

## SECTION 5: Management of equipment including Point of Care Testing

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### 5.1 Equipment

The following is a list of equipment required to carry out the NHS Health Check.

LDX Machine + adapter/circuit breaker
Capillary Tubes + plungers
Lancets
TC/HDL cassettes
Quality control Optics check cassette
alcohol cleaning wipes i.e. Sterets
Gauze swabs
Gloves
Plasters
Tape measure
Height Measure
Weighing scales
Watch/clock with second hand
Body Mass Index calculator (if not using computer for automatic calculation)
Blood Pressure Machine (BHS validated)
Sharps bin
Yellow clinical waste bag

All equipment used must be well maintained and calibrated according to manufacturer's guidelines and the GP Practice Policy. Evidence that equipment has been calibrated must be made available to Bromley Public Health upon request.

### 5.2 Point of Care Testing (POCT) - also known as Near Patient Testing (NPT)

Prior to commencing the NHS Health Check, each Provider should identify a lead clinician to be responsible for overseeing the provision of the NHS Health Check and Point of Care Testing.

Each Provider will be loaned a Cholestech LDX machine and the Provider will need to perform near patient testing for random (non-fasting) **Total Cholesterol and HDL Cholesterol** using a finger prick technique.

The Provider will be responsible for ordering the consumables required for near patient testing. These are ordered directly from Alere using the order form in Appendix 4. See also section **5.13**.

The Provider should keep accurate records of use of cassettes. The cassette Lot number should be recorded in the patient's record using the NHS Health Checks Template.

Public Health Bromley will fund the costs of consumables for the number of NHS Health Checks performed per quarter plus two quality assurance samples per month plus a further 5% of NHS Health Checks performed, as an acceptable error rate. For any consumables used over and above this amount by any Provider, there will be a charge as agreed in the SLA.

The Provider must also participate in Quality Assurance requirements as outlined in Section 5.5 below, which will be funded by Bromley Public Health.

Each LDX Machine will also be supplied with a user manual and a quick user guide which should be familiarised by all clinicians carrying out this test. The LDX machine will need configuring when it is received as this will not be performed before being sent out to surgeries. See Section 5.2 below

Clinicians performing POCT must be trained and competent in using the LDX machine. The reason for this is to protect the patient and ensure the quality of the service is appropriate to the clinical setting. This is applicable to all providers of POCT.

Training and support for clinical staff undertaking POCT will be provided either by Alere or by the Public Health Team as well as a dedicated helpline available from Alere.

Users of POCT should have an understanding of issues such as quality assurance (QA), interpretation of test results, limitations to use and liability issues.

The lead clinician should also be aware of their responsibility for clinical governance and of the medico-legal implications of an erroneous result. Liability under the Consumer Protection Act (1987) <sup>(1)</sup> will only remain with the manufacturer or supplier if the user can demonstrate that the equipment has been used in strict accordance with the manufacturer's instructions.

Only staff whose training and competence has been established and recorded should be permitted to carry out POCT. They should also receive continued support and regular updates.

## 5.3 Infection control

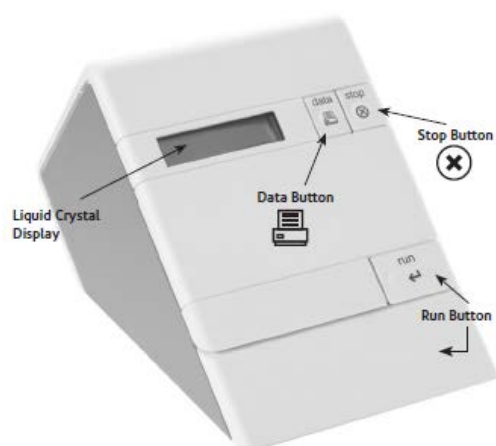
POCT users and managers should be reminded of the importance of:

- Standard (universal) infection control precautions
- The prevention of occupational exposure to blood-borne viruses, by the wearing of gloves and other protective clothing and the prevention of sharps injuries.
- Prevention of cross infection with blood-borne viruses, including selection of appropriate lancing devices
- Safe handling and disposal of healthcare waste, including sharps
- Safe medical device use, including decontamination of reusable devices.

Further detail is available in the Health and Social Care Act 2008: Code of Practice of the NHS on the prevention and control of healthcare associated infection and related guidance<sup>(2)</sup>

Further information on the use of Point of Care testing can also be found in the MHRA document: Management and use of IVD point of care test devices (see below for link).

## 5.4 Alere Cholestech LDX configuration before use



It may be necessary to configure the LDX units to mmol/L.

Use the flow chart below to enable this.

LCD Display:	To Access the Configuration Menu:	
Firmware Version ↓	Press <b>STOP</b> on the analyzer and hold until the <b>FIRMWARE VERSION</b> appears. The next display will appear automatically.	
Config menu Lang=English ↓	Press <b>DATA</b> to select <b>LANGUAGE CHOICES</b> : – English, Italiano, Español, Deutsch, or Français Press <b>RUN</b> to advance to the next option.	Select English
Config menu UNITS=mg/dL ↓	Press <b>DATA</b> to select UNITS: mg/dL or mmol/L Press <b>RUN</b> to continue. <b>NOTE:</b> U/L and mg/L will be reported when the Configuration Menu is set for either UNITS=mg/dL or UNITS=mmol/L.	Select mmol/L
Config menu SAMPLE=Whole B. ↓	Press <b>DATA</b> to select <b>SAMPLE MODE</b> : – Whole B. (Venous or capillary whole blood samples,) or – Serum (Serum, plasma, or proficiency test material.) Press <b>RUN</b> to continue. <b>NOTE:</b> Check the package insert for the test cassette you are using to determine correct Sample option when testing quality control or calibration verification material.	Select Whole B
LDL/HDL ratio ↓	Press <b>DATA</b> to select LDL/HDL RATIO OPTION: – No = reports TC/HDL ratio – Yes = reports LDL/HDL ratio Press <b>RUN</b> to continue.	Select TC/HDL ratio
Config menu Printer on ↓	Press <b>DATA</b> to select <b>PRINTER OPTIONS</b> : – On (Printer function turned on.) or – Off (Printer function turned off.) Press <b>RUN</b> to continue.	Select off

Continue to press **RUN** to exit configuration

## 5.5 Quality assurance (QA)

Quality assurance is an essential component of POCT and includes all the measures taken to ensure that investigations are reliable. These will include:

- Correct identification of the patient
- Appropriate test selection
- Obtaining a satisfactory specimen
- Analysing it and recording the results promptly and correctly
- Interpreting the result accurately
- Taking appropriate action
- Documenting all procedures and maintaining accurate records

Quality assurance also encompasses proper training and review of overall performance. Two components of quality assurance, internal quality control (IQC) and external quality assessment (EQA), can help ensure reliable results, but only if they are applied rigorously.

The Cholestech LDX machine will require two quality control tests:

- a) **Optics Check - daily** before the machine is used to check the optical system
- b) **Quality Control (QC) – once a month** to ensure the accuracy of the client test results.

## 5.6 Record keeping

It is **imperative** to keep accurate records of patient results from POCT devices. These records should include: **date; device type; batch numbers; result; operator identity; patient identity**. Documents are available to record Optics Check; cassettes used for patient testing and cassettes used for quality control testing (Appendices 5 & 6)

The cassette LOT number and expiry date should also be recorded on the NHS Health Check template in the patients' record.

## **ALERE CHOLESTECH LDX MACHINE**

This section has been taken from instructions provided by Alere.

### **5.7 Optics Check**



Run the Optics Check cassette:

- Once each day before patient samples are tested.
- After the Alere Cholestech LDX machine has been moved or serviced.
- Once before completing the monthly Quality Control testing.

**NB The Optics Check is re usable, DO NOT DISCARD**

#### **Performing the Optics Check.**

The Optics check cassette looks the same as a test cassette but has 'Optics Check' written on the cassette and is **reusable**.

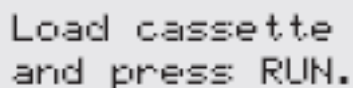
It is stored in its own case at room temperature. The expiry date of the cassette is written on the case as well as the acceptable range for the optics check numbers.

Do not touch the reaction bar or allow it to become wet, dirty or scratched.

Do not place any blood samples on the cassette.

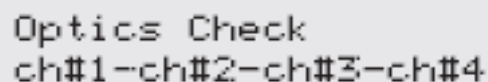


1. Press the **RUN** button. After verifying the Self-test OK message, the drawer will open. The **Load cassette and press RUN** message will display



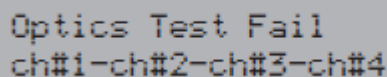
Load cassette  
and press RUN.

2. Place the Optics Check Cassette into the cassette drawer. Press the **RUN** button again and the drawer will close. The Optics check will automatically start
3. When finished the analyser will beep (2 mins) and the following screen will appear.



Optics Check  
ch#1-ch#2-ch#3-ch#4

4. Check that the numbers displayed on the screen are within the acceptable range (80 – 105) as printed on the Optics Check Cassette.
5. **Record the results** on the form shown in Appendix 5.
6. If the numbers are outside the printed range, a warning message 'Optics Test Fail' will appear.



Optics Test Fail  
ch#1-ch#2-ch#3-ch#4

If this occurs the Optics Check should be repeated. If the second check continues to show numbers outside the printed range or 'Optics Test Fail' then contact the Alere Helpline number - 0161 483 5884 (this number can also be found on the machine)

**NB The Optics Check is re usable, DO NOT DISCARD**

## 5.8 Carrying out a Cholesterol Check using the LDX machine

(Also please refer to Cholestech LDX manual provided with the LDX machine)

Universal precautions should be observed and gloves should be worn when carrying out both point of care testing and the monthly Quality Control tests.

Perform the Optics Check as above.



## **Cassette Preparation**

- **Take the sealed cassettes out of the fridge and allow to warm to room temperature for at least 10 minutes before opening.**
- Open the cassette pouch by slowly tearing at the perforation point.
- Do not touch the brown magnetic strip or black bar.
- If silica gel pouch is caught on back of cassette, remove and discard.
- Put the cassette on a suitable flat surface – magnetic brown strip on the right.

## **Performing a finger stick puncture**

In order to obtain a quality finger stick puncture the client's finger must be clean dry and warm. If the client's fingers are very cold, asking them to wash their hands in warm water can aid obtaining the blood sample. Difficulties obtaining a blood sample can also occur if the patient is dehydrated. Ensure they have had enough fluid before their test or provided water if needed.

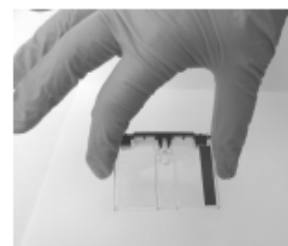
Ensure that you have all the equipment you need close to hand before commencing the test.

- Disposable gloves
- Test cassette
- Alcohol swab
- Gauze swab
- Single use safety lancet
- Capillary tube and plunger
- Plaster
- Sharps bin

Prepare the capillary by inserting a plunger into the end of the capillary. Allow the plunger to fall into the capillary tube – using force may move the small white bung resulting in an inaccurate amount of blood sample being used.



Remove the test cassette from the packaging by holding the side edges only; **do not touch the black test area or the magnetic strip**



Use the side of one of the middle fingers of the non-dominant hand and clean the finger with an alcohol swab, to remove any oily deposits.

Dry the finger thoroughly with gauze or tissue, to wipe off residual alcohol.

Prepare a single use retractable blade lancet.

Place the lancet firmly on the side of the middle finger approximately 5mm from the lateral or medial edge of the nail, and perform a deep and firm puncture.

Dispose of the lancet in the sharps container.

Create a free flowing drop of blood.

**Wipe off the first large drop of blood, as this may contain tissue fluid and tissue detritus.**

Keeping the patients hand below heart level, squeeze the finger gently until a second large drop of blood forms. Do not 'milk' the finger or squeeze the finger pad itself.

Hold the capillary tube at a slightly descending angle to the drop of blood.

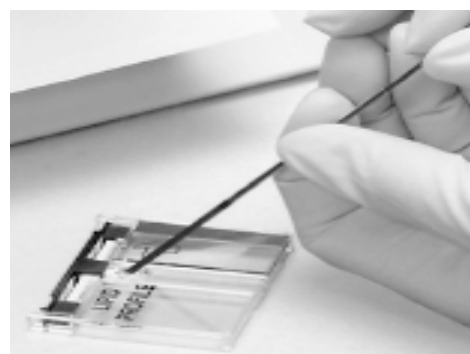
Touch the capillary tube into the drop of blood and the tube will fill by capillary action.

If there is not enough blood then the process should be repeated.



Once the sample has been collected, ask the patient to apply pressure on the puncture site with a piece of gauze.

Dispense the blood from the filled capillary tube by pressing down on the black plunger until the blood is the well in the cassette.



Dispose the used capillary tube in the sharps container.

Keep the cassette level after the sample has been applied.

Press the run button on the analyser, the cassette drawer will open and the screen will display load cassette and press run.



Press **RUN**, the drawer will close.

Check the clients finger has stopped bleeding and if it has apply a plaster (check first for allergy). If still bleeding ask them to apply pressure to the puncture site with the gauze until it has stopped.

The total test time is 4 minutes 40 seconds; at the end of this time analyser will beep and the drawer will open indicating that the test is complete.

Remove the test cassette and place in a sharps bin. Press the **STOP** button to close the drawer.

**DO NOT TRY TO PUSH THE DRAWER TO CLOSE IT AS THIS WILL DAMAGE THE MACHINE.**

The results are shown by pressing the data button on the analyser. Pressing the button twice will show the second page of results.

**Do not press the RUN button again** until the next test is performed as this will delete the current results.

The following video from E-learning for Healthcare outlines the skills involved in performing near patient testing – click on following hyperlink:

## Point of Care Testing

### Open access sessions

Please note that if you access the content below, your progress and completion of sessions will not be recorded and you will not be able to generate a record of completion.


- ▶ Introduction from Jamie Waterall
- ▶ The Health Check Process
- ▶ Skills – Point of Care Cholesterol Testing

Click on Skills- Point of Care Cholesterol Testing

#### ▼ Skills – Point of Care Cholesterol Testing

Outlines the skills involved in point of care in carrying out cholesterol testing.

Play



## Recording the LDX results

The LDX cassette LOT number and cholesterol results then need to be recorded in the patient's electronic record in the NHS Health Check template. Press the 'Data' button on the LDX machine to locate the Total cholesterol/HDL ratio. Press this button again to return to Total cholesterol and HDL results. **DO NOT PRESS 'RUN' AGAIN UNTIL RESULTS HAVE BEEN RECORDED OR THE DATA WILL BE LOST.**

**Once the LDX drawer is opened again or the machine is unplugged the data is lost.**

## Storage of LDX Test Cassettes.

Test Cassettes should be stored in the fridge until required for use. Once removed from the fridge, they **must be used within 30 days**. The date they are due to expire should be written on the side of the box or on the cassette packaging. **They should not be placed back in the fridge.**

It is advisable not to remove too many cassettes from the fridge at one time to avoid wasting cassettes if they are not used within 30 days.

## 5.9 LDX Machine Quality Control

### Internal Quality Control (IQC)

Internal quality control (IQC) assesses, in real time, whether the performance of a testing site is sufficiently similar to their previous performance. It controls reproducibility or precision, and facilitates continuity of patient care over time.

Most IQC procedures employ analysis of a control material and compare the result with predetermined limits of acceptability.

### Cholestech LDX<sup>®</sup> IQC Scheme

The Cholestech LDX IQC scheme is facilitated by Alere using an online recording system called **Image**.

Staff involved with performing the Quality Control (QC) testing each month will be provided with training and a log-in and password in order to record the QC results each month.

Information on how to use Image will be provided by the Bromley Public Health Vascular Team or the Image support team. Technical support for issues relating to the quality control testing will be provided by Alere Image, details of which can be found on the Image web page.

## Source material and Integrity

The samples are prepared from human and animal constituents in an aqueous preservative medium containing antimicrobial agents.

## Frequency of distribution

Quality Control Samples are shipped to practices monthly.

The samples should be refrigerated on arrival at the practice and the quality control testing performed as soon as possible. **The samples have a 14 day expiry date after which they should be discarded.**



QC samples are sent in a grey plastic mailing bag, which **should be refrigerated on arrival** at the surgery.



Each delivery will contain 2 QC samples



Each QC sample will have a lot number ending in either A or B e.g.

A123456A

A123456B

Both samples need to be tested

**It is recommended that a member of surgery staff is nominated to take responsibility for ensuring that the samples are refrigerated upon receipt.**

**In addition it is recommended that a member of surgery staff is nominated to take responsibility for completing the monthly Quality Control Check.**

## **5.10 Protocol for Processing QC Samples**

### **Carry out Optics Check.**

Prior to performing the QC an Optics check should be carried out as described above and the result recorded in form shown in Appendix

### **Running the QC samples**

Take 2 LDX test cassettes out of the fridge and allow to warm to room temperature for 10 minutes before opening.

Remove the QC samples from the fridge and allow to warm to room temperature for 10 minutes.

Check the expiry date on the vials.

**Gently** invert the vial(s) 5-6 times before use.

**The QC samples must be obtained using a Minipet and pipette tips.**

**Cholestech LDX capillaries and plungers must not be used.** The heparin coating inside the capillaries can interact with the sample and may cause inaccurate quality control results. It can also be difficult to ensure that the correct sample volume is being collected, hence a Minipet should be used when performing the QC.

QC samples should be analysed upon receipt. However, if analysis is not to be performed straight away, please store the QC material in the fridge





### Step 1

To Prepare the MiniPet<sup>®</sup>, place a pipette tip firmly onto the end. Please be aware a new tip must be used for each sample being tested.



### Step 2

Ensure the sample is mixed by gently inverting at 5-6 times and at room temperature before testing. Wearing gloves, remove the lid from the sample vial.



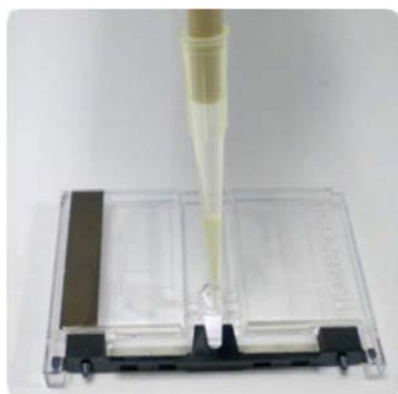
### Step 3

Hold the MiniPet<sup>®</sup> as shown. Press down firmly on the plunger on the the MiniPet<sup>®</sup> and then place the pipette tip into the sample, just below the sample level.



### Step 4

Whilst holding the tip in the sample, slowly release the plunger to draw up the sample.



Load cassette  
and press RUN.

### Step 5

To apply the sample to the test cassette, place the tip of the pipette into the sample well and press the plunger down slowly until the entire sample has been expelled.

**DO NOT RELEASE THE PLUNGER** until the pipette tip has been removed from the sample well, otherwise some sample may be drawn back up into the pipette tip and not enough will have been applied to the test cassette.

### Step 6

Run the cassette.

Record the

- Cassette LOT number & expiry date
- TC
- HDL

Repeat for both Levels of QC

Record **BOTH** QC sample results online using Image (see below)

Replace the vials in the refrigerator.

## 5.11 Recording the LDX QC results using Image

**Alere™ Image** is a web based system for recording the monthly quality control of the LDX Cholestech Analyzers.

Registration is required in order to access the Alere™ Image website. An email will be sent from [NoReply.Image@Alere.com](mailto:NoReply.Image@Alere.com) as seen below:

Click on the link to go the  
registration page

**Alere Image Registration Invitation for Bromley Council - Bromley Council**

NoReply.Image@Alere.com [NoReply.Image@Alere.com]

Sent: 16 June 2016 16:52

To: (NHS BROMLEY CCG)

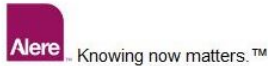
Hello

Duncan Mills has invited you to register on the Alere Image portal. Please [click this link](#) to navigate to the Alere Image registration screen and follow the on-screen instructions to register your details for a new account.

**Important:** Microsoft ended support for Internet Explorer 8, 9 & 10 on 12th January 2016 and no longer provides security updates for these products. Please contact your local technical support team if you require assistance to upgrade your browser.

Many thanks

Alere Image Support



Alere Image Support  
+44 (0)161 483 5884  
<http://www.alere.com>

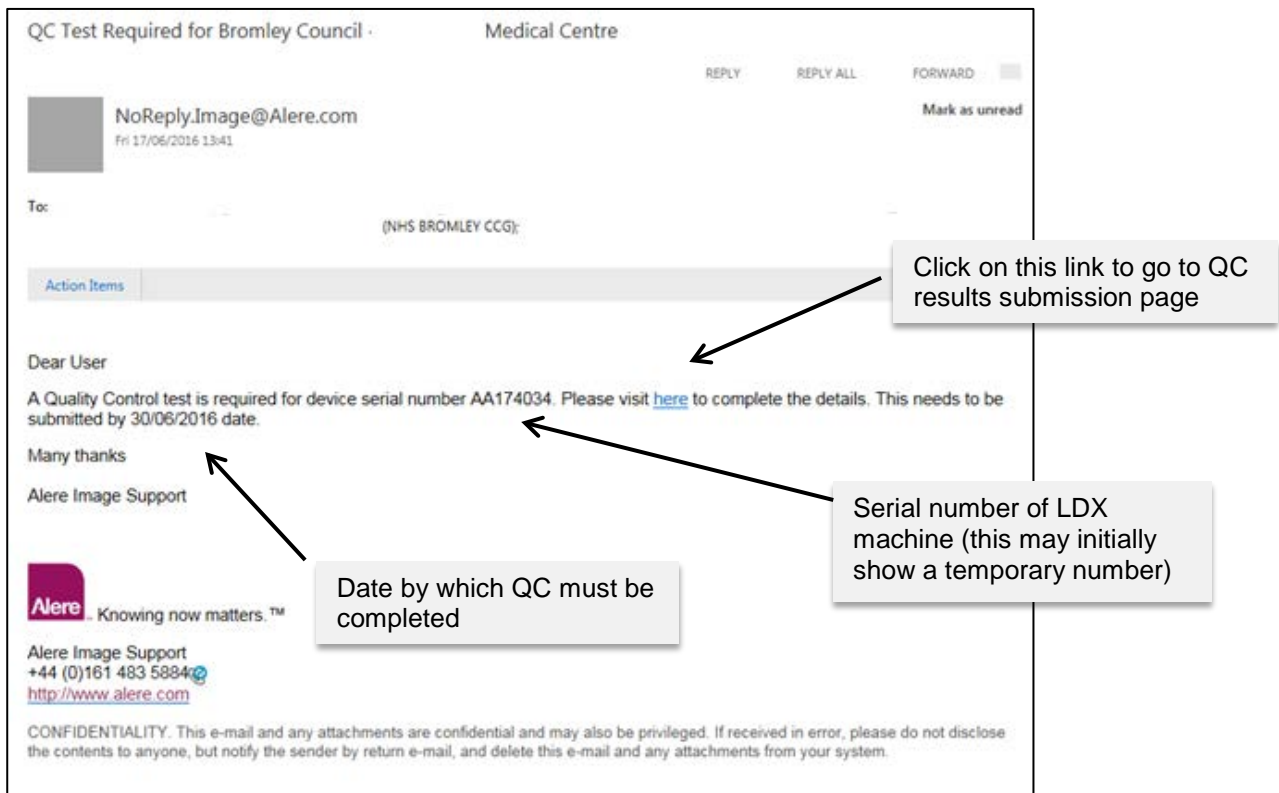
**CONFIDENTIALITY:** This e-mail and any attachments are confidential and may also be privileged. If received in error, please do not disclose the contents to anyone, but notify the sender by return e-mail, and delete this e-mail and any attachments from your system.

This link will take you to the registration page:

The screenshot shows the Alere Image registration page. The page has a purple header with the Alere logo and the text 'Alere image'. Below the header, there is a 'Register' section with the instruction 'Use the form below to register a new account.' The form contains the following fields: Username (pre-filled with 'any.nurse@nhs.net'), First Name, Last Name, Email Address (pre-filled with 'any.nurse@nhs.net'), Password, and Confirm Password. There is a checkbox for 'Show Password?' and a green 'REGISTER' button. Annotations with arrows point to various parts of the form: 'Your username will be your nhs.net email address – this cannot be changed.' points to the Username field; 'Enter you First and Last Name' points to the First Name and Last Name fields; 'Enter and confirm a password of your choice' points to the Password and Confirm Password fields; and 'Click Register' points to the REGISTER button.

When the monthly QC testing is required an email, as shown below, will be sent to each user containing a link which will give access directly to the QC results submission page.

Name of surgery shown here



**Clicking on the link will proceed to the QC submission page**

Alere image

caiken@nhs.net Log Off

HOME DEVICES QC TESTS USERS ACCOUNTS SUPPORT

Hybrid Test : **Lipids** Back

Hybrid Test Result : June 2016

Status **Pending**

Before you can proceed, please confirm the LDX has passed the optics check. **Confirm?** ☐

Please enter your Test / Cassette Lot Number here

**A201703A**

Lot No

Total Cholesterol  mmol/L

HDL Cholesterol  mmol/L

**A201703B**

Lot No

Total Cholesterol  mmol/L

HDL Cholesterol  mmol/L

**Alere Cholestech LDX® Analyzer**


Serial No

Located At

SUBMIT

Hybrid Test Result : June 2016

Status Pending



**Alere Cholestech LDX® Analyzer**

Serial No  
 Located At

AA12345 - your LDX serial number here  
 Any surgery - your surgery name here

}

Check the surgery details and LDX serial number are correct

Before you can proceed, please confirm the LDX has passed the optics check. Confirm? ☐

Please enter your Test / Cassette Lot Number here

**A201703A**

Lot No

Total Cholesterol  mmol/L

HDL Cholesterol  mmol/L

**A201703B**

Lot No

Total Cholesterol  mmol/L

HDL Cholesterol  mmol/L

Confirm that the optics check has been completed

Enter the test cassette LOT number

Enter the Total Cholesterol and HDL for QC sample A

Enter the Total Cholesterol and HDL for QC sample B  
Click Submit

}

If your QC test result has been submitted successfully, you will see the following confirmation message displayed on screen:

**“Your QC test has been submitted successfully. Thank you.”**

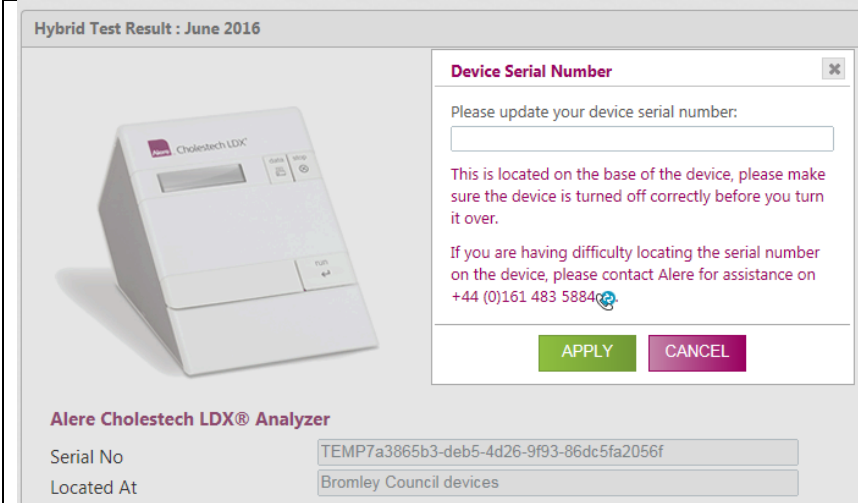
Click OK, to be returned to the dashboard view where you can monitor the system for further pending QC tasks. Once the QC has passed the test, the samples can be disposed of in clinical waste.

### **QC test failed**

If your QC test result submission is unsuccessful, i.e. you have failed to provide results within the specified range of the QC material, you will be prompted to **re-run** your QC test and the QC administrator will be notified of the failure, to assist as required.

A new email will also be sent containing the link to the Image website in order to submit your new QC test results.

## **Confirming LDX serial number**



If your LDX machine has been assigned a temporary serial no, you will be asked to update your serial number with this prompt,

Enter the serial number and click **Apply**

## **5.12 Accessing the Alere Image website**

The Alere Image website can also be accessed by using the following your web browser:

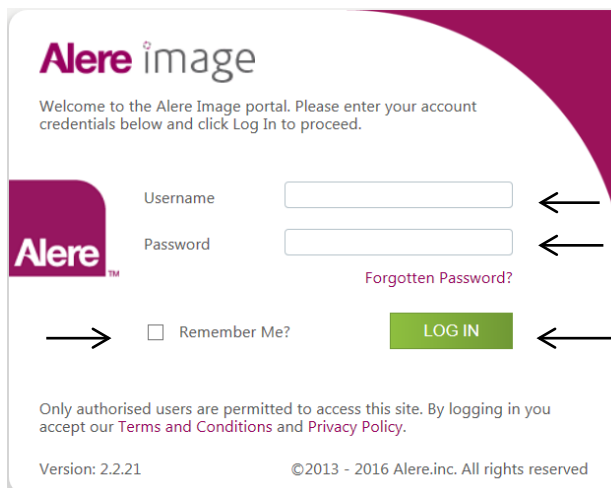
**<https://www.alereimage.co.uk>**

On accessing the **Alere™ Image** web portal you will be presented with the **Login** page.

Enter your **Username** (normally your nhs.net email address) and **Password** and click **LOG IN**

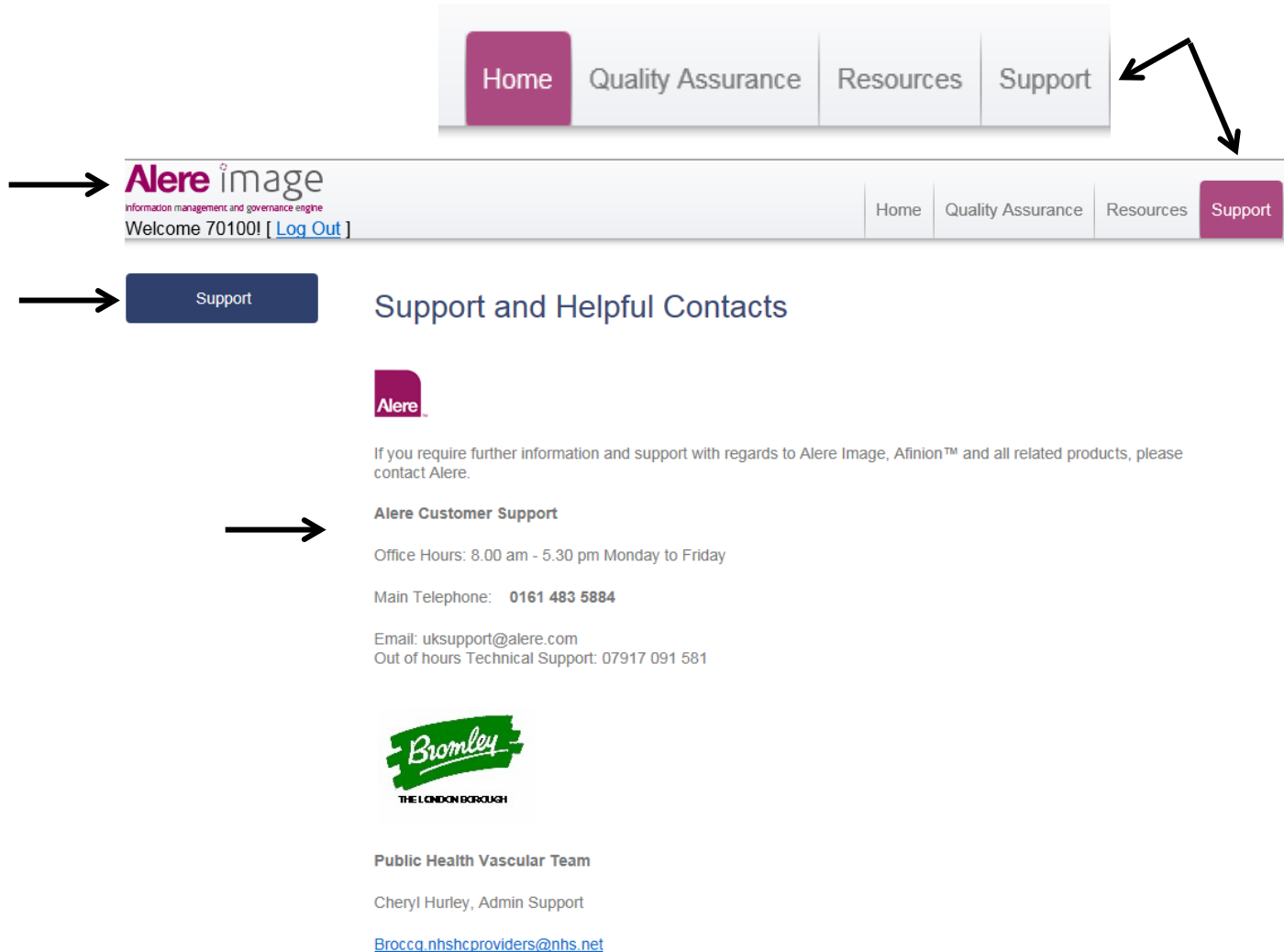
Click to check the **Remember Me?** option to enable your browser to save your username and password.

**N.B.** this action is not advised if you are using a shared compute



## Support

Clicking on the Support Tab will take you to information to enable you to get help, should you need it.



The screenshot shows the Alere Image system interface. At the top, there is a navigation bar with four tabs: Home, Quality Assurance, Resources, and Support. The Support tab is highlighted in purple. Below this, there is a header section with the Alere Image logo and the text "Information management and governance engine". Below the header, there is a navigation bar with four tabs: Home, Quality Assurance, Resources, and Support. The Support tab is highlighted in purple. Below this, there is a section titled "Support and Helpful Contacts". This section contains the Alere logo, a paragraph of text, and contact information for Alere Customer Support. Below this, there is the Bromley logo and contact information for the Public Health Vascular Team.

**Alere image**  
Information management and governance engine  
Welcome 70100! [ [Log Out](#) ]

Home Quality Assurance Resources **Support**

**Support**

### Support and Helpful Contacts

**Alere**

If you require further information and support with regards to Alere Image, Afinion™ and all related products, please contact Alere.

**Alere Customer Support**

Office Hours: 8.00 am - 5.30 pm Monday to Friday

Main Telephone: **0161 483 5884**

Email: [uksupport@alere.com](mailto:uksupport@alere.com)  
Out of hours Technical Support: 07917 091 581

**Bromley**  
THE LONDON BOROUGH

**Public Health Vascular Team**

Cheryl Hurley, Admin Support

[Broccg.nhshcproviders@nhs.net](mailto:Broccg.nhshcproviders@nhs.net)

## 5.13 LDX machine and consumables

Public Health Bromley will provide, on loan, the LDX machine but the GP Practice is the Provider and is thereafter responsible for the cost effective management and ordering of the consumables and must participate in the Quality Assurance requirements as above.

For the provision of consumables, Public Health Bromley has set up an account with Alere for Providers to order supplies as they are needed.

The following consumables can be ordered directly from Alere\*, with 48 hour delivery if ordered before 4 pm. **Orders placed on a Friday will not be dispatched until the following Monday.**

- TC – HDL test cassettes
- Capillary tubes
- Plungers
- Lancets

**\*Orders should be emailed or faxed to Alere using order form (Appendix 4)**

The Provider should estimate the amount of consumables per month and order monthly according to fridge storage capacity.

Public Health Bromley will fund the costs of consumables for the number of NHS Health Checks performed per quarter plus two quality assurance samples per month plus a further 5% of NHS Health Checks performed as an acceptable error rate.

The Provider should keep accurate records of use of cassettes. For point of care testing performed within the GP surgery, The NHS Health Check template should be used to record the cassette lot number as well as the number of cassettes used for each patient.

A log should be kept for number of cassettes, including the lot number, used for quality control each month which can be added to the record log for LDX cassettes stating the number of cassettes used for Quality Control (Appendix 6)

For any consumables used over and above this amount by any Provider, Public Health Bromley will claim back £8 per test per quarter.

### References

1. <http://www.legislation.gov.uk/ukpga/1987/43/contents>
2. [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/449049/Code\\_of\\_practice\\_280715\\_acc.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/449049/Code_of_practice_280715_acc.pdf)



Further information on point of contact testing can be found in the document - MHRA – Management and Use of IVD Point of Care Test Devices. V1.1, December 2013  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/371800/In\\_vitro\\_diagnostic\\_point-of-care\\_test\\_devices.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/371800/In_vitro_diagnostic_point-of-care_test_devices.pdf)