GENETICS INSTITUTE OF AMERICA

Genetics Institute of America
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CLIA ID: 10D-2166884

Name: Proficiency Sample 2
DOB: 1/1/1970
Sex: Male
Race/Ethnicity:
Family #:

MRN: 123456789
Referring facility: Nearby Lab
Referring physician: Dr. Doctor
Copies to:

Accession ID: 2002070001
Date of Collection: 2/7/2020
Date of Receipt: 2/8/2020
Date of Report: 2/9/2020
Specimen: Voided Urine, First Morning

Test(s) Performed: PanGIA® Prostate

Indication for test: Elevated PSA, Positive DRE

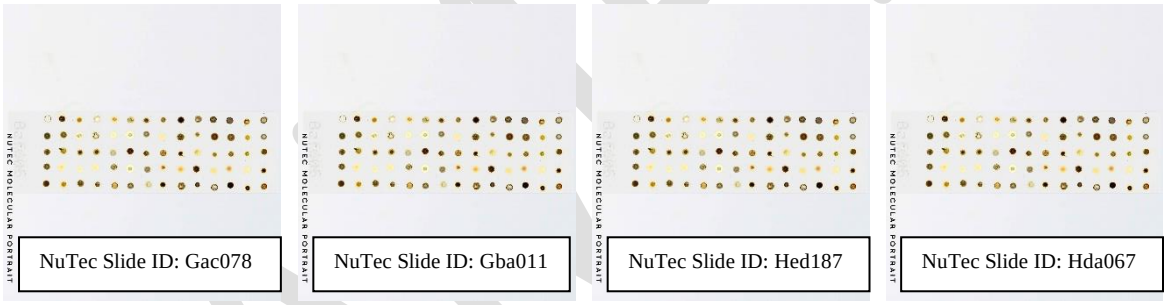
RESULT: NEGATIVE

Consistent with bio-molecular profiles from NEGATIVE examples included in the machine learning training set.

This result is NOT CONSISTENT WITH men who have prostate cancer. Repeat testing may be considered should the clinical presentation change.

YOUR SCORE: 36

Confidence Score: 96%



Methodology:

Fixed urine was prepared using NuTec slides for analysis on the OpsisDx™ neural network AI system. The NuTec signatures were analyzed and results subjected to a proprietary algorithm based on the OpsisDx™ unattended deep learning neural network artificial intelligence system and Poisson-Binomial Radius classification.

Based on the PanGIA Prostate validation study, Men with a PanGIA Prostate score below 40 have a NuTec signature consistent with men who were confirmed negative after prostate biopsy. Men with a PanGIA Prostate score above 80 have a NuTec signature consistent with men who were confirmed positive after prostate biopsy. Additionally, Patient Management should be based on the total clinical picture, clinical judgement, and shared decision-making regarding undergoing additional studies including prostate biopsy.

The OpsisDx™ artificial intelligence system was trained with 150 biopsy-confirmed positive NuTec slides and 150 biopsy-confirmed negative NuTec slides. NuTec signatures were associated with biopsy results and used to train and evaluate a basic multilayer perceptron (MLO) with a single fully connected hidden layer. Performance statistics were generated using a Leave-One-Out (LOO) framework by isolating each subject signature data in turn, training the MLP on the remaining N-1 subjects, then applying the trained MLP model to the isolated sample to predict its class (i.e. no cancer v prostate cancer). The required number of subjects/classes to optimally train the OpsisDx™ artificial intelligence was empirically determined.

Note: This test was evaluated, and its performance characteristics determined by Genetics Institute of America. It has not been cleared or approved by the U.S Food and Drug Administration. Such clearance or approval is generally not necessary. Genetics Institute of America is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity testing.