

Cholangiocarcinoma



CancerTYPE ID® Molecular Cancer Classification Test

bioTherapeutics, Inc.
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Patient & Order Information

Order ID: CTA10-000000	Sex: M	Hospital Address: ABC Hospital
Patient Name: John Doe	Site of Biopsy: Liver Core	City, State: 123 Main Street
DOB: mm/dd/yyyy	Date of Collection: mm/dd/yyyy	Anywhere, ST 12345
Medical Record: 12345678	Date Reported: mm/dd/yyyy hh:mm	Phone: (123) 456-7890
Sample ID: le: AB12-34567-C	Microdissection: Laser	Fax: (123) 456-7890
Date Received: mm/dd/yyyy		

RESULTS

Main Cancer Type: Cholangiocarcinoma (Probability 96%)
Subtype: Cholangiocarcinoma (Probability 96%)

Main Cancer Type	Probability	Histological Subtype	Probability
Cholangiocarcinoma	96%	Cholangiocarcinoma	96%

Cancer types ruled out with 95% confidence (these types have a combined probability < 5%)

Adrenal	Brain	Breast	Cervix	Endometrium
Esophagus	Gallbladder	Gastroesophageal	Germ-cell	GIST
HeadNeck	Intestine	Kidney	Liver	Lung
Lymphoma	Melanoma	Meningioma	Mesothelioma	Neuroendocrine
Ovary	Pancreas	Prostate	Sarcoma	Sex-cord-stromal-tumor
Skin	Thymus	Thyroid	UrinaryBladder	

Additional Comments:

Intended Use

CancerTYPE ID® is a molecular test that is recommended to guide the process of cancer classification. This molecular cancer classification test should not be used as a sole diagnostic tool and should be interpreted in the context of additional clinical, radiological and/or histopathological findings. This test does not determine malignancy.

Test Description and Methodology

The expression profile of 92 genes is obtained by extracting RNA from tumor-enriched sections of formalin-fixed paraffin embedded (FFPE) tissue and performing real-time quantitative RT-PCR using Taqman™ technology [1]. This test identifies the most likely tissue origin and histological type based on the degree of similarity of this 92-gene expression profile to those from tumors of known tissue origin and histological subtype [2]. The probability score is a measure of confidence for the classification. However, cancer types outside of these types may be unclassifiable or potentially misclassified.

- 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
- Data on File. Technical Report 031510, bioTherapeutics, Inc.

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This test was developed and its performance characteristics determined by bioTherapeutics, 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. bioTherapeutics is certified under the Clinical Laboratory Improvement Amendments of 1988 as qualified to perform high complexity clinical laboratory testing.