



Patient: **SAMPLE**  
**PATIENT**

DOB:  
Sex:  
MRN:

**3700 CV Health -Plasma & Serum**

Methodology: Chemiluminescent, Enzymatic, Immunoturbidimetric and NMR

**Lipid Markers**

Cholesterol			Particle Concentration & Size by NMR		
	Result	Reference Range		Result	Reference Range
LDL- Cholesterol	95	< 100 mg/dL	LDL-Particle # (LDL-P)	1,050 H	< 1,000 nmol/L
HDL- Cholesterol	48	> 39 mg/dL	HDL-Particle # (HDL-P)	2.5 L	> 34.9 µmol/L *
Triglycerides	147	< 150 mg/dL	LDL-Size	Large (Pattern A) 23.0-20.6 * Small (Pattern B) 20.0	
Total Cholesterol	158	< 200 mg/dL	Lp(a)	11	< 30 mg/dL

**Independent Risk Factors**

Result	Reference Range	Relative Risk for Cardiovascular Disease
hs-CRP: 0.89	< 1.00 mg/L	1.0
Lp-PLA <sub>2</sub> (PLAC): 245 H	< 225 nmol/min/mL	2.10
Fibrinogen: 343	198-437 mg/dL	1.7
Homocysteine: 8.8	3.7 - 10.4 µmol/L	1.0

**Insulin Resistance Score by Lipid Fractionation**

Insulin Resistance Score: 73 (Scale 0-100, < 27 IR-Score \*)

LDL <sub>L</sub>	LDL <sub>S</sub>	VLDL <sub>L</sub>	HDL Size	LDL Size	VLDL Size
2.5	255	4.5	8.4	20.0	47.6
>7.3 µmol/L *	<117 nmol/L *	<0.9 nmol/L *	>9.6 nm *	>21.2 nm *	<42.4 nm *

The Insulin Resistance Score combines Small LDL-Particle #, LDL Size, Large VLDL-Particle #, VLDL Size, Large HDL-Particle # and HDL Size to assess insulin resistance and diabetes risk.

Legend for result categories:

- Optimal (Green box)
- Borderline (Yellow box)
- Abnormal (Red box)

**Percentiles Apply to Biomarkers indicated with \* and are performed using NMR technology.**

Optimal: Either 0-25th or 75-100th percentile based on reference population.  
 Borderline: 25-75th Percentile  
 Abnormal: Inverse of Optimal (0-25th or 75-100th percentile distribution)



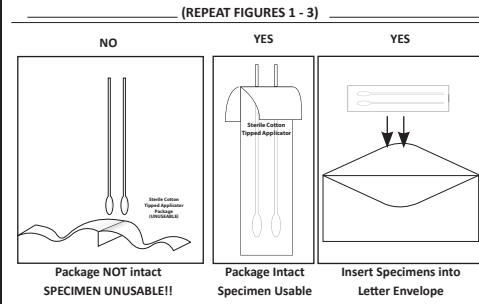
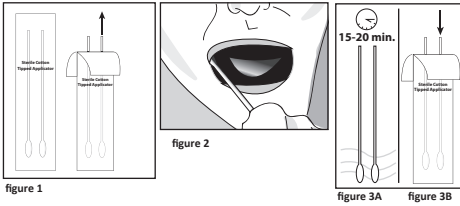
## Commentary

Methodology: Chemiluminescent, NMR, Immunoturbidometric and Enzymatic.

The LP(a), Lp-PLA<sub>2</sub> (PLAC), hs-CRP, Homocysteine and Fibrinogen analytes have been cleared by the U.S. Food and Drug Administration, and are performed by Genova Diagnostics, Inc. All other assays are performed by LabCorp, 1447 York Court, Burlington, NC 27215, CLIA#34D0655059.

The reference range for homocysteine is based on the sex-specific 5th to 95th percentile values for men and women (20 to 39 years of age) in the NHANES nutritionally replete cohort. *Annals of Internal Medicine* 1999; 131 (331-338).

The methodology for Lp-PLA<sub>2</sub> (PLAC) has been changed to measure activity. Please note the reference range and relative risk for cardiovascular disease have been updated.



## SPECIMEN PREPARATION

1. **Plan** to ship the specimen Monday – Thursday overnight delivery.
2. **Call** 1.800.GoFedEx (1.800.463.3339) to schedule shipping. When the automated system asks “How may I help you?” **say** “Return a Package”. **Tell** the FedEx representative “I am using a billable stamp” and they will walk you through the process and make it easy.
3. **Place** the envelope containing the two collected specimen swabs into the Biohazard bag. Make sure the 1 serum transfer tube, 1 plasma transfer tube, and the black-top tube **are tightly closed** and **identified** with completed labels. **Seal** the tubes in the bubble wrap bag and **put** it into the Biohazard bag, and seal it securely. *If Vitamin D add-on ordered, there will be 2 serum transfer tubes returned to the laboratory.*
4. **Print** name and collection date on specimen collection label. **Place** the specimen collection label on the biohazard bag.
5. **Lay** the Biohazard bag with specimen on top of the freezer brick in the foam box. **Secure** the foam box lid with the rubber band.
6. **Slide** the foam box back inside the kit box, and **place** the completed and signed requisition on top before closing. **Do not staple** or **tape** the box.
7. **Print** your name and address in the section marked “From” on the prepaid shipping envelope label. **DO NOT mark or write** in any other sections.
8. **Put** the kit box into the envelope and **seal** the envelope.
9. **Keep** your shipment and tracking numbers for future reference and tracking purposes.

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## CV HEALTH & CV HEALTH PLUS GENOMICS SPECIMEN COLLECTION INSTRUCTIONS

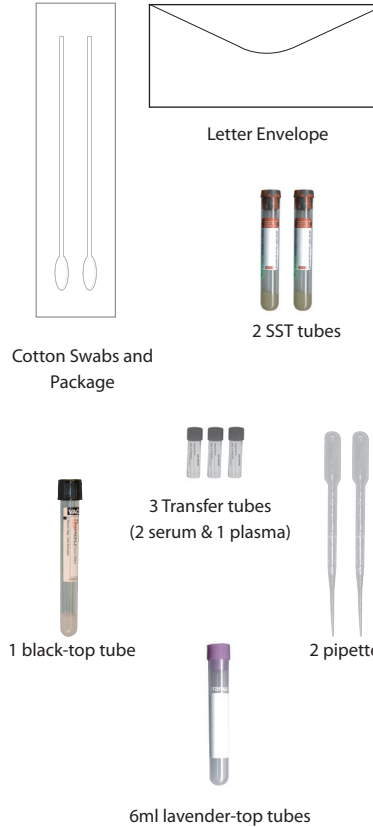


This specimen collection kit can be used for the following tests:

CV Health Profile™

CV Health Plus Genomics Profile™\*

\* Not Available in New York



## SPECIMEN

Buccal swab - saliva, Blood

## COLLECTION MATERIALS

- Cotton Swabs
- Returnable Cotton Swabs Package
- Letter Envelope
- 6 ml EDTA lavender-top tube
- 2 SST tubes
- 3 Transfer tubes (2 serum & 1 plasma)
- 1 Black-top tube
- 2 Pipettes

## SHIPPING MATERIALS\*

- 1 Foam Insulator Box
- 1 Freezer Brick
- Specimen collection kit package
- Test Requisition Form
- 2 Biohazard bags with side pocket
- 1 Absorbant Pad
- FedEx® Clinical Lab Pak and Billable Stamp
- 3 Specimen Collection Labels

*International shipping may vary, please see shipping instructions for more details.*

## IMPORTANT:

All patient specimens require two unique identifiers (*patient's name and date of birth*), as well as *date of collection*. **Patient's first and last name, date of birth, gender, and date of collection** must be recorded on the **Test Requisition Form** as well as all tube(s) and/or cup(s), using a permanent marker, or the test may not be processed.

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Please read all instructions carefully before beginning.

## PATIENT PREPARATION

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- Certain medications and supplements may influence this test, including aspirin and cholesterol-lowering drugs. Results may help demonstrate the efficacy of medications or supplements, or a clinician may elect to have the patient temporarily discontinue non-essential ones.
- Specimens from patients who are on drug therapy involving S-adenosyl-methionine may show elevated levels of homocysteine.
- Hemolyzed and lipemic specimens interfere with the test and cannot be accepted for analysis.
- Results on specimens obtained from patients taking methotrexate, carbamazepine, phenytoin, nitrous oxide, anti-convulsants, or 6-azauridine triacetates should be interpreted with caution as these substances interfere with homocysteine determination.
- **On the day before the collection:** Patients must fast overnight (at least 12 hours) prior to the blood draw. Patients should also be counseled to avoid exercise for at least 12 hours prior to the test, and to avoid alcohol consumption for at least 24 hours prior to the test.

## SCHEDULE & PREPARE FOR THE BLOOD DRAW

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- **Schedule** the patient accordingly
- **Freeze** the enclosed freezer brick a minimum of 8 hours before shipping.
- Samples **MUST be received** within 24 hours of collection. The test cannot be processed otherwise.
- **Contact** FedEx and schedule to ship the specimen overnight delivery Monday - Thursday. All serum and plasma transfer tubes **MUST** be stored frozen a minimum of 2 hours before shipping.
- **Complete** the Requisition Form with all patient and billing information. Be sure it is signed by the Patient/Responsible Party and the healthcare provider.

## BLOOD DRAW & SPECIMEN PREPARATION

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1. **Write** patient's **first and last name, date of birth, gender** and **date of collection** on the Test Requisition Form (located in the pouch on top of the Specimen Collection Kit Envelope), and the SST, lavender-top EDTA, transfer tubes, AND the collection labels. **Affix** collection labels to the black-top tube.
2. **Draw** blood to fill one SST tube (Serum), 6ml lavender-top EDTA tube, and black-top tube. The black-top tube **must be completely filled**. *If Vitamin D add-on is ordered, fill both SST tubes.* SST tube(s) and 6ml EDTA specimen **should be stored on ice** between the time of sampling and centrifugation.
3. **6ml lavender-top EDTA tube:** Within 15 minutes of blood draw, gently **mix** blood sample thoroughly. **Centrifuge** 6ml lavender-top EDTA 15 minutes at 3000 rpm.
4. **Use** a pipette to transfer the plasma from the 6ml lavender top tube into the transfer tube labeled "EDTA-Plasma". **Freeze** the plasma transfer tube and **discard** the 6ml lavender-top EDTA tube.
5. **SST tube: Allow** blood to clot by placing SST tube in a rack for 15 minutes, then centrifuge the tube for 15 minutes at 3000 RPM. *If Vitamin D add-on is ordered, follow this step for both SST tubes.*
6. **Transfer** serum from the SST tube into the transfer tube labeled "SST-Serum" using a fresh pipette. **Screw** the top on the transfer tube tightly to avoid leakage. **Freeze** the serum transfer tube and discard the SST collection tube. *If Vitamin D add-on is ordered, freeze the second transfer tube.*
7. **Black-top tube:** Within 30 minutes of blood draw, gently **invert** the tube to mix contents and allow sample to clot for 30 minutes before centrifugation. **Centrifuge** the tube for 15 minutes at 3000 RPM. **Leave** specimen intact and refrigerate black-top tube.
8. **If ordering Genomics** continue through #13, **Peel** open the package labeled, "Sterile Cotton Tipped Applicator." *Only peel back the package far enough to remove the cotton swab applicator.* Keep the packet in-tact. (See Figure 1). **Open** your mouth widely and insert applicator. **Wipe** the inside of your cheek using a back and forth and up and down motion. **Rotate** the applicator several times to ensure the swab collects a sufficient amount of cheek cells. *Note: If there is not enough DNA collected on the applicator, a recollection will be required.*
9. **Remove** one applicator taking care to avoid contact with the cotton tip.
10. **Open** your mouth widely and insert applicator. For at least 30 seconds, **aggressively scrape** the inside of your cheek using a back and forth, and up and down motion. Be sure to **rotate** the applicator several times to ensure the swab collects a sufficient amount of cheek cells. In addition, **swab** between the cheek and gums. (See Figure 2)  
**Note:** If there is not enough DNA collected on the applicator, a recollection will be required.
11. **Remove** the applicator from your mouth and allow cotton tips to air dry for 15-20 minutes (See Figure 3A) before placing it back into the original packaging, cotton swab first. (See Figure 3B)
12. **Repeat** the collection process (steps 1-3) with the second applicator on your opposite cheek.
13. **Place** the package containing the two collected specimen swabs into the letter envelope. Seal the letter envelope.

