

# Blood Collection Kit

## How to Collect Your Sample

### Instructions for Use



*By Commonwealth Diagnostics International, Inc.*

Watch the IBSchek instructional video at [www.commdx.com](http://www.commdx.com)

**Any Questions? Phone:**  
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**CDI**<sup>®</sup>  
Commonwealth  
Diagnostics  
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INC.

# Symbol Definitions



Consult the instructions for use



Caution



Do not use if broken



Do not re-use



Contains sufficient for 1 test



Manufacturer



Authorized representative in the European Community



CE Mark



*In vitro* diagnostic medical device



Batch Code



Catalog Number



Use By Date

Before drawing your sample, please read these Instructions For Use in their entirety and remember to handle all blood samples and kit components with care.

### **Kit Materials**

- (1) BD Microtainer® Tube
- (2) BD Microtainer® Contact- Activated Lancets CE0050 MDD 93/42/EEC **STERILE**
- (2) Alcohol Pads **STERILE**
- (2) Gauze Pads **STERILE**
- (2) Bandages **STERILE**
- (1) Cardboard Insert
- (1) Specimen Collection Bag with Absorbent Material Inside
- (1) Return Shipping Label
- (1) Kit Covering with Tear-away Requisition Form
- (1) Instructions for Use
- (1) Sample Label

**To avoid possible sample rejection, collections must only be performed Monday - Thursday and must be shipped the same day.**

**Must collect 500µl of blood or your sample may be rejected.**

**If packaging of any components are broken, do not use.**

This device is intended to be used by patients and healthcare providers for the collection of capillary whole-blood samples to aid in the diagnosis of Irritable Bowel Syndrome (IBS-M and IBS-D).

**1. Prepare requisition form from kit covering by tearing along the perforations and fully complete the requisition form.**

**2. Wash hands thoroughly with soap and warm water.**

**3. Select the puncture site**

You should be sitting down. Hold your hand in a downward position, allowing gravity to help increase blood flow to the hand.

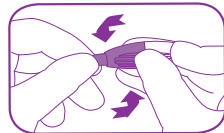
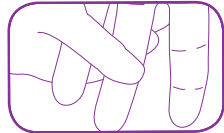
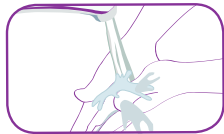
Select either your middle or ring finger and identify the desired puncture site (shaded area). Hold your selected hand in a downward position.

**4. Disinfect the site and allow to air dry**

Cleanse the puncture site using an alcohol pad. The site must be allowed to air dry in order to provide effective disinfection and best sample quality.

**5. Remove the protective tab from a lancet**

Twist off the tab to break the seal and discard. Do not use lancet if tab is damaged or missing.



## 6. Perform the puncture

Position the lancet firmly against the puncture site you selected, as illustrated.

To activate, press lancet firmly against the puncture site. Do not remove the lancet from the site until an audible click is heard. *Lancets are single use only. Once the audible click is heard it cannot be used again.*

## 7. Discard used lancet

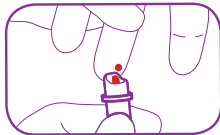
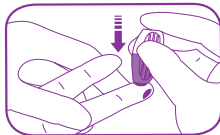
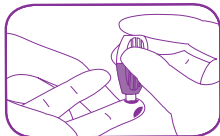
## 8. Collect the sample

Wipe away the first drop of blood with a sterile gauze pad.

Open the microtainer tube and let your arm hang loosely towards the ground. Gently hold the lip of the tube against the tip of your finger, directly beneath the puncture site and allow your sample to drip into the tube.

Fill the tube up to the 500 line (500µl). If you are not able to collect enough sample from the first puncture site, please repeat the procedure starting at step 3 on another finger.

Place cap securely back on microtainer tube by firmly pressing down until an audible click is heard. These are not twist caps. Invert the tube **8-10 times** to mix your sample.



### CAUTION:

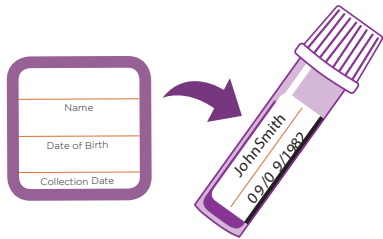
Strong repetitive pressure (milking) must be avoided, it may affect sample quality and lead to rejection.

## 9. Complete the procedure

Wipe the site dry and apply direct pressure with a sterile gauze pad until the bleeding has stopped, then apply the bandage to the site.

## 10. Label your sample

Included in your kit is a Sample Label card. Neatly print your first and last name, date of birth, and the date when you collected your sample on the sample label and then apply it to the microtainer tube. In order to process your sample when it arrives at our laboratory, we need you to label it with your first and last name, your date of birth (mm/dd/yyyy), as well as the date you collected your sample. Please write legibly using blue or black ink and place the label on your blood sample as shown.



## 11. Prepare your sample for shipment\*

Included in your kit is a specimen collection bag. Place your sample in the bag and seal the bag closed. Place your completed requisition form back into the kit box along with your sample.

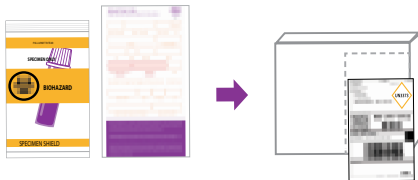


# Important

- ✓ Remember to place your completed Requisition Form into the kit.
- ✓ Close the box and place the return shipping label on the outside of the box to seal the box shut.
- ✓ Arrange sample return with the carrier indicated on the return shipping label.
- ✓ Use appropriate precautions in the collection, handling, storage, and disposal of all used and unused kit contents.
- ✓ Dispose of all used and unused kit materials.

**\*Sample must be shipped same day of draw.**

**\*Any samples received on Friday, Saturday, or a holiday will be analyzed on the next business day from the time of receipt by our laboratory.**





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IVD-1-Chek

DO NOT USE IF PACKAGE IS DAMAGED.