ROSETTAGX™

Revealing Genomic Answers

Shaded areas required for specimen processing

East Lab*
3711 Market Street • Suite 740
Philadelphia, PA 19104
888.522.7971 • 215.382.9000 • Fax: 215.382.0815

West Lab
25901 Commercentre Drive
Lake Forest, CA 92630
877.429.6643 • Fax: 949.587.7500

CLIENT INFORMATION

Client Name: _____

Ordering Physician (print): _____ NPI #: _____

Signature (Physician or Authorized Designee)**: _____

Street: _____ City: _____ St: _____ Zip: _____

Phone #: _____ Fax: _____

**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: ☐ Slides: _____ FFPE Block(s): # _____

☐ Urine ☐ Bladder Wash ☐ 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: _____

ROSETTAGENOMICS™

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

CORE™ (Cancer Origin REflex)

☐ **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)

ROSETTAGX CANCER ORIGIN™

☐ Cancer Origin + OncoGxOne™ NGS
☐ Cancer Origin

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

Tech Only ☐ FISH ☐ IHC

Individual Markers: FISH: ☐ HER2 ☐ HER2 Reflex: ☐ 1+ or 2+ ☐ 2+ only
IHC: ☐ ER/PR ☐ HER2 ☐ Ki-67 ☐ p53 ☐ PD-L1 (LDT)

ROSETTAGX™ NEXT-GEN

☐ OncoGxOne™ - (64 gene NGS profile)
☐ OncoGxSelect™ - (12 gene NGS profile with highly prevalent lung-specific genes - capacity for other tumor types)

ROSETTAGX™ PROSTATE

☐ Prognostic Profile: ERG and PTEN by FISH

Individual Markers: FISH: ☐ ERG ☐ PTEN **IHC:** ☐ Triple Stain

Tech Only ☐ FISH ☐ IHC

ROSETTAGX™ BLADDER

☐ UroVysion ☐ Urine Cytology ☐ Cytology + UroVysion
☐ Cytology w/ Reflex to UroVysion if Atypical or Suspicious

Tech Only ☐ UroVysion ☐ Cytology

ROSETTAGX™ KIDNEY

☐ mi-KIDNEY™ - (miRNA subtyping assay)

Other Solid Tumor Testing

Other Tumor Type (specify): _____
☐ **Mutation Analysis (specify):** _____
☐ **FISH (specify):** _____

ROSETTAGX™ THYROID

☐ **RosettaGX Reveal™** (Thyroid microRNA Classifier)

Complete the following if you have selected RosettaGX Reveal™

Specimen Type: ☐ FNA Smear (Diagnostic slide preferred) ☐ Cellblock** ☐ ThinPrep
Stain Used: ☐ Giemsa ☐ Pap ☐ Diff-Quik ☐ Other: _____
Number of Slides: _____ Nodule Location & Size: _____
☐ Check to Request Image of slide (email required) Email: _____

Cytology Diagnosis (Bethesda Category):
☐ Atypical/FLUS (III) ☐ Suspicious for Neoplasm (Hurthle or follicular) (IV)
☐ Suspicious for Cancer (V) ☐ Other, Please Specify: _____

ADDITIONAL COMMENTS/TEST REQUESTS:

_____

PLEASE SEE REVERSE FOR SPECIMEN REQUIRMENTS & REFLEX OPTION DETAILS – Top Copy (White) – RosettaGX Bottom Copy (Yellow) – Client

RosettaGX Next-Gen testing is performed and interpreted by Admera Health.

Test Description and Specimen Requirements

*NOTE: Send the following tests to East Lab (Philadelphia, PA): *RosettaGX Reveal, CORE, Cancer Origin (with or without reflex), mi-LUNG, mi-KIDNEY, NGS (OncoGxOne & OncoGxSelect).*
Send all other tests to West Lab (Lake Forest, CA).
Each sample component must be labeled with two unique patient identifiers.

Test Name / Methodology	Test and Reflex Descriptions	Test Specimen Requirements (Tumor Tissue FFPE Block is Preferred)
CORE (Cancer Origin Reflex)	Cancer Origin Reflex to targeted profiles as follows: • 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)	• 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.

RosettaGX Cancer Origin™ Primary Tumor micoRNA Classifier	Utilizes 64 micoRNAs to identify the most likely of 49 cancer origins.	• FFPE Blocks are the preferred specimen type
		• Primary and metastatic tumors are accepted for RosettaGX Cancer Origin, OncoGxOne, and OncoGxSelect
		• 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:
		  • 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 & OncoGxSelect - 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.

OncoGxOne™ Next-Gen Sequencing	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).	
OncoGxSelect™ Next-Gen Sequencing	12 gene NGS profile profile with highly prevalent lung-specific genes and capacity for other tumor types. 12 Oncogenes Assayed: ALK, BRAF, EGFR, ERBB2, KIT, KRAS, MAP2K1, MET, NRAS, PIK3CA, RET and ROS1.	
mi-LUNG™ microRNA subtyping	Differentiates primary lung tumors into small cell lung cancer (SCLC), squamous non-small cell lung cancer (NSCLC), non-squamous NSCLC, and Carcinoid.	
mi-KIDNEY™ micorRNA subtyping	Differentiates the 4 main histological types of primary kidney tumors: benign oncocytoma and the 3 most common subtypes of renal cell carcinomas: clear cell, papillary, and chromophobe.	
RosettaGX Reveal™ Thyroid microRNA Classifier	Indeterminate thyroid nodule classification by microRNA from a single cytology FNA smear. Differentiates indeterminate nodules as benign, suspicious for malignancy or positive for medullary carcinoma.	• The preferred specimen type is a thyroid smear slide containing sufficient amount of thyroid cells that has been used for diagnostic purposes. Cellblocks are also accepted. • Slide should be taken from a nodule >0.5 cm and be marked with two unique patient identifiers. • Acceptable stains for the test: PAP, Diff-Quik, Giemsa

FISH	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
		• FFPE tissue block is preferred specimen type - unused tumor material is returned to sender.
		• For unstained slides, submit the following:
		  • 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

IHC	PD-L1 FDA-Approved assays for determining likelihood of response to therapies such as Keytruda (pembrolizumab) and Opdivo (nivolumab).	
Mutation Analysis by PCR	EGFR, KRAS, BRAF, NRAS	
UroVysion	FDA-Approved UroVysion bladder cancer kit is designed to detect aneuploidy for chromosomes 3, 6, 17, and loss of 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens. Approved as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.	• Collect the first days urine mid-stream into the collection cup • Pour at least 30ml of urine into blue-capped cytology jar with PreservCyt® solution for UroVysion testing only (for combined Urine Cytology and UroVysion FISH testing, there should be 60 ml of urine) • Keep specimen refrigerated prior to shipping and ship specimen with ice pack placed on top of collection cup (specimen should not exceed 45° and needs to be processed within 48 hours).
Urine Cytology		

ROSETTAGENOMICS™

**The RosettaGX Reveal™ Test was validated in a blinded study on FNA smears classified as Bethesda III, IV, V. In a separate non-blinded study using cell blocks, the Test performed at the same levels as samples in the blinded validation study.