CORUS CAD

Test Requisition Form and Statement of Medical Necessity

PLACE TRF BARCODE LABEL HERE

Note: All fields outlined in **BOLD BLUE** are mandatory. Any missing information may result in delays. **Sections 1-5:** Required before submission. **Section 6:** Optional

1. Account Information

CLINIC NAME:

ADDRESS:

CITY: **STATE:** **ZIP:**

PHONE NUMBER: **FAX NUMBER:**

2. Patient Information

PATIENT'S LEGAL NAME: Last First MI

NAME OF INSURED: (IF DIFFERENT THAN PATIENT) Last First MI

HOME ADDRESS: **CITY:**

PHONE: **STATE:** **ZIP:**

DATE OF BIRTH: (mm/dd/yyyy) **SEX AT BIRTH:** MALE FEMALE

MEDICAL RECORD/PATIENT NUMBER: (optional)

3. Diagnosis Codes and Billing Information

DIAGNOSIS CODES The ICD-10 codes listed in this section are provided as a convenience for ordering clinicians. No clinician is required to use these ICD-10 codes. Ordering clinicians should report the diagnosis code that is based on documentation in the patient's medical record and best describes the reason for performing the test, regardless of whether it is included in the list below.

Typical Symptoms Suggestive of CAD

Select at least 1 from below and all others that apply.

- ☐ I20.9 Angina pectoris, unspecified
- ☐ I20.8 Other forms of angina pectoris
- ☐ R07.9 Chest pain, unspecified
- ☐ R07.89 Other chest pain
- ☐ R07.82 Intercostal pain
- ☐ R06.02 Shortness of breath

OR

Atypical Symptoms Suggestive of CAD

To be suggestive of obstructive CAD, these symptoms should be concurrent with at least one CAD risk factor. Select at least 1 code from below and at least 1 risk factor code from the right.

- ☐ R42 Dizziness and giddiness
- ☐ M54.9 Dorsalgia, unspecified
- ☐ R12 Heartburn
- ☐ R11.0 Nausea
- ☐ R11.2 Nausea with vomiting, unspecified
- ☐ R11.10 Vomiting, unspecified
- ☐ R10.9 Unspecified abdominal pain
- ☐ R53.81 Other malaise
- ☐ M79.602 Pain in left arm
- ☐ M79.622 Pain in left upper arm
- ☐ R68.84 Jaw pain
- ☐ R00.2 Palpitations

AND

Common CAD Risk Factors

Select at least 1 from below and all others that apply. Not all available ICD-10 codes for common CAD risk factors are represented in the list below.

- ☐ I25.119 Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
- ☐ I70.209 Unspecified atherosclerosis of native arteries of extremities, unspecified extremity
- ☐ I10 Essential (primary) hypertension
- ☐ Z82.41 Family history of sudden cardiac death
- ☐ Z82.49 Family history of ischemic heart disease and other diseases of the circulatory system
- ☐ E78.5 Hyperlipidemia, unspecified
- ☐ E78.2 Mixed hyperlipidemia
- ☐ E88.81 Metabolic syndrome
- ☐ F17.200 Nicotine dependence, unspecified, uncomplicated
- ☐ F17.201 Nicotine dependence, unspecified, in remission
- ☐ Z87.891 Personal history of nicotine dependence
- ☐ E66.9 Obesity, unspecified
- ☐ I65.21 Occlusion and stenosis of right carotid artery
- ☐ I65.22 Occlusion and stenosis of left carotid artery
- ☐ I65.23 Occlusion and stenosis of bilateral carotid arteries

DIAGNOSIS: If not already selected above, please provide up to 4 diagnosis codes, in order of importance that apply to this patient.

DIAGNOSIS CODES:

1. _____ 2. _____ 3. _____ 4. _____

PAYMENT INFORMATION You must provide a copy of the front and back of patient insurance card including any secondary insurance.

☐ Bill insurance ☐ Bill patient/Self pay

4. Clinician — to be completed by authorized clinician only

I, the authorized clinician named herein, deem that the patient meets the test's intended use and that the test is medically necessary to evaluate the patient's clinical conditions that are suggestive of obstructive coronary artery disease. The result may be used, along with standard clinical assessments, to guide patient care decisions. I authorize CardioDx,® Inc., or its subcontractors, to perform the necessary steps to obtain reimbursement for the Corus® CAD test.

CLINICIAN NAME:

☐ _____ ☐ _____

☐ _____ ☐ _____

☐ _____ ☐ _____

☐ _____ ☐ _____

Corus CAD is NOT intended for patients:

- Diagnosed with diabetes (or on diabetic medications[1])
- With a history of heart attack or revascularization
- With active infection or inflammatory disease
- Receiving chemotherapy in the past 12 months; or steroids/ other immunosuppressants within the past 2 months

Other exclusions: Corus CAD will not be resulted for patients <21 and >85 years old

[1] Non-diabetic patients taking metformin are not excluded from receiving the test.

SIGNATURE OF AUTHORIZED CLINICIAN: DATE: (mm/dd/yyyy) ____/____/____

5. Blood Draw Information — to be completed by phlebotomist *DO NOT COVER TUBE EXPIRATION DATE*

DATE SAMPLE TAKEN: (mm/dd/yyyy)	NAME OF PHLEBOTOMIST:	PHLEBOTOMY LAB NAME:	PHLEBOTOMY LAB PHONE NUMBER:

6. Comments — optional

_____

_____

CARDIODX

CardioDx
600 Saginaw Drive
Redwood City, CA 94063
www.cardiodx.com

Customer Service
P 866.941.4996
F 866.302.8777
service@cardiodx.com

CA License CLF00337248
CLIA #05D1083624
NY PFI: 8516

CARDIODX LAB USE ONLY

Inspection by (initials/date): _____

NanoCool® functioning? ☐ Yes ☐ No

Receipt time frame acceptable? ☐ Yes ☐ No

Tube labeled correctly? ☐ Yes ☐ No

Tube within expiration? ☐ Yes ☐ No

Other _____

Print and complete the Corus CAD TRF and place inside the Corus CAD Sample Collection Kit, along with the patient sample. Please print an extra copy for your records.

Corus® CAD Intended Use

The Corus CAD test is a quantitative in vitro diagnostic test performed in a single laboratory, using age, sex, and the gene expression profile of cells found in peripheral blood specimens to help a clinician identify the likelihood that a patient has coronary artery stenosis of at least 50%. The test should be performed on patients with a history of chest pain, with suspected anginal equivalent to chest pain, or with a high risk of coronary artery disease (CAD), but with no known prior myocardial infarction or revascularization procedures. The test is not intended for patients with acute myocardial infarction, high-risk unstable angina, systemic infectious or systemic inflammatory conditions, diabetes, or who are currently taking steroids, immunosuppressive agents, or chemotherapeutic agents.

The test is performed on a blood specimen obtained from the patient. The test incorporates age, sex, and the expression levels of multiple genes using an algorithm with weighted gene expression levels to generate a quantitative score. The results of the test should be used by clinicians in conjunction with other tests and clinical information when assessing a patient's CAD.

The Corus CAD test is for prescription use only. The test is not intended to be used to screen for stenosis among patients who are asymptomatic and not considered at high-risk for CAD, to predict or detect response to therapy, or to help select the optimal therapy for patients.

To Complete the Corus CAD Test Requisition Form

1. Account Information

Enter clinic contact information. A portion of the fields may be pre-printed for you. If so, verify that they are correct.

2. Patient Information

Patient name, date of birth and sex at birth are required to perform the Corus CAD test. A separate page containing all of the required patient demographics may be provided in lieu of completing this section of the form but the patient's name MUST be on the Test Requisition Form. Patient address is necessary for billing reasons. The test should be used in adult patients only. Entering your clinic's Medical Record/ Patient Number for the patient is optional and for your records only.

3. Diagnosis Codes and Billing Information

Diagnosis: The ICD-10 diagnosis codes must be defined to the highest level of specificity available and should reflect codes documented in the patient's medical record. The ICD-10 codes shown are listed as a convenience for the ordering clinician. No clinician is required to use these ICD-10 codes.

Method of Payment: Check the box indicating the party responsible for payment of the test. If applicable, please provide a clear copy of the front and back of the patient's primary and any secondary insurance/Medicare/Medicaid/other payer card. CardioDx® will submit claims to all private and government insurance for insured patients.

For Patients Outside of Payer Coverage: CardioDx will contact your office to coordinate obtaining a signed ABN (for Medicare patients) or written authorization (for patients with other insurance).

4. Clinician — to be completed by authorized clinician only

Enter or select authorized clinician name. Authorized clinician MUST sign his or her name on the Test Requisition Form and indicate the date the test is ordered.

5. Blood Draw Information — to be completed by phlebotomist

The person conducting the blood draw must complete this section. Indicate the date that the blood draw occurred. Also, write in the phlebotomist's name, phlebotomy lab name and phlebotomy lab phone number.

6. Comments

Provide any comments for the CardioDx Commercial Laboratory staff in this section.

To Submit the Corus CAD Test Requisition Form

Include the white copy *(top page)* of the completed Corus CAD Test Requisition Form along with the patient sample inside the shipping container.

The ordering clinician office should keep the pink copy *(bottom page)*.

The phlebotomist or laboratory should keep the yellow copy *(middle page)*.

To Reorder Corus CAD Test Requisition Forms

Contact **CardioDx Customer Service** at **866.941.4996, option 2,** to reorder. Unless rush service is specified, reorders take 1–2 weeks to arrive.