

Questions? Call Customer Service at (888) 981-8378
or email CustomerService@CDDiagnostics.com

IMPORTANT NOTE ABOUT SYNOVASURE[®] METAL ION TESTING

This metal ion test determines the concentration of Cobalt (Co) and Nickel (Ni) in the blood of patients with metal implants.

Caution: These metals are commonly found in the environment and therefore may contaminate the sample during the collection procedure leading to a false result. To avoid contamination follow these Instructions carefully and only use the supplied or specified test articles (needles and tubes). The specified test articles are known to be free of metal contamination. Do not substitute the specified test articles with other products.

SPECIMEN KITS



To ensure timely delivery and specimen processing, use the materials provided and follow the guidelines below.

Contents:

- Instruction Sheet
- Test Requisition Form
- 95 kPa Specimen Transport Biohazard Bag
- Prepaid FedEx UN3373 Pouch for biological specimens
- White, UN3373, Category B Biological Specimen Box
- 21g needle (BD368650)
- Trace Element Specimen Tubes (varies by specimen type)
 - *Whole Blood Collection Tubes*
BD368381 - Royal Blue Trace Element with EDTA
 - *Serum Collection Tubes*
BD368380 - Royal Blue Trace Element without EDTA Simport T310-5A – Serum Transfer Tubes

GENERAL INSTRUCTIONS

- Do not use iodine-containing products (Betadine) to disinfect the venipuncture site. Use alcohol.
- Use only test articles specified above. Do not substitute.
- Patients should refrain from mineral supplements and multivitamins 3 days before specimen collection.
- This test should not be performed on patients that have received gadolinium, iodine or barium contrast agents within the past 96 hours.
- Follow standard phlebotomy procedures for specimen collection.
- Tests for renal function can only be ordered on serum samples submitted for metal ion testing

Complete all information on the Test Requisition Form. A patient demographics page and copy of insurance cards can be attached. Be sure to check off the appropriate tests for the specimen type submitted.

WHOLE BLOOD COLLECTION (*FDA Recommended Specimen Type)

1. Label a whole blood collection tube (royal blue with EDTA - BD368381) with a peel off label from the Test Requisition Form.
2. Disinfect the venipuncture site with alcohol.
3. Using a 21g needle (BD368650), draw 1mL of blood into the labeled whole blood collection tube.
4. Thoroughly mix the blood and EDTA by vigorously shaking the tube.
5. Maintain and ship the sample at ambient temperature according to the instructions provided

**Metal-on-Metal Hip Implants: FDA Safety Communication
Date Issued: Jan. 17, 2013 | <http://www.fda.gov/MedicalDevices/>*

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SERUM COLLECTION

1. Label a serum collection tube (royal blue without EDTA-BD368380), and a serum transfer tube (Simport T310-5A) with a peel off label from the Test Requisition Form.
2. Disinfect the venipuncture site with alcohol.
3. Using a 21g needle (BD368650), draw 4mL blood into the labeled serum collection tube.
4. Allow the blood to clot in the tube 30 minutes to 2 hours at ambient temperature.
5. Centrifuge the tube to separate the serum from the clot. Do not insert any utensil into the sample to separate the clot from the serum.
6. Carefully open the labeled serum collection and transfer tubes avoiding contamination, and pour 2-3mL of serum into the labeled serum transfer tube and cap tightly. Avoid pouring cells into the transfer tube.
7. Maintain and ship the labeled sample transfer tube at ambient temperature according to the instructions provided.

PREPARING SPECIMENS FOR SHIPMENT

Note: Use only the materials provided to ensure compliance with regulatory and safety requirements.

1. Ensuring that the absorbent pad is at the bottom of the plastic specimen bag included, place the labeled tube(s) at the bottom of the specimen bag on top of the absorbent pad.
2. Test Requisition Form(s) must be placed in the back pouch of the specimen bag. Starting from bottom, roll up the specimen bag to eliminate as much excess air as possible.

IMPORTANT: Seal the specimen bag per the instructions provided on the bag.

3. Place rolled specimen bag into the White, UN3373, Category B Biological Specimen Box provided.
4. Close the Specimen Box and place it in the prepaid return FedEx UN3373 pouch provided. **Please retain a copy of your tracking number for your records.**
5. Call FedEx at 1-800-GOFEDEX (1-800-463-3339), at least 2 hours prior, to schedule a **PREPAID PICKUP**. You can say “representative” twice, or press “0” twice, to speak with a customer service representative, or schedule a pickup online. **Please record your pick up confirmation number.**

Note: You do not need a FedEx account to schedule a **PREPAID PICKUP**.

Synovasure[®] MI results are available within 3 business days from receipt of specimen



Call FedEx to schedule
a “**PREPAID PICKUP**”
1(800) GOFEDEX

SPECIMEN SHIPMENT & STORAGE

Monday – Thursday

- Collect and ship same day. Store at an ambient temperature.

*Friday – Sunday

- Collect and store at ambient temperature. Ship on Monday.

***For shipments collected on Friday that require expedited results, call ahead at 1-888-981-8378. Please note that additional costs may apply.**

HELPFUL HINTS

Are you submitting multiple specimens on the same day?

- Multiple specimens (up to 5 patients) can be enclosed in one white UN3373 specimen box
- Multiple white specimen boxes (up to 3) can be returned in one FedEx pouch