Reflotron® Plus Training Manual

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CONTACTS

Una Health Ltd – Customer Support 01782 575180

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Overview and Scope of this Training Guide

The training session will cover the contents of this guide. It is not intended as a replacement for the Reflotron® Plus user manual nor is it intended to replace the inserts that are supplied with the individual test kits, but will provide a good basic understanding of the system.

During the training session you will be given the opportunity to practice taking blood, run samples and QC and ask any questions you may have.

The training guide covers the following topics:

- Introduction/Clinical Background
- Principals of Method
- Collection Procedures
- Specimen Requirements
- Equipment/Reagents
- Operational procedure
- Reporting/Reviewing Results
- Quality Control & Calibration
- Training/Competency Assessment
- Knowledge Assessment
- Basic Troubleshooting
- Risk Assessment
- COSHH/MSDS

At the end of the training session you will have:

- a signed Training/Competency Assessment
- a signed Knowledge Assessment
- a signed Risk Assessment
- a Certificate

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CLINICAL BACKGROUND

(All information, instructions and pictures referring to the Reflotron® Plus Analyser and Reagent Test strips are taken from the Roche/Diavant website and courtesy of E C Hamer BSc(Hons), MSc, FIBMS.)

With the 17 clinical-chemical parameters detectable by the available Reflotron®® Test Strips, the most important indications in primary care are covered for such health problems as diabetes, lipid disorders, kidney diseases, muscle diseases, anaemia, liver diseases, pancreatitis, gout, and bone disorders.

Alkaline Phosphatase (ALP)

The main indications for determination of alkaline phosphatase (ALP) are suspicion of cholestatic liver disease, bone disease and skeletal involvement of other primary diseases. In most cases other additional tests are needed to differentiate the cause of abnormal ALP values

Amylase

α-Amylase is mainly formed in the parotid gland and the pancreas. Under normal conditions serum amylase consists of about 40 % pancreatic amylase and 60 % salivary amylase. Elevated serum α-Amylase levels are most often seen in pancreatitis, so a α-Amylase determination is primarily carried out for diagnosis and therapeutic monitoring of acute as well as of chronic pancreatitis.

Pancreatic Amylase

The real diagnostic value of the pancreatic amylase - in contrast to total amylase - is its usefulness in screening for pancreatitis because of the very high sensitivity and specificity of the test

Bilirubin

Bilirubin is a yellow-brown bile pigment which is responsible for the yellow-brown colour in serum. Bilirubin is a substrate that is mainly produced during the degeneration of haemoglobin in the liver-spleen system. There are two kinds of bilirubin. The first one is bound to albumin, and called “unconjugated” or indirect bilirubin. The second type of bilirubin is, in contrast to the first, conjugated with glucuronic acid and therefore known as “conjugated” or “direct bilirubin”. This conjugation takes place in the liver cells. Therefore the differentiation allows conclusions to be made about the origin of bilirubin.

Jaundice occurs when the bilirubin concentration rises above approximately 2 mg per 100 ml serum. The most common forms of are characterised by an increase of conjugated bilirubin.

Glucose

Measurement of blood glucose is predominantly indicated to screen for, to detect and to control hyperglycaemia due to diabetes mellitus as well as to monitor its treatment. Also, it serves to diagnose suspected hypoglycaemia. Impaired fasting glucose and impaired glucose tolerance are observed as pre-diabetes, and they are associated with a high risk for developing diabetes. There is also growing evidence that people with impaired fasting glucose are at an increased risk for micro- and macrovascular complications. The recognition of diabetes and following the progress of the disease in primary care are of prime importance in the medical practice

Creatine Kinase / CK

Creatine kinase (CK) is an enzyme that mainly occurs in muscles, heart and brain. Determination of CK activity is used for the diagnosis and monitoring of myocardial infarction and the monitoring of muscle diseases such as Duchenne progressive muscular dystrophy. Coronary heart disease and similar diseases are among the most frequent causes of death or early invalidity. In myocardial damage, such as in acute myocardial infarction, CK is released from destroyed myocardial cells. An increase of CK activity in the blood can be detected as early as 4 hours after the infarction. CK activity reaches its peak after 12 - 24 hours and returns to the reference range after 4 - 5 days

Haemoglobin

Haemoglobin (Hb) is the red blood pigment of the erythrocytes. It is the major carrier of the iron contained in the body (approx. 70 %). The function of haemoglobin is to transport oxygen from the lungs to the tissues, and the carbon dioxide produced by metabolism from the tissues back to the lungs. Decreased levels of haemoglobin together with haematocrit and red blood cell count indicate anaemia, so screening the haemoglobin value is useful for the diagnosis of anaemia, the assessment of the course of disease and response to treatment.
In addition the diagnosis has to be based on case history, clinical examination and laboratory results.

Cholesterol

Determination of total cholesterol is essential for primary and secondary prevention of cardiovascular diseases, since it is the prime risk factor for atherosclerosis and coronary heart disease (CHD). Therefore accurate measurement of cholesterol level is a mandatory part of CHD risk assessment. Attention should also be paid to the assessment of HDL cholesterol, LDL cholesterol, and triglycerides as independent CHD risk factors

HDL

High-density lipoprotein cholesterol (HDL cholesterol) has anti-atherosclerotic and cardio protective properties. For this reason, there is an inverse association between HDL cholesterol and cardiovascular risk. A low HDL cholesterol level is an independent risk factor for atherosclerosis and coronary heart disease (CHD), even in individuals with low LDL cholesterol levels. HDL cholesterol levels should therefore routinely be assessed by primary care providers as part of a lipid profile which also includes total cholesterol, LDL cholesterol, and triglycerides.

Triglycerides

Up to 30 percent of the population has elevated triglyceride values. Elevated triglyceride levels are an independent risk factor for cardiovascular diseases, commonly associated with other lipid and non lipid risk factors (e.g. high blood pressure), and metabolic diseases such as diabetes and obesity. Elevation of both LDL cholesterol and triglycerides indicates a particularly high cardiovascular risk. Thus the need to detect, monitor and treat elevated triglyceride levels in order to prevent cardiovascular diseases is of high importance.

GGT

γ (Gamma)-Glutamyltransferase (GGT) is a highly sensitive parameter for numerous disorders with involvement of the liver, but it can also be found in pancreatic, renal disorders, and myocardial infarction. Usually it is regarded as one of the enzymes that indicate cholestasis. As GGT values rise before liver damage becomes evident this enzyme is especially important for diagnosis of anicteric or symptomless forms of disease. If the values increase two-fold or more above the upper reference level, a parenchymal liver damage has to be considered.
However, unexplained mild elevations are common and may occur even after moderate alcohol intake. For differential diagnosis it is therefore reasonable to take into account other enzyme parameters like GPT, GOT, ALP or bilirubin, in addition to GGT.

GOT (AST)

Glutamic-oxaloacetic transaminase (GOT) - also known as aspartate aminotransferase or AST, is an enzyme found in the mitochondrion and cytoplasm of all cells. The evaluation of GOT (AST) activity is a basic procedure for the diagnosis and the monitoring of hepatocellular disorders or muscle damage. The increase in GOT (AST) correlates in general well with the extent and severity of cellular damage. The differential diagnosis of liver disease requires the determination of GPT, ALP & GGT in addition to GOT. The ratios of creatine kinase/GOT and GOT/GPT may provide further information about the organ damaged (liver vs. muscle) and the severity of the disease.

GPT (ALT)

Glutamic-pyruvic transaminase (GPT) - also known as alanine aminotransferase or ALT - is a cytoplasmic hepatocellular enzyme, whose increase in blood is highly indicative for liver damage, e.g. by hepatitis, cirrhosis or hepatic tumours.
Serum values more than 15-fold above the upper reference limit always indicate an acute hepatocellular damage of either viral, toxic or circulatory origin. In most types of liver disease GPT activity is higher than that of GOT, an exception is in alcoholic hepatitis. The ratio of GPT and GOT may provide further information about the severity of the disease and may serve as a prognostic indicator

Potassium

The human body normally contains approximately 50 mmol potassium per kg body weight. 98 % of it is found in cells and only 2 % is found in extra-cellular fluids. This concentration gradient plays a major role in maintaining the membrane potential of the cells. This electric potential is responsible for the excitability of muscles and nerves - including the heart. Potassium is also influenced by acid-base disturbances (e.g. treatment of very high blood glucose concentrations with insulin, which can cause hypokalaemia). Potassium is mainly excreted by the kidneys (90 %) and to a minor degree in the faeces (10 %).
Disorders of the water and electrolyte balance occur mainly as a consequence of other diseases. They may characteristically alter the underlying disease or may occur as a complication of the clinical picture.

Creatinine

Creatinine is the most important marker for renal function, because it is steadily produced in the muscles and excreted via the kidneys in the urine. Renal insufficiency will cause a rise in serum creatinine levels because it is not excreted in the normal quantities and accumulates in the blood.

Urea

Urea is the most important breakdown product of protein metabolism and is produced in the liver. Adults accumulate approximately 16 g of urea daily. This amount is mainly eliminated via the kidneys through glomerular filtration. About 40 - 50 % of urea is partially reabsorbed in the tubules. The rest is excreted via the intestines and perspiration.
Elevated urea levels are a clearly indication of renal insufficiency, but creatinine and urea do not reflect renal insufficiency to the same degree. Therefore both parameters should be tested at the same time to determine the degree of renal insufficiency.

Uric acid

Uric acid is the end product of purine metabolism. A large proportion of the purines in food will be reused, while the rest is degraded to uric acid. Up to 70 - 80 % of uric acid is excreted via the kidneys, and an additional 20 - 30 % leaves the body via the intestines.
Hyperuricaemia is the hallmark of gout. In most cases hyperuricaemia is due to a disorder of uric acid excretion by the kidneys. In rare cases, it is caused by an enzyme defect resulting in an increase of purine degradation and overproduction of uric acid. Determination of the uric acid concentration in the blood allows you to evaluate the patient's risk, to diagnose and to monitor the therapy of gout or kidney stones.

PRINCIPLES OF METHOD

The Reflotron®® Plus is an in vitro diagnostic device designed for the quantitative determination of clinical chemistry parameters using Reflotron®® Test reagent strips. It works on the principle of reflectance photometry and ensures rapid and reliable results while being easy to use.

An incorporated plasma separating system in the Test strips make it possible to use whole blood (capillary or venous) aswell as plasma and serum,

A reflectance measurement is recorded based on the colour change on the test strip:

Reflotron® Alkaline Phosphatase
Rapid test results from whole blood

Test principle

o-cresolphthalein phosphate + methylglucamine $\xrightarrow{ALP}$ o-cresolphthalein + methylglucamine phosphate

Measuring range >>20 – 1250U/L

Reflotron® Amylase
Rapid test results from whole blood

Test principle

indolyl-α,D-maltoheptaoside $\xrightarrow[\alpha\text{-glucosidase}]{\alpha\text{-amylase}}$ indolyl + glucose

indolyl + 2-methoxy-4-morpholinophenyldiazoniumtetrachlorozinkate → purple dye

Measuring Range >> 29 – 860U/L

Reflotron® Bilirubin

Rapid test results from whole blood

Test principle: Bilirubin + 2-methoxy-4-nitrophenyldiazoniumtetrafluoroborate → azobilirubin
Indirect bilirubin is released by means of dyphilline

Measuring Range >>8.5 - 205µmol/L

Reflotron® Cholesterol

Rapid test results from whole blood

Test principle:

$$\text{cholesterol ester} + H_2O \xrightarrow{\text{cholesterol esterase}} \text{cholesterol} + \text{RCOOH}$$

$$\text{cholesterol} + O_2 \xrightarrow{\text{cholesterol oxidase}} \text{cholestenone} + H_2O_2$$

$$H_2O_2 + \text{indicator} \xrightarrow{\text{POD}} \text{dye} + H_2O$$

Measuring Range >>2.59 – 12.9 mmol/L

Reflotron® CK

Rapid test results from whole blood and urine

Test principle:

$$\text{creatine phosphate} + \text{ADP} \xrightarrow{\text{CK}} \text{creatine} + \text{ATP}$$

$$\text{glycerol} + \text{ATP} \xrightarrow{\text{GK}} \text{glycerol-3-P} + \text{ADP}$$

$$\text{glycerol-3-P} + O_2 \xrightarrow{\text{GPO}} \text{dihydroxyacetone phosphate} + H_2O_2$$

$$H_2O_2 + \text{indicator (red.)} \xrightarrow[\text{POD}]{} \text{indicator (ox.)} + H_2O$$

Measuring Range >> 37^0C 24.4 - 1400 IU/L

30^0C 15.4 - 900 IU/L

25^0C 10.0 - 600 IU/L

Reflotron® Creatinine

Rapid test results from whole blood and urine

Test principle

creatinine + H_2O $\xrightarrow{\text{creatinine iminohydrolyse}}$ N-methylhydantoin + NH_3

N-methylhydantoin + H_2O + ATP $\xrightarrow{\text{N-methylhydantoinase}}$ N-carbamoylsarcosine + ADP + P_i

N-carbamoylsarcosine + H_2O $\xrightarrow{\text{carbamoylsarcosine hydrolase}}$ sarcosin + CO_2 + NH_3

sarcosine + H_2O + O_2 $\xrightarrow{\text{sarcosine oxidase}}$ glycine + HCHO + H_2O_2

H_2O_2 + indicator $\xrightarrow{\text{peroxidase}}$ dye+ H_2O

Measuring Range >>44.5 - 884 µmol/L

Reflotron® GGT

Rapid test results from whole blood

Test principle

glycylglycine + γ-glutamyl-3-carboxy-1,4-phenylenediamine $\xrightarrow{\text{γ-GT}}$ γ-glutamylglycylglycine + 3-carboxy-1,4-phenylenediamine

3-carboxy-1,4-phenylenediamine + N-methylanthranilic acid + 6 $[Fe(CN)_6]^{3-}$ $\longrightarrow$ dye + 6 $[Fe(CN)_6]^{4-}$

Measuring Range >> 37^{0}C 5.0 - 3500U/L

30^{0}C 3.85 - 2700U/L

25 ^{0}C 2.80 - 2000U/L

Reflotron® Glucose

Rapid test results from whole blood

Test principle

glucose + O_2 $\xrightarrow{\text{GOD}}$ δ-D-gluconolactone + H_2O_2

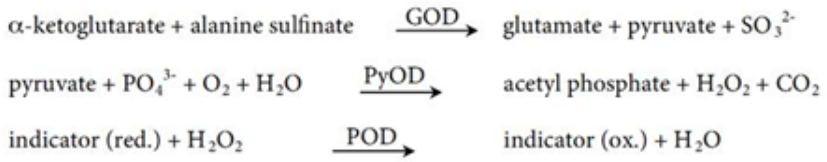
H_2O_2 + indicator $\xrightarrow{\text{POD}}$ dye + H_2O

Measuring Range >>0.56 – 33.3mmol/L

Reflotron® GOT (AST)

Rapid test results from whole blood

Test principle



Endogenous pyruvate is eliminated in a pre-reaction.

Measuring Range >> 37^0C 5.0 - 500U/L

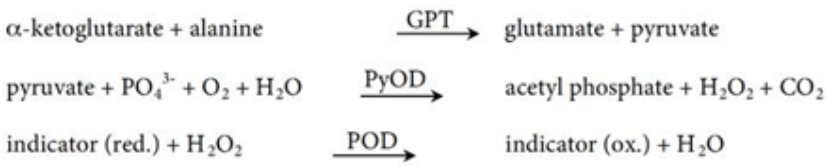
30^0C 3.25 - 325U/L

25^0C 2.25 - 225U/L

Reflotron® GPT (ALT)

Rapid test results from whole blood

Test principle



Endogenous pyruvate is eliminated in a pre-reaction.

Measuring Range >> 37^0C 5.0 - 2000U/L

30^0C 3.8 - 1520U/L

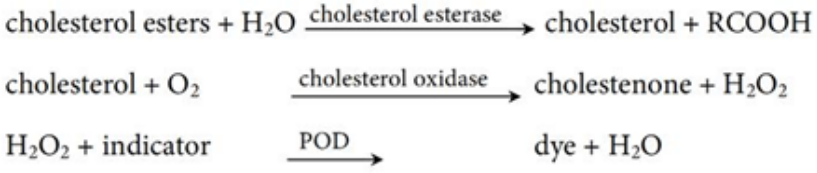
25^0C 2.66 - 1060U/L

Reflotron® HDL Cholesterol

One step test

Test principle

After the application of the EDTA plasma sample to the reagent carrier, LDL fractions and chylomicrons are precipitated by means of magnesium ions and dextran sulphate.

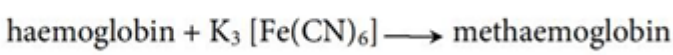


Measuring Range >>0.26 – 2.59mmol/L

Reflotron® Hemoglobin

Rapid test results from whole blood

Test principle



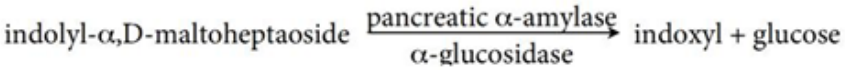
Measuring Range >>5.0 – 20.0g/dl

Reflotron® Pancreatic Amylase

Rapid test results from whole blood

Test principle

The salivary amylase is inhibited by two different monoclonal antibodies.



indoxyl + 2-methoxy-4-morpholinophenyldiazonium tetrachlorozinkate

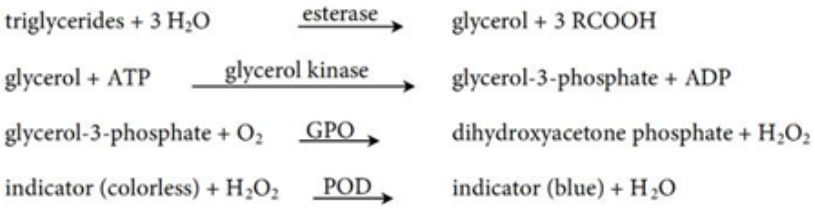
→ purple dye

Measuring Range >>14 - 850U/L

Reflotron® Triglycerides

Rapid test results from whole blood

Test principle



Measuring Range >>0.80 – 6.86mmol/L

Reflotron® Urea
Rapid test results from whole blood

Test principle

$$(NH_2)_2CO + H_2O \xrightarrow{\text{urease}} 2\,NH_3 + CO_2$$

$$NH_3 + \text{indicator (yellow)} \longrightarrow NH_4^+ + \text{indicator (blue)}$$

Measuring Range >>3.33 – 50.0mmol/L

Reflotron® Uric Acid
Rapid test results from whole blood

Test principle

$$\text{uric acid} + O_2 + H_2O \xrightarrow{\text{uricase}} \text{allantoin} + H_2O_2 + CO_2$$

$$H_2O_2 + \text{indicator} \xrightarrow{\text{POD}} \text{dye} + H_2O$$

Measuring Range >>120 - 1190µmol/L

Reflotron® K^+ (Potassium)
Rapid test results from plasma, serum

Test principle

In the two-phase reaction film, the potassium diffuses from the aqueous phase into the organic phase where it forms a complex with valinomycin. To balance the charge, a pH indicator dissolved in the organic phase gives off a proton and forms a coloured anion. An optimum change of the reflectance is achieved by addition of a strong acid, which forms a colorless anion, to compete with the indicator.

Measuring Range >>2.0 – 12.0mmol/L

LDL cholesterol may be calculated using Cholesterol, Triglycerides, HDL results and the Friedewald formula in the inbuilt software

HAZARD WARNINGS

See COSHH & Risk Assessments (Appendix 4 & 5)

RESPONSIBILITIES

Personal Liability

The healthcare provider on duty at the time a person accesses the service has overall responsibility for the service provision, whether or not they are personally undertaking the test.

It must be someone who has been trained by Una Health Ltd that undertakes the test.

Consultation area requirements

The consultation area must be used to conduct the blood test and to communicate results. Ensure:

- It is clean and tidy – a cleaning and disinfecting rota should be in place to ensure that cleanliness standards are achieved.
- It has 2 chairs & small table (or suitable workbench).
- Access to a supply of warm water.
- The paperwork, support material & equipment are available.
- Relevant health advice leaflets & information are on display.

Health & Safety

- Any accidental blood contamination of equipment or surfaces must be cleaned immediately with disinfectant in accordance with standard operating procedures, whist still wearing protective clothing.
- Personal Protective Equipment (PPE) must be available at all times
- No food or drink is consumed in the area.
- No smoking allowed in the area.
- Correct waste disposal procedures are followed according to standard operating procedures.

(UK Health Depts., Guidance for Clinical Healthcare Workers: Protection against infection with Blood Bourne Viruses, Dept. Of Health (DOH) 1998)

COLLECTION PROCEDURES

Sample type – requires fingerstick collection of whole blood

Healthcare provider must:

- Wash & dry their hands thoroughly
- Ensure any cuts or grazes are covered with a plaster
- Put on protective gloves

Ask the client to wash & dry their hands thoroughly, if there is no sink in the consultation area you should supply the client with:

- A small bowl of hot soapy water and paper towels to dry their hands OR
- A non alcohol based hand cleaning solution that does not require water
- Ask client to rub hands together to induce better circulation
- Offer a plaster at the end of the procedure

The following procedure should be adopted if the client feels unwell at any time during the test

- Stop the test
- Allow the client to remain seated until they feel well again
- Offer the client a drink of water
- After recovery, ask the client if they wish to proceed with the test
- Arrange an alternative appointment if required

The following procedure should be adopted if there is any risk that exposure to Hepatitis B infection has taken place e.g. blood to blood contact

- Immediately wash out the wound thoroughly with soap & water
- Immediately contact the nearest hospital accident & emergency dept to seek medical advice
- Record the incident in the accident book
- Advise the Line Manager

(UK Health Depts., Guidance for Clinical Healthcare Workers: Protection against infection with Blood Bourne Viruses, Dept. Of Health (DOH) 1998)

SPECIMEN REQUIREMENTS

- Preferred volume of whole blood is 32µl. (minimum 30µl)
- Sample material capillary or venous blood, heparinised/EDTA blood, plasma, serum (See Appendix 1 for individual tests as requirements do vary))
- The sample should be tested immediately.
- No storage required.
- Specimen must be disposed of as clinical waste.
- Using the Reflotron® Potassium (K) test, samples can be heparinised venous plasma or serum. Capillary or haemolytic sample material is unsuitable to determine potassium. Other anticoagulants, especially anticoagulants containing potassium, may not to be used.
- Using Reflotron® Uric Acid, only heparins should be used as an anticoagulant. Other anticoagulants should not be used.
- Reflotron® Pancreatic Amylase, urine can also be used as sample material.
- Reflotron® Bilirubin cannot be used for tests on neonates due to the specific rheological and physiological properties of this sample material.

EQUIPMENT & REAGENTS

Equipment & Material Supplied:

The Reflotron® Plus Analyser

Power cable

Keyboard

Workstation

Single use lancets

Reflotron® test strips

Clean & Check strips

32µl pipette & tips

Blood collection tubes (EDTA/Heparin)

Plastic coated capillary tubes & applicator

Workstation

Equipment & Material NOT Supplied:

Clinical waste disposal service

Information booklets & leaflets

Hand washing/sanitizing facilities

Yellow clinical waste containers

Protective gloves

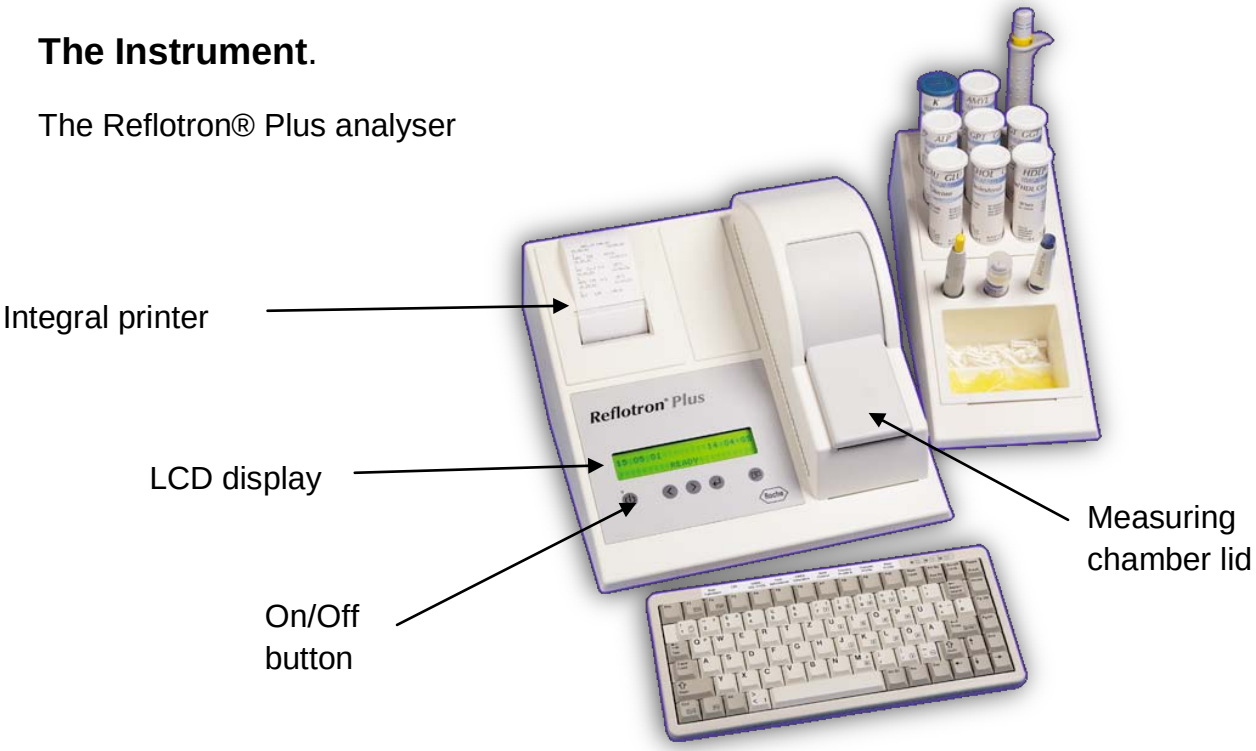
Alcohol swabs

Sterile gauze swabs

Sharps disposal bins (yellow)

The Instrument.

The Reflotron® Plus analyser



Specifications

Analyser

Weight – approx. 5.3 kg

Size – 300 x 350 x 210mm

Display – alpha numeric, 2 lines each with 24 characters, LCD

Connections – 1 RS 232, Keyboard, 5 pin DIN

Data Memory Capacity – 60 results

Power Supply

Mains – 115 – 230 v AC

Operating Conditions

Temperature – +15^{o}C to +34^{o}C

Humidity – 95% max

Storage/Transport

Temperature - -20^{o}C to +55^{o}C

Humidity – 5 – 95%

Operational details

Connection to the power supply does not turn the analyser on, there is an on/off button on the front of the instrument

Automatic start up procedure and a warming up time follow.

The instrument is set up using the buttons on the front of the analyser.

At the end of the test, the result is displayed on the screen.

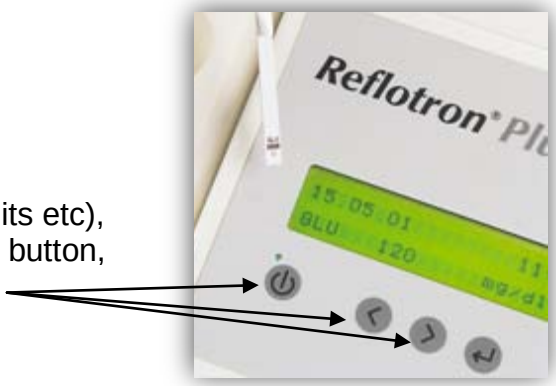
All parameter – specific data are encoded in the magnetic strip on the reverse side of the test strip

Results are stored in the Analyzer memory, Up to 60 patient & control results can be stored on the analyser.

The analyser is calibrated by the manufacturer and there are no user-serviceable parts.

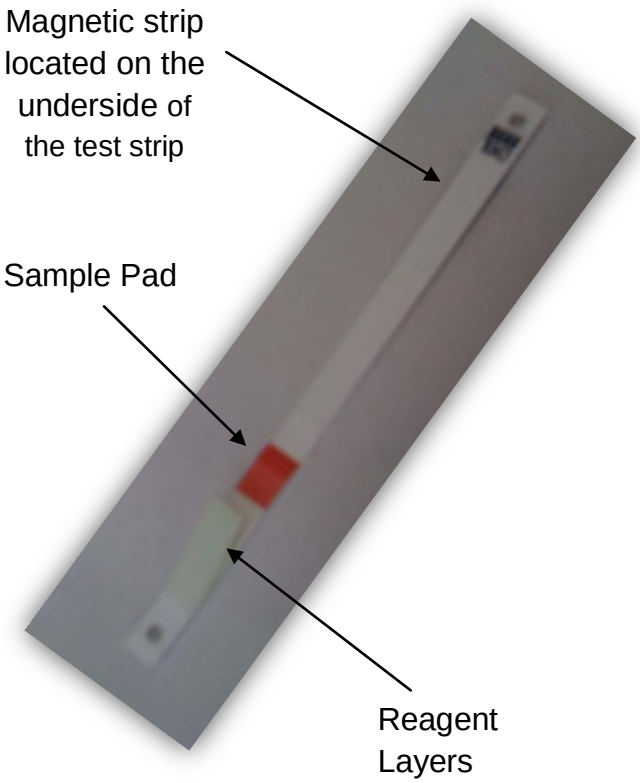
Daily maintenance required comprised of cleaning the instrument and running a check strip

To enter the main set up menu (language, units etc), with the analyser switched off, press the start button, and the left & right arrows simultaneously.



To enter the short menu (change date/time etc), with the analyser switched on press the left and right arrow simultaneously

The Test Strips



- No preparation required
- Storage conditions – most at RT (see Appendix 2 for individual tests)
- The test strip containers have desiccants contained in the lids to keep the strips dry. The lid must be replaced after every opening.
- Once the strip has been removed it must be used within the hour
- Once the blood sample has been added , the test strip must be tested immediately
- Shelf life – 6 – 12 months (see expiry date on strip container)
- Must be disposed of as clinical waste

Calibration

- No calibration required – all calibration information is stored on the magnetic strip on the reverse of the test strip

METHOD

Stage 1 - Preparation of the Test System

Starting up the Reflotron®

- Ensure that the Reflotron® is set up away from direct sunlight and sources of heat (radiators, heaters or instruments that radiate heat). Room temperature should be between +15^{0}C and +34^{0}C.

- Plug the power cable into the back of the Reflotron® and then into a normal 240v wall socket.

- Switch power on at the wall.

- Switch Reflotron® to “ON” by pressing the power switch on the front of the instrument.

- The Reflotron® will then warm up and conduct some self-checks before displaying the message “READY”.

NB. Never obstruct the vents or fan outlets on the instrument.

Daily Maintenance

a) Clean and Check Strip

The check strips are special strips which are used to check the optical system.

Running a Clean & Check Strip

- Open the container and remove one Check Strip, replace lid

- Open the lid of the measuring chamber and insert the check strip. Close the measuring chamber lid
- The Reflotron® will now read the magnetic strip on the underside of the Check Strip and will automatically begin the test
- The Check takes approximately 1 minute

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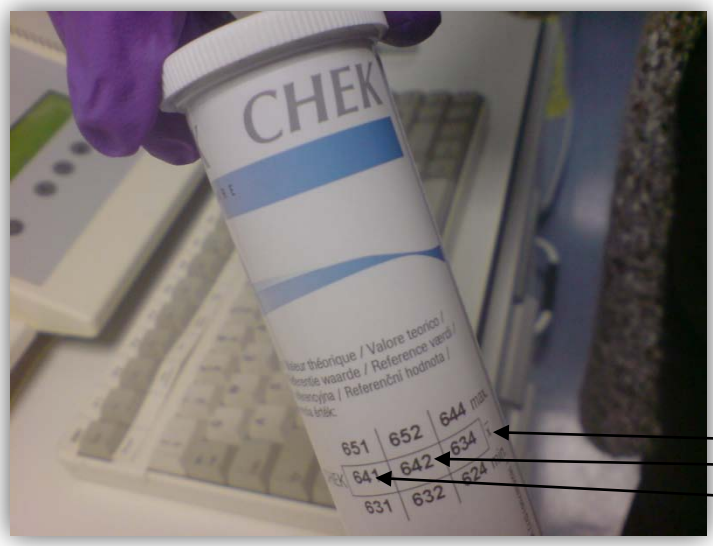
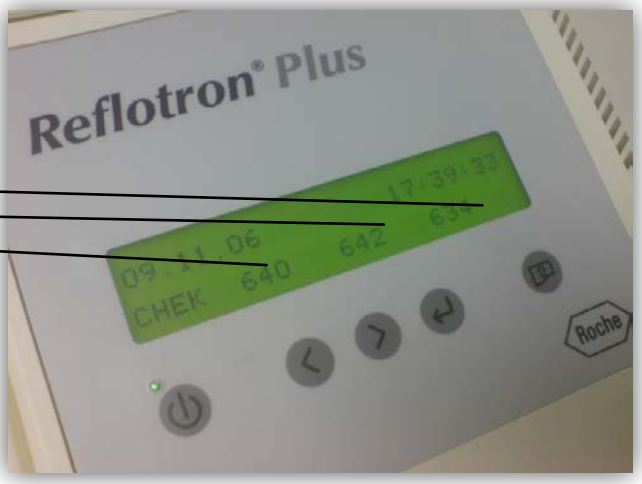
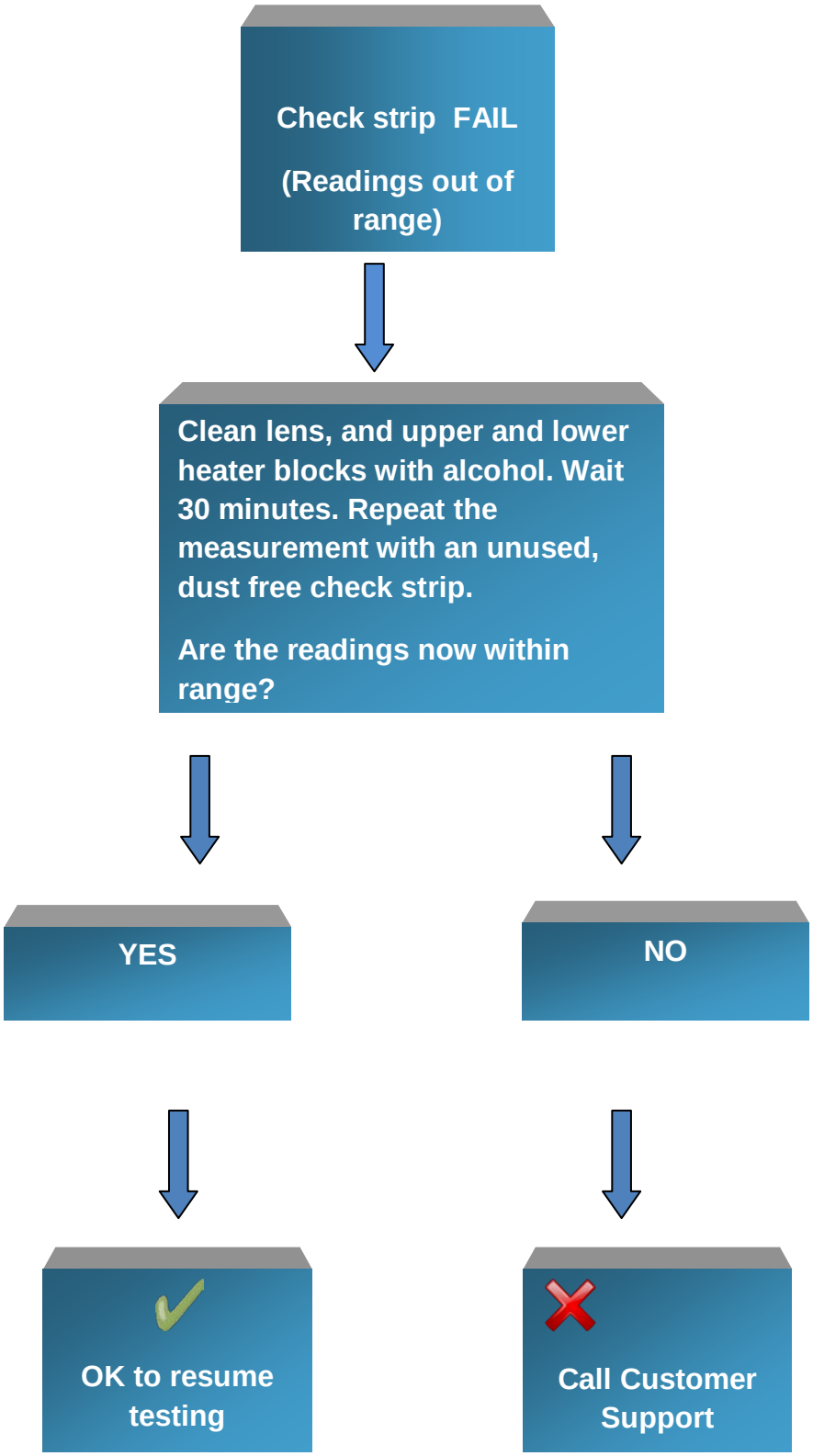
- At the end of the check time, three values will be displayed. These values must be as close as possible to the middle row of numbers on the label of the check strip vial, and definitely between the ‘maximum’ and ‘minimum’ values.





- Record the results

What to do if check strips are out of range



- The values obtained on the instrument should not vary significantly from week to week and must always lie within the minimum and maximum values as specified on the label of the vial.

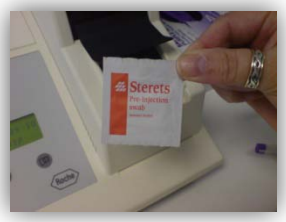
- Ideally a new Check strip should be used each day. However it is acceptable for one strip to be used for a week before being discarded provided that the grey test area is well protected and free from scratches.

NB. The lid must be kept on the check strip container at all times as the strips are light sensitive and must be kept dry.

b) Cleaning Procedure (preferably at the end of the day/session)

Clean the heating blocks and apertures using an alcohol wipe. DO NOT USE THE REFLOTRON® FOR AT LEAST 30 MINUTES AFTER CLEANING. (H&S Guideline)

Cleaning the Reflotron®



- First ensure the instrument is SWITCHED OFF.
- Open the measuring chamber lid.
- Clean the following areas using an alcohol wipe:

  - Upper and lower heating blocks.
  - Circular optical window in the centre of the upper heating block
  - Magnetic head

- Close / Replace the lid.

The analyser is now ready for testing

Stage 2 – Performing the test

Step 1

- Remove the appropriate test strip from the container and place on a flat clean surface
- Choose appropriate blood collection device
- Prepare the patient as outlined in " Collection Procedures" page 20

Step 2

A trained member of the healthcare provider team should perform the blood test in accordance with the standard operating procedure and training provided.

How to undertake a fingerstick blood test – step by step

(Pictures for the fingerstick procedures courtesy of E C Hamer BSc.Hons, MSc, FIBMS)

Use a single use safety lancet to prick the patient's finger to get a good sized drop of blood about the same width as the blood collector.

- Select a lancet device
- Hold and twist off the sterility cap by turning in either direction
- Discard the cap

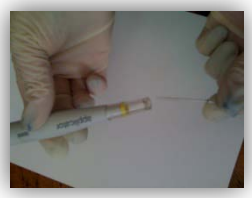
- Press the lancet device against the side of the client's fingertip (not on the central pad) and press the lever to activate the lancet

- Dispose of the used lancet device in the sharps bin.
- **Do not squeeze too hard** as this may haemolyse the specimen or cause dilution of the sample with interstitial fluid.

Step 3

a) For single test

- Insert a 32µl capillary tube into the applicator device



- Gently squeeze the patient's finger and release to allow blood flow. Repeat this squeeze and release action as required.
- Allow the blood to rise slowly up the capillary to the black line indicating the correct volume of 32µl

- Apply cotton wool pad with pressure to the customer's finger until the bleeding stops, discard the cotton wool pad as clinical waste and offer a plaster.

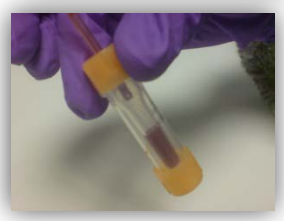
- Place the capillary directly over the pad of the test strip and gently push the plunger down, ejecting the blood sample onto the middle of the sample pad
- Do not allow the capillary to touch the pad
- A further downward push on the plunger releases the capillary into the sharps bin

b) For multiple tests

- Collect a sample of the correct volume using a blood collection device such as a Microvette capillary tube

- Insert the free end of the capillary tube into the drop of blood

- Gently squeeze the patient's finger and release to allow blood flow. Repeat this squeeze and release action as required.
- Allow the blood to rise slowly up the capillary and into the collection tube until the blood reaches the line on the tube indicating the correct volume has been collected



- Apply cotton wool pad with pressure to the customer's finger until the bleeding stops, discard the cotton wool pad as clinical waste and offer a plaster.

- Discard the capillary tube from the collection device and recap if needed

- Using the dedicated 32µl pipette and a clean dry tip, press the plunger down to the first stop then lower the tip into the blood sample
- Once the tip is below the surface, gently release the plunger fully
- Check there are no bubbles in the tip
- Hold the pipette and tip vertically over the sample pad on the test strip
- Press the plunger down slowly, releasing the blood onto the sample pad

- Dispose of the tip into the clinical waste container

Step 4

- Open the Reflotron® measuring chamber lid
- **Immediately** insert the test strip into the Reflotron® measuring chamber

- When the strip is inserted correctly PLEASE CLOSE LID will appear on the display. Close the lid.

- The Reflotron® will read the magnetic strip on the reverse of the test strip

- Countdown of test will appear on the screen.

- At the end of the countdown, the result will be displayed on the screen and printed.

Step 5

- Open the Reflotron® measuring chamber lid and remove the test strip
- **Discard the test strip into a clinical waste container. All soft waste e.g. gloves, swabs etc., should be disposed of as clinical waste in a yellow bag.**
- **Any accidental blood contamination of equipment surfaces must be wiped immediately using a disinfectant - protective gloves must be worn**

NB. Some tests require a sample of plasma (refer to Appendix 2 for individual test sample requirements)

In this event, the whole blood sample collected as described in Step 3 b) Page 31 will need to be centrifuged as follows:

Step 6

- Place the blood collection tube containing the remainder of the sample into a mini centrifuge.
- Balance with another blood collection tube containing approximately the same amount of water.
- Close the lid and switch on for approximately 2 minutes.

Step 7

- Pipette 32µl of plasma from the “spun” collection tube onto the appropriate test strip.
- Insert test strip into the Reflotron® and follow Steps 4 – 5 above.

Stage 3 – Reviewing the Results

The Healthcare provider should review the results against the referral criteria and advise the client of the next appropriate steps

(NICE Guidelines, May 2008)

Communicating the results and referring

- The healthcare provider is responsible for communicating the test results and providing advice to the client.

Confidentiality

Healthcare providers should ensure that the requirements of the Data Protection Act 1998 for data collection and use are complied with. Information obtained in the course of professional activities is confidential and should be disclosed only with the consent of the patient other than in specific circumstances.

INTERNAL QUALITY CONTROL (IQC)

(All information, instructions and pictures referring to the Reflotron®® A1C Quality Control are taken from the QC pack insert)

Running a Quality Control (QC)

The QC should be assayed in the same manner as patient samples

As for clinical specimens, all QC samples should be handled as if capable of transmitting infection. Appropriate procedures should be used for their disposal.

The Reflotron® Quality Control (QC) Kit

The Reflotron® Quality Control should be used with the Reflotron® test strips to ensure that the strips are working correctly and giving accurate and reliable results.

Precinorm Hb QC kit should be used with the Hb test strips

- 4 x 2ml bottles for reconstitution with 2mls deionised/distilled water
- 4 x level 1

Precinorm HDL QC kit should be used with the HDL test strips

- 4 x 2ml bottles for reconstitution with 2mls deionised/distilled water
- 2 x level 1, 2 x level 2

Precinorm U QC kit should be used for all other test strips

- 4 x 2ml bottles for reconstitution with 2mls deionised/distilled water
- 4 x level 1

QC should be run:-

- With each new lot of test strips.
- With each new shipment of test strips.
- Whenever there is any concern that the test result may be wrong; test strips not stored correctly; there is concern that a user may not be performing the test correctly.
- Every 30 days to ensure correct storage of test strips.
- Use controls according to local quality standards.

Always check the pack insert with each box of controls to ensure correct preparation and usage

Storage & Stability

- Unopened control kit kept in fridge at 2-8^{o}C can be kept till the expiry date on the box
- Once reconstituted Precinorm U & HDL is stable at room temperature for 8 hours, or 14 days when refrigerated at 2-8^{o}C. Alternatively it can be stored for one month frozen at -20^{o}C.
- Once reconstituted Precinorm Hb is stable at room temperature for 8 hours or 14 days refrigerated at 2-8^{o}C. This control is unsuitable for freezing.

Preparing the Controls

For the Precinorm U & Hb –

- using a 2ml pipette and clean plastic tip, add 2mls of deionised/distilled water to one control bottle
- Place on a roller or gently mix and leave for 30 mins making sure that the contents are completely dissolved

For the Precinorm HDL –

- using a 2ml pipette and clean plastic tip add 2 mls of deionised/distilled water to each of one bottle of level 1 and one bottle of level 2
- Place on a roller or gently mix and leave for 30 mins making sure that the contents are completely dissolved

The controls are now ready for use.

Running the controls

Preparing the Reflotron® test strip

- Remove the appropriate strip from its container and replace lid
- Place strip on a clean dry surface

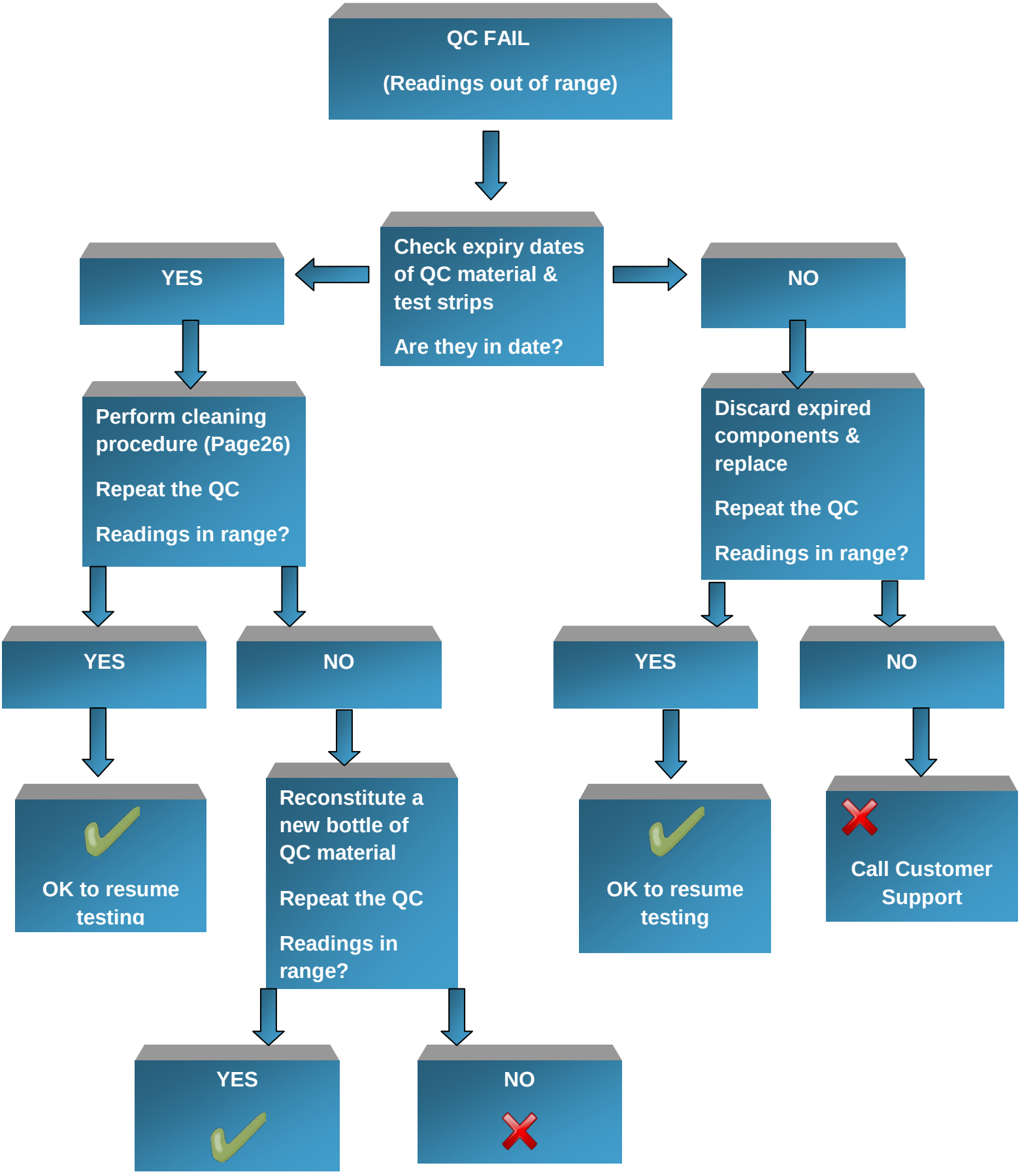
Adding the control

- Using the dedicated 32µl pipette and a clean dry tip, dispense 32µl of reconstituted control onto the appropriate test strip
- Check there are no bubbles in the tip
- Hold the pipette and tip vertically over the sample pad on the test strip
- Follow the steps as for patient sample –Page 32 to 33 Steps 4 – 5

Reviewing the Results

- Check the result against the values provided in the appropriate pack insert
- If the control is within the acceptable range, record the result and continue testing
- If the control is outside the acceptable range, record the result and repeat the test

What to do if the Reflotron® QC results are unacceptable



Training/Competency Assessment

Method	Steps	Pass/Fail	Sign/Comments
Preparation of Reflotron® Analyser	Preparation of the test system		
Fingerstick procedure	Carried out correct preparation of – self & patient Demonstrates good use of lancet device Carried out successful fingerstick		
Patient test on Reflotron® analyser	Successful use of blood collector Correct application of sample to test strip Correct placement of test strip in analyser Successful test Read the results Reviewed the results		
IQC on Reflotron® analyser	Carried out correct QC sample prep Successful use of blood collector Correct application of sample to test strip		

IQC on Reflotron® analyser (cont)	Correct placement of test strip in analyser Successful test Read the results Reviewed the results		
Understands	The Reflotron® Analyser Results IQC Health & Safety Limitations		

Complete your details below:

Name _____

Position _____

Test site _____

Signature _____

Date _____

Training representative to complete and confirm **practical training assessment** has been passed and the above person is confident and competent to undertake a blood screening test:

Name _____

Signature _____

Position _____

Date _____

Training Knowledge Assessment

Please answer on sheets provided over page.

1) What is the storage temperature of the Reflotron® test strips?

2) What is the purpose of QC?

3) How often should you run a QC?

4) How should QC material be stored?

5) What should you do if the QC is out of range?

6) How is the analyser calibrated?

7) What are the main Health & Safety risks identified in running a test?

8) What control measures are in place to reduce the risks of occupational exposure to BBVs?

9) What Health & Safety procedures should be maintained in the test area?

10) Who should you contact in the event of a problem with the Reflotron® analyser or the reagent kits?

Training Knowledge Assessment (cont)

Answers

Training Knowledge Assessment (cont)

Answers

Training Knowledge Assessment (cont)

Complete your details below:

Name _____

Position _____

Test site _____

Signature _____

Date _____

Training representative to complete and confirm the **training knowledge assessment** has been passed and the above person is confident and competent to undertake a blood screening test:

Name _____

Signature _____

Position _____

Date _____

Appendix 1 - Basic Troubleshooting

Trouble Shooting Guide & Error Messages

Message/Problem	Description	Resolution
Cannot read magnetic strip	When strip inserted & lid closed, magnetic strip not read	Clean magnetic strip reader & repeat test If problem persists contact customer support
Cannot detect test strip	When lid closed still saying "insert strip" When strip removed still saying "remove strip"	Check mechanism for holding strip, if loose or broken call customer support
Strip will not click in place		Clean round mechanism, check if loose or broken. If problem persists contact customer support
QC (Precinorm) Fail	Readings out of range	Check expiry dates. Perform cleaning procedure (Page 26) & repeat. If problem persists contact customer support
Check strips fail	Readings too low Readings too high	Check storage conditions/perform cleaning procedure (Page 26) and repeat. If problem persists contact customer support Recalibration of instrument may be required – contact customer support
Test readings consistently low	One specific test strip only All test strips affected	Repeat with QC. If problem persists contact customer support Perform cleaning procedure. If problem persists contact customer support
Result <	Result is "less than"	Is an indication that something is wrong with the blood sample e.g. insufficient Repeat test, repeat with QC if QC OK refer patient to GP If problem persists contact customer support
Instrument rattles		May be problem with the fan. If problem persists contact customer support
CHECKSUM EEPROM	Software problem	Contact customer support

Appendix 2 – Reflotron® test strips general information

Reflotron®® Tests Strips	Indications	Storage temp	Sample type
Reflotron® Alkaline Phosphatase	Liver disorders, bone disorders	+ 2°C to + 30°C	A
Reflotron® Amylase	Pancreatitis (acute parameter)	+ 2°C to + 30°C	A
Reflotron® Bilirubin	Liver disorders, anaemia	+ 2°C to + 30°C	B
Reflotron® Cholesterol	Lipid disorders	+ 2°C to + 30°C	B
Reflotron® CK	Muscle diseases	+ 2°C to + 8°C	A
Reflotron® Creatinine	Diabetes, kidney diseases, gout (acute parameter)	+ 2°C to + 30°C	B + F
Reflotron® GGT	Liver disorders	+ 2°C to + 30°C	B
Reflotron® Glucose	Diabetes, lipid disorders (acute parameter)	+ 2°C to + 30°C	B
Reflotron® GOT (AST)	Liver disorders (acute parameter), myocardial infarction	+ 2°C to + 30°C	A
Reflotron® GPT (ALT)	Liver disorders, myocardial infarction	+ 2°C to + 30°C	A
Reflotron® HDL Cholesterol	Diabetes, lipid disorders	+ 2°C to + 30°C	D
Reflotron® Haemoglobin	Anaemia, kidney diseases (acute parameter)	+ 2°C to + 30°C	C
Reflotron® K+ (Potassium)	Kidney diseases (acute parameter)	+ 2°C to + 30°C	E
Reflotron® Pancreatic Amylase	Pancreatitis (acute parameter)	+ 2°C to + 30°C	A + F
Reflotron® Triglycerides	Diabetes, lipid disorders	+ 2°C to + 30°C	B
Reflotron® Urea	Gout, kidney diseases	+ 2°C to + 30°C	B
Reflotron® Uric Acid	Gout, kidney diseases	+ 2°C to + 8°C	A

A Capillary /venous whole blood, heparinised whole blood / plasma, serum

B Capillary /venous whole blood, heparinised/EDTA whole blood / plasma, serum

C Capillary /venous whole blood, heparinised/EDTA whole blood

D EDTA plasma only

E Heparinised plasma, serum

F Pre-diluted urine

Appendix 3 – The keyboard functions

Any key	PSI in the 1st line
Key F2	CHD risk calculator
Key F3	LDL calculation according to Friedewald
Key F4	CHOL/HDL cholesterol ratio calculation
Key F5	"EDITEXT" additional test information
Key F6	Creatinine Clearance calculation
Key F7	Marking of a control measurement
Key F8	Profile transmission II to EDP
Key F9	Profile transmission to EDP
Key F10	Profile printing
PRINT SCREEN	Display hardcopy

Appendix 4 - Risk Assessment

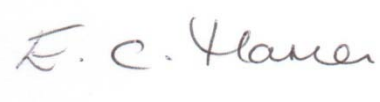
Hazard Identification

HAZARDS	Control Measures	Risk Low/Med/High
Manual Handling (non patient)	Small analyser Weight – approx. 5.3 kg Size – 300 x 350 x 210mm	LOW
Manual Handling (Patient)	NA	LOW
Fall	NA	
Contact with Hot/Cold	No exposed parts	LOW
Cut with Sharp Item e.g. Needlestick	Single use safety lancet device with completely retractable blade	LOW
Exposure to blood & body fluids	• Use of the single use safety lancing device. • Nurses must cover any pre existing open wounds with water-proof plasters. • Plasters will be offered to clients, after the finger-prick blood test to cover their puncture wound. • protective gloves should be available at all times during the procedure • All blood contaminated material should be disposed of as clinical waste • Standard control measures such as hand washing and cleaning are part of the service protocol Post-exposure procedure detailed in the Occupational Health policy (UK Health Depts. Guidance for Clinical Healthcare workers, 1998)	LOW
Trapped between surfaces	Analyser has no exposed moving parts	LOW
Contact with Electricity	Always use correct power supply	LOW
Exposure to Hazardous substances	Dry Chemistry – no exposure	LOW
Exposure to moving mechanical parts	Analyser has no exposed moving parts	LOW

Persons at Risk? - Staff & Patients

Is a significant risk assessment required? - NO

(A significant risk assessment is required should any medium/high risks be identified)

Assessed by Signature	Elizabeth C Hamer BSc.(Hons)., MSc., FIBMS 
Job Title	Biomedical Scientist
Date Assessed	01.04.10

Any staff members unable to sign to accept the policy cannot undertake patient sample testing and should not be trained to do so.

Risk Assessment Acceptance

The Healthcare worker providing the service must sign below to confirm they have read and understood the risk assessment.

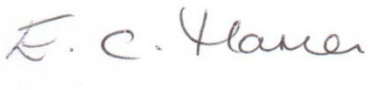
Name	Date	Signature

Appendix 5 - COSHH Assessment

1. General description of work	Point of Care testing for 17 different chemistry analytes.
2. Specific activity assessed	Use of Reflotron® Plus Analyser & Reagent strips
3. Who carries out the task	Name & Job Title - Healthcare provider
4. On observation, does the actual working practice deviate from that intended?	No
5. Is the substance being used hazardous to health?	Trade Name - Reflotron® plus test strip Dry chemistry – no hazards identified
6. Do you have to use this substance? Can you eliminate or substitute it?	(Yes)/No Yes/(No)

7. Identify the possible route/s of exposure.	*Circle* *NA* Inhalation (Ingestion) Absorption (Eye contact)
8. Evaluate the risk without controls in place.	*Circle as appropriate* **Severity** / **Likelihood** (1. Minor) / (1. Rare) 2. Serious, Medical treatment / 2. Unlikely 3. Major, Excessive injuries / 3. Moderately likely 4. Single fatality / 4. Likely 5. Catastrophic / 5. Certain **Score (I x L)** / **Risk Rating** (1 – 3) / (Low) 4 – 7 / Moderate 8 – 12 / Significant 15 -25 / High
9. List control measures required	None No maintenance required
10. Re evaluate the risk if controls are in place, maintained and monitored.	Severity [1] Likelihood [C] Risk Score [C] Rating……1……

11. Further notes on working practice	Disposal – reagent strip to be disposed of in a clinical waste container
12. Spillage procedure	NA
13.First Aid	NA
14. Has any monitoring/health surveillance been carried out? Specify	No
15. Summary & conclusions. Is exposure adequately controlled?	yes ☑ no ☐
16. Action to be taken by Manager/ Person in Charge if not adequately controlled.	NA

Assessed by Signature	Elizabeth C Hamer BSc.(Hons)., MSc., FIBMS 
Job Title	Biomedical Scientist
Date Assessed	01.04.10

References

MHRA Device Bulletin: Management & use of IVD Point of Care Test Devices; DB2010 (02) Feb 2010.

UK Health Depts., Guidance for Clinical Healthcare Workers: Protection against infection with Blood Bourne Viruses, Dept. Of Health (DOH) 1998

www.labtestsonline.org.uk

www.nice.org.uk

www.doh.gov.uk

www.mhra.gov.uk

www.roche-diagnostics.co.uk

www.diavant.com