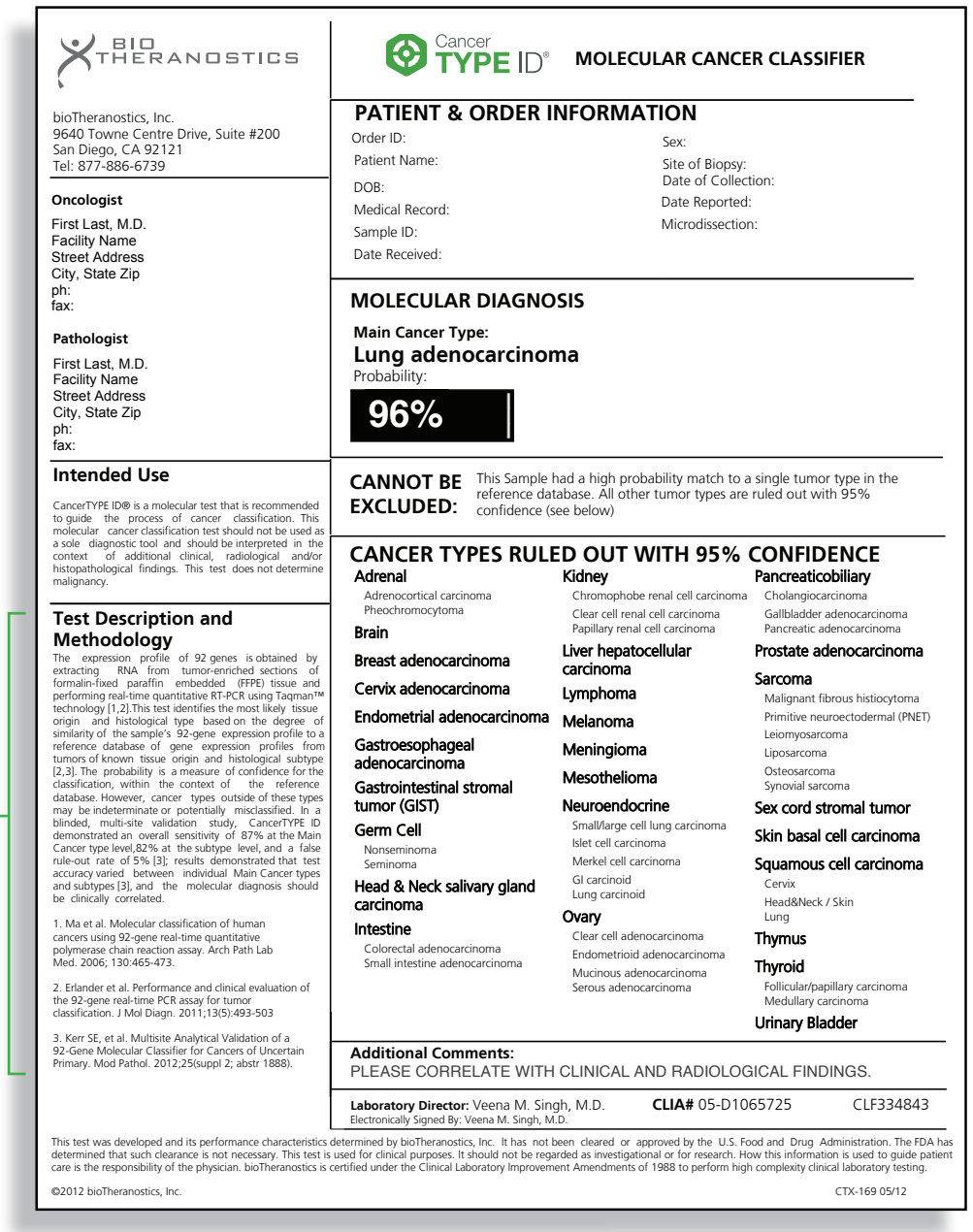
Cancer TYPE ID®

THE CancerTYPE ID TEST REPORT IS DESIGNED TO PROVIDE YOU WITH CLARITY AND QUANTITATIVE RESULTS FOR A MAIN TUMOR TYPE, AND WHEN APPLICABLE, TUMOR SUB-TYPES



BIO THERANOSTICS

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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 [1,2].This test identifies the most likely tissue origin and histological type based on the degree of similarity of the sample's 92-gene expression profile to a reference database of gene expression profiles from tumors of known tissue origin and histological subtype [2,3]. The probability is a measure of confidence for the classification, within the context of the reference database. However, cancer types outside of these types may be indeterminate or potentially misclassified. In a blinded, multi-site validation study, CancerTYPE ID demonstrated an overall sensitivity of 87% at the Main Cancer type level,82% at the subtype level, and a false rule-out rate of 5% [3]; results demonstrated that test accuracy varied between individual Main Cancer types and subtypes [3], and the molecular diagnosis should be clinically correlated.

1. Ma et al. Molecular classification of human cancers using 92-gene real-time quantitative polymerase chain reaction assay. Arch Path Lab Med. 2006; 130:465-473.

2. Erlander et al. Performance and clinical evaluation of the 92-gene real-time PCR assay for tumor classification. J Mol Diagn. 2011;13(5):493-503

3. Kerr SE, et al. Multisite Analytical Validation of a 92-Gene Molecular Classifier for Cancers of Uncertain Primary. Mod Pathol. 2012;25(suppl 2; abstr 1888).

Cancer TYPE ID® **MOLECULAR CANCER CLASSIFIER**

PATIENT & ORDER INFORMATION

Order ID:
Patient Name:
DOB:
Medical Record:
Sample ID:
Date Received:
Sex:
Site of Biopsy:
Date of Collection:
Date Reported:
Microdissection:

MOLECULAR DIAGNOSIS

Main Cancer Type:
Lung adenocarcinoma
Probability:
96%

CANNOT BE EXCLUDED: This Sample had a high probability match to a single tumor type in the reference database. All other tumor types are ruled out with 95% confidence (see below)

CANCER TYPES RULED OUT WITH 95% CONFIDENCE

- **Adrenal**
  - Adrenocortical carcinoma
  - Pheochromocytoma
- **Brain**
- **Breast adenocarcinoma**
- **Cervix adenocarcinoma**
- **Endometrial adenocarcinoma**
- **Gastroesophageal adenocarcinoma**
- **Gastrointestinal stromal tumor (GIST)**
- **Germ Cell**
  - Nonseminoma
  - Seminoma
- **Head & Neck salivary gland carcinoma**
- **Intestine**
  - Colorectal adenocarcinoma
  - Small intestine adenocarcinoma
- **Kidney**
  - Chromophobe renal cell carcinoma
  - Clear cell renal cell carcinoma
  - Papillary renal cell carcinoma
- **Liver hepatocellular carcinoma**
- **Lymphoma**
- **Melanoma**
- **Meningioma**
- **Mesothelioma**
- **Neuroendocrine**
  - Small/large cell lung carcinoma
  - Islet cell carcinoma
  - Merkel cell carcinoma
  - GI carcinoid
  - Lung carcinoid
- **Ovary**
  - Clear cell adenocarcinoma
  - Endometrioid adenocarcinoma
  - Mucinous adenocarcinoma
  - Serous adenocarcinoma
- **Pancreaticobiliary**
  - Cholangiocarcinoma
  - Gallbladder adenocarcinoma
  - Pancreatic adenocarcinoma
- **Prostate adenocarcinoma**
- **Sarcoma**
  - Malignant fibrous histiocytoma
  - Primitive neuroectodermal (PNET)
  - Leiomyosarcoma
  - Liposarcoma
  - Osteosarcoma
  - Synovial sarcoma
- **Sex cord stromal tumor**
- **Skin basal cell carcinoma**
- **Squamous cell carcinoma**
  - Cervix
  - Head&Neck / Skin
  - Lung
- **Thymus**
- **Thyroid**
  - Follicular/papillary carcinoma
  - Medullary carcinoma
- **Urinary Bladder**

Additional Comments:
PLEASE CORRELATE WITH CLINICAL AND RADIOLOGICAL FINDINGS.

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

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. bioTheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 to perform high complexity clinical laboratory testing.

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Molecular Diagnosis:
CancerTYPE ID reports a predicted main type and any associated sub-types in rank-order by quantitative probabilities. Probabilities are based on the tumor's gene expression similarity to the CancerTYPE ID database of over 2,000 tumors

Rule Ins:
Any tumor types that the CancerTYPE ID test cannot exclude from diagnostic consideration are listed here

Rule Outs:
The CancerTYPE ID test report also lists tumor types that can be ruled-out with 95% confidence. This may provide useful information in instances with a differential diagnosis where 2 or more potential tumor types are suspected

Test Description and Methodology:
This section describes how CancerTYPE ID is performed

CancerTYPE ID Indications for 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 patient 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. This test was developed and performance characteristics have been determined by bioTheranostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. 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. bioTheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 as qualified to perform high-complexity clinical laboratory testing.

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