any questions about this test, please visit us at www.imaware.health or connect with us via email at support@imaware.health.

In good health,
The imaware™ team

Celiac Disease Monitoring Test - Medical Sciences Team

The imaware™ team designs and validates each at-home test alongside world-renowned medical doctors and scientists.



Dr. Stefano Guandalini, MD
Professor Emeritus, University of Chicago.



Dr. Detlef Schuppan, MD Ph.D.
Director, Celiac Disease and Fibrosis Center, UMC Mainz.

Celiac Disease Monitoring Test - Your Results Summary

Jane, you do not have elevated celiac disease related antibody levels
based on biomarker sampling as well as patient specific considerations.^[1-15]

BIOMARKER SAMPLING

A biomarker ("biological marker") refers to a category of objective signs that indicate a medical state. Elevated biomarker levels in your blood can signal the presence of disease. We tested your blood for the following four (4) biomarkers that are associated with celiac disease:

tTG IgA	tTG IgG	DGP IgA	DGP IgG
Normal	Normal	Normal	Normal

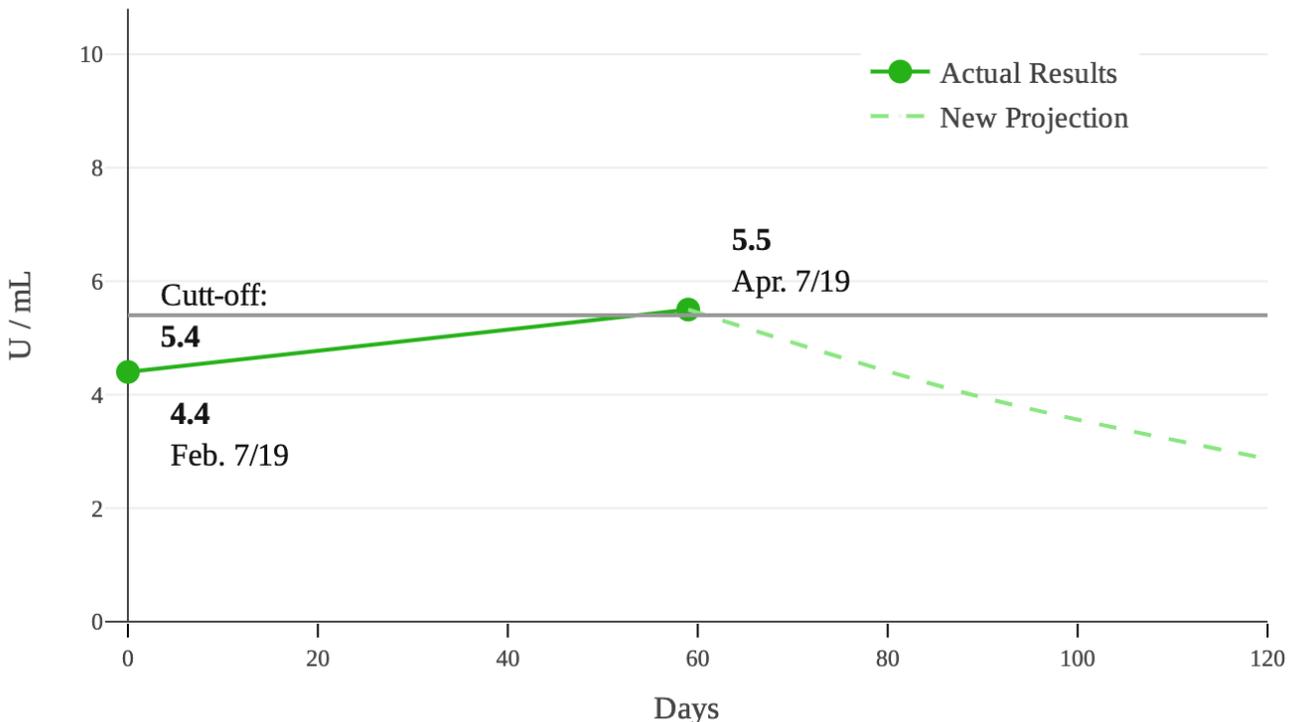


Visualizing your Progress

We have used your latest results to help you set a target date of when your immune response will return to normal levels, which is indicative of the healing process.

We utilize the known "half life" of celiac related biomarkers to calculate this curve and target date.

Measured using tTG IgA biomarker



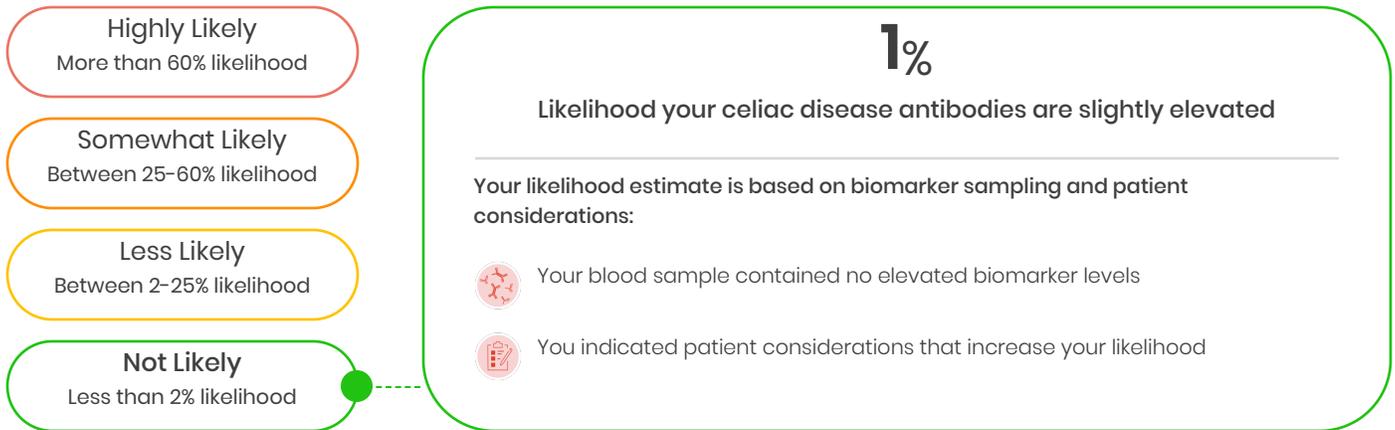
YOUR PROJECTED DATE

Based on maintaining your current diet and lifestyle, you can anticipate that your immune response levels will return to non-elevated levels on . This indicates that your body is responding well to the gluten-free lifestyle and more complete healing can take place.

HOW WE CALCULATED YOUR PROGRESS

We utilized the biomarker as the basis for our calculation. The graph above highlights the target value based on the cutoff value of "normal activity" for this biomarker. Normal values are what indicate that your autoimmune system is not responding to the presence of gluten, and is the basis for measuring effectiveness of the gluten-free diet.

Your overall likelihood is compared to the possible scenarios



Your Next Steps

In all scenarios, the imaware™ team is here to help, please reach out to us if you have any other questions or need support or guidance on how to action these results.



If your results are following the original projected curve, then your diet and lifestyle are performing as expected and your immune response to gluten is decreasing. This is great news!



If your results are above the projected curve, and you have not been able to get your values lower, you may want to consult a Registered Dietitian who can help you enhance your gluten-free diet to ensure immune response decreasing and healing take hold.

Celiac Disease Monitoring Test - Detailed Results

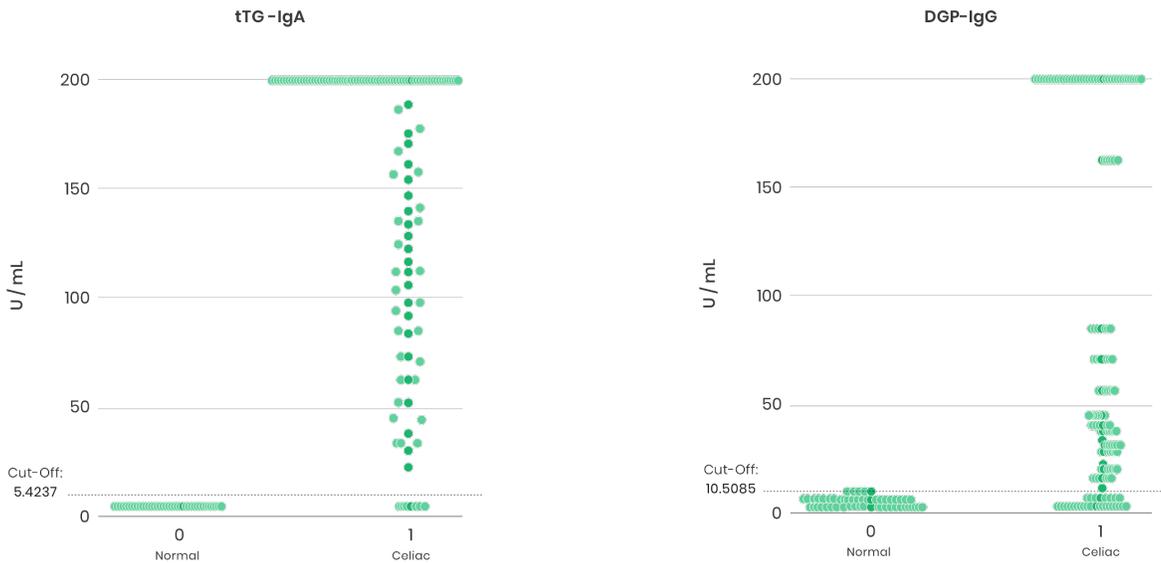
The following pages provide additional information that should be shared with your healthcare professional.

DETAILED PATIENT RESULTS TABLE

Analyte	Quantitative (U/mL) & Qualitative Result	Cutoff (U/mL)	Sensitivity (+/- 95% CI)	Specificity (+/- 95% CI)
tTG IgA	5.5 - Negative	5.4	95%	99%
tTG IgG	6.8 - Negative	6.4	88%	98%
DGP IgA	4.9 - Negative	14.7	81%	93%
DGP IgG	4.0 - Negative	10.5	82%	92%

Robust and Validated Clinical Performance of imaware™ Assay

The following ROC Analysis dot plots showcase range, cut-off, sensitivity, and specificity of celiac disease positive and normal samples. Overall sensitivity and specificity are further increased through use of combined likelihood ratios.^[1-15]



TEST NOTES AND LIMITATIONS

- These test results should be shared with your healthcare provider
- This test is not intended to diagnose rheumatoid arthritis - only your healthcare provider can make that determination, in light of your overall health history and the results of other testing they may decide to order
- Please consult your healthcare provider before making any lifestyle changes
- Patient sample was processed on by Trinity Lab. CLIA #33D0170905, located at 10 Earhart Drive, Suite 100, Williamsville, NY, 14221 - Dr. Thomas Shanahan, Director of Clinical Laboratory Services.

SCIENTIFIC REFERENCES CONTINUED

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