

## NHS Health Checks - Quality Control testing guide

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(Hybrid - Internal and External)



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(Hybrid - Internal and External)



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Please ensure you have enough Alere test cassettes to carry out the Quality Control testing.

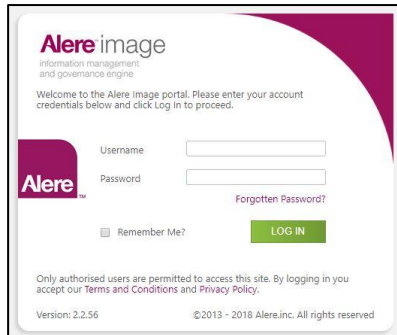
If you haven't registered with Alere to submit your results, please email Alere at [imagesupport@alere.com](mailto:imagesupport@alere.com) to request a login.

### Afinion HbA1c Quality Control (Hybrid Internal & External)

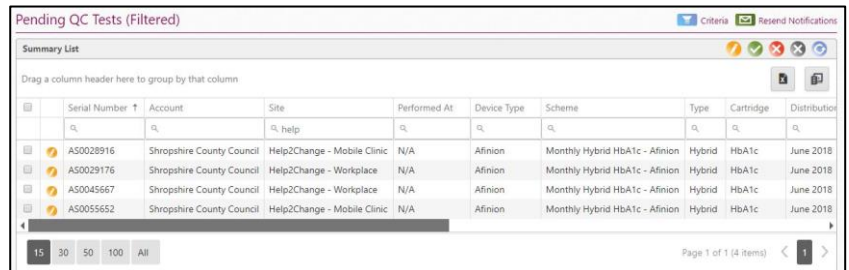
- Delivered every month, shipped in a clear plastic container via Royal Mail (see delivery schedule, page 5)
  - Test once a month after receiving an email from Alere, which will include the link to the ALERE Image QC Test Page to record results.
- 
- Please run your QC test as soon as you receive the samples; if it is not practical to do so, the samples must be stored refrigerated (2 - 8°C).
  - When running the hybrid HbA1c QC test, allow the control to reach a temperature of 15 - 25°C (room temperature) before use, which takes approximately 10 minutes.
  - Mix the sample well by gently inverting the vial 5-6 times, then gently swirling the vial for 5-10 seconds, ensuring there are no air bubbles in the sample.
  - Run the sample on your instrument as per instructions and then input the results into the Alere Image portal, which will notify you of a pass or fail, based on the acceptable range of results for the HbA1c sample. The following page shows you **what the entry screen looks like**. If you fail your initial test, you will be prompted via an email link to repeat the test.
  - **Once the tests have been run successfully and the results have been submitted, please dispose of any unused samples.**

## Result Submission: **HbA1c** Quality Control (Hybrid Internal & External)

Once the results are available on your instrument screen, log into Alere Image, using your email address as your user name, and click on the serial number of your Afinion machine, giving you a link to the QC test results submission page.

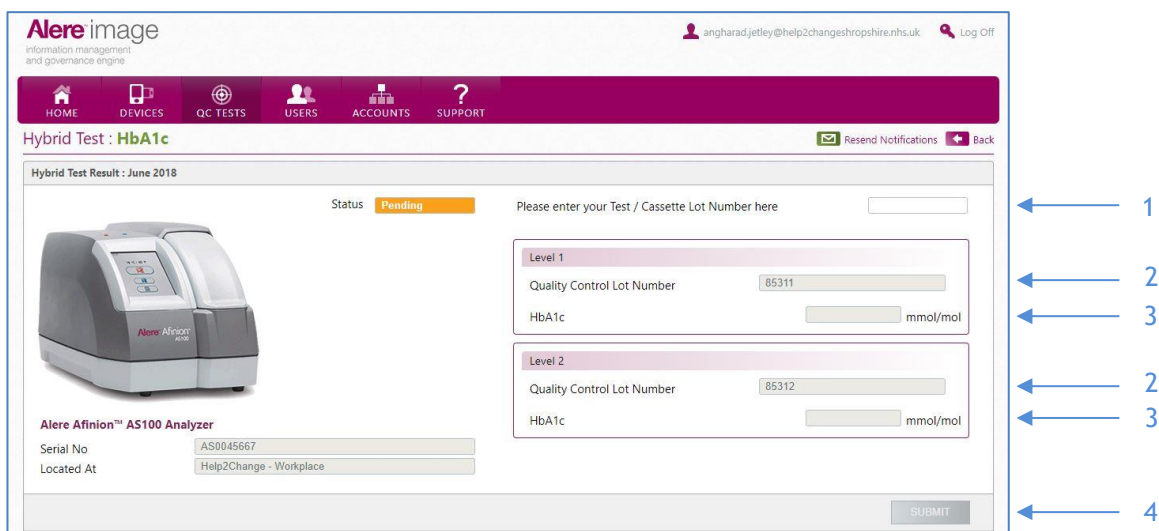


The login page for Alere image features a purple header with the logo and tagline 'information management and governance engine'. Below the header, a welcome message asks the user to enter their account credentials. There are input fields for 'Username' and 'Password', a 'Remember Me?' checkbox, and a 'LOG IN' button. A 'Forgotten Password?' link is also present. At the bottom, it states 'Only authorised users are permitted to access this site. By logging in you accept our Terms and Conditions and Privacy Policy.' and includes version information 'Version: 2.2.56' and copyright '©2013 - 2018 Alere, Inc. All rights reserved.'



The table displays a list of pending QC tests. The columns are: Serial Number, Account, Site, Performed At, Device Type, Scheme, Type, Cartridge, and Distribution. The data rows show tests performed at various sites like 'Mobile Clinic' and 'Workplace' using 'Afinion' devices. The table includes search filters, a 'Criteria' button, and a 'Resend Notifications' button. At the bottom, there are pagination controls for 15, 30, 50, 100, and 'All' items, and a page indicator 'Page 1 of 1 (4 items)'.

### QC test results submission page:



The submission page is titled 'Hybrid Test : HbA1c' and shows a 'Pending' status. It features a navigation bar with icons for Home, Devices, QC Tests, Users, Accounts, and Support. The main content area includes an image of the 'Alere Afinion™ AS100 Analyzer' with its serial number 'AS0045667' and location 'Help2Change - Workplace'. There are two input fields for 'Quality Control Lot Number' (pre-filled with '85311' and '85312') and corresponding 'HbA1c' result fields in 'mmol/mol'. A 'SUBMIT' button is at the bottom right. Blue arrows on the right side of the page point to the lot number and HbA1c fields for both levels, and the submit button.

1. In this field you need to type the lot number that's printed on the plastic wrapping of the test cassettes you use. **Both cassettes used should come from the same box, so should each have the same lot number.**
2. The Quality Control Lot Number fields on Alere Image are **pre-completed with the numbers printed on each vial.**

Each sample has a different Lot Number printed on the vial: eg **85311** and **85312**



3. Please ensure you enter the HbA1c results (mmol/mol) from the correct vial in the correct field.
4. Only once you have entered all of the above information will you be able to click on the 'SUBMIT' button.

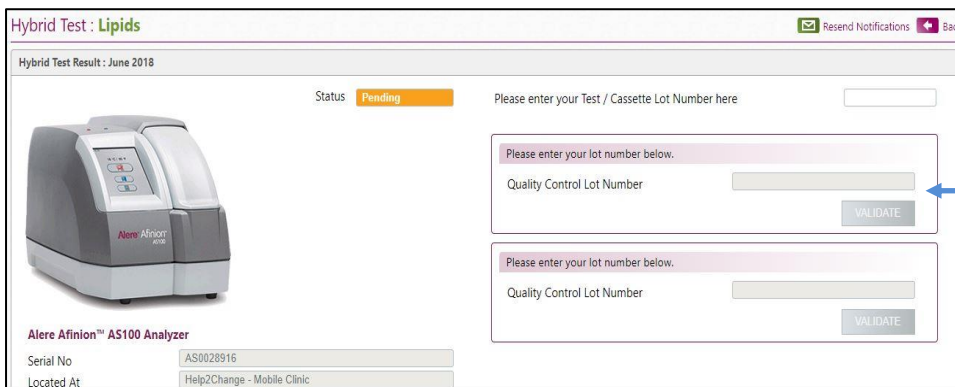
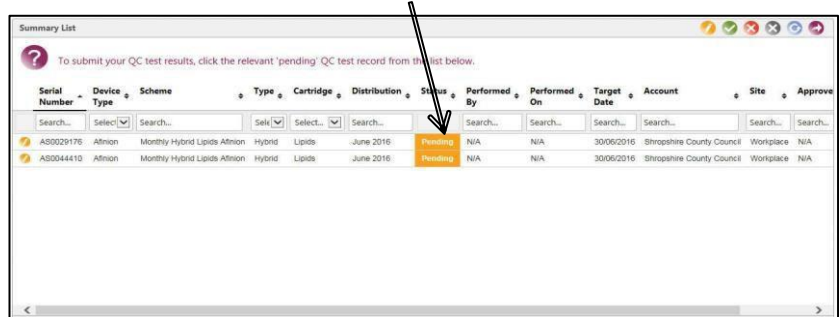
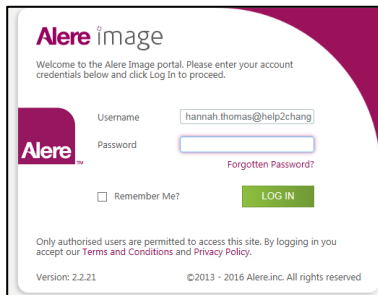
# Hybrid Afinion Lipid Panel Quality Control (WEQAS Internal and External)

- QC samples are delivered via Royal Mail, once a month (see delivery schedule, page 5).
- The samples arrive in a clear plastic container and there are 2 vials:  
**Lipid Control A (white label) and Lipid Control B (blue label)**

Each sample has a different Quality Control Lot Number printed on the vial: eg A201902A and A201902B



- If you are unable to run the samples immediately, store the controls refrigerated (2 - 8°C).
- Once you are ready to run the tests, the controls can be used directly from the refrigerator. Mix thoroughly by gently inverting 8 - 10 times.
- Once the results are available on your instrument screen, log into Alere Image, using your email address as your user name, and clicking on your serial number link on the QC test page.



Enter the Quality Control Lot Number of each sample where prompted and then select 'Validate'.

- Once the Quality Control Lot Number of each sample has been validated, input the **Total Cholesterol** and **HDL Cholesterol** results in mmol/L on the Alere Image Portal, taking care to enter the correct level into the correct box on the portal screen.
- If you fail your initial test, you will be prompted via an emailed link to repeat the test.

## **Quality Control samples - delivery**

Quality Control (QC) samples will be delivered on a regular (monthly) basis, and currently the HbA1C samples and the Lipid samples are delivered separately, about a week apart. Please store all QC samples in the fridge until ready to use. The hybrid HbA1c QC samples need to be brought up to room temperature before testing (about 10 minutes), whilst hybrid lipid samples can be used **straight from the fridge**.

Run QC tests (both HbA1c and Lipid) as close to their delivery dates as possible, but before the end of the month, and submit the QC results on Alere Image.

**Important: Once you have run the monthly QC tests, please dispose of any unused QC samples in clinical waste.**

**Do not put any unused QC samples back in the fridge for future use.**



**Alere™ Image** is a web portal for customers and their authenticated users to manage and maintain their assigned **Alere™** device(s). **Alere™ Image** supports the **Alere Afinion™ AS100 Analyzer** and **Alere Cholestech LDX® Analyzer** to collate, analyse and report on QC data submitted from field deployed analysers.

## Access

### Login

Upon accessing the **Alere™ Image** web portal, you will be presented with the **Login** page. *Fig. 1-1*

Enter the **username** and **password** provided by your administrator or Alere representative into the respective fields and click the **Login** button.

### Remember me

Click to check the **Remember me?** option to enable your browser to save your username and password and automatically authenticate you onto **Alere™ Image** web portal for future visits.

**Note:** This action is not advised for users who are using a shared computer.

A screenshot of the Alere Image login page. The page has a white background with a purple decorative element in the top right corner. At the top left, there is a purple square with the word "Alere" in white. The main heading is "Alere image" in a purple serif font. Below the heading is a welcome message: "Welcome to the Alere Image portal. Please enter your account credentials below and click Log In to proceed." There are two input fields: "Username" and "Password". To the right of the "Password" field is a link for "Forgotten Password?". Below the input fields is a checkbox labeled "Remember Me?". To the right of the checkbox is a green button labeled "LOG IN". At the bottom of the page, there is a disclaimer: "Only authorised users are permitted to access this site. By logging in you accept our Terms and Conditions and Privacy Policy." and footer information: "Version: 2.2.14" and "©2013 - 2016 Alere.inc. All rights reserved".

*Fig. 1-1*

## Submit your QC test results

Following the task link in the email you have been sent and you will gain access to the QC Test Results submission page. You may be asked to add your instrument serial number before you can add your results. This can be found on the underside of your instrument.

**Note:** - Shut down your instrument fully before turning it over. Failing to do this can damage the instrument.

The resulting page will display the QC test details (*Fig 14-2*),

To submit your QC test results, you may be requested to enter the required lot numbers from the QC Packaging and QC result measurements. Then click the **Submit** button at the bottom of the **QC Test Result** panel to commit your submission.

As a final check, upon submission you will be prompted to confirm the device serial number and site are correct.

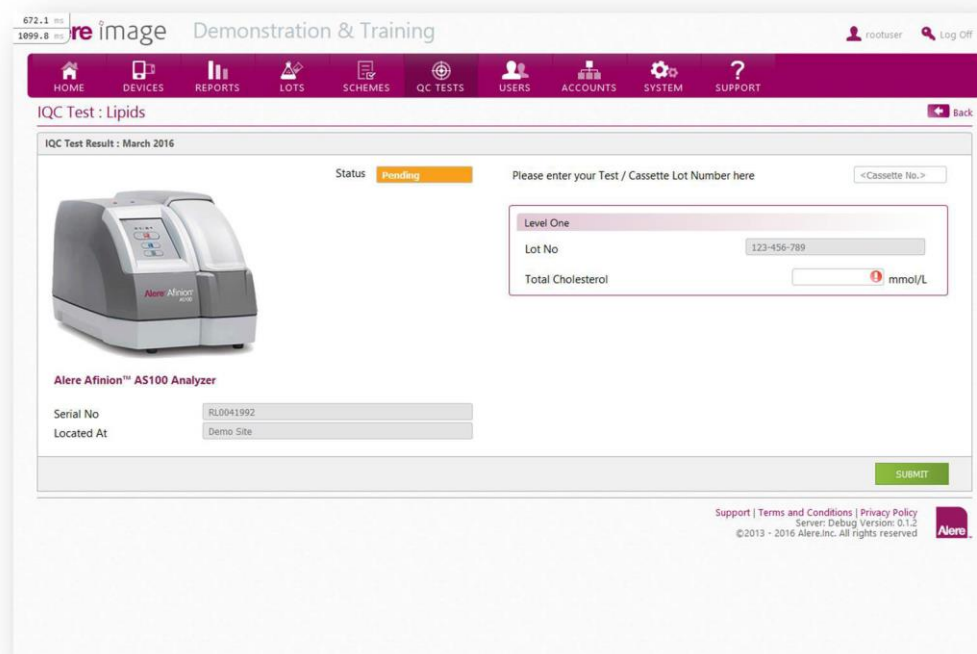
**Note:** if you attempt to submit a QC test record without populating the required information or provide a result outside of the specified range of the device being tested, then you will be prompted to address the highlighted field before you can complete the submission.

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.

**Note:** 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.



The screenshot shows a web application interface for submitting QC test results. At the top, there is a navigation bar with icons for HOME, DEVICES, REPORTS, LOTS, SCHEMES, QC TESTS, USERS, ACCOUNTS, SYSTEM, and SUPPORT. The main content area is titled "IQC Test : Lipids" and includes a "Status" indicator set to "Pending". A form prompts the user to enter their "Test / Cassette Lot Number here" with a dropdown menu. Below this, there is a section for "Level One" results, with a "Lot No" field containing "123-456-789" and a "Total Cholesterol" field with a red error icon and the unit "mmol/L". A small image of the "Alere Afinion™ AS100 Analyzer" is shown on the left. Below the image, the device name "Alere Afinion™ AS100 Analyzer" is displayed, along with "Serial No" (RL0041992) and "Located At" (Demo Site). A green "SUBMIT" button is located at the bottom right of the form. The footer contains "Support | Terms and Conditions | Privacy Policy", "Server: Debug Version: 0.1.2", "©2013 - 2016 Alere, Inc. All rights reserved", and the Alere logo.

Fig. 14-2