Policy for the Notification to Users of UKAS Accreditation Status

Reviewed by	Approved by	Summary of Changes
<Signature>	<Signature>	Changes from previous version in Blue
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June 2023	June 2023	

ASSOCIATED PROCEDURES & FORMS	Selection and Evaluation of Referral Laboratories [PF-GEN-MP-42] List of Referral Laboratories and their status Template [PF-GEN-MF-112] UKAS Accreditation Update – Handbook page [PF-PIP-59] UKAS GEN 6 – Reference to accreditation and multilateral recognition signatory status by UKAS accredited bodies [PF-GEN-EXT-83]
COPY NUMBER	None
LOCATION OF HARD COPIES	

CONTENTS

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.

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 of Accreditation 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. This is particularly the case when users of referral labs are selecting / evaluating a service. As a result of this reports may contain a combination of accredited and non-accredited 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 for in house tests when assessing the laboratory (7880) and conferring accreditation. UKAS publish the laboratory test schedule on their website to indicate which tests are accredited. Only tests found on this schedule can be considered to be accredited. Other tests may be awaiting the completion of an Extension to Scope but remain unaccredited until they have been successfully assessed and any findings cleared. This does not necessarily indicate that these tests are of inferior quality, as they will be carried out under the same QMS, just that they are yet to be accredited. Please note that as of 2019 Phlebotomy (when carried out by IPP staff) is now also accredited ensuring the end to end quality of service.

For tests that are referred to other laboratories, Pathology First select a suitable laboratory to undertake the work. This will be based on UKAS accreditation, EQA performance and Turnaround times. In some cases, for specialist tests, there may only be one laboratory that is able to undertake the work. As Pathology First are responsible to the end to end service, they will always select the most appropriate laboratory for every referral and will then periodically evaluate the service they are getting. For example if TAT's are failing then an alternative laboratory may be sought. In addition to this the UKAS accreditation status of each test that is referred is checked (usually annually) to ensure they remain accredited. In some cases a referral lab may be chosen or retained even if a test is not accredited, provided other quality assurance can be demonstrated.

Pathology First are happy to share information about accreditation with their users and make this information available on their website – please see PF-PIP-59 for more information.

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

From GEN 6 section 2 there is now a mandatory requirement for the reference to accreditation:
Work conducted under accreditation shall be reported in a clear and unambiguous way. Reports and certificates issued by accredited bodies shall make it clear to any recipient of that document whether or not the work was performed under UKAS accreditation. To this end, it is a mandatory requirement that all accredited bodies clearly

reference accreditation on all reports and/or certificates that include accredited results and outcomes, unless explicitly agreed in a legal or documented arrangement between the accredited body and its customer, subject to the following:

- *Where, through agreement, the report / certificate does not refer to accreditation then the accredited body shall inform its customer that the report / certificate cannot be regarded as having been issued under its accreditation, and therefore it is not covered by the multilateral agreements that UKAS is a signatory of.*
- *However, agreements not to make reference to accreditation cannot be applied when the reports / certificates containing accredited results and outcomes relate to activities where accreditation is mandatory by law or under contractual conditions or when they are to be displayed or sent to third parties. In such cases, the use of the accreditation symbol or a claim of accreditation status is mandatory, unless prevented by legal or regulatory requirements.*
- *When employing databases or other electronic means to transmit the results of accredited conformity assessment activities, every effort should be taken to maintain the above principles and to find a way to clearly mark the accreditation status of these results. In many cases this should be possible through design of the reporting tools and/or by usage of comment-boxes, etc. However, where data is added directly into a database which is then accessed by users it can be considered that this does not constitute a report/certificate but only a data-transfer. Where this is the case, the requirements placed on reports and certificates regarding reference to accreditation do not apply.*

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 Operations Managers to “own” their section of the test schedule for in house tests and also to maintain a list of referral labs and which tests are sent there including their accreditation status and UKAS reference number – plus the date the UKAS website was checked. They are also responsible for ensuring the User Handbook Test Pages are correct and up to date. This may be delegated to the most appropriate Principal BMS.

It is the responsibility of the Quality Manager to notify UKAS of any new tests that they have added to the test repertoire and when they wish to have them assessed. This may be accredited automatically (if it is on an existing analyser platform and used the same method, may be assessed remotely upon submission of the relevant verification documentation or may not be accredited until after the next assessment visit has taken place. The Quality Manager will liaise with the UKAS Assessment Manager and where necessary submit an AC6 form for Extension to Scope

It is the responsibility of anyone involved in the distribution of information to be clear about the laboratories accreditation status, this includes but is not limited to request forms, reports, publicity material and job advertisements.

3. Definitions

Accreditation – a process by which the Quality of the laboratory can be confirmed / assessed
CEG – Clinical Engagement Group
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
GEN 6 – UKAS publication – Reference to accreditation and multilateral recognition signatory status by UKAS accredited bodies
KPI – Key performance Indicators
MSE – Mid & South Essex NHS Trust
QMS – Quality Management System
SOP – Standard Operating Procedure
UKAS – United Kingdom Accreditation Service

4. Records

All records / documentation generated as a result of a process shall be entered onto Q-pulse

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 UKAS 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 it's 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 UKAS reference number:
    - Pathology First – 7880
- 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 the User Handbook website - **https://tests.synlab.co.uk**

The hospital Trust 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.

Recently it has become possible to add the UKAS logo, as required by GEN 6, to the Pathology First paper Report header. A rule has then been added to any test that is not accredited (either in house or referral) so that users are clearly aware. Please note that on the paper report the UKAS icon displayed is for our registration number (7880) as Pathology First are responsible for the end to end service. However these icons are now also being added to the User Handbook test pages and here the 7880 icon is used for in house tests but where a test is referred the appropriate icon for that lab is used at the end of each handbook page. This process has been started and is planned to be completed during 2023.

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

There are occasions where it may be necessary to use a non UKAS accredited laboratory for referrals. In these cases other methods need to be used to assess the Quality of the service they provide. This will include, but is not limited to:

- EQA performance
- KPI's
- Turnaround times
- Any other aspects of their QMS

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 is 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 non-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

Until recently it has not been possible for the final report to indicate which tests are accredited and which are non-accredited. This is now being introduced by attaching the icon to the header and then indicating any tests that are Not accredited. The only exception to this is where an in house test is accredited on one site but not on all sites. Therefore due to the fact that tests may be analysed on different sites / analysers but using the same multi-site IT system – however additional sites etc will be added via and ETS where required. It is therefore important to note that reports may contain results that can be both accredited and non-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.

5.5 Publication of UKAS status

Pathology First strives never to be misleading about the accreditation status of the laboratory at any time and takes the misuse of the UKAS logo, claims of accreditation status and reference to ISO 15189 very seriously.

The Pathology User Handbook states that the laboratory is regularly inspected / assessed by various organisations and directs users into being able to find out whether the tests they are requesting are accredited or not, but does not say that the Laboratory as a whole is accredited.

Please see PF-PIP-59 for more details

The same applies to request forms and recruitment material which must not make reference to accreditation status. Non-technical departments such as HR and our Trust partners have been made aware of this and know not to use statements about ISO 15189 or UKAS accreditation on any documents. If in doubt please check with the Quality Manager &/or the General Manager.

6. References

ISO 15189:2012 standard section 4.5
GEN 6 [PF-GEN-EXT-83]