

ASSESSMENT REPORT

Name & Address of Organisation	NHS Blood and Transplant 500 North Bristol Park Northway Filton Filton BS32 7QH	Type of Assessment	ETS
		UKAS Reference Number	8740
		Date(s) of Assessment	12/11/2020
Assessment Location(s)	Address RCI Laboratory NHS Blood and Transplant Barnsley Blood Centre unit D, Capital way Dodworth Barnsley S75 3HG	Project references	302640
Assessment Standard / Criteria	ISO15189:2012	Schedule Issue No(s)	Draft v004
Name & Role of UKAS Assessment Team	Sue Gascoigne-Barnett (AM, Cheryl Pylypczuk (TA)	Date(s) of Assessment Plan	Revised 02/11/2020
		No. of (M) Findings: Action Mandatory	
Name of Organisation Representative(s)	Mark Williams	No. of (M) Findings: Require Evidence to UKAS	
Report Issued By	Sue Gascoigne-Barnett	No. of (R) Findings: Action Recommended	
Report Issued Date	Exec Summary 12/11/2020	Method of Reviewing Evidence	Remote

Report Acknowledged By	Mark Williams	Quote for Reviewing Evidence	
Report Acknowledged Date	As Email	Agreed Action Completion Date	
Report Acknowledged Method	Email	Please return evidence to: Medlabscustomerservice@ukas.com Quoting the UKAS Ref.No in the subject field	

AREAS SAMPLED AT ASSESSMENT (marked as 'X')			
ORGANISATION		IMPARTIALITY & INTEGRITY	
Legal Status	x	Independence, Impartiality & Integrity	
Liability Cover (CB / IB only)	NA	Confidentiality	
Management of Finances (CB/IB only)	NA	EVALUATION PROCESSES	
Resources	x	Design & Development of Methods / Schemes	
Organisation Structure	x	Enquiries, Tenders, Contracts	
Responsibility & Authority		Planning & Resource Allocation	
MANAGEMENT		Testing/ Calibration/ Inspection/ Audit *	x
Management System Including Documented Policies & Procedures	x	Reports & Certificates	
Roles & Responsibilities for Quality	x	Decisions/ Opinions	
Control of Documents and Records		Certification & Maintenance of Certification (CB only)	NA
Management of Sub Contractors and Purchases		TECHNICAL COMPETENCE	
Service to Clients (Test / Cal only)		Personnel	x
Handling of Complaints / Appeals / Disputes	x	Methods / Schemes	
Control of Non-Conforming Items Dealing with Corrective & Preventive Actions and Improvements	x	Facilities / Equipment (Test/Cal/IB only) / Environmental conditions (Test/Cal only)	x
Internal Audit and Management Review	x	Assurance of Quality of test / calibration Cooperation (IB only)	x
Supervision & Monitoring of Staff		Witnessed Activities	Remote
Conditions for Granting & Maintaining Certification (CB only)	NA	*OTHER (specify)	

*Delete as applicable

Executive Summary and Recommendation

This is an extension to scope remote desktop exercise to assess objective evidence of the transfer of NHSBT RCI services from the current laboratories in Leeds and Sheffield to a custom new build facility in Barnsley.

The original assessment was planned as an on-site assessment of facilities and management of change /integrity of the QMS and desktop assessment of reverification/calibration/acceptance testing of transferred equipment and reagents/kits to assure ongoing conformity to the requirements of ISO15189:2012. Due to current COVID restrictions imposed by the government, the on site assessment was transferred to a desktop exercise supplemented with photographic evidence of the laboratory, office and storage facilities and Microsoft Teams meetings with key staff to review the current status of the transition plans and the maintenance of the QMS and technical processes prior to the move and going forward following relocation.

The project has been planned since 2017 and an overarching management of change with supplementary change controls to manage specific aspects of the move including equipment/reagents/samples and staff have been recorded in QPulse and updated frequently.

The relocation is managed by a specialist removal company and the function has effectively risk assessed all aspects of the move. There have been no changes to the test repertoire or to method principles. Some equipment has been transferred from either Sheffield and Leeds and re verified on transfer. New accredited equipment has been purchased and fully verified prior to use. Suitable reverification/acceptance testing mechanisms, following documented procedures have been implemented for all methods/equipment/reagents where required.

There is no change in the overarching management structure. Staff have transferred from Sheffield and Leeds so the skills and competencies are retained. The quality management system has been maintained and planned to incorporate the Barnsley site moving forward.

All users have been fully informed of the relocation via a range of methods including email, Customer Service communications, presentations to user groups and the NHSBT website. The quality manual, MPD46v12 and the user guide INF66 v10 have both been updated with appropriate information.

Recommendation:

It is recommended that accreditation to ISO15189:2012 for the documented scope defined in UKAS schedule 8740 v004 is extended to include the addition of Barnsley site (Unit D, Capital Way, Dodworth, Barnsley, S75 3FJ) and removal of Sheffield and Leeds sites. All activities specified for Sheffield and Leeds will be transferred to Barnsley.

Following:

Submission of evidence to address any findings within 12 weeks of the assessment

Satisfactory clearance of all findings

Agreement of an independent decision maker within UKAS