INF1438/2.2 – International Blood Group Reference Laboratory (IBGRL) quality system questionnaire response

NHS Blood and Transplant
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General Information			
Supplier Name		NHS Blood and Transplant	
Supplier Address		International Blood Group Reference Laboratory NHS Blood and Transplant Northway Filton BS34 7QH	
Molecular Diagnostics	+44 (0)117 921 7572	Email	molecular.diagnostics@nhsbt.nhs.uk
Red Cell Reference	+44 (0)117 921 7500	Email	bits.ibgrl@nhsbt.nhs.uk
IBGRL Website	https://ibgrl.blood.co.uk		

IBGRL Organisation Structure			
Contacts	**Name**	**Title**	**Email**
IBGRL	Nicole Thornton	Interim Head of IBGRL	nicole.thornton@nhsbt.nhs.uk
IBGRL	Kirstin Finning	Head of Molecular Diagnostics (also IBGRL Quality Co-ordinator)	kirstin.finning@nhsbt.nhs.uk
IBGRL	Nicole Thornton	Head of Red Cell Reference	nicole.thornton@nhsbt.nhs.uk
Quality Assurance	Jess Mead	Quality Assurance Manager, Filton	Jess.mead@nhsbt.nhs.uk
Facilities and Personnel			
Quality assurance is managed independently from diagnostic services. Each laboratory is supported by clinical consultant staff. Laboratory staff are supervised by registered Biomedical or Clinical Scientists.			
Diagnostic services provided Molecular Diagnostics: Application of molecular genetic techniques for red cell genotyping, fetal genotyping, fetal sex determination. Red Cell Reference: Investigation of complex red cell immunohaematology cases including antibody identification and elucidation of rare or novel blood group antigens.			
Information regarding tests provided, turnaround times, sample requirements and request forms can be found at the website above in the departmental user guides (INF1135, INF1259, INF1136)			

Current Quality System Regulation / Accreditation	
IBGRL	UKAS ISO 15189:2012 - Medical Laboratories (customer number 9765) A copy of the schedule of accreditation showing tests which are accredited can be obtained from the following website https://www.ukas.com using the 'Search Accredited Organisation' function and 9765 as the search criteria

Quality Management System (QMS)

IBGRL's documented QMS includes:

- Quality Manual
- Quality Policy
- Quality management review
- Document and data control
- Record retention policy and procedure
- Staff training and competency assessment
- Risk management
- Non-conformance, corrective and preventative action procedures
- Root cause analysis
- Customer complaint handling
- Change control and validation
- Continuous improvement
- Internal audit
- Participation in all relevant external quality assessment
- Internal quality control
- Supplier assessment
- Materials management
- Equipment management and calibration
- Standard operating procedures for all laboratory investigation

Participation in External Quality Assessment

Molecular Diagnostics	NEQAS Red Cell Genotyping BioArray Proficiency Testing – HEA Assay NEQAS NIPT for fetal sex pilot scheme EQA NI fetal RHD genotyping scheme (Copenhagen), formerly known as CoBrA
Red Cell Reference	NEQAS Blood Transfusion Laboratory Practice and Red Cell Genotyping.

- All NEQAS/EQA results are promptly reviewed. Any episodes of poor performance or trends that indicate an adverse impact on the quality of diagnostic testing/results are immediately managed through the corrective action system with records of root cause analysis and preventative action. IBGRL does not release details of specific EQA results but will notify users of anything that would affect the quality of test results, including significant failures in EQA.

Internal quality control (IQC)

NHSBT's Diagnostic Laboratories IQC:

- Extends through the laboratories' repertoire of diagnostic tests
- Is based on external reference material/standards where available
- Includes positive/sensitivity and negative/specificity controls where applicable
- IQC results are validated as a part of test result authorisation
- Records of IQC are maintained

Materials management

Materials management consists of:

- Purchase from assessed suppliers according to a written/approved specification.
- Goods inwards/acceptance testing of critical materials including reagents
- Inventory management including stock checks and rotation
- Rejection and segregation of any non-conforming materials
- Reporting of defects to the Competent Authorities where appropriate

Equipment, Facilities and Utilities

Facilities / equipment is managed to GMP standards, including:

- Access is restricted to authorised personnel.
- Key equipment is qualified, and full details maintained on an asset register.
- Calibration and preventative maintenance activities are scheduled and verified.
- Equipment / facility cleaning and pest control measures are in place with records.
- Dedicated work areas are provided for critical activities such as result reporting.
- Drinking and eating are prohibited in any laboratory, manufacturing or storage area.
- A waste disposal system is in place including for biohazardous material.
- NHSBT provides a safe and suitable workplace for its employees through its health and safety Policy and procedures.

Information security

NHSBT protects sensitive information as follows:

- Implementation of information governance, Data Protection Act / General Data Protection Regulation and MHRA guidance on data integrity.
- Access control to confidential records including those on IT systems.
- Staff training and assessment on information security.