

Policy for the Notification to Users of UKAS Accreditation Status

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ASSOCIATED PROCEDURES & FORMS	Selection and Evaluation of Referral Laboratories [PF-GEN-MP-42] List of Referral Laboratories [PF-GEN-MF-112]
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1. Purpose and Scope

The purpose of this policy is to ensure users of Pathology First services are able to easily identify which tests and sites are UKAS accredited to ISO 15189:2012 [and which are not](#).

Historically Basildon Hospital laboratory was accredited to ISO 15189:2012 as one of the pilot sites for these standards, but much of that repertoire has now moved to different analyser platforms or to the Hub laboratory [and is therefore not accredited until it has been re-assessed under Extension to Scope](#). Southend Hospital laboratory was accredited to CPA standards and has been in transition awaiting the accreditation visit to become ISO 15189 accredited. [The Hub is yet to be assessed to ISO 15189:2012 and is awaiting assessment under Extension to Scope](#).

Cellular Pathology has largely been through this transition and Extension to Scope and Histology at Basildon Hospital and Cytology at the Hub are ISO 15189 accredited.

However due to the nature of the way in which UKAS confers accreditation, it is the test that is accredited and not the laboratory. UKAS maintains a register of laboratories that are accredited and the schedule that is attached to this laboratory record indicates the tests for which they are accredited. Therefore whilst a laboratory may be accredited for a number of tests, there could be some that remain unaccredited and users may wish to be certain that all tests they are sending for analysis are accredited. [Also as a result of this, at the present time, reports may contain a combination of accredited and unaccredited test results](#).

Details of all assays (tests) have been submitted to UKAS for each department in Pathology First. This gives information about:

- The site where the test is performed
- The analyser platform / method of analysis used
- The SOP's and documents supporting the method / test

UKAS use this information when assessing the laboratory and conferring accreditation. UKAS then publish the laboratory test schedule on their website. Only tests found on this schedule can be considered to be accredited. Other tests may be awaiting the completion of Extension to Scope and / or the Transition from CPA, but remain unaccredited until they have been successfully assessed. This does not necessarily indicate that these tests are of inferior quality, just that they are yet to be accredited.

This policy gives details as to [the various ways in which](#) this information can be obtained [and covers all users of the service](#).

2. Responsibility

[Whilst Pathology First strives to be open and honest at all times about which sites and tests are accredited](#), it is [ultimately](#) the responsibility of users of the service to satisfy themselves as to the accreditation status of each test and site within Pathology First. However every assistance will be given by Pathology First to help users understand which tests are accredited and which are not.

It is the responsibility of the Quality Manager to notify UKAS of any new tests that are added to the test repertoire. This may be accredited automatically or may not be accredited until after the next assessment visit has taken place.

3. Definitions

Accreditation – a process by which the Quality of the laboratory can be confirmed / assessed

CEG – Clinical Engagement Group

CPA – Clinical Pathology Accreditation – the previous accreditation system that is now being phased out in the transition to ISO 15189:2012

Extension to Scope – the process by which un-accredited elements of a service can be brought in to scope with previously accredited elements

ISO – International Standards Organisation

SOP – Standard Operating Procedure

Transition – the process of moving from CPA accreditation to UKAS accreditation

UKAS – United Kingdom Accreditation Service

4. Records

All records / documentation generated as a result of a process shall be entered onto the departments Storage of Clinical Material, Records and External Documents Matrixes / Policies.

5. Process

5.1 Process of checking **UKAS Accreditation Status of a Laboratory or Test**

It is possible for users to check for themselves whether a test is accredited. This relies on them being familiar with the UAKS website and will generally only be done by other laboratories who may be referring tests to Pathology First in the same way as Pathology First checks out the accreditation status of its referral laboratories

To check the accreditation status of any laboratory or test follow the steps below:

- Log onto an Internet search engine
- Search UKAS Accredited Laboratories
- Type in the laboratory name – [Pathology First llp](#) (or UKAS reference number if known)
- Click on the laboratory service required
- Review the schedule that opens up for the test / site in question

If any user prefers to, they can contact the laboratory for up to date information about accreditation status for any test / site.

5.2 Process of notifying Users about Accreditation

Users will be made aware of / have access to this policy and of the procedure to follow in 5.1 via joint Governance Group meetings and CEG meetings. Users will also be kept up to date about the status of our accreditation directly at Governance meetings, CEG meetings and via the User Handbook and Website – however this will indicate which sites and disciplines are accredited and not specifically which tests are accredited. This information will come from the UKAS website or by directly contacting the laboratory only

The hospital Trusts receives direct information about current accreditation status from their representatives on the Joint Governance Committee. Any accreditation updates will be minuted at these monthly meetings.

Members of the Pathology First senior management team attend CEG meetings – usually on a quarterly basis. These meetings are attended by GP users and members of the CCG (Clinical Commissioning Group) and again up to date accreditation status is made available.

Currently reference to Accreditation Status has been removed from the User Handbook and the Pathology First Website and this will not be updated until successful completion of Transition and Extension to Scope.

5.3 Accreditation of Referral Laboratories

Pathology First maintains a list of referral laboratories and their status [PF-GEN-MF-112] and this should be reviewed annually to ensure continuing UKAS accreditation of those laboratories. See SOP PF-GEN-MP-42 for more information about the evaluation of accreditation status and the continued use of referral laboratories.

The information held about the referral laboratories includes:

- Name and address of the referral lab
- Name of the laboratory contact / Quality Manager or Consultant
- Details of UKAS accreditation to ISO 15189 for the specific tests referred
- EQA status
- Q-Pulse SLA reference number
- Turnaround times
- Sample requirements
- Reference ranges
- Justification of use if the lab or a test is not UKAS accredited

In instances where a sample needs to be sent and it cannot be sent to an agreed referral laboratory, the laboratory should send the sample to the most appropriate referral laboratory to prevent delay in processing the sample. In these circumstances the laboratory must ensure that the non- agreed laboratory be assessed for approval within 14 days. If after assessment the laboratory is selected as the preferred laboratory, then the list of approved laboratories shall be updated to reflect this change. If it decided that this laboratory cannot be added to the list, then an alternative laboratory shall be chosen to prevent sending the sample to the unapproved laboratory in future.

Where the requesting clinician has specified that they want a test send to a particular laboratory, it is the responsibility of Pathology First to check the Accreditation status of that laboratory for the tests being referred. If the laboratory is un-accredited or where there are concerns about quality standards, an alternative lab should be found and the requesting clinician contacted to inform them that their preferred laboratory cannot be used.

Similarly it is the responsibility of any other laboratory referring tests to Pathology First to check our accreditation status for that test and if it is un-accredited to satisfy themselves as to the quality standards in place. Pathology First will assist in any reasonable requests for information about EQA benchmarking, KPI's and any other quality standards.

5.4 Assessing Reports for Accredited tests

It is impossible for the final report to indicate which tests are accredited and which are un-accredited due to the fact that tests may be analysed on different sites / analysers but using the same multi-site IT system. It is therefore important to note that reports may contain results that can be both accredited and un-accredited.

That being said the whole laboratory works to the same Quality standards and the same QMS and the fact that a test is un-accredited may be due to the fact that it has not yet been assessed, rather than the fact that it does not comply with good quality standards.

6. References

ISO 15189:2012 standard section 4.5