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1. Scope

This Standard Operating Procedure (SOP) applies to the staff and students using the Reflotron® in the laboratories of the Pharmacy Department, University of Malta.

2. Objective

To describe the procedure for the operation, quality control, maintenance and troubleshooting of the Reflotron®.

3. Definitions

3.1. Applicator: Used to facilitate the delivery of capillary blood onto the sample application area of a test strip.

3.2. Clinical Chemistry Parameter: A substance that can be quantified from a sample of whole blood, serum or plasma. The Reflotron® is capable of performing such quantitative tests on 12 different parameters i.e. glucose, haemoglobin, triglycerides, urea, γ-glutamyltransferase (GGT), uric acid, aspartate-aminotransferase (AST), alanine transaminase (ALT), bilirubin, amylase, cholesterol and creatinine. Refer to SOP/PD/321_02/A1 for further details on each of these parameters.

3.3. Control Material: Contains control sera that are used to test the performance of the Reflotron® and the Reflotron® Strips. Precinorm® U is the universal control material used for most tests whilst Precinorm® HB is used for the haemoglobin test. These should still be handled using the same caution employed when handling actual samples.

3.4. Dilution: Performed whenever a result lies above the measuring range of the particular test being carried out (refer to SOP/PD/321_02/A1 for details on how to carry out different dilution processes for the different clinical chemistry parameters).

3.5. Printer: An incorporated printing device within the Reflotron® System which prints out all the important information including results and error signals.

3.6. Reflotron® - Check Control Strip: A strip that contains a grey area with a defined reflectance value used for checking the performance of the optical system and also to help new users practice with the equipment.
3.7. **Reflotron® Pipette**: Used to deliver the volume of blood, serum and plasma onto the respective Reflotron® test strips. It is capable of delivering 32 μL of sample.

3.8. **Reflotron® System**: A reflectance photometer used for the quantitative determination of clinical chemistry parameters from whole blood, serum or plasma.

3.9. **Reflotron® Test Strip**: Reagent carrier used for the determination of clinical chemistry parameters from undiluted samples.

3.10. **Temperature Selector Switch**: To change the result of an enzyme determination according to temperature i.e. between 25°C, 30°C and 37°C.

3.11. **Units Selector Switch**: To change the units of substrate tests between conventional or SI units i.e. for glucose mg/dl or mmol/l, haemoglobin g/dl or mmol/l, cholesterol mg/dl or mmol/l, triglycerides mg/dl or mmol/l, urea mg/dl or mmol/l, uric acid mg/dl or μmol/l, bilirubin mg/dl or μmol/l and creatinine mg/dl or μmol/l.

4. **Responsibility**

4.1. The members of the Department of Pharmacy (staff and students) are responsible for following this SOP.

4.2. The designated Laboratory Officer or Laboratory Assistant is responsible for ensuring that this SOP is followed.

5. **Procedure**

5.1. **Operation**

5.1.1. Plug in the mains cable into a suitable mains electricity supply.

5.1.2. Plug in the mains cable into the mains connection socket at the rear of the equipment.

5.1.3. Switch On the mains electricity supply.

5.1.4. Push the black mains switch to the [I] position.

5.1.5. Wait until the following display messages are displayed consecutively: [0000000000000000], [REFLOTRON XXX], [WARMING UP XXX] and [READY]. If [REMOVE STRIP] is displayed instead, open measuring chamber flap and remove the strip or press the release lever if the measuring chamber is empty.
5.1.6. Slide the switch of the printer to the [I] position if printing of results is desired.

5.1.7. Remove a strip from the storage container that contains the abbreviation for the desired clinical chemistry parameter.

5.1.8. Check that the clinical chemistry parameter abbreviation on the strip coincides with that of its storage container.

5.1.9. Close the storage container immediately to protect the remaining strips from moisture.

5.1.10. Gently peel off the protective foil from the strip.

5.1.11. Place the strip into the insertion ledge of the Reflotron® System to anchor it whilst sample is being applied.

5.1.12. Working with samples of whole blood, serum or plasma

5.1.12.1. Attach a pipette tip to the Reflotron® pipette.

5.1.12.2. Depress the pipette plunger to the first stop whilst immersing tip in the sample.

5.1.12.3. Slowly release the pipette plunger to the original position to aspirate sample.

5.1.12.4. Remove the pipette tip from sample.

5.1.12.5. Wipe off any sample material if it is adhering to the outside of the pipette tip.

5.1.12.6. Gently depress the pipette plunger up to the second stop to eject the sample onto the red application zone of the test area.

5.1.12.7. Depress the pipette plunger further to eject the pipette tip into a sharps container.

5.1.12.8. Horizontally insert the strip in the transporter within 15 seconds of applying the sample to it.

5.1.12.9. Wait until [PLS CLOSE FLAP] is displayed to indicate that the strip has been inserted correctly.

5.1.12.10. Close the measuring chamber flap.

5.1.12.11. Wait until the abbreviation for the clinical chemistry parameter that is being tested is displayed together with the remaining test time.

5.1.12.12. Wait for the result to be displayed together with the concentration units. For enzyme determinations, temperature will also be displayed.

5.1.12.13. Set the units selector switch between [CON] and [SI] to select between displaying the results with conventional or SI units.
5.1.12.14. Set the temperature selector switch between 25, 30 or 37 to display the results of enzyme determinations at different selected temperatures.
5.1.12.15. Open the measuring chamber flap.
5.1.12.16. Press the release lever to remove the strip.
5.1.12.17. Discard the strip in a sharps container.
5.1.12.18. Push the black mains switch to the [O] position to switch off the equipment.

5.1.13. Working with Capillary Blood

5.1.13.1. Warm up the centre of the finger tip to be punctured.
5.1.13.2. Disinfect the site with a swab moistened with 70% alcohol.
5.1.13.3. Puncture the site using a suitable lancing device.
5.1.13.4. Wipe off the first drop of blood.
5.1.13.5. Push the dark-coloured end of a capillary pipette tip into its applicator until it meets resistance.
5.1.13.6. Slightly touch the free end of the capillary tube to the blood droplet to allow it to flow up to the coloured ring.
5.1.13.7. Wipe off any sample material if this is seen to be adhering to the outside surface of the capillary tube.
5.1.13.8. Press the button of the applicator to the first stop to dispense the sample onto the red application zone of the test area.
5.1.13.9. Push the button of the applicator to the second stop to eject the capillary tube into a sharps container.
5.1.13.10. Repeat steps 5.1.12.8 to 5.1.12.18.

5.2. Quality Control

5.2.1. Refer to sections 5.1.4. and 5.1.5. to switch on the device.
5.2.2. Push the measuring chamber flap right up.

5.2.3. Quality Control of the Optical System

5.2.3.1. Take out a control test strip from its storage vial.
5.2.3.2. Close the storage vial immediately to prevent entry of dust.
5.2.3.3. Insert the control strip with its brown magnetic tape pointing down and with its grey area near the leading edge.
5.2.3.4. Hold the strip horizontally and let it slide onto the transporter.
5.2.3.5. Push the control strip so that it is locked into position at the leading edge.

5.2.3.6. Wait until [PLS CLOSE FLAP] message is displayed. If this is not displayed, press the release lever and feed the control strip in again until it locks into position.

5.2.3.7. Close the measuring chamber flap.

5.2.3.8. Wait until [CHEK XX sec] is displayed to indicate that the control strip has been inserted correctly and the equipment has read and stored its full magnetic code.

5.2.3.9. Wait for [CHEK XXX XXX XXX] is displayed to indicate that the grey area has been scanned and that its reflectance has been measured at 3 different measuring wavelengths.

5.2.3.10. Compare the 3 readings displayed with the three ranges given on the storage vial of the control strips.

5.2.3.11. Repeat the test with a new control strip if one or more of the 3 readings does not coincide with those on the storage vial.

5.2.3.12. Clean the measuring chamber (refer to section 5.3.4) if reading/s still does not coincide and repeat test.

5.2.3.13. Open the measuring chamber flap.

5.2.3.14. Press the release lever to remove the control strip.

5.2.3.15. Close the measuring chamber flap to delete the readings.

5.2.4. Quality Control of Reflotron® and Reflotron® Strips

5.2.4.1. Open a bottle of control material and add to it exactly 2ml of redistilled water.

5.2.4.2. Close the bottle.

5.2.4.3. Occasionally swirl and invert the bottle to dissolve its content, avoiding foam build up.

5.2.4.4. Wait for the reconstitution time stated on the control material bottle to elapse.

5.2.4.5. Repeat steps 5.1.7 to 5.1.2.1 with the contents of the control material as the sample.

5.2.4.6. Compare the result obtained with the values specified in the table that is provided with the control material bottle.

5.2.4.7. Conduct the following steps if the value lies outside of the specified confidence limits:

5.2.4.7.1. Clean the measuring chamber (refer to section 5.3.4).

5.2.4.7.2. Check the expiry date of the strips and of the control material.
5.2.4.7.3. Check the performance of the optical system (refer to section 5.2.4).

5.2.4.7.4. Repeat the test with a new strip.

5.2.4.8. Conduct the following steps if the value still lies outside of the specified confidence limits:

5.2.4.8.1. Repeat the test using a new control material bottle and a strip from a new storage container.

5.3. Maintenance

5.3.1. Replacing Printer Paper Roll

5.3.1.1. Press the clip of the printer cover to remove it.
5.3.1.2. Slide the switch of the printer to the \([I]\) position.
5.3.1.3. Insert the loose end of the paper roll into the take-up slit.
5.3.1.4. Press the paper feed button.
5.3.1.5. Cut or fold diagonally the loose end of the paper roll if problems are encountered during the paper feed process.

5.3.2. Changing Printing Ribbon

5.3.2.1. Press the clip of the printer cover to remove it.
5.3.2.2. Slide the switch of the printer to the \([I]\) position.
5.3.2.3. Press down the narrow side of the ribbon cassette marked with \([PUSH]\).
5.3.2.4. Insert the new ribbon cassette.
5.3.2.5. Check that the paper is passing between the ribbon and the body of the ribbon cassette.

5.3.3. General Cleaning

5.3.3.1. Clean the outside of the equipment with a moist cloth and a mild cleaning agent.
5.3.3.2. Disinfect the outside of the equipment with a moist cloth and 70% alcohol solution if any spillages occur.
5.3.3.3. Use a brush to remove the dust accumulated on the air filter screen on the underside of the equipment at least once monthly.
5.3.4. Cleaning and Disinfecting the Measuring Chamber

5.3.4.1. Check that the mains switch is in the \[O\] position.
5.3.4.2. Push the flap of the measuring chamber upwards and keep supporting it this way with thumb.
5.3.4.3. Release the upper edge of the measuring chamber cover with the index and middle finger whilst still keeping the flap open with thumb.
5.3.4.4. Remove the measuring chamber cover.
5.3.4.5. Moist a small lint-free cloth with 70% alcohol.
5.3.4.6. Use the moist cloth to clean and disinfect the upper heater through a rotary action.
5.3.4.7. Gently wipe the transporter and the lower heater with the moist cloth.
5.3.4.8. Allow the measuring chamber to dry naturally for at least 10 minutes.
5.3.4.9. Attach the lower edge of the measuring chamber cover into position, keeping the flap open with thumb.
5.3.4.10. Push its upper edge into position, keeping the flap open with thumb.
5.3.4.11. Close the measuring chamber flap.
5.3.4.12. Allow the equipment to stand for at least 15 minutes before any operation.
5.3.4.13. Perform a quality control test of the optical system (refer to section 5.2.4) before performing any tests.
5.4. Troubleshooting

<table>
<thead>
<tr>
<th>Display Message</th>
<th>Cause/s</th>
<th>Solution/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>YYY (^1) (&lt;) XX.X (^2) mg/dl</td>
<td>Result is below the measurement range</td>
<td>Check that a sufficient amount of sample was properly transferred onto strip</td>
</tr>
<tr>
<td>YYY (&gt;) XXX.X mg/dl</td>
<td>Result is above the measurement range</td>
<td>Dilute the sample according to the test to be performed (refer to SOP/PD/321_02/A1)</td>
</tr>
<tr>
<td>YYY (&lt;) XXX.XX U/I XXC</td>
<td>Reaction did not follow linear kinetics</td>
<td>Repeat test possibly after diluting the sample (refer to SOP/PD/321_02/A1)</td>
</tr>
<tr>
<td>DILUTE YYY</td>
<td>- Enzyme activity is too high</td>
<td>Dilute sample according to the recommended procedure (refer to SOP/PD/321_02/A1)</td>
</tr>
<tr>
<td></td>
<td>- Sample colour is too intense</td>
<td></td>
</tr>
<tr>
<td>REMOVE STRIP</td>
<td>Used strip left in measuring chamber after switching on</td>
<td>Open flap and remove strip. If chamber is empty, press the release lever.</td>
</tr>
<tr>
<td>NO STRIP</td>
<td>Flap closed without inserting strip</td>
<td>Open flap and insert a new strip</td>
</tr>
<tr>
<td>NO PROGRAM</td>
<td>Processor received no data from strip</td>
<td>Check that brown magnetic tape of strip is pointing downwards and test area is pointing forwards</td>
</tr>
<tr>
<td>CODE ERROR</td>
<td>Processor received some but not the full set of data</td>
<td>Check that brown magnetic tape of strip is pointing down and test area is pointing forwards</td>
</tr>
<tr>
<td>MEAS. INTERRRUPT and PLS CLOSE FLAP</td>
<td>Measurement has been interrupted because flap was opened prematurely</td>
<td>Close flap and wait for some time</td>
</tr>
<tr>
<td>MEAS. INTERRRUPT and REMOVE STRIP</td>
<td>Measurement has been interrupted because flap was opened prematurely</td>
<td>Open flap - Remove used strip - Repeat test with a new strip - Ensure that strip is inserted correctly</td>
</tr>
<tr>
<td>Display Message</td>
<td>Cause/s</td>
<td>Solution/s</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------</td>
<td>------------</td>
</tr>
</tbody>
</table>
| **TEMP. XX.XC or TEMP. > 32C** | Temperature inside measuring chamber is too high | - Transfer equipment to a lower temperature location or decrease temperature of current location  
- Clean air filter (refer to 5.3.3.3) and let the equipment cool before switching it off |
| **TEMP. < 15C** | Temperature inside measuring chamber is too low | - Transfer equipment to a higher temperature location or increase temperature of current location  
- Let equipment warm up while it is switched on before performing further tests |
| CALL SERVICE 18 | Fault in power supply | Switch Off and On again |
| CALL SERVICE 22 | Excessive interference or excessive power fluctuations | Switch Off and On again and repeat analysis if [READY] is displayed. Call supplier if this is not displayed |
| CALL SERVICE 36 | The closing of the measuring aperture is obstructed possibly by contaminants | - Clean the measuring aperture  
- Switch Off and On again  
- Perform a quality control test on the optical system if [READY] is displayed (refer to section 5.2.4)  
- Repeat the analysis |
| CALL SERVICE 38 | Mechanical parts may be too stiff | - Check if there is any foreign body in the measuring chamber and if so remove it  
- Switch Off and On again  
- Repeat analysis if [READY] is displayed  
- If this is not displayed, contact supplier |
| CALL SERVICE XX | Unidentified error | - Switch Off and On again  
- If error reappears, contact supplier |
| No Display | No power supply received or equipment is out of order | - Switch Off and On again  
- If error re-appears, operate another equipment using the same electrical socket and check that the mains cable is appropriately inserted into mains connection socket |

1 Y denotes a letter  
2 X denotes a number
5.5. Flow Charts

5.5.1. Operation

- **Start**
  - Plug in mains cable into a suitable mains electricity supply
  - Wait until following display messages are displayed consecutively: 
    - [0000000000000000]
    - [REFLOTRON XXX]
    - [WARMING UP XXX] and [READY]
  - [REMOVE STRIP] displayed

- Open measuring chamber flap

- Measuring chamber empty

- Press release lever

- Printing of results desired

- Slide switch of printer to the [I] position

- No: Remove strip

- Yes: Slide switch to the [I] position
1. Remove strip from storage container that contains abbreviation for desired clinical chemistry parameter.

2. Check that clinical chemistry parameter abbreviation on strip coincides with that of storage container.

3. Close storage container immediately to protect remaining strips from moisture.

4. Gently peel off protective foil from strip.

5. Place strip into insertion ledge of Reflotron® System to anchor it whilst sample is being applied.

   a. Sample is whole blood, serum or plasma.
      - Yes: Attach pipette tip to Reflotron® pipette.
      - No: Capillary blood is used as sample.

   b. Depress pipette plunger to first stop whilst immersing tip in sample.

   c. Slowly release pipette plunger to original position to aspirate sample.

   d. Remove pipette tip from sample.

   e. Sample material adhering to outside of pipette tip.
      - Yes: Slightly touch free end of capillary tube to blood droplet to allow it to flow up to coloured ring.
      - No: Wipe off.

6. Warm up centre of finger tip to be punctured.

7. Disinfect site with swab moistened with 70% alcohol.

8. Puncture site using a suitable lancing device.

9. Wipe off first drop of blood.

10. Push dark-coloured end of capillary pipette tip into its applicator until it meets resistance.

11. Slightly touch free end of capillary tube to blood droplet to allow it to flow up to coloured ring.
Gently depress pipette plunger up to second stop to eject sample onto red application zone of test area

Depress pipette plunger further to eject pipette tip into sharps container

Horizontally insert strip in transporter within 15 seconds of applying sample

Wait until [PLS CLOSE FLAP] is displayed to indicate that strip has been inserted correctly

Close measuring chamber flap

Wait until abbreviation for clinical chemistry parameter being tested is displayed together with remaining test time

Wait for result to be displayed together with its concentration unit

Set units selector switch between [CON] and [SI] to select between displaying results with conventional or SI units

Displaying results of enzyme determination

Set temperature selector switch between 25, 30 or 37 to display result at different temperatures

Open measuring chamber flap

Press release lever to remove strip

Discard strip in sharps container

Sample material adhering to outside of capillary tube

Yes

Wipe off

Press button of applicator to first stop to eject sample onto red application zone of test area

Press button of applicator to second stop to eject capillary tube into sharps container

No
5.5.2. **Quality Control**

Start

Switch on the instrument (see sections 5.1.4. and 5.1.5.)

[REMOVE STRIP] displayed

Yes

Open measuring chamber flap

Measuring chamber empty

Yes

Press release lever

Push measuring chamber flap right up

Perform quality control of optical system

Yes

Take out control test strip from storage vial

Close storage vial immediately to prevent entry of dust

Insert control strip with its brown magnetic tape pointing down and with its grey area near leading edge

No

Remove strip

2

3
1. Hold strip horizontally and let it slide onto transporter

2. Push strip so that it is locked into position at leading edge

3. [PIS CLOSE FLAP] displayed
   - Yes: Close measuring chamber flap
   - No: Press release lever and feed control strip again until it locks into position

4. Wait until [CHEK XX sec] is displayed to indicate that control strip is inserted correctly and equipment has read and stored its full magnetic code

5. Wait for [CHEK XXX XXX XXX] to be displayed to indicate grey area has been scanned and its reflectance has been measured at 3 different measuring wavelengths

6. Compare 3 readings displayed with 3 ranges given on storage vial of control strips

7. All 3 readings coincide
   - Yes: Open measuring chamber flap
   - No: Repeat test with a new control strip

8. Open measuring chamber flap

9. Press release lever to remove control strip

10. Close measuring chamber flap to delete readings

11. Yes: Clean measuring chamber (refer to 5.5.3)
    - No: 3
Wait for reconstitution time stated on control material bottle to elapse

Follow operation flow chart for performing a test on whole blood, serum or plasma with contents of control material as the sample (Refer to 5.5.1)

Compare result obtained with values specified in table provided with control material bottle

Value lies outside specified confidence limits

Yes

Clean measuring chamber (refer to 5.5.3)

Check expiry date of strips and of control material

Perform quality control of optical system

No

Yes

Open bottle of control material and add to it exactly 2ml of redistilled water

Close bottle

Occasionally swirl and invert bottle to dissolve its contents, avoid foam build up

Perform quality control Reflotron® and Reflotron® Strips

No

Valid for: 2 years from approval
Repeat test with new test strip

Value still lies outside specified confidence limits

Repeating test:

- Repeat test using new control material bottle and strip from a new container

End
5.5.3. Maintenance

Start

- Need to replace printer paper roll
  - Press clip of printer cover to remove it
  - Slide switch of printer to [I] position
  - Insert loose end of paper roll into take-up slit
  - Press paper feed button

- Encountered problem during paper feed process
  - Cut or fold diagonally the loose end of the paper

- Need to change printing ribbon
  - Press clip of printer cover to remove it
  - Slide switch of printer to [I] position
  - Press down narrow side of ribbon cassette marked with [PUSH]
  - Insert new ribbon cassette
  - Check that paper is passing between ribbon and body of ribbon case

- Need to clean/disinfect outside of equipment
  - Clean with a moist cloth and a mild cleaning agent
  - Disinfect with a moist cloth and 70% alcohol
  - Use a brush to remove dust accumulated on air filter screen on underside of equipment at least once monthly

- Need to clean/disinfect measuring chamber
  - Check that black mains switch is in [O] position
  - Push flap of measuring chamber upwards and keep supporting it this way with thumb
  - Release upper edge of measuring chamber cover with index and middle finger whilst still keeping flap open with thumb
  - Remove measuring chamber cover
  - Moist a small lint-free cloth with 70% alcohol
1

2

Use moist cloth to clean and disinfect upper heater through a rotary action

Gently wipe transporter and lower heater with moist cloth

Allow measuring chamber to dry naturally for at least 10 minutes

Attach lower edge of measuring chamber cover into position, keeping flap open with thumb

Push upper edge into position, keeping flap open with thumb

Close measuring chamber flap

Allow equipment to stand for at least 15 minutes before any operation

Perform a quality control of optical system (refer to 5.5.2) before performing any tests

End
6. Precautions

6.1. Do not expose the equipment to direct sunlight.
6.2. Do not put the equipment near sources of heat like heaters or other equipment that radiate heat.
6.3. Keep the equipment at least 4m away from ultrasonic devices as this may affect the functioning of the equipment.
6.4. Operate the equipment in an ambient temperature of +15°C to +32°C.
6.5. Do not obstruct the vents that are located at the top of the equipment.
6.6. Always use a new control strip each time a quality control test is to be performed.
6.7. Do not put used control strips back into their storage vial.
6.8. Do not touch the grey area on a control strip to prevent changing its reflectance.
6.9. Do not perform any tests with expired strips.
6.10. Keep the strips away from strong magnetic fields.
6.11. Do not bend the strips in any way since this can damage the test area.
6.12. Avoid the inclusion of air whilst samples are being taken up by the pipette.
6.13. Do not touch the pipette tip with the test area while transferring samples.
6.14. Do not spray any cleaning agents directly into the measuring chamber.
6.15. Ensure that the measuring chamber flap is open whenever the measuring chamber cover is to be removed to prevent bending the release lever.
6.16. Handle control materials with the same caution as normal samples since these also contain sera.
6.17. Do not press the puncture site when handling capillary blood since this will increase the proportion of haemolysis.
6.18. When using capillary blood, gently dispense the sample onto the strip in order to prevent any possible splattering.
6.19. Store all test and control strips as well as control materials according to their appropriate storage instructions.

7. References


8. Appendices

SOP/PD/321_02/A1 – Clinical Chemistry Parameter Table
9. Revision History

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Amendments/ Reasons for change</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Initial Release</td>
</tr>
<tr>
<td>02</td>
<td>Inclusion of subheading titles of Procedure section in Table of Contents Update of entire SOP to Version 2</td>
</tr>
</tbody>
</table>
SOP/PD/321_02/A1 – Clinical Chemistry Parameter Table

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Abbreviation</th>
<th>Range of Measurement</th>
<th>Sample</th>
<th>Dilution &amp; Remarks</th>
</tr>
</thead>
</table>
| Glucose        | GLU          | 10.0 – 600mg/dl      | Fresh capillary or venous blood – use within 2-3 mins | 1+1 serum or plasma with serum or plasma having a defined glucose concentration C = 2Cv-Co  
|                |              | 0.56-33.3mmol/l      | Heparinised or EDTA blood – use within 10 mins | Were C = actual concentration C_o = defined concentration C_v = displayed concentration |
|                |              |                      | Serum – use within 2 hrs                    | Serum must be separated from cellular elements immediately after sedimentation and plasma immediately after sample collection |
|                |              |                      | Heparinised or EDTA plasma – use within 2 hrs | Serum, heparinised plasma or EDTA plasma samples may be kept in a closed container for 24 hr at +2 to 8°C |

| Haemoglobin    | HB           | 5.00-20.0g/dl        | Fresh capillary or venous blood – use within 2-3 mins | 1+1 with 0.9% NaCl solution C = 2C_v  
<p>|                |              | 3.10-12.4mmol/l      | EDTA, citrated or heparinised blood – keep in closed container and use within 24 hrs | Were C = actual concentration C_v = displayed concentration |
|                |              |                      | Adequately fill micro-cuvette of strip since values may be too low | Shake well EDTA, citrated or heparinised blood samples before use |</p>
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Abbreviation</th>
<th>Range of Measurement</th>
<th>Sample</th>
<th>Dilution</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triglycerides</td>
<td>TG</td>
<td>70.0-600mg/dl</td>
<td>Fresh capillary or venous blood – use within 2-3 mins</td>
<td>Serum or plasma at 1+1 with 0.9% NaCl solution</td>
<td>Do not freeze sample/s</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.80-6.86mmol/l</td>
<td>Heparinised or EDTA blood - keep in close container and use within 8 hrs</td>
<td>C = 2C_v</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Serum and EDTA or heparinised plasma – keep in closed container and use within 8 hrs if stored at +20-25°C or 24 hrs at +2-8°C</td>
<td>Were</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td>C=actual value</td>
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<td>Cv=displayed value</td>
<td></td>
</tr>
<tr>
<td>Urea</td>
<td>UREA</td>
<td>20.0-300 mg/dl</td>
<td>Fresh capillary or venous blood – use within 2-3 mins</td>
<td>Serum or plasma at 1+1 with 0.9% NaCl solution</td>
<td>When sedimentation of cellular elements takes place, supernatant plasma can be used provided that the sample is not shaken</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.33-50.0mmol/l</td>
<td>Heparinised or EDTA blood – keep in closed container and use within 8 hrs</td>
<td>C = 2C_v</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Serum and heparinised or EDTA plasma – keep in closed container and use within 24 hrs if stored at +15-25°C or 3 days at +2-8°C</td>
<td>Were</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C=actual value</td>
<td></td>
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<td>Cv=displayed value</td>
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<td></td>
<td>Do not use ammonium heparinate as an anticoagulating agent</td>
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<td></td>
<td>Presence of deeply coloured individual spots on test zone are due to dispensing</td>
</tr>
<tr>
<td>Parameter</td>
<td>Abbreviation</td>
<td>Range of Measurement</td>
<td>Sample</td>
<td>Dilution</td>
<td>Remarks</td>
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</tbody>
</table>
| GGT       | GGT          | 5.00-approx. 3500U/I at 37°C | Fresh capillary or venous blood – use within 2-3 mins | Serum or plasma at 1+1 with 0.9% NaCl solution | A = 2Aᵥ
<pre><code>        |              | 3.85-approx. 2700U/I at 30°C | Heparinised or EDTA blood – keep in closed container and use within 8 hrs | Were A=actual enzyme activity | Aᵥ=displayed enzyme activity |
        |              | 2.80-approx. 2000U/I at 25°C | Serum and heparinised or EDTA plasma – keep in closed container and use within 7 days if stored at +2-25°C | When sedimentation of cellular elements takes place, supernatant plasma can be used provided that the sample is not shaken |
</code></pre>
<p>| Uric Acid | UA           | 2.00-20.0mg/dl 120-1190umol/l | Fresh capillary or venous blood – use within 2-3 mins | N/A | When sedimentation of cellular elements takes place, supernatant plasma can be used provided that the sample is not shaken |
|           |              |                      | Heparinised blood – keep in closed container and use within 8 hrs | Serum and heparinised plasma – keep in close container and use within 5 days if stored at +2-25°C | Only heparin may be used as an anticoagulant |</p>
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Abbreviation</th>
<th>Range of Measurement</th>
<th>Sample</th>
<th>Dilution</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST (GOT)</td>
<td>GOT</td>
<td>5.00-approx. 1500U/I at 37°C</td>
<td>Fresh capillary or venous blood – use within 2-3 mins</td>
<td>Serum or plasma at 1+4 with 0.9% NaCl</td>
<td>Only heparin may be used as an anticoagulant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.25-approx. 975U/I at 30°C</td>
<td>Heparinised blood – keep in close container and use within 1 hr</td>
<td>A = 5A_v</td>
<td>Supernatant plasma can be used after sedimentation of the cellular components has occurred</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.25-approx. 675 U/I at 25°C</td>
<td>Serum and heparinised plasma – keep in close container and use within 8 hrs if stored at +20-25°C or for 3 days if stored at +2-8°C</td>
<td>A_v = displayed enzyme activity</td>
<td></td>
</tr>
<tr>
<td>ALT (GPT)</td>
<td>GPT</td>
<td>5.00-approx. 2000U/I at 37°C</td>
<td>Fresh capillary or venous blood – use within 2-3 mins</td>
<td>Serum or plasma at 1+1 with 0.9% NaCl</td>
<td>Only heparin may be used as an anticoagulant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.80-approx. 1520U/I at 30°C</td>
<td>Heparinised blood – keep in closed container and use within 1 hr</td>
<td>A = 2A_v</td>
<td>Supernatant plasma can be used after sedimentation of the cellular components has occurred</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.66-approx. 1060U/I at 25°C</td>
<td>Serum and heparinised plasma – keep in closed container and use within 8 hrs if stored at +20-25°C or within 3 days if stored at +2-8°C</td>
<td>A_v = displayed enzyme activity</td>
<td></td>
</tr>
<tr>
<td>Parameter</td>
<td>Abbreviation</td>
<td>Range of Measurement</td>
<td>Sample</td>
<td>Dilution</td>
<td>Remarks</td>
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<tr>
<td>Bilirubin</td>
<td>BIL</td>
<td>0.5-12mg/dl</td>
<td>Fresh capillary or venous blood – use within 2-3 mins</td>
<td>Serum or plasma at 1+1 with 0.9% NaCl</td>
<td>When sedimentation of the cellular elements takes place, supernatant plasma can be used provided that the sample is not shaken. Cannot use test in neonates. Store samples in the dark since bilirubin is a light sensitive substance.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8.5-204 µmol/l</td>
<td>Heparinised blood – keep in closed container and use within 2 hrs</td>
<td>C = 2C&lt;sub&gt;v&lt;/sub&gt;</td>
<td>C&lt;sub&gt;v&lt;/sub&gt;=displayed value</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Serum and heparinised plasma – keep in closed container and use within 2 hrs if stored at +4-25°C</td>
<td>Were</td>
<td></td>
</tr>
<tr>
<td>Amylase</td>
<td>AMYL</td>
<td>60-approx. 1800 U/I at 37°C</td>
<td>Fresh capillary and venous blood – use within 2-3 mins</td>
<td>Serum or plasma at 1+2 with 0.9% NaCl</td>
<td>Only heparin may be used as an anticoagulant. When sedimentation of the cellular elements takes place, the supernatant plasma can be used provided that the sample is not shaken.</td>
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<tr>
<td></td>
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<td>44.4-approx. 1330U/I at 30°C</td>
<td>Heparinised blood – keep in closed container and use within 8 hrs</td>
<td>A = 3A&lt;sub&gt;v&lt;/sub&gt;</td>
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<tr>
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<td>34.8-approx. 1050U/I at 25°C</td>
<td>Serum and plasma – enzyme activity after 5 days falls by 0% at both +4°C and +20-25°C</td>
<td>Were</td>
<td></td>
</tr>
<tr>
<td>Parameter</td>
<td>Abbreviation</td>
<td>Range of Measurement</td>
<td>Sample</td>
<td>Dilution</td>
<td>Remarks</td>
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<tr>
<td>Cholesterol</td>
<td>CHOL</td>
<td>100-500mg/dl</td>
<td>Capillary or venous blood</td>
<td>EDTA or heparinised blood</td>
<td>See test strip package insert for more details</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.59-12.9mmol/l</td>
<td>EDTA or heparinised blood</td>
<td>EDTA or heparinised plasma</td>
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<td>Serum</td>
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<td>Capillary or venous blood</td>
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<td>EDTA or heparinised blood</td>
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<td>EDTA or heparinised plasma</td>
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<td>Serum</td>
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<td>Pre-diluted urine</td>
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<tr>
<td>Creatinine</td>
<td>CREA</td>
<td>0.50-10.0mg/dl</td>
<td>Capillary or venous blood</td>
<td>EDTA or heparinised blood</td>
<td>See test strip package insert for more details</td>
</tr>
<tr>
<td></td>
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<td>44.5-884µmol/l</td>
<td>EDTA or heparinised blood</td>
<td>EDTA or heparinised plasma</td>
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<td>Serum</td>
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<td></td>
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<td>Pre-diluted urine</td>
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</table>