PIK3CA Mutation CDx Test Request Form

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

Account name: _____

NeoGenomics Laboratories will conduct tumor tissue testing using the QIAGEN *therascreen*® PIK3CA RGQ PCR Kit.[1] Appropriate patients may receive one tumor tissue PIK3CA mutation test at no cost 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.

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.

Questions?
Please call **1-866-776-5907**

To order a plasma test, contact NeoGenomics Client Services at **1-866-776-5907, option #1.**

DATE (MM/DD/YYYY)

Physician information

ORDERING PHYSICIAN NAME		PHYSICIAN NPI	
ADDRESS			
CITY	STATE	ZIP CODE	PHONE #
	FAX #		

Treating physician

TREATING PHYSICIAN NAME	NPI

Patient information

LAST NAME		FIRST NAME
DATE OF BIRTH (MM/DD/YYYY)	GENDER ☐ Male ☐ Female	MRN/PATIENT ID

Specimen/clinical information

COLLECTION DATE (MM/DD/YYYY)	BODY SITE
SPECIMEN TYPE (QUANTITY) ☐ Paraffin Block(s) _____ ☐ Unstained Slides (6-12 slides + H&E) _____	SPECIMEN ID

Specimen retrieval Client Services will request specimen from Pathology site

LOCATION OF SPECIMEN			
ADDRESS	CITY	STATE	ZIP CODE
PHONE #	FAX #		

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

AUTHORIZED SIGNATURE	DATE (MM/DD/YYYY)

Existing NeoGenomics customers
Please include the pathology report and submit by fax to 1-239-690-4237, or include with patient specimen in the provided shipper.

First time ordering with NeoGenomics?
Please fax this form and pathology report to 1-239-690-4237 so we can set up your account prior to receiving the specimen. A Client Services representative will contact you to assist you with your first order.

therascreen is a registered trademark of QIAGEN group.

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Please see indication and Important Safety Information for alpelisib on next page or click here for full Prescribing Information.

NEO GENOMICS

Indication

PIQRAY® (alpelisib) tablets is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

Important Safety Information

PIQRAY is contraindicated in patients with severe hypersensitivity to it or any of its components.

Severe Hypersensitivity: Severe hypersensitivity reactions, including anaphylaxis and anaphylactic shock, can occur in patients treated with PIQRAY. Severe hypersensitivity reactions were manifested by symptoms including, but not limited to, dyspnea, flushing, rash, fever, or tachycardia. Angioedema has been reported in the postmarketing setting in patients treated with PIQRAY. Advise patients of the signs and symptoms of severe hypersensitivity reactions. Permanently discontinue PIQRAY in the event of severe hypersensitivity.

Severe Cutaneous Adverse Reactions (SCARs): PIQRAY can cause SCARs, including Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS). Interrupt PIQRAY if signs or symptoms of SCARs are present (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy), until etiology of the reaction has been determined. Advise patients of the signs and symptoms of SCARs. Consider consultation with a dermatologist. Permanently discontinue PIQRAY if a SCAR is confirmed.

Hyperglycemia: PIQRAY can cause severe hyperglycemia, in some cases associated with hyperglycemic hyperosmolar non-ketotic syndrome (HHNKS) or ketoacidosis. Fatal cases of ketoacidosis have occurred in the postmarketing setting. Before initiating treatment with PIQRAY, test fasting plasma glucose (FPG), HbA1c, and optimize blood glucose. After initiating treatment, monitor fasting glucose (FPG or fasting blood glucose) at least once every week for the first 2 weeks, then at least once every 4 weeks, and as clinically indicated. Monitor HbA1c every 3 months and as clinically indicated. Monitor fasting glucose more frequently for the first few weeks during treatment in patients with risk factors for hyperglycemia. Initiate or optimize antihyperglycemic medications as clinically indicated. Interrupt, reduce dose, or discontinue PIQRAY if severe hyperglycemia occurs. The safety of PIQRAY in patients with type 1 and uncontrolled type 2 diabetes has not been established. Patients with a history of diabetes mellitus may require intensified hyperglycemic treatment. Closely monitor patients with diabetes.

Advise patients of the signs and symptoms of hyperglycemia (eg, excessive thirst, urinating more often than usual or higher amount of urine than usual, or increased appetite with weight loss).

Pneumonitis: PIQRAY can cause severe pneumonitis, including acute interstitial pneumonitis and interstitial lung disease. Monitor for clinical symptoms or radiological changes. Consider a diagnosis of noninfectious pneumonitis in patients presenting with nonspecific respiratory signs and symptoms such as hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams and in whom infectious, neoplastic, and other causes have been excluded by means of appropriate investigations. Interrupt or discontinue PIQRAY if severe pneumonitis occurs. Advise patients to immediately report new or worsening respiratory symptoms.

Diarrhea or Colitis: PIQRAY can cause severe cases of diarrhea, resulting in dehydration and in some cases in acute kidney injury. Colitis has been reported in the postmarketing setting in patients with PIQRAY. Monitor patients for diarrhea and additional symptoms of colitis, such as abdominal pain and mucus or blood in stool. Based on the severity of the diarrhea or colitis, PIQRAY may require dose interruption, reduction, or discontinuation. Advise patients to start antidiarrheal treatment, increase oral fluids, and notify their health care provider if diarrhea occurs while taking PIQRAY. For patients with colitis, additional treatment, such as enteric-acting and/or systemic steroids, may be required.

Embryo-Fetal Toxicity: PIQRAY can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. Refer to full Prescribing Information of fulvestrant for pregnancy and contraception information.

Most common adverse reactions, including laboratory abnormalities (all grades, incidence ≥20%) were glucose increased (79%), creatinine increased (67%), diarrhea (58%), rash (52%), lymphocyte count decreased (52%), gamma-glutamyl transferase increased (52%), nausea (45%), alanine aminotransferase increased (44%), fatigue (42%), hemoglobin decreased (42%), lipase increased (42%), decreased appetite (36%), stomatitis (30%), vomiting (27%), weight decreased (27%), calcium decreased (27%), glucose decreased (26%), activated partial thromboplastin time prolonged (21%), and alopecia (20%).

Please click here for full Prescribing Information.

Reference: 1. *therascreen*® PIK3CA RGQ PCR Kit instructions for use. QIAGEN Inc., Germantown, MD; 2019.

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