PocDoc Lipid Test
Instructions for Use

for Professional Users

⚠
Read these Instructions for Use
in full before initiating testing.

PocDoc Lipid Test
FFP0140
April 2026
PocDoc TF001 – 2.1 v13

1. Product warnings

⚠
All components are single use.

⚠
The PocDoc test is only intended for use with a compatible mobile device as listed at: https://pocdoc.co/compatible-devices. Do not use any device that is not on the list.

⚠
Use finger-prick blood only.

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

⚠
Blood will coagulate after being exposed to the air for a few minutes. It is therefore important to complete the blood transfer step from the finger-prick to the test cassette quickly while the blood is flowing freely. In the event that blood is coagulated or the transfer pipette becomes blocked, the test cannot be performed. Discard the cassette and repeat the procedure using a new cassette and a fresh finger-prick sample.

⚠
Follow local policy regarding Personal Protection Equipment (PPE) and blood sample collection. Obtain appropriate medical attention in the event of any exposure to blood samples (e.g. through a puncture injury) since samples may transmit viral hepatitis, HIV (AIDS), or other infectious diseases.

2. Intended use

Intended purpose

PocDoc Lipid Test is intended to be used to measure the levels of lipids in finger-prick blood samples from adults >18 years old.

The biomarkers measured include:

- Total Cholesterol (direct measurement)
- non-HDL (inferred calculation)
- LDL (inferred calculation)
- HDL (direct calculation)
- Total Cholesterol/HDL ratio (inferred calculation)
- Triglycerides (direct measurement).

This may be valuable information for professionals conducting preventative healthcare checks, wellness checks or cardiovascular health screens.

PocDoc results can be used as part of a decision-making process to assess disease risk associated with hyperlipidemia, to help making positive behavioural change and to monitor effectiveness of changes made to lifestyle. All therapy must be done in consultation with a healthcare professional.

The device is an in vitro diagnostic medical device (IVD) intended for testing human blood samples only, outside of the human body. As with any IVD, erroneous results may occur. For suspected product-related issues, contact support@mypocdoc.com

Intended users

PocDoc is intended to be used by professionals in healthcare settings where they will be conducting testing.

Intended users must be trained and able to take the blood sample using Lancet and transfer pipette and apply it to the PocDoc cassette. Steps on the accompanying mobile application will guide the user through utilisation of the device and the display of results.

3. Summary

Cholesterol management guidelines recommend measuring a lipid profile, including Total Cholesterol (TC), High-density Lipoprotein (HDL) and Triglycerides (TG). These measurements are made in blood plasma, using a lateral flow-based cassette to perform colorimetric reactions, to quantify the different lipids. The colour is measured by a compatible mobile device with PocDoc Pro software. This data can be used to evaluate cardiovascular disease risk.

4. Principles of the procedure

Principle of the assay

The lipids in blood sample react with enzymes which are embedded in the test cassette. A different enzyme will react with each of the three types of lipids (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 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 app on a compatible device, an image is uploaded for analysis. Cloud-based software is used to analyse the colour of the reaction. 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 in the app.

Cholesterols

Cholesterol and cholesterol esters are hydrolysed by cholesterol esterase into cholesterol, which is then oxidized by cholesterol oxidase into the ketone cholest-4-en-3-one. Hydrogen peroxide (H_2O_2) formed as a bi-product reacts with 4-aminophenazone and a dye in the presence of horseradish peroxidase (HRP) to generate a visible colour. Both TC and HDL are detected using this method. The HDL reaction includes an additional step to separate the non-HDL fragments within the cassette before detection.

Triglycerides

The triglycerides in the sample are hydrolysed by a combination of microbial lipases to produce glycerol and fatty acids. The glycerol is phosphorylated by adenosine triphosphate (ATP) in the presence of glycerol kinase to produce glycerol-3-phosphate. The glycerol-3-phosphate is oxidized by molecular oxygen in the presence of glycerol phosphate oxidase (GPO) to produce dihydroxyacetone phosphate. Hydrogen peroxide (H_2O_2) formed as a bi-product reacts with 4-aminophenazone and a dye in the presence of peroxidase (POD) to generate a visible colour.

The user takes a picture of the lateral-flow cassette through the PocDoc Pro App. Algorithms then quantify the levels of colour change, using the coloured matrices either side of the test sites to correct the image for ambient colour and shade conditions. Non-HDL, LDL and the TC:HDL ratios are calculated from these levels, and the App reports the results on-screen and optionally by email to the patient, if they request it.

LDL is calculated only when total cholesterol is between 2.5–7.5 mmol/L, HDL is between 1.0–2.5 mmol/L, and triglycerides are between 1.0–4.5 mmol/L. Outside these ranges, LDL is not reported.

Composition of reagent

The test kit does not contain any liquid reagents that could leak from the device. The test cassette contains enzymes (reactive ingredients as listed below) coated onto a nitrocellulose membrane. The enzymes are purified proteins, immobilised on the membrane and produced from bacterial species that are harmless to humans.

Analyte	Reactive ingredient
Total cholesterol	Cholesterol esterase
	Cholesterol oxidase
	Peroxidase
HDL cholesterol	Cholesterol esterase
	Cholesterol oxidase
	Peroxidase
	PWA / Magnesium chloride
Triglycerides	Lipoprotein lipase
	Glycerokinase / Magnesium chloride
	Glycerol phosphate oxidase
	Lipoprotein lipase

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

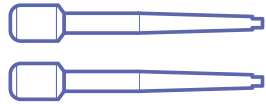
5. Traceability

The PocDoc algorithms contain pre-programmed calibration curves constructed using Human Blood Samples measured in UKAS ISO15189:2012 accredited laboratory by Roche Cobas Photometry method.

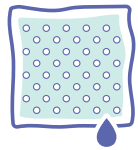
6. Kit contents

2 transfer pipettes per test are provided in case a 2nd attempt to collect / transfer blood is needed.

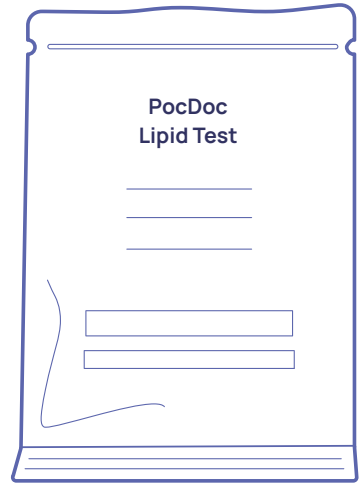
Sterile lancet



Transfer pipettes (capillaries)



Wet wipe



Lipid test

⚠

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

⚠

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

7. Materials required but not included

- Compatible mobile device - refer to list of compatible devices at: https://pocdoc.co/compatible-devices
- Wi-Fi, or 4G or better mobile data connection
- PocDoc Pro App (on request from support@mypocdoc.com)
- Gauze
- Sticking plaster
- Clinical waste and/or sharps bin
- Gloves

8. Storage & handling

- When transferring blood 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.
- Human blood can transmit infectious agents. Consider all blood derivatives potentially infectious.
- Wear disposable gloves and follow local policy for appropriate personal protective equipment (PPE).
- Store the cassettes as indicated on the cassette pouch.
- Operate test devices at ambient room temperature, between 15 and 30°C.
- Keep away from heat and direct sunlight.
- Do not freeze the test cassette(s).
- The device is for single use only. Do not re use the test.

9. Disposal

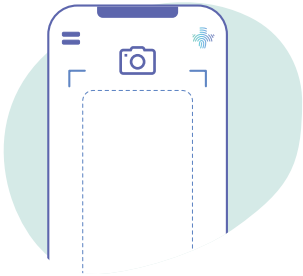
- Handle and dispose of the PocDoc cassette and kit components as potentially bio hazardous materials in a clinical waste and/ or sharps bin.
- Do not dispose of any items from the kit into recycling waste.
- Dispose of used and expired tests as clinical waste in accordance with local procedures

10.Training

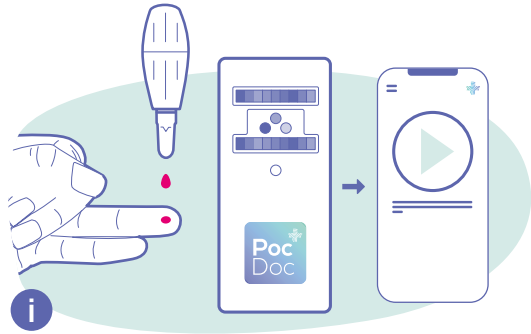
- The PocDoc Pro app and IFU provide information as to how to use the test.
- Additional information is provided on the company website.
- For additional training or technical guidance, contact support@mypocdoc.com

11. Instructions

For complete instructions, open the PocDoc Pro app, tap on the Help Guide to follow the on-screen video and step-by-step guidance throughout the procedure.



Open the PocDoc Pro app & scan the cassette to verify the expiry date.



Detailed video and step-by-step instructions are provided under the Help Guide in the PocDoc Pro App.

12. Interpreting test results

The PocDoc Lipid 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 presented with a graphical reference range indicator aligned to published NHS guideline thresholds.

The patient will receive a results report if they provided an email address. 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	Guideline healthy limit for adults (mmol/L)	UK data source
TC	5 or below	NHS https://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	Below 6	
TGs	1.7 or below	
LDL	Below 3	

13. Limitations of the procedure

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.

Ensure the patient is adequately hydrated prior to sampling, as dehydration may affect specimen quality and measured values.

Haematocrit

Haematocrit levels vary based on age and ethnicity.

Normal ranges:

Adult men: 41%-50%.

Adult women: 36%-44%.

- No haematocrit effect was observed for samples between 30% and 50% HCT.
- It is uncommon in the general population to have a haematocrit level above 50%, but in this 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 methyldopa could decrease the lipid results in PocDoc Lipid test.

CONTRA-INDICATIONS AND/OR LIMITATIONS

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

- Cholesterol levels naturally increase during pregnancy, especially in the second and third trimesters. This physiological change needs to be considered when interpreting results.
- Current guidelines do not recommend routine testing cholesterol during pregnancy. However, women with pre-existing high cholesterol or other risk factors may benefit from monitoring.

14. Performance characteristics

Measuring range:

Total Cholesterol (HC)	2.5 - 7.5 mmol/L
High Density Lipid (HDL)	1.0 - 2.5 mmol/L
Triglycerides	1.0 - 4.5 mmol/L

Precision

Estimates of precision were established through repeated measurements of samples, conducted in accordance with current CLSI guidelines.

Precision studies were performed with whole blood samples. 40 replicates of 2 levels of cholesterol, HDL cholesterol and triglycerides were tested and the following results were obtained:

	Total Cholesterol		HDL Cholesterol		Triglycerides	
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2
Coefficient of Variation (CV%)	4.2 %	3.7 %	3.8 %	3.3 %	6.0 %	5.7 %

Average precision values are reported. Small device-to-device variation may occur across supported mobile devices.

Accuracy

Estimates of accuracy were established through systematic sample measurements conducted in accordance with current CLSI guidelines.

Accuracy is convincingly represented by measuring total analytical error (TAE). TAE shows the biggest acceptable difference between the test result and the true value, taking into account both random variation and systematic bias.

The performance of the PocDoc Lipid Test for total cholesterol, HDL cholesterol and triglycerides was determined in a study, in which 132 samples measured by a Reference Method were compared to PocDoc Lipid Test results using the same samples:

	Total Cholesterol	HDL Cholesterol	Triglycerides
PocDoc Lipid Test Total Analytical Error (TAE)	7.1 %	8.9 %	8.6 %
Recommended NCEP TAE limit	< 9%	< 13%	< 15%

Average total analytical error is reported, and small device-to-device variation may occur across supported mobile devices.

It is unlikely that the PocDoc Lipid 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 +0.9 mmol/L or -0.7 mmol/L from the true cholesterol result. This means, for example, a reference value of 5.0 mmol/L may correspond to a PocDoc result between 4.3 and 5.9 mmol/L.

HDL

Results can differ up to +0.4 mmol/L or -0.2 mmol/L from the true HDL result. This means, for example, a reference value of 1.5 mmol/L may correspond to a PocDoc result between 1.3 and 1.9 mmol/L.

Triglycerides

Results can differ up to ± 0.5 mmol/L from the true triglycerides result. This means, for example, a reference value of 3.5 mmol/L may correspond to a PocDoc result between 2.5 and 3.5 mmol/L.

15. Diagnostic Sensitivity and Specificity

Diagnostic Sensitivity and Specificity quantify how well a diagnostic test identifies true positives (sensitivity) and true negatives (specificity) compared to a reference standard.

Sensitivity is the proportion of people with a lipid level that the test correctly identifies as having a lipid level outside the healthy range.

Specificity is the proportion of people with normal lipid levels that the test correctly identifies as healthy.

Analyte	Diagnostic Sensitivity	Diagnostic Specificity
Total cholesterol	81 %	92 %
HDL cholesterol	83 %	80 %
Triglycerides	86 %	93 %

16. Image capture

To ensure reliable analysis, the image must be captured under the conditions shown in the PocDoc Pro App.

The mobile device camera lens and test cassette must be clean and free from contamination, and the cassette must be positioned on a clean, flat, un-patterned, neutral coloured surface without direct reflection or glare from glass or other reflective surfaces.

Images should be taken in focus, evenly illuminated, and free from shadows or strong backlighting. Remove objects from the field of view that may interfere with image analysis. Do not hold the device at an angle that causes reflected light to enter the camera or obscures the test window.

If the image does not meet pre-determined image quality criteria a void result may be displayed. In this event, the test will need to be repeated with a new sample and a new cassette.

17. Technical support

IF THE TEST DOES NOT PERFORM AS EXPECTED

Any complaints or technical problems with the test should be reported to: support@mypocdoc.com

EU member states and Northern Ireland only: In the event of a serious incident, please inform us and your national competent authority.

18. Further information

NHS guidelines levels for lipids: https://www.nhs.uk/conditions/high-cholesterol/cholesterol-levels/

National Cholesterol Education Program (NCEP) guidelines for total cholesterol triglyceride, HDL-cholesterol, and LDL-cholesterol measurements: National Heart, Lung, and Blood Institute, NIH Publication No. 02-5215, 2002; https://www.nhlbi.nih.gov/files/docs/resources/heart/atp-3-cholesterol-full-report.pdf

NHS England summary of national guidance for lipid management: NICE guideline NG238, 2023 https://www.nice.org.uk/guidance/ng238

19. Explanation of symbols

STERILE R	Sterilized by Gamma irradiation (lancet)
30°C 2°C	Store at 2 to 30°C
	Keep away from sunlight
	Keep dry
	Single use only
	Do not use if packaging is damaged
	Use by date
	Read the instructions
IVD	In vitro diagnostic medical device
MD	Medical device
	Warning
LOT	Lot / batch number
REF	Catalogue number
	Manufacturer
Σ n	Number (n) of devices supplied
CE	EC declaration of conformity
UK CA	UK declaration of conformity

20. Regulatory information

Component	GMDN Code	Manufacturer	UK Responsible Person	Classification (Regulation)
PocDoc Lipid Test cassette and PocDoc Pro App	65849	Vital Signs Solutions Ltd, Unit 6, 3960, Cambridge Research Park, Waterbeach, CB25 9PE, UK	N/A	General IVD (UKCA MDR)
Wet wipe	61694	BSN medical GmbH Quickbornstrasse 24 20253 Hamburg Germany	Essity UK Ltd. Southfields Road Dunstable Beds LU6 3EJ, UK	Class I (EU MDR)
Lancet	61578	Becton, Dickinson and Co. Ltd. 1, Becton Drive, Franklin Lakes, NJ07417, USA	Becton, Dickinson UK Ltd. 1030, Eskdale Road Winnersh Triangle, Wokingham, Winnersh RG41 5TS United Kingdom	Class IIa (EU MDD)
Transfer pipettes (capillaries)	35770	Vital Signs Solutions Ltd, Unit 6, 3960, Cambridge Research Park, Waterbeach, 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

PocDoc