

PIK3CA Mutation CDx - Plasma Test Request Form

Account #: _____ (Leave blank if no account number exists)

DATE (MM/DD/YYYY)

Account Name: _____

Eligible patients may receive one free plasma and a tumor tissue test using the QIAGEN theascreen® PIK3CA RGQ PCR test for the purpose of determining whether or not the patient has a PIK3CA mutation and is eligible for alpelisib for an FDA-approved indication, without regard to purchase of any prescribed drug or any other product.

SAMPLE PRE-QUALIFICATION IS REQUIRED.
Please call **1-866-776-5907** to review test information and special sample collection/handling requirements with NeoGenomics Client Services before arranging patient's blood draw.

CLIENT INFORMATION

STREET ADDRESS	CITY	ST	ZIP
PHONE	FAX		
ORDERING PHYSICIAN (PLEASE PRINT: LAST, FIRST)	NPI#		
TREATING PHYSICIAN (PLEASE PRINT: LAST, FIRST)	NPI#		

PATIENT INFORMATION

LAST NAME	FIRST NAME	M.I.
DATE OF BIRTH (MM/DD/YYYY)	GENDER <input type="checkbox"/> Male <input type="checkbox"/> Female	MRN/PATIENT ID

SELECT A TEST ORDER

- Test plasma only - there is no tissue currently available for this patient, or the only tissue available is decalcified bone
 Test plasma and if negative, then test tissue (TAT for tissue results at least 20 days from receipt of blood and request form)
 Test plasma and tissue concurrently

SPECIMEN INFORMATION – PLASMA

SPECIMEN ID	COLLECTION DATE (MM/DD/YYYY)	COLLECTION TIME <input type="checkbox"/> AM <input type="checkbox"/> PM
PLASMA PROCESS TIME <input type="checkbox"/> AM <input type="checkbox"/> PM	SPIN TIME (HOURS/MINUTES)	IMMEDIATELY STORED AT -80 °C AFTER PROCESSING <input type="checkbox"/> Yes <input type="checkbox"/> No

SPECIMEN INFORMATION – TISSUE

To order tests other than PIK3CA CDx, please use separate requisition.

SPECIMEN ID	BODY SITE	COLLECTION DATE (MM/DD/YYYY)	SPECIMEN TYPE (QUANTITY) <input type="checkbox"/> Paraffin Block(s) _____ <input type="checkbox"/> Unstained Slides (6-12 slides + H&E) _____
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SPECIMEN RETRIEVAL

If ordering testing on off-site tissue, complete this section and fax form with pathology report to 239-690-4237.

LOCATION OF SPECIMEN	PHONE	FAX	
STREET ADDRESS	CITY	ST	ZIP

CLINICAL INFORMATION

DIAGNOSIS/ICD CODE(S)

Required: Please attach patient Pathology Report, clinical history, and other applicable report(s).

BILLING INFORMATION

Required: Please include the face sheet of patient demographics. No patient, health care program, or beneficiary shall be billed for this mutation test. The test shall not be included in a bundled payment to any health care facility including, but not limited to, a hospital. The ordering physician shall not be compensated any fees in connection with this mutation testing, such as for specimen collection, handling, or data reporting. Program is not valid where prohibited by law. Novartis reserves the right to rescind, revoke, or amend the program without notice.

I certify that I am the health care professional who has ordered the above testing for the identified patient, who has consented to the testing, that I have made an independent judgment that the above testing is medically necessary for the care and treatment of this patient, and that the information provided is accurate to the best of my knowledge.

AUTHORIZED SIGNATURE

DATE (MM/DD/YYYY)



Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080



NeoGenomics.com
Phone 866.776.5907 / Fax 239.690.4237
CORP-MRKT-0005 Rev. 091521

Blood Collection, Separation, and Storage

Please Note: Whole blood **must be processed within 4 hours of collection** to isolate plasma. Failure to do so may result in test failure.

1. Collect blood in 3 purple-top 10 ml K2 EDTA BD Vacutainer® tubes.
2. Place whole blood in Vacutainer tubes in centrifuge with swing-out rotor and appropriate buckets.
3. Centrifuge blood samples for 10 min at 1900 x g and 4°C temperature setting.
4. Carefully aspirate plasma supernatant without disturbing the buffy coat layer. About 4-5 ml plasma can be obtained from one 10 ml primary blood tube.
5. Transfer aspirated plasma into fresh 15 ml centrifuge tubes with conical bottom (required). These tubes are included in the transport kit.
6. Centrifuge plasma samples for 10 min at 16,000 x g (in fixed-angle rotor) and 4°C temperature setting.
7. Carefully remove supernatant to a new tube with a pipette without disturbing the pellet. Use orange-capped cryogenic vials included with the transport kit. Label tubes/vials with patient's name and date of birth.
8. Keep plasma frozen in -80°C freezer until packaged for transport (-70°C to -90°C acceptable).

Plasma Packaging and Shipment

Please Note: Plasma specimens should be stored **at -80°C** at all times until it is packaged for shipping to NeoGenomics. Plasma will be shipped to NeoGenomics priority overnight using a DeepFreeze™ Shipper by Nanocool. DeepFreeze insulated shippers are qualified to ship on dry ice for up to 96 hours without re-icing. Please ship Monday-Thursday. Friday shipments are not recommended. Do not ship on Saturday. Please ensure the pickup is scheduled prior to packaging the specimen for shipment.

1. Complete the NeoGenomics PIK3CA Mutation CDx Plasma Test Request Form and include a copy of the patient's Pathology Report.
2. If requesting testing on a tissue specimen that NeoGenomics must retrieve from the pathology site on your behalf, fax the completed requisition form along with the pathology report to 239.690.4237. This will expedite the tissue retrieval process.
3. Ensure the plasma specimen tubes/vials are labelled with the patient's name and date of birth.
4. Place the specimen inside the biohazard bag with absorbent pad. Remove air from the bag and seal it. Place the folded test requisition form and pathology report in the pocket on side of biohazard bag.
5. Place the sealed bag into the smaller inner box and fill it completely with dry ice.
6. Place the inner box in between the spacer sets provided and then fill the DeepFreeze box completely with dry ice.
7. Close and tape the box shut. Affix the FedEx label to the top of the box and verify the delivery address is our Aliso Viejo, CA laboratory.
8. Place the packaged shipper in the pickup area provided to Client Services.

IMPORTANT!

You will need to completely fill both the inner box and the DeepFreeze insulated box with dry ice to keep the specimen at the required temperature during transportation. Failure to do so will render the specimen untestable.

NEOGENOMICS INTERNAL USE ONLY

Plasma Specimen Passed Accessioning Quality Check: Yes No

Accessioning Initial _____

MM/DD/YYYY _____



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