A. CLINIC INFORMATION

Clinic Name/Account #

Clinic Street Address

City, State, Zip Code

CRESTAR LABS

Pharmacogenetic Requisition

rev20190327

CAP ACCREDITED — COLLEGE of AMERICAN PATHOLOGISTS

B. SAMPLE INFORMATION — All fields **REQUIRED** for processing

Requesting Provider	Date & Time Collected	Collector Initials	Specimen Type
	/ / : AM PM		☐ Buccal Swab

C. PATIENT INFORMATION — All fields **REQUIRED** for processing

Must provide a front/back copy of insurance card(s) and Driver's License

ATTN PROVIDER: DO NOT PERFORM TESTING if patient 1) has had a liver, bone marrow, or stem cell tranplant or 2) is currently experiencing kidney or liver failure

Last Name	First Name	MI	Date of Birth	Gender
			/ /	☐ M ☐ F

Patient Address	City	State	Zip	Phone #

Ethnicity

☐ African-American ☐ Asian ☐ Caucasian ☐ Hispanic ☐ Other (specify) _____

Current Patient Medication(s)	ICD-10 Dx Code(s)

Insurance Information ☐ Commercial ☐ Medicare ☐ Medicare Adv ☐ Medicaid ☐ Workers Comp ☐ Patient Payment Auth ☐ Clinic Payment Auth

Ins. Name(s):	ID/Claim/Policy #(s):

☐ **Provider requests Crestar Labs to facilitate Prior-Authorization per payor requirements**

D. PGx TESTING — NOTE: All orders include Current Regimen Risk Analysis

	Select Individual Gene(s)	OR Genes Relevant to : Cardiac Conditions	Mental Conditions	Anti-Inflam Conditions	Genetic Thrombosis	Warfarin Risk	ADHD	_____	_____	_____
ADRA2A	☐						☐	☐	☐	☐
ANKK1	☐							☐	☐	☐
APOE	☐	☐						☐	☐	☐
ATM	☐							☐	☐	☐
COMT	☐						☐	☐	☐	☐
CYP1A2	☐							☐	☐	☐
CYP2B6	☐	☐	☐	☐				☐	☐	☐
CYP2C19	☐	☐	☐	☐				☐	☐	☐
CYP2C9	☐	☐	☐	☐		☐		☐	☐	☐
CYP2D6	☐	☐	☐	☐			☐	☐	☐	☐
CYP3A4	☐	☐	☐	☐			☐	☐	☐	☐
CYP3A5	☐	☐	☐	☐				☐	☐	☐
CYP4F2	☐	☐				☐		☐	☐	☐
Factor II	☐	☐			☐			☐	☐	☐
Factor V	☐	☐			☐			☐	☐	☐
GRIK4	☐							☐	☐	☐
HLA-B	☐		☐	☐				☐	☐	☐
HTR2A	☐							☐	☐	☐
MTHFR	☐	☐	☐	☐	☐			☐	☐	☐
OPRM1	☐							☐	☐	☐
SLCO1B1	☐	☐						☐	☐	☐
TPMT	☐			☐				☐	☐	☐
VKORC1	☐	☐				☐		☐	☐	☐
_____	☐							☐	☐	☐
_____	☐							☐	☐	☐

F. PATIENT GENETIC COUNSELING — *Required counseling is dependent upon patient's insurance plan, additional billing may occur*

☐ **Pre-Test Counseling** with a Crestar Genetic Counseling affiliate ☐ **Post-Test Counseling** with a Crestar Genetic Counseling affiliate

E. AUTHORIZATION — All signatures **REQUIRED** for processing

By signing my name, I hereby authorize Crestar Labs to perform the indicated genetic tests on my sample of DNA. I acknowledge that I have read the "Informed Consent for Pharmacogenetic Testing" and I understand the benefits and limitations of this type of testing. Signing this form authorizes Crestar Labs to perform specimen testing, release test results to the ordering provider and bill my insurance provider directly for payment. I further authorize Crestar Labs and my provider to release to my insurance company any medical information necessary to process this claim.

Patient Signature _____ **Date** _____

By submitting this physician order for testing at Crestar Labs and the Provider Referral located on the reverse of this requisition, I agree to the following. I acknowledge only medically necessary testing should be ordered. I confirm that the requested test(s) are ordered specifically for this patient, are reasonable and/or medically necessary, and that results will be used in the medical management & treatment decisions for this patient as indicated in the Provider Referral. I agree to document in the patient's records a written order and medical necessity to support the ordering of tests. I confirm the patient has been supplied information regarding this test and agree to provide Crestar with all necessary patient information.

Provider Signature _____ **Date** _____

CLIA #44D2080511 2001 Campbell Station Pkwy., Suite C-2, Spring Hill, TN 37174

CLIA #21D2117107 12091 Somerset Ave, Princess Anne, MD 21853

CLIA #45D2098649 1651 N Collins Blvd, Richardson, TX 75080

COPY 1 - LABORATORY

ATTN PROVIDER
Completion of the Provider Referral located on the reverse side of Copy 1 is REQUIRED.

Patient Informed Consent for Pharmacogenetic Testing

ATTENTION PATIENT: The following information explains your patient rights, as well as the test's purpose & benefits.
Pharmacogenetic testing can assist your provider in prescribing medications that are most likely to work for you, based on your unique genetic profile. This test may also help your provider make critical adjustments to the dosages of certain medications, as well as avoid prescribing combinations of drugs that may cause you to experience an adverse reaction.

Using a sterile swab, a clinician will collect cells from the inside of your cheek. This swab will be sent to Crestar Labs, LLC for analysis. Results are sent directly to your provider, who may use those results to create a personalized treatment plan.

Discuss any questions with your provider before consenting to this test. Crestar will submit a claim to your insurance but coverage is not guaranteed. Patients should contact their insurance carrier to identify any potential out-of-pocket costs.

Provider Referral for Pharmacogenetic Testing

ATTENTION INSURANCE REPRESENTATIVE: The following information is provided as proof of medical necessity. For additional information and provider signature, please see the full requisition located on the reverse of this form.

Crestar Labs' Unique Pharmacogenetic Analysis
Information obtained from Crestar's Pharmacogenetic report is based on the highest clinically actionable genetic data approved by the Clinical Pharmacogenetics Implementation Consortium (CPIC®). Unlike competitor reports, Crestar offers providers access to an interactive portal to update a patient's report at any time to reflect changes in the patient's lifestyle, medical conditions, and medication regimen. Providers may also model the prospective use of alternative medications using the patient's previously determined genotype/phenotype results. Alternative medications are assessed for associated risks, efficacy, and estimated cost. An updated report is then created with no additional testing or expense to the payor or patient.

Gene List: ANKK1 APOE ATM COMT CYP1A2 CYP2B6 CYP2C19 CYP2C9 CYP2D6 CYP3A4 CYP3A5 CYP4F2 F2 F5 GRIK4 HLAB HTR2A MTHFR OPRM1 SLCO1B1 TPMT VKORC1
CPT List: 81225 81226 81227 81230 81231 81240 81241 81291 81328 81335 81355 81381 81400 81401 81479

Reasons for Pharmacogenetic Testing

• Reduce medical liability through targeted treatments	• Reduce repeat visits for dosage adjustments
• Reduce health care costs – ER visits, secondary medications to treat primary medication side effects	• Address acute care issues with proper medication before they trend into chronic care issues
• Identify & reduce unnecessary risks related to drug-drug interactions, contraindications, anticholinergic burden, adverse drug reactions, Beers criteria, & lifestyle factors	• Improved patient compliance & patient outcome by reducing unnecessary side effects, time to resolve health issues, and costs related to current drug regimen.
• Reduce Adverse Drug Reactions (ADRs) – responsible for over 117,000 deaths in 2013	• Adherence to FDA Black Box Warning guidelines and to support the growing trend of companion diagnostics

My patient (full name & DOB recorded in Section C of the requisition on the reverse of this form) has medical conditions requiring multiple prescription drugs. Given this patient's current or potential polypharmacy regimen, testing for drug metabolism and certain genetic risk factors is medically necessary. These indications are clearly documented in the patient's medical record.

I, the provider, have ordered this testing for this specific patient in order to understand the possible dangers and risks for suboptimal outcomes for specific medications currently prescribed or under consideration.

This test will assess the following for this patient:

• High potential for adverse drug reaction/episodic events	• Efficacy of current and/or future drug therapy
• Potential risk of developing venous thrombosis and/or cardiovascular disease	• Drug therapy best matched to patient's metabolic genotype/phenotype
• Identify potential source(s) of side-effect type illnesses	• Reduce number of necessary medications in regimen
• Correct dosage(s) to maximize therapeutic effect	• Other:

Provider Indications (please initial) – I plan to use information obtained from this test to improve this patient's care and to:

☐ Identify current medications that may be causing adverse reactions such as _____	☐ Determine the optimal dosage(s) for current or future prescriptions to ensure maximum therapeutic efficacy
☐ Identify and prescribe cost effective medication(s) to maximize therapeutic efficacy while minimizing the potential risk of adverse reactions	
☐ Other:	

Providers are not required to use the below ICD-10 codes. Providers should report diagnosis code(s) based on information recorded in the patient's medical record that best describe the reason for testing, regardless of the below content. This information is intended to assist clinicians with identifying medical necessity for testing but does not guarantee coverage for any genetic test. Crestar Labs LLC requires multiple ICD10 codes which 1) are patient specific 2) prove the medical necessity of the ordered test and 3) are a billable code of the highest specificity.

GENETIC SCREENING - REQUIRED for medical necessity	
Z13.79	Encounter for other screening for genetic and chromosomal anomalies

PSYCHIATRY - 1 or more of the following codes are REQUIRED for CYP2D6 medical necessity							
F32.89	Other specified depressive episodes			**F32.9**	Major depressive disorder, single episode,		
Major depressive disorder, recurrent:							
F33.9	unspecified	**F33.1**	moderate	**F33.3**	severe with psychotic	**F33.41**	in partial remission
F33.0	mild	**F33.2**	severe without psychotic	**F33.40**	in remission, unspecified	**F33.42**	in full remission
Bipolar Disorder, Current Episode Depressed:							
F31.30	unspecified	**F31.32**	moderate	**F31.5**	severe, with psychotic	**F31.76**	in full remission, most
F31.31	mild	**F31.4**	severe, without psychotic	**F31.75**	in partial remission, most	**F31.9**	unspecified
Bipolar Disorder, Current Episode Mixed:							
F31.60	unspecified	**F31.62**	moderate	**F31.64**	severe, with psychotic	**F31.78**	in full remission, most
F31.61	mild	**F31.63**	severe, without psychotic	**F31.77**	in partial remission, most		
Other							
G10	Huntington's disease						

CARDIOVASCULAR & THROMBOSIS - Z79.02 AND 1 or more of the following codes are REQUIRED for CYP2C19 medical necessity							
Z79.02	Long term (current) use of antithrombotics/antiplatelets - **REQUIRED**						
Atherosclerotic Heart Disease of Native Coronary Artery:							
I25.10	without angina pectoris			**I25.111**	with angina pectoris with documented spasm		
I25.110	with unstable angina pectoris			**I25.118**	with other forms of angina pectoris		
Ischemic Heart Disease							
I25.5	Ischemic cardiomyopathy			**I25.89**	Other forms of chronic ischemic heart disease		
I25.6	Silent myocardial ischemia			**I25.9**	Chronic ischemic heart disease, unspecified		
Atherosclerosis of autologous artery coronary artery bypass graft(s) with							*** coverage limited**
I25.720	unstable angina pectoris	**I25.728**	other forms of angina*	**I25.721**	angina pectoris with documents spasm		
Atherosclerosis of bypass graft of coronary artery of transplanted heart:							
I25.760	with unstable angina			**I25.768**	with other forms of angina pectoris		
I25.761	with angina pectoris with documented spasm			**I25.812**	without angina pectoris		
Atherosclerosis of other coronary artery bypass graft(s):							
I25.790	with unstable angina pectoris			**I25.798**	with other forms of angina pectoris		
I25.791	with angina pectoris with documented spasm			**I25.810**	with other forms of angina pectoris		
Coronary Atherosclerosis Due To:							
I25.83	lipid rich plaque			**I25.84**	calcified coronary lesion		
Cerebral Infarction Due to Thrombosis of Bilateral:							
I63.013	vertebral arteries	**I63.033**	carotid arteries	**I63.313**	middle cerebral arteries	**I63.323**	anterior cerebral arteries
I63.333	posterior cerebral arteries			**I63.343**	cerebellar arteries		
Cerebral Infarction Due to Embolism of:							
I63.113	bilateral vertebral arteries	**I63.133**	bilateral carotid arteries	**I63.433**	posterior cerebral arteries	**I63.443**	bilateral cerebellar arteries
I63.413	bilateral middle cerebral arteries			**I63.423**	bilateral anterior cerebral arteries		
Cerebral Infarction Due to Unspecified Occlusion or Stenosis of:							*** coverage limited**
I63.213	bilateral vertebral arteries	**I63.233**	bilateral carotid arteries	**I63.543**	bilateral cerebellar arteries*	**I63.59**	other cerebral artery
I63.511	right middle cerebral artery	**I63.512**	left middle cerebral artery	**I63.519**	unspecified middle cerebral artery		
I63.513	bilateral middle cerebral arteries*	**I63.523**	bilateral anterior cerebral arteries *	**I63.533**	bilateral posterior cerebral arteries *		
Occlusion or Stenosis of:							
I66.01	right middle cerebral artery			**I66.03**	bilateral middle cerebral arteries		
I66.02	left middle cerebral artery			**I66.8**	other cerebral arteries		
Embolism of Thrombosis - REQUIRED for Factor II , Factor V							*** coverage limited**
I82.91	Chronic embolism and thromsosis of unspecified vein*			**Z79.01**	Long-term (current use of) Anticoagulants*		
Angina							
I20.0	Unstable angina			**I20.8**	Other forms of angina pectoris		
I20.1	Angina pectoris with documented spasm			**I20.9**	Angina pectoris, unspecified		
ST elevation (STEMI) myocardial infarction							
I21.09	involving other coronary artery of anterior wall			**I21.4**	Non-ST elevation (NSTEMI) myocardial infarction		
I21.19	involving other coronary artery of inferior wall			**I21.9**	Acute myocardial infarction, unspecified		
I21.11	involving right coronary artery	**I21.A1**	Myocardial infarction type 2	**I21.A9**	Other myocardial infarction type		
I21.29	involving other sites	**I21.3**	of unspecified site				
Other							
I24.0	Acute coronary thrombosis not resulting in myocardial infarction			**I24.9**	Acute ischemic heart disease, unspecified		
I24.1	Dressler's syndrome			**I24.8**	Other forms of acute ischemic heart disease		
I24.8	Other forms of acute ischemic heart disease			**I24.9**	Acute ischemic heart disease, unspecified		