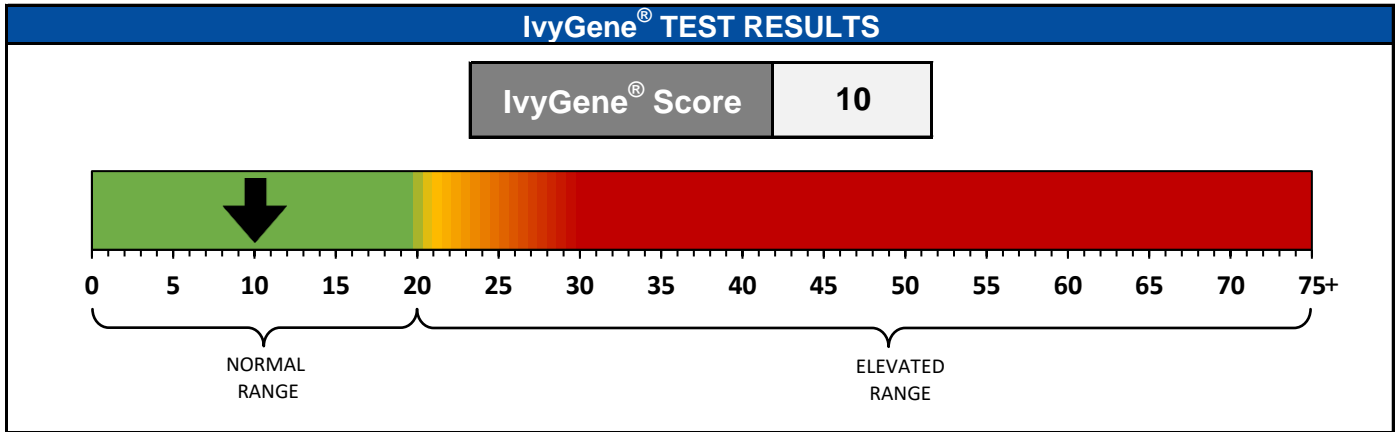


IvyGene®
LABORATORY REPORT



DOCTOR	SAMPLE	PATIENT
SAMPLE DOCTOR 123 Main Street Anytown, USA 12345 Customer Number: (0001)	IvyGene® Number: 1234 Unique ID: ivy-5789 Date Received: 1/8/2018 Date of Report: 1/10/2018	SAMPLE PATIENT DOB: 7/20/1969 AGE: 48 SEX: F



TEST INFORMATION

The IvyGene® Test measures the methylation status of cell-free DNA extracted from blood samples at target sites within the MYO1G and the TNFAIP8L2 genes. These target sites have been demonstrated to be hypermethylated when certain cancers are present. Test results are reported as a quantitative IvyGene® Score, which indicates the methylation status of the target sites. The IvyGene® Score is calculated as a composite average of cell-free DNA that is methylated at the target sites as a fraction of the total cell-free DNA present.

IvyGene® Score
0-19 = normal range, 20-75+ = elevated range

The IvyGene® Test is an adjunct clinical test that is intended to be based on the independent medical judgement of the ordering physician in conjunction with the patient's complete medical history and the results of standard of care testing. The IvyGene® Test has been validated with four (4) cancer tissues of origin: breast, colon, liver and lung cancers. The presence of other cancer types may also result in an elevated IvyGene® Score. A large-scale clinical trial to demonstrate the efficacy of the IvyGene® Test as a cancer screening test has not been conducted. Cancer screening is not an approved utility of the IvyGene® Test.

The IvyGene® Test was evaluated and its performance characteristics determined by Mor-NuCo Enterprises Inc., a subsidiary of the Laboratory for Advanced Medicine (LAM). Mor-NuCo Enterprises Inc. is CLIA-registered and CAP-accredited to perform high complexity testing. The IvyGene® Test has not been cleared or approved by the FDA. Instead, the IvyGene® Test meets current U.S. Food and Drug Administration (FDA) requirements as a qualified laboratory developed test (LDT).

COMMENTS

This result has been reviewed and approved by Laboratory Director: David J. Taggart, PhD NRCC

Date of Review: 1/10/2018