



# CLIENT SERVICES MANUAL

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## DIRECTORY

Helomics Corporation  
91 43<sup>rd</sup> Street, Suite 110  
Pittsburgh, PA 15201  
CLIA ID Number: 39D2008853

***VP, Operations and Pathology Services & Medical Director:*** Arlette H. Uihlein, MD, FCAP, FASCP

### Client Services:

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***Toll Free:*** 800.547.6165  
***Fax:*** 800.549.6407  
***Hours:*** 8:00 am - 4:30 pm (*Eastern Time*) Monday - Friday  
***Email:*** [clientservices@helomics.com](mailto:clientservices@helomics.com)

### Supplies (Specimen Collection Kits):

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***Toll Free:*** 800.547.6165  
***Hours:*** 8:00 am - 4:30 pm (*Eastern Time*) Monday - Friday  
***Email:*** [clientservices@helomics.com](mailto:clientservices@helomics.com)

## ABOUT HELOMICS

### OUR MISSION

To improve the standard of care for patients through **innovative research** and development partnerships with pharmaceutical, diagnostic, biotechnology and academic organizations, leading to better and **more personalized treatments** and diagnostic technologies for human disease.

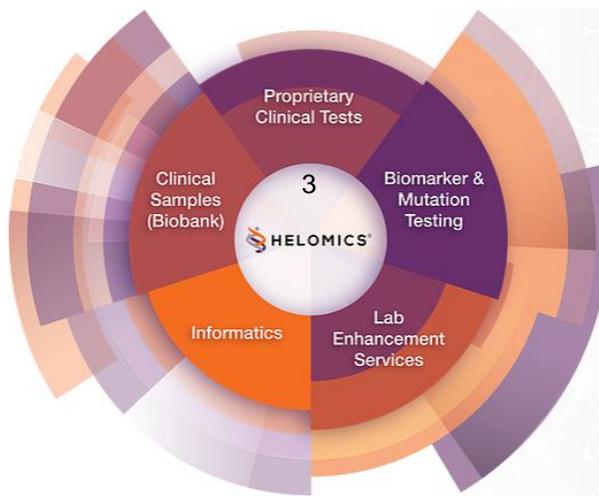
At Helomics, we promote the broad participation of industry, academia, and government to foster the development and commercialization of new technologies that will positively impact patient care.

We utilize our unique live tissue culture platform in association with partners in government, academia, and in the pharma, diagnostic, and biotechnology industries. Through these relationships, we develop and commercialize new bioanalytical methods and technologies.

We strive to positively impact patient care through a better understanding of the biology of a patient's tumor, leading to better informed and truly personal medical decisions.

We deliver a customized and differentiated solution to our partners in the pharmaceutical, diagnostic, biotechnology, and research industries for their specific project needs.

Our Lab Enhancement Services include consultation for a client's specific laboratory or commercialization needs, including reagent evaluation and qualification, method development, performance qualification, regulatory approval, commercialization and market strategy, and more.



# CLINICAL TEST CATALOG

## WHAT IS CHEMOFX®?

ChemoFx is a Treatment Selection Marker. It determines how an individual gynecologic cancer patient is likely to **respond to various types of chemotherapy** by testing the treatment options on that patient's **live cancer cells** and measuring cell response. ChemoFx provides valuable insights that help **guide physicians' treatment decisions**, giving you an edge against gynecologic cancer.

## WHY CHEMOFX?

Your physician is using every advantage available to improve the odds in your fight against cancer. ChemoFx is designed to **reduce your risk of receiving therapies that are ineffective** or to **identify alternatives** when the typical treatments recommended for your type of cancer cannot be tolerated.

## WHAT IS BIOSPECIFX®?

BioSpeciFx is a group of clinically relevant cancer-related **biomarker tests** that look to your genetics to predict your cancer's **response to various types of chemotherapy** and/or the course your disease is likely to take. The biomarkers included in BioSpeciFx testing are well validated and supported by current research and key opinion leaders.

## WHY BIOSPECIFX?

Physicians utilize BioSpeciFx test results to help them better understand the **unique characteristics** of your particular cancer. The results can help them choose between multiple, equivalent therapies, to make decisions on how **aggressively** to treat your cancer, or to suggest certain **clinical trials** for you, if you should qualify.



## NON-CLINICAL TESTING

HELOMICS IS AN

### INTEGRATED CLINICAL CONTRACT RESEARCH ORGANIZATION

Helomics' services are tailored to the **specific requirements of our clients** within the pharmaceutical, diagnostic, biotechnology and academic industries. Projects are performed on a fee-for-service basis according to a project proposal that specifies a detailed scope of work, timeline, and budget.

We bring a unique combination of **live and fixed cell** bioanalytical capabilities, backed by extensive expertise, to help you achieve your project goals.

Our **services are truly customized** to our client's needs, so please reach reach out to us and have a conversation about your unique goals. A member of our team will discuss how Helomics' capabilities can best be put to work for you.

Schedule a visit to our **17,400 square foot laboratory** and office space in Pittsburgh, PA, optimized for a new generation of biotechnology products.

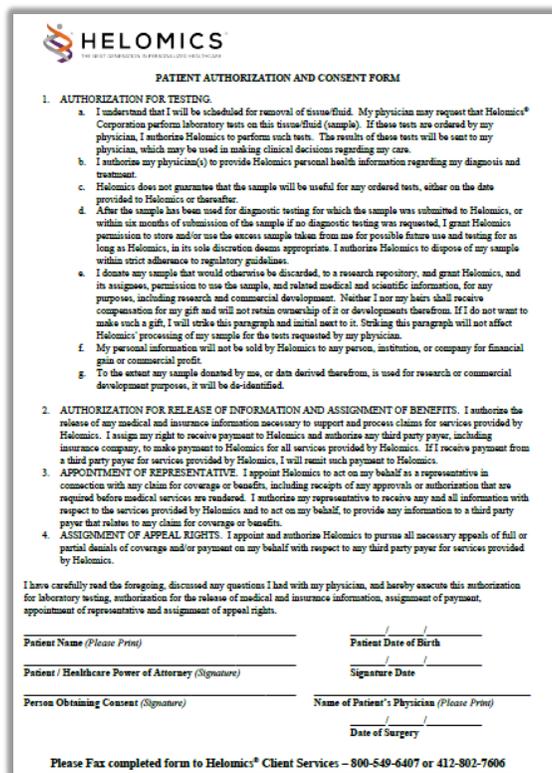
To obtain additional information or for assistance with any questions on contract research opportunities, please call **1-800-547-6165** or email: **ICCRO@helomics.com**.

# ORDERING SUPPLIES

To order any Helomics test...

1. **Contact our Client Services team** via phone, email, or our contact form on [www.helomics.com](http://www.helomics.com). Our representative will ask you for shipment information and send a specimen collection kit to your facility.

2. Obtain the patient's signature on Helomics' Universal Informed Consent Form:



**HELOMICS**  
THE BEST GUARANTEED SUPPLEMENTAL HEALTHCARE

**PATIENT AUTHORIZATION AND CONSENT FORM**

1. AUTHORIZATION FOR TESTING

- a. I understand that I will be scheduled for removal of tissue/fluid. My physician may request that Helomics<sup>®</sup> Corporation perform laboratory tests on this tissue/fluid (sample). If these tests are ordered by my physician, I authorize Helomics to perform such tests. The results of these tests will be sent to my physician, which may be used in making clinical decisions regarding my care.
- b. I authorize my physician(s) to provide Helomics personal health information regarding my diagnosis and treatment.
- c. Helomics does not guarantee that the sample will be useful for any ordered test, either on the date provided to Helomics or thereafter.
- d. After the sample has been used for diagnostic testing for which the sample was submitted to Helomics, or within six months of submission of the sample if no diagnostic testing was requested, I grant Helomics permission to store and/or use the excess sample taken from me for possible future use and testing for as long as Helomics, in its sole discretion deems appropriate. I authorize Helomics to dispose of my sample within strict adherence to regulatory guidelines.
- e. I donate any sample that would otherwise be discarded, to a research repository, and grant Helomics, and its assignees, permission to use the sample, and related medical and scientific information, for any purposes, including research and commercial development. Neither I nor my heirs shall receive compensation for my gift and will not retain ownership of it or developments therefrom. If I do not want to make such a gift, I will strike this paragraph and initial next to it. Striking this paragraph will not affect Helomics' processing of my sample for the tests requested by my physician.
- f. My personal information will not be sold by Helomics to any person, institution, or company for financial gain or commercial profit.
- g. To the extent any sample donated by me, or data derived therefrom, is used for research or commercial development purposes, it will be de-identified.

2. AUTHORIZATION FOR RELEASE OF INFORMATION AND ASSIGNMENT OF BENEFITS. I authorize the release of any medical and insurance information necessary to support and process claims for services provided by Helomics. I assign my right to receive payment to Helomics and authorize any third party payer, including insurance company, to make payment to Helomics for all services provided by Helomics. If I receive payment from a third party payer for services provided by Helomics, I will remit such payment to Helomics.

3. APPOINTMENT OF REPRESENTATIVE. I appoint Helomics to act on my behalf as a representative in connection with any claim for coverage or benefits, including receipt of any approvals or authorization that are required before medical services are rendered. I authorize my representative to receive any and all information with respect to the services provided by Helomics and to act on my behalf, to provide any information to a third party payer that relates to my claim for coverage or benefits.

4. ASSIGNMENT OF APPEAL RIGHTS. I appoint and authorize Helomics to pursue all necessary appeals of full or partial denial of coverage and/or payment on my behalf with respect to any third party payer for services provided by Helomics.

I have carefully read the foregoing, discussed any questions I had with my physician, and hereby execute this authorization for laboratory testing, authorization for the release of medical and insurance information, assignment of payment, appointment of representative and assignment of appeal rights.

Patient Name (Please Print) \_\_\_\_\_ Patient Date of Birth \_\_\_\_\_  
Patient / Healthcare Power of Attorney (Signature) \_\_\_\_\_ Signature Date \_\_\_\_\_  
Person Obtaining Consent (Signature) \_\_\_\_\_ Name of Patient's Physician (Please Print) \_\_\_\_\_  
Date of Surgery \_\_\_\_\_

Please Fax completed form to Helomics<sup>®</sup> Client Services – 800-549-6407 or 412-902-7606

UIC forms are available for download at <https://www.helomics.com/patients-forms> and can also be requested from the Client Services representative processing your kit order.

3. Immediately following the patient's surgery, follow the specimen submission instructions to secure the patient specimen in the collection kit and ship to the Helomics lab. Include the completed requisition form found inside the kit and a patient face sheet, if available.

# SPECIMEN PREPARATION INSTRUCTIONS

## SPECIMEN PREPARATION & SUBMISSION INSTRUCTIONS



### DISSECT AWAY EXCESS TISSUE

USING ENCLOSED STERILE SCALPEL AND FORCEPS, **DISSECT VIABLE TUMOR** AWAY FROM NECROTIC AND NORMAL TISSUE



### SLICE INTO STRIPS

PLACE TUMOR ONTO ENCLOSED STERILE PAD. SLICE INTO THIN STRIPS (3mm) TO MAXIMIZE SURFACE AREA CONTACT WITH MEDIA



### PLACE INTO LIVE TRANSPORT MEDIA

PLACE SLICED TUMOR SAMPLE INTO **COLD MEDIA VIAL** PROVIDED IN THE HELOMICS® COLLECTION KIT. CAP BOTTLE SECURELY



### AFFIX PATIENT LABEL

**PEEL OFF COMPLETED PATIENT LABEL** FROM REQUISITION AND **AFFIX TO MEDIA VIAL**



### REFRIGERATE UNTIL PICKUP

IT IS IMPORTANT TO KEEP THE SAMPLES AND MEDIA COLD TO **ENSURE SUCCESSFUL TESTING**

**IF SUBMITTING NEEDLE BIOPSIES:** COMBINE ALL SAMPLES INTO VIAL. RECOMMENDATIONS: 14g NEEDLE: 2 CORES, 16g NEEDLE: 4 CORES, 18g NEEDLE: 6 CORES.



### VIABLE TISSUE

SELECT SOLID, **VIABLE TISSUE** WITH **MALIGNANT CHARACTERISTICS**



### PLACE IN FORMALIN

**PLACE SPECIMEN INTO THE PROVIDED BIOSPECIFX® FORMALIN VIAL.** CAP BOTTLE SECURELY



### AFFIX PATIENT LABEL

**PEEL OFF COMPLETED PATIENT LABEL** FROM REQUISITION AND **AFFIX TO FORMALIN VIAL**



### TUMOR SIZE REFERENCE BOTH TESTS



THERE IS NO MINIMUM SIZE. TESTING IS ALWAYS ATTEMPTED, ALTHOUGH SUCCESS RATES MAY BE DIMINISHED.

## PACKING AND SHIPPING INSTRUCTIONS



PLACE CHEMOFX® VIAL **BETWEEN COLD MEDIA VIAL** PROVIDED IN THE HELOMICS® COLLECTION KIT. CAP BOTTLE SECURELY

PLACE BIOSPECIFX® SPECIMEN VIAL INTO BIOHAZARD BAG AND SEAL



PLACE BIOHAZARD BAG INTO **PURPLE CHEMOFX® THERMAL PACK** AND SEAL

SEAT BIOSPECIFX® FORMALIN VIAL UPRIGHT IN INSULATING FOAM HOLDER



PLEASE INCLUDE THE **FULLY COMPLETED TISSUE TRANSPORT REQUISITION (TTR) FORM** AND **PATIENT INFORMATION** INSIDE OF KIT BOX

**AFFIX AIRBILL** ON PROVIDED FEDEX CLINICAL PAK

PLACE KIT INTO CLINICAL PAK AND SEAL

CALL HELOMICS® CLIENT SERVICES AND PROVIDE **FEDEX TRACKING INFORMATION** AT 1-800-547-6165

REFRIGERATE KIT AS LONG AS POSSIBLE BEFORE SHIPPING TO MAINTAIN SPECIMEN VIABILITY.

## ACCEPTANCE CRITERIA

***All samples submitted to Helomics must be properly labeled with 2 unique patient identifiers to avoid rejection upon receipt.***

### ChemoFx:

- ChemoFx only provides results on confirmed gynecological tumors
- Specimen must be fresh tissue shipped in 10% McCoy's growth medium provided in Helomics' standard Tumor Profiling Kits:
  - Specimen cannot be exposed to a fixative (i.e. formalin, acetone, ethanol)
  - Specimen cannot be frozen
- Specimen must have an extraction date that is  $\leq 5$  days post extraction
- Pathology report or confirmed gynecological diagnosis from the ordering physician received for the submitted sample
- Acceptable signature and date on the order form
- Complete patient demographics and insurance

### BioSpeciFx:

- Helomics provides two standard kit options for BioSpeciFx samples:
  - Tumor Profiling Kit: Tissue specimens must be shipped in 10% neutral buffered formalin
  - FFPE Kit: Specimens must be shipped as slides or tissue blocks
- Pathology report or confirmed diagnosis from the ordering physician received for the submitted sample
- Acceptable signature and date on the order form
- Complete patient demographics and insurance

## REJECTION CRITERIA

### *For All Helomics' Products*

If any of the following criteria are met, then a specimen will be rejected and a Termination Report will be issued to the ordering physician:

- If a specimen is not properly labeled
- If a specimen arrives in an unacceptable medium
- If the pathology criterion (origin, histology, stage) is not met or is inappropriate for the requested test
- If a physician's order is not completed and signed
- If a patient's demographics and insurance information is not received

***Clients will be contacted as soon as possible for resolution if issues are identified.***

## TURNAROUND TIMES BY PRODUCT

- BioSpeciFx:** 10–14 days after receipt of the order form and sample; Sample may arrive prior to the order form, but testing will not begin until the order form is received
- ChemoFx:** 28–35 days after receipt of the fresh tissue and all required paperwork; depending on the growth profile of the sample

# PAPERWORK EXAMPLES

## Requisition Forms:

### ChemoFx and BioSpeciFx





**TISSUE TRANSPORT REQUISITION**     24 HOUR CLIENT SERVICE  
 1-800-547-6165

**COMPLETION OF ALL 3 STEPS IS CRITICAL**

**1. FILL OUT PATIENT ID LABELS AND APPLY INDIVIDUALLY TO VIALS**

**ChemoFx LABEL**

PATIENT NAME: LAST, FIRST, MI \_\_\_\_\_

MEDICAL RECORD # OR SSN \_\_\_\_\_ D.O.B. \_\_\_\_\_

REQUESTING PHYSICIAN \_\_\_\_\_ 027969

**I.D. NUMBER**  
**027969**

**BioSpeciFx LABEL**

PATIENT NAME: LAST, FIRST, MI \_\_\_\_\_

MEDICAL RECORD # OR SSN \_\_\_\_\_ D.O.B. \_\_\_\_\_

REQUESTING PHYSICIAN \_\_\_\_\_ 027969

A minimum of 2 patient identifiers on each label is required.

**2. SPECIMEN EXTRACTION INFORMATION**

A. EXTRACTION DATE (MM/DD/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_  
 PATH ID#: \_\_\_\_\_

B. ORIGIN OF CANCER:                      C. CANCER IS:

BREAST

CERVICAL

COLON

ENDOMETRIAL

GYN. SARCOMA

LUNG

PANCREATIC

OVARIAN

OTHER: \_\_\_\_\_

PRIMARY

RECURRENT

E. ANATOMIC SITE OF SPECIMEN: \_\_\_\_\_

F. TIME PLACED IN FORMALIN (BioSpeciFx only): \_\_\_\_\_  AM  PM  
 EASTERN  CENTRAL  MOUNTAIN  PACIFIC

G. IS COLD ISCHEMIC TIME < 1 HOUR?  YES  NO

**3. PERSON PREPARING SPECIMEN AND FACILITY CONTACT**

NAME AND TITLE OF PERSON THAT SELECTED AND CUT TISSUE: \_\_\_\_\_

PATHOLOGY CONTACT: \_\_\_\_\_

PHONE: \_\_\_\_\_

FACILITY/HOSPITAL: \_\_\_\_\_

EMAIL: \_\_\_\_\_

**PLEASE ENCLOSE THE FOLLOWING IN THE HELOMICS TUMOR PROFILING KIT BOX:**

1. THIS COMPLETED FORM
2. PATIENT DEMOGRAPHIC AND INSURANCE INFO.



TOP COPY: RETURN TO HELOMICS+    CARBON COPY: FOR YOUR RECORDS    PRESS FIRMLY

# PAPERWORK EXAMPLES

## Order Forms:

### ChemoFx

**ChemoFx® Order Form**

HELOMICS USE ONLY: 410320000 # 07XXXXXX

**1. PATIENT INFORMATION**

NAME: LAST, FIRST, MI: \_\_\_\_\_ ALLEGE: \_\_\_\_\_ PHO: \_\_\_\_\_ MAIL:  MAIL:

DOB: MM/YY: \_\_\_\_\_ SOCIAL SECURITY NUMBER: \_\_\_\_\_ DATE OF BIRTH: \_\_\_\_\_ DATE: \_\_\_\_\_

INSURANCE AUTHORIZATION INFORMATION (IF APPLICABLE): POLICY NUMBER: \_\_\_\_\_ EXT-DI CODE: \_\_\_\_\_

AUTHORIZATION NUMBER: \_\_\_\_\_ EXPIRATION DATE: 08/31/2008 DISCHARGE DATE: \_\_\_\_\_

**2. CLINICAL INFORMATION (DIAGNOSIS REQUIRED FOR TESTING)**

A. ORIGIN OF CANCER:  Cervical  Endometrial  Ovarian  Ovarian/Sarcoma  Other: \_\_\_\_\_

B. SITE OF SPECIMEN: \_\_\_\_\_

C. CANCER IS:  Primary  Recurrent

D. STAGE: \_\_\_\_\_

**3. AGENT SELECTION (MARK THE APPROPRIATE BOX ( ) TO SELECT AGENTS)**

Complete testing on ALL agents listed at right OR  Complete testing only on agents selected. A final report can only be generated for the agents listed below. Please do not add additional agents.

CARBOPLATIN  
 CARBOPLATIN/OMECETABINE  
 CARBOPLATIN/PACITAXEL  
 CISPLATIN  
 CYCLOPHOSPHAMIDE  
 DOXIFLAXEL  
 DOXORUBICIN  
 ETOPOSIDE  
 OMECETABINE  
 IFOSFAMIDE  
 PACITAXEL  
 TOPOTECAN

**4. PHYSICIAN INFORMATION (REPORTS WILL BE SENT TO PHYSICIANS LISTED)**

REQUESTING PHYSICIAN: NAME: Gerald Karish, M.D. ADDRESS: 91 43rd Street Pittsburgh, PA 15201 PHONE: 1-800-547-6165 FAX: 1-800-549-6407

SEND COPIES TO: NAME: ADDRESS: PHONE: FAX:

**5. REQUESTING PHYSICIAN'S SIGNATURE**

I CERTIFY THAT CHANGES IS MEDICALLY NECESSARY TO PROVIDE ADDITIONAL INFORMATION TO ASSIST IN THE TREATMENT OF THIS PATIENT.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

This test is not to be used independently for purposes of medical diagnosis, prognosis, or treatment, but only to be used in conjunction with other recognized, standard, laboratory and diagnostic tests and procedures, in accordance with current literature and practice guidelines, and with the experience and clinical judgment of a physician. This test was developed, and its performance characteristics determined, by Helomics Corporation. It has not been tested or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that each element or approval is not necessary. This test is used for clinical purposes and should not be reported as investigational or for research purposes.

Formal 1/2002 Fax Completed Form to 1-800-549-6407 or 412-802-7606 Doc#10104

### BioSpeciFx

**BioSpeciFx® Order Form**

HELOMICS USE ONLY: ChemoFx# \_\_\_\_\_ BioSpeciFx# 0XXXXXX

**1. PATIENT INFORMATION**

NAME - LAST, FIRST, MI: \_\_\_\_\_ SOCIAL SECURITY NUMBER: \_\_\_\_\_ DATE OF BIRTH: \_\_\_\_\_ DATE: \_\_\_\_\_

INSURANCE AUTHORIZATION INFORMATION (IF APPLICABLE): POLICY NUMBER: \_\_\_\_\_ EXT-DI CODE: \_\_\_\_\_

AUTHORIZATION NUMBER: \_\_\_\_\_ EXPIRATION DATE: 08/31/2008 DISCHARGE DATE: \_\_\_\_\_

**2. CLINICAL INFORMATION (DIAGNOSIS REQUIRED FOR TESTING)**

A. ORIGIN OF CANCER:  Breast  Lung  Sarcoma  Colon  Ovarian  Other: \_\_\_\_\_

B. SITE OF SPECIMEN: \_\_\_\_\_

C. CANCER IS:  Primary  Recurrent

D. STAGE: \_\_\_\_\_

**3. BIOMARKER SELECTION (MARK THE APPROPRIATE BOX ( ) TO SELECT BIOMARKERS - TESTS ARE DIC UNLESS OTHERWISE SPECIFIED)**

The complete test specification cannot be printed. However, testing will be conducted for the tests listed below. Please indicate any other performance below.

GVN	LUNG	COLON	PANCREATIC	BREAST
<input type="checkbox"/> AB EGFR Pathway	<input type="checkbox"/> AB EGFR Pathway	<input type="checkbox"/> AB EGFR Pathway	<input type="checkbox"/> AB EGFR Pathway	<input type="checkbox"/> AB EGFR Pathway
<input type="checkbox"/> PTKCA (Mutation)	<input type="checkbox"/> ALK	<input type="checkbox"/> EGFR (Mutation)	<input type="checkbox"/> EGFR (Mutation)	<input type="checkbox"/> EGFR (Mutation)
<input type="checkbox"/> KRAS (Mutation)	<input type="checkbox"/> KRAS (Mutation)	<input type="checkbox"/> KRAS (Mutation)	<input type="checkbox"/> KRAS (Mutation)	<input type="checkbox"/> KRAS (Mutation)
<input type="checkbox"/> BRAF (Mutation)	<input type="checkbox"/> BRAF (Mutation)	<input type="checkbox"/> BRAF (Mutation)	<input type="checkbox"/> BRAF (Mutation)	<input type="checkbox"/> HER2
<input type="checkbox"/> HER2	<input type="checkbox"/> PTFH	<input type="checkbox"/> PTKCA (Mutation)	<input type="checkbox"/> PTKCA (Mutation)	<input type="checkbox"/> PTFH
<input type="checkbox"/> PTFH	<input type="checkbox"/> Progrome	<input type="checkbox"/> PTFH	<input type="checkbox"/> PTFH	<input type="checkbox"/> PTFH
<input type="checkbox"/> AR DNA Repair	<input type="checkbox"/> AR DNA Repair	<input type="checkbox"/> AR DNA Repair	<input type="checkbox"/> AR DNA Repair	<input type="checkbox"/> AR DNA Repair
<input type="checkbox"/> MMR Panel	<input type="checkbox"/> ERCC1	<input type="checkbox"/> MMR Panel	<input type="checkbox"/> MMR Panel	<input type="checkbox"/> ERCC1
<input type="checkbox"/> MLH1/MSH2/MSH6/PMS2	<input type="checkbox"/> TS	<input type="checkbox"/> MLH1/MSH2/MSH6/PMS2	<input type="checkbox"/> MLH1/MSH2/MSH6/PMS2	<input type="checkbox"/> TS
<input type="checkbox"/> ERCC1	<input type="checkbox"/> Topo2a	<input type="checkbox"/> TS	<input type="checkbox"/> TS	<input type="checkbox"/> Topo2a
<input type="checkbox"/> ERCC1	<input type="checkbox"/> ERCC1	<input type="checkbox"/> ERCC1	<input type="checkbox"/> ERCC1	<input type="checkbox"/> ERCC1
<input type="checkbox"/> VEGF	<input type="checkbox"/> VEGF	<input type="checkbox"/> VEGF	<input type="checkbox"/> VEGF	<input type="checkbox"/> VEGF
<input type="checkbox"/> PDGFR	<input type="checkbox"/> PDGFR	<input type="checkbox"/> PDGFR	<input type="checkbox"/> PDGFR	<input type="checkbox"/> PDGFR
<input type="checkbox"/> AB Other	<input type="checkbox"/> AB Other	<input type="checkbox"/> AB Other	<input type="checkbox"/> AB Other	<input type="checkbox"/> AB Other
<input type="checkbox"/> KIA-47	<input type="checkbox"/> KIA-47	<input type="checkbox"/> KIA-47	<input type="checkbox"/> KIA-47	<input type="checkbox"/> KIA-47
<input type="checkbox"/> P53	<input type="checkbox"/> P53	<input type="checkbox"/> P53	<input type="checkbox"/> P53	<input type="checkbox"/> P53

**4. PHYSICIAN REQUESTING INFORMATION (REPORTS WILL BE SENT TO PHYSICIANS LISTED)**

REQUESTING PHYSICIAN: NAME: GERALD KARISH, M.D. ADDRESS: 91 43RD STREET PITTSBURGH, PA 15205 PHONE: 800-547-6165 FAX: 800-549-6407

SEND COPIES TO: NAME: ADDRESS: PHONE: FAX:

**5. SIGNATURE OF THE REQUESTING PHYSICIAN OR AUTHORIZED REPRESENTATIVE**

I CERTIFY THAT I AM CONSULTING ON AND/OR TREATING THIS PATIENT AND WILL USE BIOPECIFX RESULTS IN THEIR DIAGNOSIS, TREATMENT OR MANAGEMENT.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

This test is not to be used independently for purposes of medical diagnosis, prognosis, or as the basis for making therapeutic decisions, but may be used in conjunction with other recognized, standard laboratory and diagnostic tests and procedures, in accordance with current literature and practice guidelines, and with the experience and clinical judgment of a physician. A patient's medical and medical history should always be considered when making any treatment decision. These tests were developed and their performance characteristics determined by Helomics Corporation. They have not been tested or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that each element or approval is not necessary. This test is used for clinical purposes and should not be reported as investigational or for research purposes.

This test is not to be used independently for purposes of medical diagnosis, prognosis, or as the basis for making therapeutic decisions, but may be used in conjunction with other recognized, standard laboratory and diagnostic tests and procedures, in accordance with current literature and practice guidelines, and with the experience and clinical judgment of a physician. A patient's medical and medical history should always be considered when making any treatment decision. These tests were developed and their performance characteristics determined by Helomics Corporation. They have not been tested or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that each element or approval is not necessary. This test is used for clinical purposes and should not be reported as investigational or for research purposes.

Formal 1/2002 Fax Completed Form to 1-800-549-6407 or 412-802-7606 Doc#10104



For more information about Helomics' services or to take a virtual tour of our lab please visit:

**<https://www.helomics.com/>**

We thank you for your interest!

