Title: Pathology Evaluation and Selection of Referral Laboratories or other 3rd Party Services

Unique Identifying Index Number	MP/PA/GP/REF/001
Version number	5
Issue Date (this version)	See Qpulse
Document Type	Standard Operating Procedure
Accreditation or Licensing Standard to which this applies	ISO 15189:2012
Review Interval	Biennially
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Authorised By (individual or group)	Pathology Departmental Managers
Relevant Staff Groups to which document applies	All Pathology Management Staff
Copy No	1
Location of Copies	1. Qpulse 2. 3. 4.

Mark relevant procedures/policies

DSE	Lifting/ Handling	COSHH	Spillage	Disposal	Sharps	Risk Assessment	MSDS
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The below risk/safety assessments must be read and understood before carrying out this procedure. Details are recorded in the main text of the document.

Relevant safety data, COSHH and risk assessments: -

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1. Introduction

A single Pathology service covers the Trust, and there are laboratories at the acute sites of Darlington and Durham, with a Blood issue fridge available at Bishop Auckland Hospital. These laboratories provide services for the Trust and primary care, with direct access requests from GPs accounting for a majority of the workload of the service. As with any service there is a requirement for 3rd party support for services not provided directly by Pathology or the Trust such as specified referral work, equipment calibration and maintenance (where not provided as part of a Managed Service Contract).

2. Scope & Purpose

The intended scope of this document is for Pathology staff only when considering selection of a service or product from a 3rd party external to the Trust. The purpose of this document is to describe how the department selects and monitors referral laboratories or other external services such as second opinions and the documentation maintained for these service providers.

NOTE: This procedure does not replace the Trust's Standing Financial Instructions but is additional to this as local guidance to Pathology Staff.

3. Definitions

Accredited Laboratories - Procedure by which an authoritative body (UKAS, HTA, MHRA) gives formal recognition that a laboratory is competent to carry out specific tasks. The accredited laboratory will have a number and a certificate specifying the accreditation body and other information.

Change Control - a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. It reduces the possibility that unnecessary changes will be introduced to a system without forethought, introducing faults into the system or undoing changes made by others. The goals of a change control procedure usually include minimal disruption to services and cost-effective utilisation of resources involved in implementing the change.

Diagnostic Testing Procedures
A test or investigation such as pathological tests performed to determine diagnoses; monitor patients during treatments and to inform future treatment options.

Diagnostic Result
The result of a diagnostic test as received by the relevant clinician and may be in the form of a report, an image or both.

Documentation
Written entries or filed documents such as results, letters, forms, standard operating procedures. Documentation may be electronic or paper/hard copy.

Standing Operating Procedures (SOPs)
A clear, step-by-step instruction of how to carry out agreed actions that promote uniformity to help clarify and augment processes. SOPs document the way activities are to be performed to facilitate consistent conformance to requirements and to support data quality. SOPs provide individuals with the information needed to perform a job properly and consistently.

Systems – A group of interacting, interrelated, or interdependent elements forming a complex whole or an organised and coordinated method for a complex activity

4. Responsibilities & Authorities

Pathology staff who have responsibility for the strategy and operations of the service have the responsibility and authority to select appropriate 3rd parties services as required by the department. The staff have the authority to perform the selection as a proposal and this will be ratified by one or more of the Pathology Operational Group (POG), the Directorate of Pathology (DOP) group and the Care Group through procurement or other committee.

5. Procedure

If there is a requirement for a new service or product from a 3rd Party or a change to a current service or product, then the change control procedure must be initiated. The change control documentation will outline the route to follow in consideration of the potential change, including a reason for the change, impact of the change and who is to be involved. If the change requires the department to go out to Tender then the Trusts procurement and tendering process must be followed and the documentation within this will form part of the change control evidence.

5.1 Change control procedure initiated (see local change control procedures within each department)

5.2 If the purchase or contract is over £5000 then the Trust Standing Financial Instructions must be followed and a business case must be documented, a tender process must be followed and specifications must be identified.

5.3 The department will select, where possible, a referral laboratory, service or second opinion that:

- Provides the required test, service or second opinion
- Is competent to perform such a test, service or second opinion
- There are no conflicts of interest
- has achieved good standing with the regulatory requirements in its jurisdiction or is accredited by a recognised accreditation authority and/or complies with the referring laboratory Quality Management specifications, examples would be referral laboratories by UKAS accredited for the test required, Consultant to be MRCPath / FRCPath, calibration laboratories with accreditation by UKAS or other to ISO/IEC 17025.
- Where possible an accredited laboratory is preferred. Where a laboratory does not have accreditation status, but is the preferred provider, it is the responsibility of the Clinical team to ensure that the service the laboratory provides is fit for patient reporting via evidence of quality assurance such as EQA scheme or sample swap assessment.
- where required, participates in an appropriate external quality assurance program or internal scheme if no external scheme is available
- provides turnaround times that meet the laboratory and clinical needs
- is cost effective
- Regional laboratories with CDDFT courier links are preferred due to the ease of transporting samples.

5.4 The department will select referral laboratories or services that provide turnaround times that meet laboratory and clinical needs. The turnaround times are monitored by a designee and where it is related to referral testing, through outstanding or referral test work lists, the turnaround times to be monitored must be appropriate to the service examples could be turnaround time for a specific referral test in days/weeks, delivery times in days/weeks, engineer response times in hours, telephone response times in minutes.

5.5 The department will conduct annual reviews of the selected referral laboratories, to ensure accreditation status, quality assurance status and turnaround times . A draft letter is available on Qpulse (MF/PA/GP002) to be sent out to referral laboratories requesting the information, Should a laboratory fail to respond, the UKAS status of that laboratory must be checked and a note added to the record on suppliers module of QPulse. If the laboratory does not have appropriate or suspended status the use of the laboratory is required to be discussed at speciality and /or quality group level to determine the continued use of the referral laboratory. A record of non-response should be recorded after 1 month of the letter being set to suppliers. As an alternative to sending the letter to the selected referral laboratories departments may if they choose check the accreditation status on the UKAS website, if this method is chosen this mist be documented in the suppliers module.

5.6 The department will ensure all evidence provided by the 3rd party for the items above is reviewed and documented appropriately either in paper format or on QPulse and that any documentation provided by the 3rd party as part of the service provision is documented appropriately in the department as per the document control procedure, examples of documentation could be maintenance records, transfer lists, receipts, delivery sheets etc.

5.7 The department will select and monitor the selected service to ensure they continually provide an acceptable quality of service (timeframe as required by the department) and will notify the selected service if the service is not as expected (verbal, email or written is acceptable). The lab will request that they be notified as soon as possible by the selected service of any changes to service, issues or problems when they occur or if there is potential for future changes.

5.8 The laboratory will use user testimonials where available to add to the evidence on which they base the decision.

5.9 Where a third party is required to be onsite within the laboratory area this must be monitored accordingly following the Pathology health & safety documentation and visitors rules and where this is for the first time for the 3rd party or the individual working for the 3rd party this should be more closely monitored to ensure safe and quality practice is being followed. Evidence of this monitoring can be with the visitor log, work permission slips and equipment handover sheets or other equivalent records. The selected 3rd party must be made aware of this requirement so as the individual onsite understands the need for this.

5.10 The individual or group who perform the selection must use a scoring matrix to show how the decision was made and evidence how each element of the selection criteria was prioritised and scored for each supplier/service.

5.11 Although selection is based primarily on the quality of services provided, the cost of services is considered during the evaluation and selection.

5.12 Once a decision has been made and a supplier is chosen, then the supplier and service will be reviewed regularly, there will be a post implementation review and the supplier and service will become part of the audit system, to ensure it is included in the quality management system.

6. Process for documenting the evaluation and selection of referral laboratories or other 3rd party services.

The following are examples of the documentation required, this list is not exhaustive and any other documentation thought to be relevant can be included.

- Copy of lab license, including appended list of tests for which the lab is licensed and a list of tests for which the lab has applied for a license
- Copy or proof of any accreditation (ISO, HTA,MHRA etc.)
- List of external quality assurance programs in which the lab participates and, as required, documentation confirming proficiency or identifying any significant concerns or deficiencies cited
- Contact name, e-mail and phone number

7. Monitoring compliance

Monitoring Criterion	Response
Who will perform the monitoring?	Departmental Leads/ Service Managers
What are you monitoring?	• Pathology leads undertake an annual audit of compliance or provide national compliance data
When will the monitoring be performed?	Annually
How are you going to monitor?	Receive reports from departments through Quality Meetings
What will happen if any shortfalls are identified?	Shortfalls should be discussed at the Pathology Operational Group and escalated to the Directorate of Operations Group.
Where will the results of the monitoring be reported?	Pathology Operational Group and DOP
How will the resulting action plan be progressed and monitored?	Actions will be monitored by Pathology Operational Group.
How will learning take place?	Shared learning through departmental Quality groups and Quality management group.