

THEROS CancerTYPE ID[®] Test Report

Patient details:

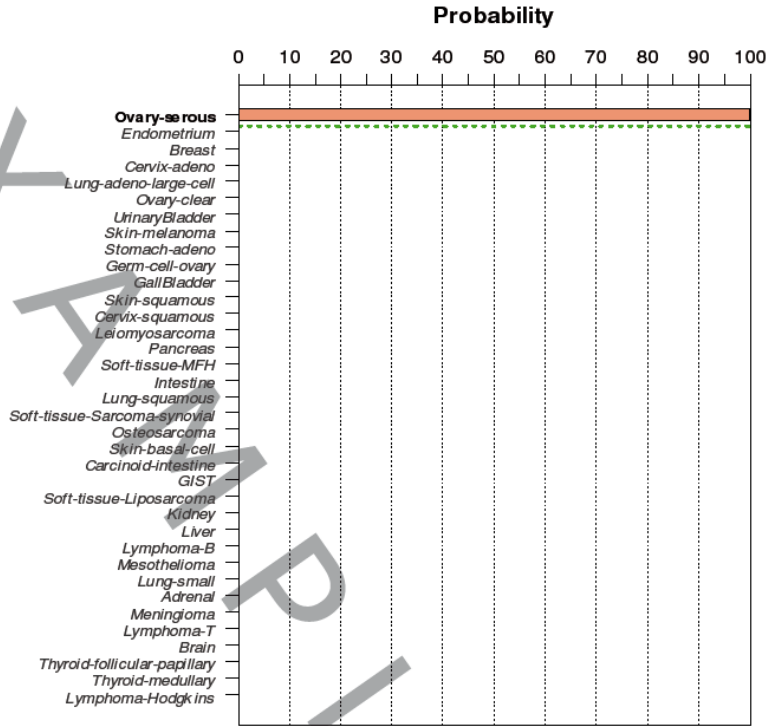
First name: _____ Last name: _____
 Date of birth (DD/MM/YY): _____ Lab21 ID: _____
 Site of biopsy: _____ Date of biopsy: _____

THEROS CancerTYPE ID[®] Molecular Cancer Classification Test

Sample quality:	Sufficient
Microdissection:	Yes
Cancer Type	Probability
Ovary-serous	99.7%

Additional Test Information
 The test sample is most similar to the cancer type listed in the table above. The probability is a direct measure of the confidence for the prediction.

How it works. The probability for each cancer type is based on the 92-gene expression profile of the test sample. The probability scores for all cancer types sum to 100%. The cancer type with the highest probability represents the most likely type. When the difference between the highest and the second highest probability is small, the top two or three types are listed as predictions to reach >80% cumulative probability.



Note: cancer types below the horizontal dashed line are ruled out with 95% confidence.

Intended Use

THEROS CancerTYPE ID[®] is a molecular test that is recommended to guide the process of cancer classification.

Test Description and Methodology

This test identifies the most likely tumor origin based on the expression profiles of 92 genes analyzed by RT-PCR and is capable of classifying up to 39 tumor classes. The 92-gene expression profile is obtained by extracting mRNA from tumor-enriched sections of formalin-fixed paraffin embedded (FFPE) tissue and performing real-time quantitative RT-PCR using Taqman[™] technology. This RT-PCR based test has been shown to have an accuracy of 86% in classifying 39 cancer types[1,2]. However, cancer types outside of these 39 types may be unclassifiable or potentially misclassified.

1. Ma et al. Molecular Classification of Human Cancers Using a 92-Gene Real-Time Quantitative Polymerase Chain Reaction Assay. Archives of Pathology and Laboratory Medicine. 2006;130:465-473
 2. Data on File, Technical Report 051909, bioTheranostics, Inc.

Laboratory Director: **Veena M. Singh, M.D.** CLIA # 05-D1065725 CA # CLF334843

This test was developed and its performance characteristics determined by bioTheranostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. This molecular cancer classification predictive testing should be interpreted in the context of additional clinical and/or histopathological findings and not in lieu of such studies.

The THEROS CancerTYPE ID[®] test was conducted by bioTheranostics, Inc, US.

 Signature Position Date

If you wish to have a follow-up consultation, please contact Lab21 Customer Services to arrange a call with the bioTheranostics Medical Director in the US.

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