LetsGetChecked Blood Sample ImPress IFU 122

SPECS AND INSTRUCTIONS

Colour Reference:
CMYK

Size:
108.5mm wide by 152.5mm high **folded**

Paper:
135gsm silk

Fold type:
6 page accordion

Font:
Proxima Nova
(Regular, Semibold and Bold)

Part Number:
QR-IFU-122-RA Apr-2025

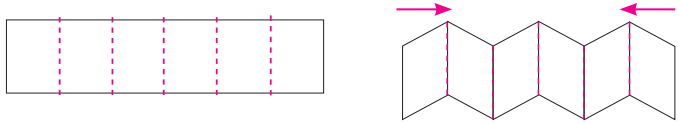
*Visual reference for how to fold down the sheet so the front page is the first one to see. Artwork and page count may vary.

LetsGet Checked

FOLD GUIDE

Fold

Accordion fold



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1 Before you start

Estimated time needed: 10-15 minutes.

You should be fasted when you collect your sample. This means not consuming any food or drink, other than water, for 8 hours before sample collection. Cholesterol (Total, LDL, and HDL) and triglyceride levels may be high if not fasting.

Consuming large amounts of protein (red meat, protein shakes, supplements) may temporarily elevate creatinine levels.

Collect your sample in the morning Monday-Friday and return it on the same day.

Plan your sample return in advance. Check the return delivery card in your kit for details.

Watch a video on how to collect your sample. Visit **LetsGetChecked.com/instructions/blood-122-sample-collection** or scan:

Read all the instructions including the warnings.

Have a timer ready to set for 10 minutes.

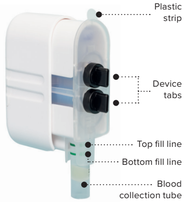
Short sleeves are recommended while the device is in use.

This is a single use device. Once you have removed the tabs, do not press the device until it is positioned on the arm and you are ready to begin sample collection.

Contact customer support at **help.LetsGetChecked.com** if you have any questions or if the device does not function as described.

Check your kit contents

ImPress device



Biohazard bag

Return envelope

Blood collection tube cap

Bandages × 2

Alcohol swabs × 2

Sterile gauze

Kit box

Also required but not provided: timer and medical gloves.

2 Prepare for sample collection

Fill in the label on the biohazard bag.

Wash and dry your hands. The use of medical gloves is recommended.

Remove the device and tube cap from the packaging. You will use the cap later to seal the sample in the blood collection tube.

3 Collect your blood sample

Clean the upper arm with an alcohol swab and allow to air-dry.

Take note of the two fill lines on the tube. You will aim to fill to the top line with blood. The top fill line may be hard to see once the device is placed on your arm.

Twist and remove the black tabs from the device.

Peel off the clear plastic strip using the tab at the top of the device.

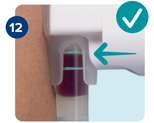
Remain in an upright seated position. Keep the arm straight and fingers pointing down towards the floor.

Stick the device on the upper arm with the blood sample tube pointing downwards.

Using your palm, firmly press the device against the arm until you hear a click. Release to start the collection process.

Please continue overleaf.

Start a timer for 10 minutes. It can take up to two minutes to see the first drop of blood in the sample tube.



Follow the next step to remove the device when:

- Blood has filled to the top line or
- 10 minutes have passed.

Peel the device from the arm while keeping the tube upright.

To remove the tube from the device, gently pull it downwards. Discard the device.

Place the cap on the blood sample tube and press down firmly until you hear a click. Clean arm with gauze and apply a bandage if needed.

Turn the tube upside down 10 times to mix the sample. Gently tap or flick the tube to get blood moving if needed.

Place the blood collection tube in the biohazard bag and seal the bag.

Wash and dry your hands.

4 Package and return

Place the biohazard bag into the kit box. Make sure you have filled in the label on the biohazard bag.

Place the kit box in the return envelope provided.

Send the kit back on the same day. Check the return delivery card in your kit box for your return method.

⚠ WARNING:

About using this test:

- You must be over the age of 18 to use this sample collection kit.
- Failure to follow these instructions may impact the accuracy of your test results or cause your sample to be rejected by the laboratory.
- Test results should be considered with your medical history and physical exam. You should share your results with your doctor.
- The sample and information provided must be your own. Test results may not be released to a third party.
- The sample must be returned in the kit box.
- Do not use after the expiration date.
- Discard the entire device and used kit contents after use. Follow local guidelines for discarding used sharps as a biohazard material.
- Contact our team at +1 929-376-0056 before using this device if you have any questions or concerns.

Limitations:

- Some medications, supplements, and medical conditions may impact your test results. Consult a healthcare provider if you are unsure.
- Hemoglobin A1c test results should not be used to diagnose diabetes in pregnant women or children.
- Do not use kit if you have been diagnosed with any of the following medical conditions. Consult a healthcare provider if you are unsure:
  - Abnormal levels of hemoglobin variants
  - Hemolytic disease such as hemolytic anemia, hereditary spherocytosis, or Sickle Cell disease
  - Sickle Cell Trait
  - Chronic blood loss or recent significant blood loss
  - Malignancies
  - Abnormal liver function or chronic liver or kidney disease
  - Recent onset of hyperglycemia (high blood sugar)
  - Rapidly evolving type 1 diabetes
  - Gammopathy (e.g. Waldenstrom's Macroglobulinemia).
- Do not use kit if you are taking any of the following medications. Consult a healthcare provider if you are unsure:
  - Ascorbic acid and calcium dobesilate
  - Metamizole, Dicynone (Etamsylate), Rifampicin, Levodopa, Calcium dobesilate (e.g. Dexium), Methyldopa, N-ethylglycine, DL-proline, Pheniindion.

For safety:

- Do not use this device without consulting a healthcare provider if you have:
  - A history of fainting or a medical condition that increases your risk of fainting
  - A bleeding disorder
  - A condition associated with an increased risk of infection, impaired wound healing, skin ulceration, or swelling in the arms.
- Do not make any changes to your medications without consulting your healthcare provider.
- If collecting a sample for a test that requires fasting, consult your healthcare provider, particularly if you have any medical conditions, to make sure fasting is safe for you.
- Single use only. Not intended for more than one use. For use only on a single patient.
- Not for use on infant heels.
- Do not resterilize.
- For external use only.
- Use personal protective equipment when handling biohazardous materials.
- Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.
- Minor bruising and tenderness may appear on the arm. Do not use the device on damaged, scarred, or infected skin. There is a small possibility of pain, nerve damage, scarring, bone damage, or infection. Consult a healthcare provider if you are concerned.
- Stay seated during sample collection, as fainting may occur. If you begin to feel unwell, remove the device immediately.
- Do not use the kit if any of the contents are damaged or missing. Do not tamper with the kit contents — risk of serious injury.
- Choking hazard – keep out of reach of children.

Purpose/Intended use of device:

The ImPress device is a lithium heparin coated single use device intended to produce and collect capillary blood samples from the upper arm in both clinical and home settings (healthcare professionals and lay users ≥18 years) for analysis in PrivaPath Laboratories (d.b.a. LetsGetChecked Inc). Testing is limited to the following analytes for analysis in PrivaPath Laboratories (d.b.a. LetsGetChecked Inc):

HbA1c. The LGC HbA1c assay is intended for use as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Total Cholesterol (quantitative determination of cholesterol in human plasma). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood, of lipid and lipoprotein metabolism disorders.

HDL-C-Cholesterol (quantitative determination of the HDL-cholesterol concentration in human plasma), LDL-Cholesterol (calculated). Measurements of HDL-Cholesterol and LDL-Cholesterol are used in the diagnosis and treatment of lipid disorders such as diabetes mellitus, atherosclerosis, and various liver and renal diseases.

Triglycerides (quantitative determination of Triglycerides in human plasma). Measurements of triglycerides are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstructions, other diseases involving lipid metabolism, or various endocrine disorders.

Lipoprotein-a (Lp(a)) (quantitative determination of Lp(a) in human plasma). The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation and other lipoprotein tests.

Creatinine (quantitative determination of creatinine in human plasma), estimated glomerular filtration rate (eGFR, calculated). The measurement of creatinine and calculated eGFR is useful in evaluating kidney function in conjunction with clinical evaluation and other biomarkers.

PrivaPath Diagnostics Ltd.,
Unit 1, Northern Cross Business Park,
North Road, Dublin 11,
D11 X726, Ireland.

Temperature limit: 15°C — 25°C.

For explanation of symbols see **LetsGetChecked.com/symbol-glossary**

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ImPress blood collection

For investigational use only

QR-IFU-122-RA-Apr-2025