



Healthy Heart Check

Instructions for Use



Read this leaflet fully
before starting the test

What is this test for?

This test is intended for self-testing by adults in a home environment.

This test is intended to be used to measure the levels of different types of lipids in finger-prick blood samples.

The types of lipids measured include:

- Total Cholesterol (TC)
- High Density Lipoprotein (HDL) (sometimes referred to as “good” cholesterol)
- Triglycerides (TG)

From these measurements, other information can be derived as follows:

- non-HDL (sometimes referred to as “bad” cholesterol)
- Total Cholesterol/HDL ratio
- Low Density Lipoprotein (LDL) (sometimes referred to as “bad” cholesterol)

Knowing the relative amounts of the “good” and “bad” lipids in the blood in relation to other information, e.g. age, height, weight, smoker/non-smoker, blood pressure and medical history enables conclusions to be drawn about your risk of heart disease, enabling healthcare professionals to recommend action required to reduce your risk, if necessary.

If any follow-up action is indicated, based on the results of your test (i.e. if you receive an “unhealthy” result), this must be done in consultation with a healthcare professional (e.g. your doctor or physician). You can choose to have your results sent automatically to your doctor via the app.

Storage & handling

- Store the kit at 2 - 30°C
- Keep away from heat and direct sunlight
- Perform the test at room temperature (15 - 30°C)
- Do not place used components in recycling waste

Composition of reagents

The test kit does not contain any liquid reagents that could leak from the device.

The test cassette contains enzymes coated onto a nitrocellulose membrane. The enzymes are purified proteins extracted from bacteria and are immobilised by the membrane.

The alcohol wipes are impregnated with isopropyl alcohol BP (70%w/v).

Warnings and precautions



The device is an in vitro diagnostic medical device (IVD) intended for testing human blood samples only. Note that, as with any IVD, there is a remote possibility that the test could give an incorrect result, so if you have any concerns about the validity of your result, please contact us.



Do not use the test after the expiry date stated on the carton label (this will be the same as the shortest dated component within the kit).



Blood will coagulate after being exposed to the air for a few minutes. It is therefore important to complete the blood transfer step from your finger-prick to the test cassette quickly while the blood is flowing freely. In the event that blood is coagulated or the capillary becomes blocked, it will not be possible to run the test and you will need to try again. A second capillary is provided in case the first one should become blocked.



When transferring blood from your finger to the test with the capillary **DO NOT PRESS THE END OF THE CAPILLARY DIRECTLY ONTO THE TEST STRIP**. Allow a small gap between the end of the capillary and the sample site to avoid scratching the paper strip.



Leave the test device, alcohol wipe and gauze sealed in their immediate packaging until just before starting the test (opened for a maximum of 10 minutes).



Keep away from children (swallowing / choking hazard)



Do not use lotions and hand creams immediately before taking a finger-prick sample.



Use finger-prick blood only.



Do not prick the fifth (little) finger because the tissue depth may be insufficient to prevent bone injury.



An image of the test cassette should be taken, using your smartphone, after 7 minutes. The image will need to be captured within the time shown on the app display. If it is exceeded another test must be conducted.



Do not remove the "PEEL HERE" part of the label covering the test area of the PocDoc cassette until prompted by the PocDoc App (an alert will be displayed and an alarm will sound 7 minutes after starting the timer).



Take an image of cassette placed on a flat, well-lit surface. Dim light or strong shadow can affect the ability of the image recognition software to successfully capture the test cassette image.



Place used items inside the empty foil bag after use. Seal the bag and dispose of in general domestic waste. Do not recycle any items that have been in contact with blood.

Kit contents

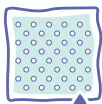
Check that the kit contains the following items.



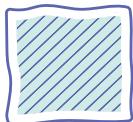
Sterile lancet



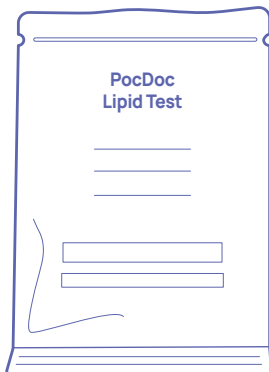
Capillaries x2*



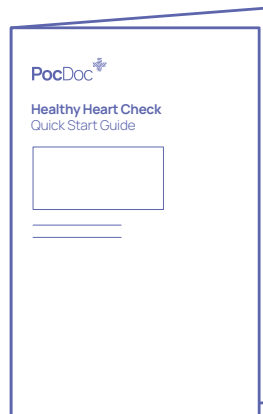
Alcohol wipe



Sterile gauze



Lipid test



Quick Start Guide



If the packaging of any component is damaged, or if the lancet cap is detached, do not use the test.

Remove the alcohol wipe and gauze from their sterile packs at the point of use.

The test cassette is packed inside a sealed foil pouch with a desiccant bag. Unpack the test cassette from the sealed foil pouch and discard the desiccant bag immediately prior to taking your blood sample.

DO NOT REMOVE THE “PEEL HERE” LABEL UNTIL PROMPTED TO DO SO BY THE APP.

2 capillaries are provided in case you need a 2nd attempt to collect / transfer your finger-prick blood sample.

*The bag containing the capillaries and lancet can be used as a disposal bag after use.

If you have any questions, contact support@mypocdoc.com

Materials required but not included

- Compatible mobile device - refer to list of compatible devices at: <https://pocdoc.co/compatible-devices>

Before you start

- Wash your hands thoroughly with warm water to improve blood flow.
- **Drink plenty of water before starting.** This will make blood collection easier.
- Ensure your smartphone is connected to Wi-Fi.



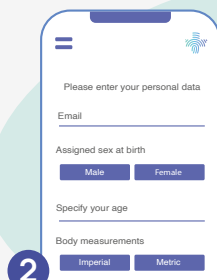
- Download and open the PocDoc App on your smartphone, either from the AppStore or Google Play.
 - Register your details via the app.
 - The screen menu on the PocDoc App will guide you how to use the device and interpret results.
- Ensure you are in a well-lit area.

Test procedure



1

Click start test and fill out the questionnaire.



2

After completing the health questionnaire, the app will guide you through the test.



3

Open the foil pouch, remove the test and lay on a clean, flat surface with coloured barcode strips facing upwards. Do not peel off the label, and do not touch the coloured barcodes.



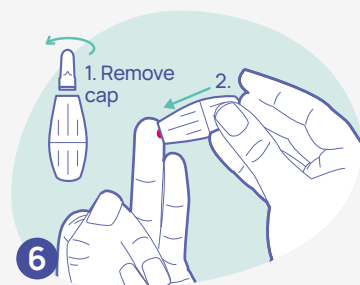
4

Remove the capillary and lancet from the Accessory Pack and remove the sterile gauze and alcohol wipe from their packaging.



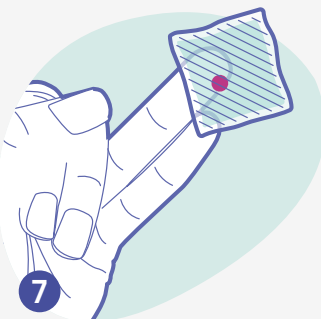
5

Choose a finger from your non-dominant hand to collect blood from, and clean it with alcohol wipe.



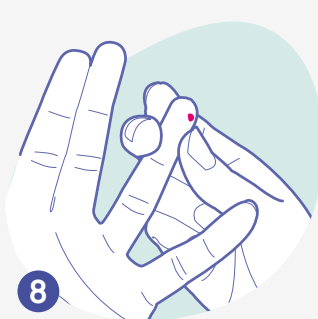
6

1. Remove the lancet cap by twisting off. 2. Firmly press the lancet against the finger to get a droplet of blood.



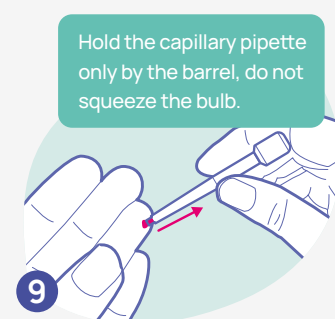
7

Use the gauze to wipe away the first small drop of blood.



8

Squeeze the finger to produce a blood droplet.



9

Touch the capillary pipette to the droplet of blood, at an angle of between zero to 45 degrees and blood should flow up the pipette tube.

Ensure you are in a brightly lit room without direct light pointed at the test. Avoid dark areas or shadows falling across the test.

Hold the capillary pipette only by the barrel, do not squeeze the bulb.



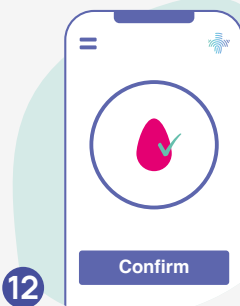
10

Blood will flow up the capillary pipette by capillary action; keep going until blood reaches the black line on the pipette.



11

Deposit **all** the blood from the capillary onto the deposit area of the PocDoc test, without touching the capillary onto the test. Gently squeeze the bulb to deposit the blood sample.



12

The app will ask you to confirm when you have put the blood sample onto the test.



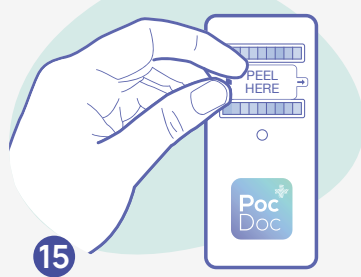
13

When you press 'Confirm' the app will automatically start a timer for 7 minutes.



14

As soon as the timer reaches 7 minutes, the app will automatically open the image capture page with an outline of the test.



15

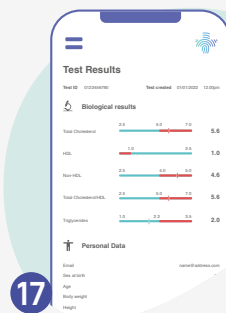
At this point remove the label over the test sites.

Complete the next step within the time shown on the app display screen.



16

Hold the tablet or smartphone over the test, ensuring you match the outline of the test to the visual guide in the app. Press the button to take a photo, and the app will show you the image you have taken. The image should not be blurry, not in heavy shadow and well lit. Once you are happy, press "submit".



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The PocDoc app will display your actual level of each marker, and will show you how your results compare to the healthy levels recommended by clinical experts.

Disposal

Used tests can present an infection hazard to others due to the presence of blood.

After completing the test, place all used kit components into a plastic bag (the bag containing the capillaries and lancet may be used for this purpose), seal and dispose of in household waste.

Do not place anything from the kit into recycling waste.

Interpreting test results

The PocDoc Lipid Self-Test software will analyse the photo of the test to determine the levels of lipids present in the blood sample.

Results are displayed by the app as millimoles per litre (mmol/L) and plotted in a simple chart to show where the result stands in relation to the NHS guideline healthy limit for each marker. The NHS guidelines are defined as follows:

- In the event that the test malfunctions or insufficient blood sample is loaded onto the cassette, a “FAIL” result will be returned and the test will need to be repeated.
- If follow-up action is indicated, i.e. if an “unhealthy” result is indicated for one or more of the biomarkers, seek advice from your GP or physician.
- For further information, e.g. to explain the context of a result outside the healthy range, touch the app result screen for the appropriate marker.

Do not take any decisions relating to starting or stopping medication or changing medication, or medical treatment, without first consulting your GP.

- You will receive a results certificate. It contains some basic information about each marker which has been provided by Heart UK, a registered charity in the UK, dedicated to prevention of cardiovascular disease.

Marker	NHS guideline healthy limit (mmol/L)	Reference
TC	5 or below	NHS: www.nhs.uk/conditions/high-cholesterol/cholesterol-levels/
HDL	1 or above for men 1.2 or above for women	
Non-HDL	4 or below	
TC:HDL ratio	6 or below	
TG	2.3 or below	Heart: www.heartuk.org.uk/cholesterol/understanding-your-cholesterol-test-results-
LDL	Below 3	

Note – these values are for guidance and interpretation of health status and will take into account other information in addition to the test data, e.g. age, BMI, medical history, etc.

In the event that the test malfunctions or insufficient blood sample is loaded onto the cassette, a "FAIL" result will be returned and the test will need to be repeated.

If follow-up action is indicated, i.e. if an "unhealthy" result is indicated for one or more of the biomarkers, seek advice from your GP or physician.

For further information, e.g. to explain the context of a result outside the healthy range, touch the app result screen for the appropriate marker.

Do not take any decisions relating to starting or stopping medication or changing medication, or medical treatment, without first consulting your GP.

How do I know if the test has performed correctly?

The test image analysis software can recognise certain situations where the sample cannot be analysed, for example:

- Poor image quality (e.g. shadows, blurred image, test cassette not positioned within camera viewfinder)
- Blood does not reach one or more of the 3 reaction sites on the cassette
- One or more of the 3 test site reactions not identified (e.g. because "PEEL HERE" label not removed prior to taking photo)
- Failure to detect a PocDoc Lipid test in an image

An error message will be displayed by the app in these cases and no results will be calculated. An on-screen error message will explain what you have to do next, for example: retake the photo, reconnect to Wi-Fi and wait for image to upload, take a new test, etc.

What could affect the result?

Test results may be affected by the following:

Dehydration

- Dehydration may lead to low plasma levels in the blood, resulting in the test failing to run or giving results that are lower than the true values.
- **For these reasons, it is advised that you drink plenty of water prior to performing the test.**

Haematocrit

- A haematocrit measures the percentage of red blood cells in the blood. Normal haematocrit levels vary based on age and ethnicity. In adults, normal levels for men range from 41%-50%. For women, the normal range is slightly lower: 36%-44%. A haematocrit level below the normal range is called anaemia. A haematocrit level above the normal range may indicate polycythaemia or erythrocytosis.
- No haematocrit effect was observed for samples between 30% and 50% HCT.
- It is very rare to have a haematocrit level above 50%, but in this rare event results could be significantly reduced, or the test could fail to function.

Medicines

- The presence of aspirin, paracetamol and ibuprofen have no significant effect on the test results.
- The presence of high levels of methyl dopa could decrease the lipid results in PocDoc Lipid Self-test.

Endogenous substances (substances found naturally in blood)

- The presence of high levels of sodium ascorbate, bilirubin and haemoglobin had no significant effect on the test results.

Fat, lipids and cholesterol

What are lipids?

Lipids are an important part of a healthy diet. The body uses lipids as an energy store, as insulation (in the form of fat) and to make cell membranes.

How does the body use lipids?

Every cell in your body has a cell membrane which is made of lipids. Some hormones, including sex hormones, are made from a lipid called cholesterol.

Fat is also an important energy store for the body. In addition, the layer of fat under your skin provides insulation and thin layers of fat protect vital organs.

How much lipid do you need?

Lipids are an essential component of a balanced diet. In the body, lipid molecules can be broken down to make smaller molecules of fatty acids and glycerol.

Some fatty acids, called essential fatty acids, are vital for health. They can be found in foods such as nuts, seeds or fish.

It is important not to eat too much fatty or oily food. This is because small amounts of lipid-rich foods can store large amounts of energy. Eating too much fatty or oily food, whilst not getting enough exercise, may cause obesity. Adults and teenagers are advised to eat no more than 70 g of fat per day.

Your liver makes cholesterol for your body. Cholesterol is a type of lipid found in every cell in your body. You also can get cholesterol from the foods you eat. Meat, fish, eggs, butter, cheese, and milk all have cholesterol in them. Fruits, vegetables, and grains (like oatmeal) don't have any cholesterol.

You need cholesterol to help your brain, skin, and other organs do their jobs. But eating too

much fat and cholesterol is a bad idea as it can lead to health problems, especially in later life.

Cholesterol floats around in your blood and can get into the walls of the blood vessels. This can cause the blood vessels to get stiffer, narrower, or clogged. If the clogging gets worse over many years, it can cause a heart attack or stroke in adults.

Cholesterol can start to build up in childhood, but more often builds up to high levels in later life, especially over the age of 40.

What are the types of cholesterol?

Cholesterol in the blood doesn't move through the body on its own. It combines with proteins to travel through the blood-stream. Cholesterol and protein traveling together are called lipoproteins.

The two main types of cholesterol are:

LDL (low-density lipoprotein) cholesterol, or "bad cholesterol," carries cholesterol from the liver into the bloodstream, where it can stick to the blood vessels.

HDL (high-density lipoprotein) cholesterol, or "good cholesterol," carries the cholesterol in the blood back to the liver, where it is broken down.

Triglycerides

Triglycerides are a type of blood fat. They are our main source of energy and are essential for good health. But if you have too much in your blood, this can raise the risk of heart disease.

How can I prevent high cholesterol?

Here are a few things you can do to keep your cholesterol under control:

- Eat a healthy diet that includes lots of fruit, vegetables and whole grains.
- Limit drinks and foods that have a lot of fat or sugar, like sugary drinks, treats, and fried foods.
- Get plenty of exercise.

How does this test work?

The lipids in your blood sample react with substances called enzymes which are embedded in the test cassette. A different enzyme will react with each of the three types of lipid (TC, HDL or TG) in the blood sample. A different lipid is tested within each of the three test sites on the cassette. The reactions take a few minutes. At the end of the reaction time, a coloured substance is formed. The intensity of the colour produced is proportional to the amount of lipid in the blood. Using the camera in your smartphone linked to image analysis software in an app, the colour of the reaction can be measured. Since the colour intensity of the reaction is dependent on the amount of lipid present in the sample, the concentration of each lipid present in the sample can be calculated. The calculated results are displayed on the app.

Performance characteristics

Measuring range:

- Total Cholesterol (HC) 2.5 - 7.0 mmol/L
- High Density Lipid (HDL) 1.0 - 2.5 mmol/L
- Triglycerides 1.0 - 2.5 mmol/L

Precision

Precision is a measure of how consistent the test result is when the same sample is tested multiple times.

40 replicates of 2 different levels of cholesterol, HDL cholesterol and triglycerides were tested and the following results were obtained:

		Estimate of repeat-ability (S _r)	Between-days SD (S _{dd} ²)	Between run SD (S _{rr} ²)	Precision (S _r)	Avg. mean [mM]	Standard deviation [mM]	Coefficient of variation [%]
Total Cholesterol	Level 1	1.0	-2.0	3.6	0.9	3.0	0.1	2.1
	Level 2	1.3	-9.4	19.8	1.1	6.5	0.3	3.9
HDL Cholesterol	Level 1	0.58	-0.24	0.65	0.50	1.03	0.03	3.02
	Level 2	0.72	-0.55	0.84	0.62	1.56	0.03	1.99
Triglycerides	Level 1	0.6	-0.2	0.6	0.5	1.0	0.0	0.0
	Level 2	0.7	-0.5	1.12	0.6	1.4	0.0	3.3

The Coefficient of Variation is an indicator of test repeatability, and the obtained values are all within the US National Cholesterol Education Program (NCEP) recommended limit of < 4%.

Accuracy

Accuracy is a measure of how close the test result values are to an established reference laboratory test method.

The performance of the PocDoc tests for total cholesterol, HDL cholesterol and triglycerides was determined in a study, in which 125 samples measured by a Reference Method were compared to PocDoc Lipid Test results using the same samples:

Analyte	PocDoc Healthy Heart Check Total Analytical Error (TAE)	Recommended NCEP TAE limit
Total Cholesterol	6.9%	< 9%
HDL Cholesterol	7.7%	< 13%
Triglycerides	5.7%	< 15%

What accuracy can I expect?

It is unlikely that your PocDoc Lipid Self-Test result will precisely match the result obtained from a professional clinical laboratory. Different technologies are used in clinical environments to determine lipid levels. Every test, including laboratory and home testing technologies have a degree of variation. Examples of how results can vary, based on the accuracy study, are given below:

Total Cholesterol

Results can differ up to 0.7mM from the true cholesterol result. This means, for example, that if you have a true value of 5.0 mM, PocDoc Lipid Self-Test could read between 4.3 and 5.7 mM.

HDL

Results can differ up to 0.1mM from the true HDL result. This means, for example, that if you have a true value of 1.5 mM, PocDoc Lipid Self-Test could read between 1.4 and 1.6 mM.

Triglycerides

Results can differ up to 0.1mM from the true triglycerides result. This means, for example, that if you have a true value of 1.2 mM, PocDoc Lipid Self-Test could read between 1.1 and 1.3 mM.

Further information

NHS guidelines levels for lipids

<https://www.nhs.uk/conditions/high-cholesterol/cholesterol-levels/>

Heart UK information on lipids

<https://www.heartuk.org.uk/cholesterol/what-is-cholesterol>

Understanding PocDoc Lipid Test Results

<https://pocdoc.co/articles/understanding-pocdoc-lipid-test-results>



PocDoc's Guide to Lipids

<https://pocdoc.co/articles/pocdocs-guide-to-lipids>



If the test does not perform as expected

Any complaints or technical problems with the test should be reported to:

support@mypocdoc.com

Explanation of symbols on labels

 Sterilized by gamma irradiation

 Sterilized by ethylene oxide

 Store between 2°C and 30°C

 Keep away from sunlight

 Keep dry

 Single use only – do not reuse

 Do not use if packaging is damaged

 Expiry date

 Refer to the instructions

 Self-test IVD

 In vitro diagnostic medical device

 Medical device

 Warning

 Lot number

 Catalogue number

 Date of manufacture

 Manufacturer

 Number (n) of tests

 EU Conformity Assessment mark

 UK Conformity Assessment mark (the number below identifies the Notified Body responsible for performing the conformity assessment)

Regulatory information

Component	GMDN Code	Manufacturer	UK Responsible Person	Classification (Regulation)
PocDoc Lipid self-test cassette	65850	Vital Signs Solutions Ltd. Unit 6, 3960 Cambridge Research Park, Waterbeach, Cambridge CB25 9PE, UK	N/A	General IVD (UKCA MDR)
Alcohol wipe	61694	BSN medical GmbH Quickbornstrasse 24 20253 Hamburg Germany	Essity UK Ltd. Southfields Road Dunstable Beds LU6 3EJ United Kingdom	Class I (EU MDR)
Gauze	48131	Suzhou Sunmed Co. Ltd. No. 88 ShiShan Road, Suzhou City, China 215011	SUNGO Certification Company Ltd. 3rd Floor, 70, Gracechurch St, London EC3V 0HR, UK	Class I(s) (EU MDR)
Lancet	61578	Becton, Dickinson and Co. Ltd. Pottery Road, Dun Laoghaire, Co. Dublin, Ireland	Becton, Dickinson UK Ltd. 1030, Eskdale Road Winnersh Triangle, Wokingham, Winnersh RG41 5TS, UK	Class IIa (EU MDD)
Capillary tube	35770	Vital Signs Solutions Ltd. Unit 6, 3960 Cambridge Research Park, Waterbeach, Cambridge CB25 9PE, UK	N/A	General IVD accessory (UKCA MDR)



Manufacturer: Vital Signs Solutions Ltd.
Unit 6, 3960 Cambridge Research Park,
Waterbeach, Cambridge CB25 9PE, UK
www.pocdoc.co