imaware™

Haptoglobin Genetic Test Report

Date Presented - July 6, 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, 2019
Sent: July 1, 2019
Tested: July 5, 2019
Source: Capillary Blood

Welcome To Your Results

Dear Jane Smith,

We received your small volume dried blood sample, and tested it for your haptoglobin genotype.

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 show haptoglobin genotypes.

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 PCR validation studies comparing this process to known controls in a CLIA and CAP accredited laboratory.

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. David Vigerust
Professor at Vanderbilt University

Haptoglobin Genetic Test - Your Results Summary

Jane, our tests indicate you have the **haptoglobin genotype Hp 1-1**

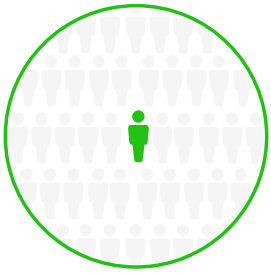
based on biomarker sampling. Patient specific information is listed below.

BIOMARKER SAMPLING & GENOTYPE

A biomarker ("biological marker") refers to a category of objective signs that indicate medical state. Biomarkers sometimes exist in several distinct forms called a genotype which can affect your risk for a disease. We tested your blood for your haptoglobin genotype:

Haptoglobin Genotype

Hp 1-1



PATIENT SPECIFIC INFORMATION

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

- You indicated that you do have diabetes
- You indicated that you normal cholesterol levels
- You indicated that you don't have a family history of cardiovascular disease

Your overall likelihood is compared to the possible scenarios

High Risk
Hp 2-2

Intermediate Risk
Hp 1-2

Lower Risk
Hp 1-1

Lower Risk

Likelihood of additional risk for Cardiovascular Disease as measured by Hp2

Your likelihood estimate is based on biomarker sampling and preconditions:

Your blood sample indicated a genotype that may increase your risk of this condition

You indicated a pre-condition that may increase your risk of 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.

Haptoglobin Genetic Test - Detailed Results

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

DETAILED PATIENT RESULTS TABLE

Test Performed	Quantitative Result	Qualitative Result	Reportable Outcomes
Haptoglobin Genotype	Hp 1-1	Lower Risk	Hp 1-1, Hp 1-2, Hp 2-2

PATIENT DISEASE AND SYMPTOMS STATUS

- You indicated that you do have diabetes
- You indicated that you normal cholesterol levels
- You indicated that you don't have a family history of cardiovascular disease

Haptoglobin Genetic Test - Detailed Scientific Validation

MyGenetx Laboratory, LLC proprietary Haptoglobin test is confirmed to be highly accurate and precise. The following data can be reviewed by your medical professional to better understand the validity of the MyGenetx test.

Interpretation

The results of this Haptoglobin Genotype Test indicate that your patient is Hp 1-1 and has high additional risk for Cardiovascular Disease (CVD). Patients with an Hp1-1 genotype are at decreased risk for retinopathy, nephropathy and microvascular complications.

COMMENTS

Significance

Haptoglobin genotype is a screening for diabetic patients at risk for cardiovascular disease (CVD). Haptoglobin (Hp) is an acute-phase protein that binds to freely circulating hemoglobin. Haptoglobin exists as two distinct forms, Hp1 and Hp2.

The larger Hp2 form has been associated with cardiovascular events and mortality in individuals with type 2 diabetes.

Haptoglobin allele frequency in European populations is 40% for Hp1 and 60% for Hp2. The expected genotype frequencies in the western world are 16% for Hp 1-1, 48% for Hp 1-2 and 36% for Hp 2-2.

Risk

In patients with diabetes, the antioxidant capacity of Hp for glycosylated hemoglobin is reduced

Consider

Haptoglobin genotype is a predictor of CVD in the diabetic population but not in the general population. Diabetic patients with the Hp 2-2 genotype are 5 times more likely to have CVD than patients with Hp 1-1. Diabetic patients with Hp 1-2 are 3 times more likely to have CVD than patients with Hp 1-1.

The Haptoglobin genotype is performed by Real-Time PCR using a fluorescently labeled primerence assay. The clinical interpretation is a Laboratory Developed Test (LDT). The Haptoglobin Genotype test was developed and its performance characteristics determined by MyGenetx Laboratory (MGL), LLC. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and is accredited to perform high-complexity clinical testing. The test has not been approved by the U.S. Food and Drug Administration. Such approval is not necessary. MGL is not liable for any outcomes arising from clinicians' treatment protocols and decisions.

Haptoglobin Genetic Test - Additional Information

SCIENTIFIC REFERENCES

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9. Blum S, Vardi M, Levy NS, Miller-Lotan R, Levy AP. (2010). The effect of vitamin E supplementation on cardiovascular risk in diabetic individuals with different haptoglobin phenotypes. Atherosclerosis.211:25–27.

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PERFORMING LABORATORY INFORMATION

- Patient Sample was performed on July 5, 2019 by MyGenetx Laboratory, LLC.
- CLIA Number 44D2031868
- Lab Location: 4037 Rural Plains Cir., Suite 150, Franklin, TN 37064
- Lab Director: Jack T. Pearson, M.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