UKAS
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TPS 71

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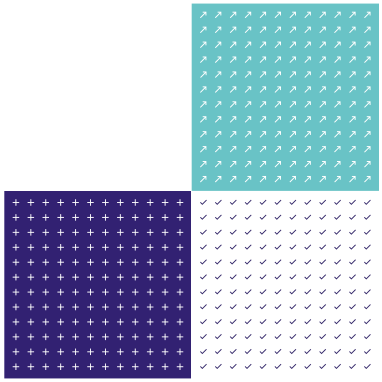
Accreditation of healthcare diagnostic pathways delivered between multiple UKAS customers



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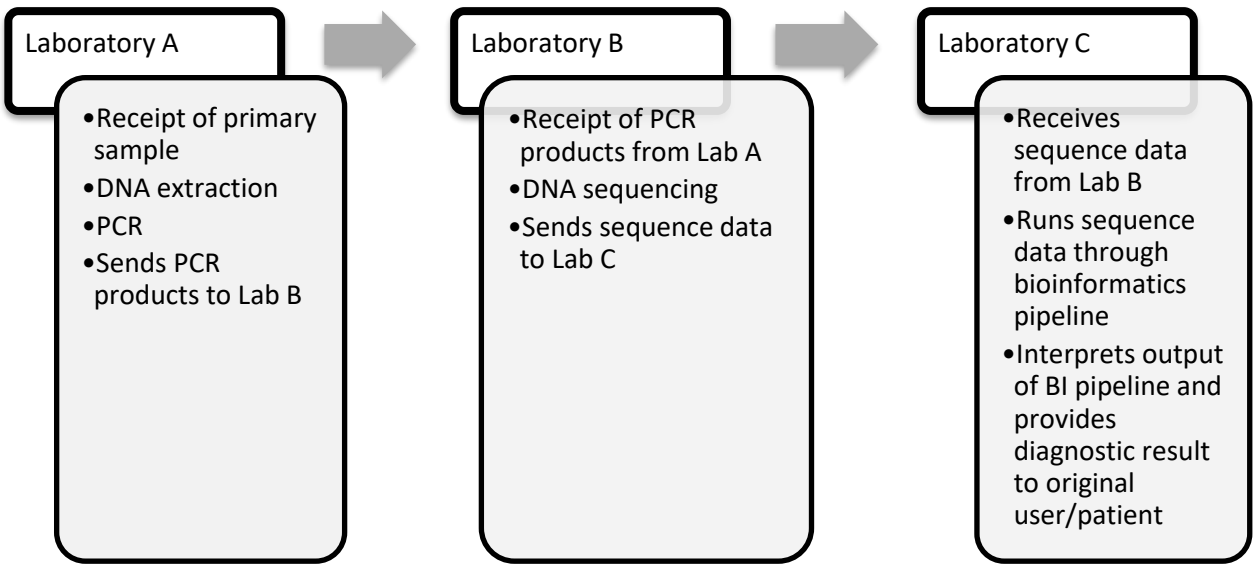
Changes since last edition

Correction – paragraph 4.4 amended to read "Where a service *not* holding a relevant accreditation…"

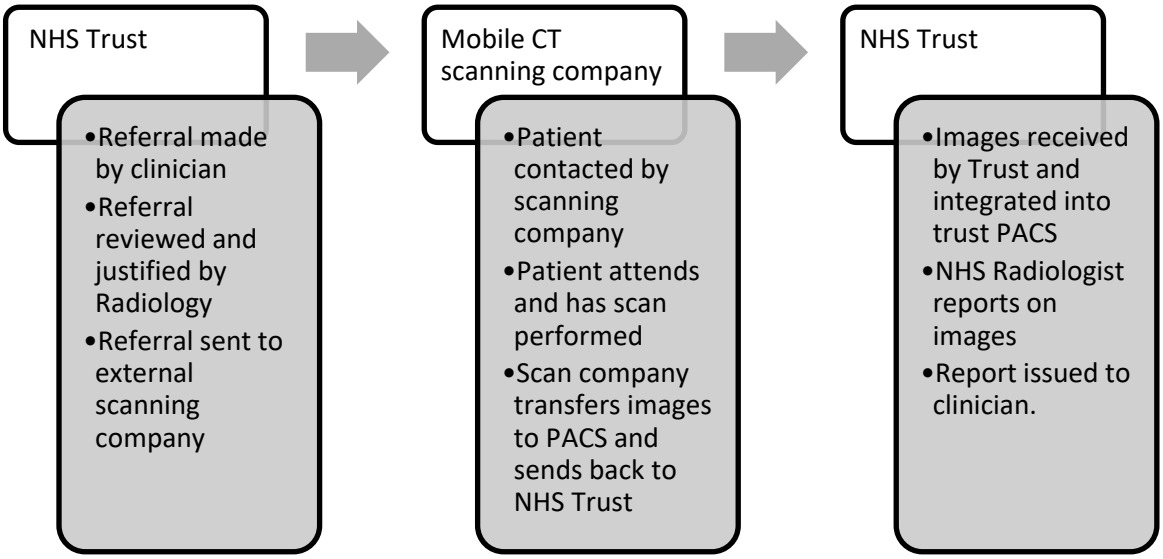
1. Introduction

1.1 As Healthcare diagnostic services develop in the UK, there is an increased focus on centralisation and networking of services to promote efficient and cost-effective diagnostic processes. Many diagnostic pathways now involve transfer of electronic data and/or physical samples between UKAS customers as part of the initial diagnostic process. Examples of these types of service/pathway are shown below:

Example 1



Example 2



The different services involved in each diagnostic pathway shall work together to ensure an effective and competent service is provided to each patient.

Note that these diagnostic pathways differ from diagnostic processes involving referral for specialist testing or second opinion, in that the primary diagnosis is only made once all services in the pathway have performed their respective testing/interpretation. This document is not applicable to diagnostic processes involving referral for specialist testing or second opinion.

1.2 This document outlines the UKAS assessment approach where a single applicant or accredited UKAS customer does not perform or manage all stages of the end-to-end examination process; in other words where critical parts of the pre-examination, examination/testing or post examination process are carried out by separately accredited UKAS customers. This includes UKAS customers which are a separately accredited within the same legal entity (e.g. separately accredited pathology disciplines) and/or UKAS customers in different legal entities. In some instances, parts of the examination process may be performed by non-accredited services (see paragraph 4.4).

1.3 This document will assist UKAS customers in the formulation of effective policies and procedures when they are seeking accreditation for such examinations and provide assessors with support in the assessment process.

2. Scope

2.1 This document applies to applicant and accredited healthcare services.

3. Terminology

3.1 Examination/test – activities, observations, or measurements required to determine the value or characteristics of a property.

3.2 Pre-examination processes/pre-analytical phase - processes that start, in chronological order, from the user's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the accredited service, and end when the examination begins.

3.3 Post-examination processes/post-analytical phase - processes following the examination including review of results, formatting, releasing, reporting and retention of examination results, retention and storage of clinical material, sample and waste disposal

4. Policy

4.1 The overall diagnostic pathway shall be defined and documented with formal agreements/contracts in place between the separately accredited UKAS customers involved, and also any non-accredited services. Each UKAS customer shall hold documentation detailing the end-to-end pathway; for example, this could be a simple flowchart detailing the diagnostic pathway from start to finish, which could be included in the formal agreements/contracts held between the different UKAS customers. In example 1 above, contracts/agreements shall be in place between Labs A & B, and Labs B & C. Labs A & C do not need a direct contract, as any specific requirements of Labs A and C will be included in their contracts with Lab B.

4.2 Agreements/contracts should include:

- Defined roles/responsibilities for each UKAS customer or non-accredited service that is a signatory to the contract
- Defined input (e.g. sample/patient attendance or referral) and output (data/report/result) for each step. Acceptance criteria shall be defined and implemented for input and output for the part of the process carried out by each entity.
- Bi-directional governance arrangements between the entities, including arrangements for sample traceability, quality assurance processes and investigating and responding to complaints or nonconforming work as relevant to the examination.
- Accreditation and/or regulatory requirements
- Other operational information as required including, but not limited to, agreed turnaround times, responsibilities and requirements for sample transport, clinical considerations, patient and other users' needs, assurance of staff competence, contact details, financial arrangements.

4.3 UKAS customers involved in the diagnostic pathways shall identify, manage, and, where possible mitigate, risks in the pathway to ensure that the pathways are optimised for patient care. UKAS customers, and any non-accredited services, in a single pathway should work together to manage risks associated with the interfaces between them, for example where pathology samples are transferred from one laboratory to the next or where CT scans are passed from a mobile CT scanning service back to the NHS for review and reporting.

4.4 Where a service *not* holding a relevant accreditation (for example ISO 15189, ISO/IEC 17025, QSI, IQIPS or other healthcare standard) carries out a stage of the examination process (including any pre/post-examination stages) the formal agreement/contracts relating to the diagnostic pathway will include mechanisms to be used to assure all parties of the competence of the non-accredited

organisations involved. These mechanisms may include review of quality assurance processes and results, validation/verification reports, training/competency records, internal audits, user feedback, and/or reports by any relevant external body (e.g. CQC, MHRA). UKAS will assess the competence of the accredited service to perform this review, and the effectiveness of the review process.

4.5 Where the accredited diagnostic service routinely does not perform or manage all stages of the end-to-end examination process in-house, they shall ensure their users are aware of this. This would usually be detailed in any service agreements between users and the accredited service, or as part of the user handbook or equivalent

4.6 UKAS customers are only able to be accredited for activities which they perform and take legal responsibility for. Where diagnostic pathways are split between multiple UKAS customers, the input (sample type) and the expected output will be clearly defined on the schedule of accreditation. For example:

Example 1:

Laboratory A

Materials/Products tested	**Type of test/Properties measured/Range of measurement**	**Standard specifications/ Equipment/Techniques used**
Nasal swab	Isolation and identification of bacteria of clinical significance	Using manual culture and biochemical identification methods **equipment and SOP references**
Bacterial colonies	Identification of bacterial DNA for subsequent sequencing by an external laboratory, to identify bacteria of clinical significance	DNA extraction and PCR using **equipment and SOP references**

Laboratory B

Materials/Products tested	**Type of test/Properties measured/Range of measurement**	**Standard specifications/ Equipment/Techniques used**
PCR products, generated both internally and by external laboratories	Production of DNA sequence data for subsequent analysis, interpretation and reporting of bacteria of clinical significance by an external laboratory'	Next Generation Sequencing using **equipment and SOP references**

Laboratory C

Materials/Products tested	**Type of test/Properties measured/Range of measurement**	**Standard specifications/ Equipment/Techniques used**
Externally generated DNA sequence data	Data analysis and interpretation for identification of anaerobic bacteria of clinical significance	Analysis, interpretation and reporting of DNA sequence data using **equipment and SOP references**

Example 2

Modality	Type of Examination/Procedure Performed	Equipment/Techniques used
Computerised Tomography	General CT Neuro CT Interventional CT CT Reporting	Manufacturer and model CT Scanner PACS and RIS manufacturer Selected examinations may be reported by external teleradiology company

Activity	Type of Examination/Procedure Performed	Equipment/Techniques used
Teleradiology	Case assignment to radiologists Retrieval and management of images Elective and 'Out of hours' Reporting Imaging examinations Reporting MRI/CT/CR/PET Auditing for Clients US/ MRI/CT/CR/PET Auditing MRI/CT/CR/PET	Manufacturer and model: • RIS • Voice Recognition software • Workstations • Monitors

4.7 UKAS will assess the effectiveness and documentation relating to the above arrangements. Key areas of focus will be the effectiveness of investigation of non-conforming work (including complaints) and risk management, as errors may occur in the first UKAS customer in the pathway which only become apparent when the last UKAS customer performs its activities.

5. References

5.1 ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

5.2 ISO 15189 Medical laboratories - Particular requirements for quality and competence

5.3 QSI Standard - The Quality Standard for Imaging

5.4 IQIPS Standard Improving Quality in Physiological Services

5.5 BS 70000 Medical physics, clinical engineering and associated scientific services in healthcare. Requirements for quality, safety and competence.