imaware™

Prediabetes Test Report

Date Presented - July 5, 2019

Ordering Doctor

Name: Dr. Jody Smith
License #: 00515515
UPIN #: A999Z9
NPI #: 9999999999

Patient Details

Jane Smith
Patient Number: 100523
DOB: Jan 1, 1980
Gender: Female
Ph: (234) 234-2343

Specimen Details

Collected: July 1, 2018
Sent: July 1, 2019
Tested: July 5, 2019
Source: Capillary Blood

Welcome To Your Results

Dear Jane Smith,

We received your small volume blood sample, and tested it for the presence of certain biomarkers commonly associated with prediabetes.

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 our lab partners have completed validation studies comparing this process to established testing methods.

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

Medical Advisory Team

Dr. Eleftherios Diamandis
Head of Clinical Biochemistry
at Mount Sinai Hospital

Dr. Stefano Guandalini
Professor Emeritus at
University of Chicago

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Prediabetes Test - Your Results Summary

Jane, you are **highly likely to have prediabetes**
based on biomarker sampling as well as patient specific considerations.

BIOMARKER SAMPLING

A biomarker ("biological marker") refers to a category of objective signs that indicate medical state. Elevated biomarker levels in your blood can signal the presence of a disease. We tested your blood for the following three (3) biomarkers that are associated with prediabetes:

Hb-A1c	Glucose	EAG (Est. Avg. Glucose)
ABNORMAL	ABNORMAL	ABNORMAL

PATIENT SPECIFIC CONSIDERATIONS

We included specific aspects of your history and condition as part of this test in order to confirm your likelihood.

• You indicated that you have not been previously diagnosed

• You indicated that you have family history of Type 2 Diabetes

Your overall likelihood is compared to the possible scenarios

Highly Likely
More than 60% likelihood

Somewhat Likely
Between 25-60% likelihood

Less Likely
Between 2-25% likelihood

Not Likely
Less than 2% likelihood

Highly Likely

Likelihood you have prediabetes

Your likelihood estimate is based on biomarker sampling and preconditions:

Your blood sample contained abnormal biomarker levels

You indicated a pre-condition that may increase your likelihood of having this condition

Your Next Steps

Share these results with your doctor, who can review your results and provide an action plan before you make any major lifestyle changes.

If you begin to make any doctor recommended lifestyle changes, imaware™ can help you monitor the effectiveness of your lifestyle changes and treatment.

Prediabetes Test - Detailed Results

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

DETAILED PATIENT RESULTS TABLE

Analyte	Quantitative	Qualitative	Reportable Range	Cutoff	Target Range
Hb-A1c	6.5%	Positive	4.0% - 14.0%	5.7%	4.0% - 5.7%
Blood Glucose	135 mg/dL	Positive	60 - 400 mg/dL	100 mg/dL	60 - 100 mg/dL
EAG (Est. Avg. Glucose)	145 mg/dL	Positive		117 mg/dL	68 - 117 mg/dL

PATIENT DISEASE AND SYMPTOMS STATUS

• You indicated that you have not been previously diagnosed

• You indicated that you have family history of Type 2 Diabetes

• You indicated that you do currently smoke

Prediabetes Test - Detailed Scientific Validation

imaware™ tests are tested to be highly accurate and precise. The following data can be reviewed by your medical professional to better understand the validity of the imaware test.

HEMOGLOBIN A1C TEST - SCIENTIFIC VALIDATION

Accuracy

Paired whole blood samples versus dried blood spots containing varying concentrations of Hemoglobin A1c were tested to determine comparability of the two different collection methods. A1c concentrations were determined using a latex enhanced immunoturbidimetric assay and statistically analyzed by simple regression:

| N=30		
Correlation Coefficient		0.9898
Slope		0.99
Intercept		0.09
	DBS A1c	Comparable Whole Blood Method
Mean Hemoglobin A1c	6.8	6.8
Standard Deviation of Range	1.8	1.8

$y = 0.99x + 0.09$
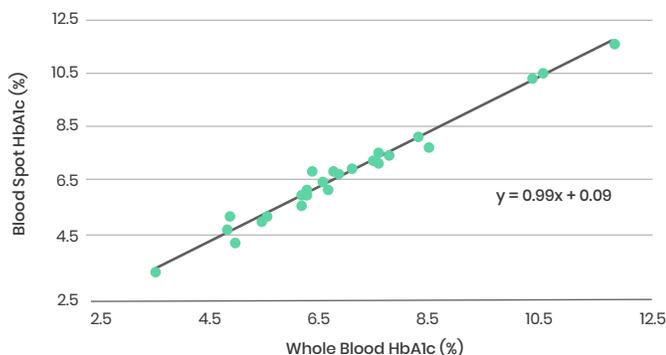
GLUCOSE TEST - SCIENTIFIC VALIDATION

Accuracy

Paired serum and dried serum spot samples containing varying concentrations of Glucose were tested. Glucose concentrations observed for the dried serum (DS) samples versus serum (enzymatic colorimetric method) were statistically analyzed by simple regression:

N=27		
Correlation Coefficient		0.98
Slope		0.91
Intercept		7.59
	DS Glucose	Comparable Serum Method
Mean Glucose	112.0	114.6
Standard Deviation of Range	64.9	70.4

$y = 0.9115x + 7.5805$
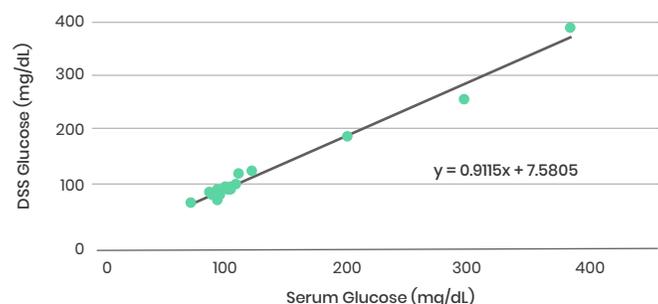
Prediabetes Test - Additional Information

SCIENTIFIC REFERENCES

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2. Ivana R Sequeira, Sally D Poppitt1
   2017, HbA1c as a marker of prediabetes: A reliable screening tool or not,
   Review Article - Insights in Nutrition and Metabolism () Volume 1, Issue 1

3. Ike S. Okosun, J. Paul Seale, Rodney Lyn and Y. Monique Davis-Smith.
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4. Ho-Pham LT, Nguyen UDT, Tran TX, Nguyen TV.
   August 17, 2017, Discordance in the diagnosis of diabetes: comparison between HbA1c and fasting plasma
   PLOS ONE. doi:10.1371/journal.pone.0182192

5. Simmons RK, Rahman M, Jakes RW, et al.
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   Diabetologia.; 54(2): 312–319.

PERFORMING LABORATORY INFORMATION

- Patient Sample was performed on July 5, 2019 by CoreMedica Labs.
- CLIA Number 26D2013888 CAP Accreditation 7537862
- Lab Location: 200 NE Missouri, Ste 302, Lees Summit, MO, 64081
- Lab Director: Dr. Cristian Saez, Ph.D.

TEST NOTES AND LIMITATIONS

- These test results should be shared with your healthcare provider
- This test is not to diagnose any health condition - 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 dietary changes