CARDIOCHEK® PA+

The CardioChek® Professional Analyser (PA) is an easy to use Point-of-care system ideal for multiple clinical settings and applications. It is intended for in vitro diagnostic use, using whole-blood samples. The CardioChek® PA device is fast, portable, and reliable.

Operating Principle

The device uses light reflectance to measure an end-point enzymatic chemical reaction. The test strips are impregnated with enzymes which are specific for the analyte to be measured. When blood is applied to the test strip, the sequence of chemical reactions that occurs results in a colour change on the strip which is then measured by light reflectance. The intensity of this colorimetric substance is directly proportional to the amount of analyte in the blood. Using a stored standard calibration curve, the device calculates and displays the result on the screen.

Storage and Stability

<table>
<thead>
<tr>
<th>Analyser and consumables</th>
<th>Operating temperature (°C)</th>
<th>Storage temperature (°C) &amp; Shelf Life</th>
<th>Time to bring to Operating temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>CardioChek strips</td>
<td>20-30°C</td>
<td>20-30°C until expiry. May also be stored at 2-8°C</td>
<td>If refrigerated, allow adequate time to warm to room temperature</td>
</tr>
<tr>
<td>Internal Quality Control Solutions</td>
<td>20-30°C</td>
<td>20-30°C until expiry. May also be stored at 2-8°C</td>
<td>Once opened stable for 10 months, or until expiry (whichever is lesser)</td>
</tr>
<tr>
<td>Analyser</td>
<td>10-40°C</td>
<td>10-40°C</td>
<td>Allow minimum of 30 minutes to equilibrate to room temperature, if required</td>
</tr>
</tbody>
</table>

If refrigerated, allow adequate time to warm to room temperature.
Control Solutions

Quality control checks are needed to ensure the proper performance of the CardioChek® Analyser:

- That the device is working correctly
- That the test strips are being used by the device properly

This will ensure that the results are reliable and accurate within the limits of the system.

There are two types of Control Solution: Multi-Chemistry and HDL Cholesterol. Each contains two vials which are different levels of control solution – one normal range, and one out-of-range. A quality control range card is also included to check the results by.

Multi-Chemistry Controls

This solution contains cholesterol, triglycerides, and glucose, which react with the test strips to produce colour. The result for each level of control should be in the range specified on the quality control range card included with these solutions.

HDL Cholesterol Controls

This solution contains HDL cholesterol, which reacts with test strips to produce colour. The darker the colour, the higher the HDL cholesterol concentration. Again, the result for each level of control should be in the range specified on the quality control range card included.
### Types of PTS Panel®

<table>
<thead>
<tr>
<th>PTS Panel test strip</th>
<th>Total Cholesterol (TC)</th>
<th>High Density Lipids (HDL)</th>
<th>Triglycerides (TG)</th>
<th>TC/HDL</th>
<th>Glucose (Glu)</th>
<th>Low Density Lipids (LDL)</th>
<th>Ketones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol</td>
<td></td>
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<td>HDL Cholesterol</td>
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<tr>
<td>Triglycerides</td>
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<tr>
<td>Glucose</td>
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<tr>
<td>Ketone</td>
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</tbody>
</table>

- **Chol/Glu**
- **Chol/HDL**
- **Lipid Chol/HDL/TG**
- **Chol/HDL/Glu**
Test Procedure

The CardioChek® PA test system consists of three main parts. These include the device, PTS Panel® test strips, and a MEMO Chip® (included with each pot of test strips).

Turn the device on by pressing any button.

Install the memory (MEMO) chip into the top of the analyser, checking that the LOT number on the chip matches the LOT number on the test strips.

Take a test strip out of the pot and install it into the machine.

Wash/wipe sample-site with soap/alcohol/saline swab and allow to dry or wipe dry with lint-free tissue/swab.

Make sure the lancet is set to the correct setting. Use the lancet halfway between the side and the pad of the finger.

Apply gentle pressure to finger from base-up to obtain a good whole-blood sample. Hold the capillary between the two-coloured bands (keeping it at a horizontal angle) and collect the sample.

Once the capillary is filled to the black line dispense blood onto the test strip. The machine will start the test automatically after 2-3 seconds.

Once finished, the result will be displayed on the screen.