



CancerTYPE ID®
Molecular Cancer Classification Test

bioTherapeutics, Inc.
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Patient & Order Information

Order ID:	CTA10-000000	Sex:	F	Hospital:	ABC Hospital
Patient Name:	Jane Doe	Site of Biopsy:	Submandibular Gland	Address:	123 Main Street
DOB:	mm/dd/yyyy	Date of Collection:	mm/dd/yyyy	City, State:	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: **HeadNeck (Probability 92%)**
Subtype: **Salivary gland (Probability 92%)**

Main Cancer Type	Probability	Histological Subtype	Probability
HeadNeck	92%	Salivary gland	92%
		Squamous cell carcinoma	0%

Less likely types: Breast (4%)

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

Adrenal	Brain	Cervix	Cholangiocarcinoma	Endometrium
Esophagus	Gallbladder	Gastroesophageal	Germ-cell	GIST
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 and Limitations

CancerTYPE ID is indicated for use in tumor specimens from patients diagnosed with malignant disease and is intended to aid in the classification of the tissue of origin and tumor subtype in conjunction with standard clinical and pathological assessment by a qualified physician. CancerTYPE ID is not intended to predict survival benefit, treatment efficacy or to distinguish between benign versus malignant lesions. Tumor types not included in the CancerTYPE ID reference database may exhibit RNA expression patterns that are similar to RNA expression patterns within the reference database.

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.

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 031510, bioTherapeutics, Inc.

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

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.