

CLIENT INFORMATION

Client Name: _____
 Ordering Physician (print): _____ NPI #: _____
 Signature (Physician or Authorized Designee)**: _____
 Street: _____ City: _____ St: _____ Zip: _____
 Phone #: _____ Fax: _____
 Additional Physicians in Practice: _____

The signatory declares by his signature that he/she is authorized to order the services.

REFERRING PHYSICIAN (Copy of report will be provided)

Name: _____
 Facility/Office Contact: _____
 Phone: _____ Fax: _____

PATIENT INFORMATION

(Please attach patient face sheet, clinical history, prior pathology report along with front and back of primary and secondary insurance card)

Name (Last, First): _____
 Date of Birth: ____/____/____ Sex: M F
 Patient Status: Hospital Inpatient Hospital Outpatient Non-hospital Patient
 Address: _____
 City: _____ State: _____ Zip: _____
 Home Phone #: _____ Work Phone #: _____
 Medical Record #: _____
 Hospital/Facility Name: _____

BILLING Copies of Insurance Cards Attached

Bill To: Medicare Insurance Client Patient
 Insurance Name: _____
 Policy #: _____ Group #: _____
 Policy Holder Name: _____ DOB: _____
 Relationship: Self Spouse Child Other Referral #: _____
 Address: _____ Phone #: _____
 City: _____ State: _____ Zip: _____
 Secondary Insurance: _____

CLINICAL/SPECIMEN INFORMATION

ICD-10 Codes - Primary _____ Secondary _____
 Specimen Site: _____ Date of Collection: ____/____/____
 Clinical History: _____ Date of Discharge: ____/____/____
 Block ID: _____ Date Retrieved from Archive: ____/____/____
 Permission to Exhaust Block: Yes No (If yes, indicate test prioritization)
 Specimen Type: Unstained Slides: # _____ FFPE Block(s): # _____
 Core Needle Biopsy Biopsy Site: _____
 Fixative used (10% NBF recommended): _____
 Time to Fixation (Cold Ischemic Time): _____ Duration of Fixation: _____
 Treatment Status: New Diagnosis Recurrent/Progression/Metastasis
 Therapy: _____

PATHOLOGY/LAB SPECIMEN REQUEST

Copy of Pathology Report Attached
 If Pathology Contact information is filled out below, Rosetta will retrieve specimen:
 Pathology Dept. / Contact: _____
 Phone: _____ Fax: _____

TEST OFFERINGS Testing performed as Global unless Tech Only is checked.

*NOTE: Send the following tests to East Lab (Philadelphia, PA): CORE, Cancer Origin (with or without reflex), OncoGxOne & OncoGxLung.
 Send all other tests to West Lab (Lake Forest, CA).

ROSETTAGX™ CANCER ORIGIN™ Cancer Origin + OncoGxOne™ NGS
 Cancer Origin

CORE™ (RosettaGX Cancer Origin microRNA Classifier Reflex to Targeted Profile for Lung, Colon, Melanoma or Breast Cancer or OncoGxOne NGS for Other Solid Tumors – see reverse for test descriptions)
 Cancer Origin Reflex

ROSETTAGX™ LUNG

Targeted: EGFR Mutation, ALK & ROS1 FISH, PD-L1 (FDA-Keytruda)
 Reflex to NGS: If targeted tests are negative, reflex to OncoGxOne™
 Expanded: EGFR, KRAS, BRAF, ALK, ROS1, RET, MET, FGFR1, PD-L1 (FDA-Keytruda)

Individual Markers: FISH: ALK ROS1 RET MET FGFR1 Tech Only FISH

Mutation Analysis: EGFR KRAS BRAF

IHC: PD-L1 (FDA 223C-Keytruda) (FDA 28-8 Opdivo) ALK

miRNA: mi-LUNG™ - (miRNA subtyping assay)

Liquid Biopsy (Biocept): Call East Lab for Ordering information 888.522.7971

ROSETTAGX™ COLON

Microsatellite Instability (MSI) by PCR

Mutation Analysis: KRAS NRAS BRAF

ROSETTAGX™ MELANOMA

Mutation Analysis: BRAF IHC: PD-L1 (FDA 223C-Keytruda)

ROSETTAGX™ BREAST

Comprehensive Profile: ER/PR, HER2, Ki-67, p53 by IHC; PathVysion HER2 by FISH

HER2 Reflex: ER/PR, HER2 by IHC; reflex to PathVysion HER2 FISH: 1+ or 2+ 2+ only

Individual Markers: FISH: HER2 HER2 Reflex: 1+ or 2+ 2+ only

IHC: ER/PR HER2 Ki-67 p53 PD-L1 (LDT)

Tech Only
 FISH
 IHC

ROSETTAGX™ NEXT-GEN

OncoGxOne™ - (64 gene NGS profile)

OncoGxLung™ - (Lung-Specific NGS Profile: EGFR, ALK, ROS1, KRAS, BRAF)

Other Solid Tumor Testing

Other Tumor Type (specify): _____

Mutation Analysis (specify): _____

FISH (specify): _____

Histology (H&E) Tumor Type: _____

Immunohistochemistry (IHC)

PD-L1 ALK Other markers: _____

Tech Only
 IHC

ADDITIONAL COMMENTS/TEST REQUESTS:

Test Descriptions and Specimen Requirements:

Test Name / Methodology	Test and Reflex Descriptions	Test Specimen Requirements (Tumor Tissue FFPE Block is Preferred)
<p style="text-align: center;">CORE (Cancer Origin Reflex)</p>	<p>Cancer Origin Reflex to targeted profiles as follows:</p> <ul style="list-style-type: none"> • Lung Primary - Reflex to EGFR Mutation, ALK FISH, ROS1 FISH, PD-L1 IHC. If all tests are negative, reflex to OncoGxOne NGS. If no tissue available, liquid biopsy available. • Breast Primary - Reflex to HER2 FISH (PathVysion) • Colorectal Primary - Reflex to KRAS, BRAF and NRAS Mutation Analysis • Melanoma Primary - Reflex to BRAF Mutation Analysis and PD-L1 IHC • Other Solid Tumor - Reflex to OncoGxOne NGS Profile (64 actionable genes) 	<ul style="list-style-type: none"> • For CORE testing, FFPE block is highly recommended as tissue requirements vary based on reflex algorithm. • Primary and metastatic tumors are accepted • If unstained slides are submitted instead of the block, prepare twenty (20) 5 µm unstained slides and provide 1 H&E slide at 4-5 µm. • OncoGxOne - Prepare ten (10) 5 µm unstained slides (of which a minimum of 20% is confirmed tumor content) and at least one (1) H&E slide at 4-5 µm. The tissue surface area should be > 25mm(2) on each slide.
<p style="text-align: center;">RosettaGX Cancer Origin™ Primary Tumor microRNA Classifier</p>	<p>Utilizes 64 microRNAs to identify the most likely of 49 cancer origins.</p>	<ul style="list-style-type: none"> • FFPE Blocks are the preferred specimen type • Primary and metastatic tumors are accepted for RosettaGX Cancer Origin, OncoGxOne, and OncoGxLung • Minimum tumor cell area is 2.5mm(2) • Specimens from cytology are accepted only for mi-LUNG and must be primary tumors only • If unstained slides are submitted instead of the block, prepare the following: <ul style="list-style-type: none"> • RosettaGX Cancer Origin & mi-LUNG - Twelve (12) 5 µm unstained slides (total tissue needed is 60 µm) and at least one (1) H&E slide at 4-5 µm. 2 H&E slides flanking unstained slides is preferred. • OncoGxOne & OncoGxLung - Prepare ten (10) 5 µm unstained slides (of which a minimum of 20% is confirmed tumor content) and at least one (1) H&E slide at 4-5 µm. The tissue surface area should be > 25mm(2) on each slide.
<p style="text-align: center;">OncoGxOne™ Next-Gen Sequencing</p>	<p>An NGS profile that provides clinically actionable results to enable tailored treatment options. Detects all currently known, clinically relevant alterations in 64 cancer genes (56 related to targeted cancer therapy and 8 related to chemotherapy).</p>	
<p style="text-align: center;">OncoGxLung™ Next-Gen Sequencing</p>	<p>Lung specific NGS profile that detects all currently known alterations in EGFR, ROS1, ALK, KRAS and BRAF genes.</p>	
<p style="text-align: center;">mi-LUNG™ microRNA subtyping</p>	<p>Differentiates primary lung tumors into small cell lung cancer (SCLC), squamous non-small cell lung cancer (NSCLC), non-squamous NSCLC, and Carcinoid.</p>	
<p style="text-align: center;">FISH</p>	<p>FISH (Fluorescence in Situ Hybridization) is offered both as a Global or Tech Only service for the following genes: ALK (Vysis FDA), ROS1, MET, RET, FGFR1, HER2 (PathVysion FDA), PTEN, ERG</p>	<ul style="list-style-type: none"> • FFPE tissue block is preferred specimen type - unused tumor material is returned to sender. • For unstained slides, submit the following: <ul style="list-style-type: none"> • FISH: minimum of 3 unstained slides on positively charged slides at 5 µm for each individual test ordered (i.e. 6 total slides if 2 tests/markers are ordered). Or, submit 2 unstained slides per test plus an H&E • IHC: minimum 2 unstained slides at 3 µm per biomarker ordered • Mutation Analysis: minimum of 5 slides at 5 µm per test ordered
<p style="text-align: center;">IHC</p>	<p>PD-L1 FDA-Approved assays for determining likelihood of response to therapies such as Keytruda (pembrolizumab) and Opdivo (nivolumab).</p>	
<p style="text-align: center;">Mutation Analysis by PCR</p>	<p>EGFR, KRAS, BRAF, NRAS</p>	