NHS Fetal Anomaly Screening Programme: laboratory quality assurance evidence requirements

ISO 15189	ISO Requirement	NHS Fetal anomaly screening programme: laboratory quality assurance requirements Down's syndrome, Edwards' syndrome and Patau's Syndrome	Examples of evidence required
1,2,3	Introductory sections - As ISO 15189		
4.	**MANAGEMENT REQUIREMENTS**		
4.1	**Organisation and management**		
4.1.1	**General**	The laboratory must provide UKAS with data on how many samples are throughput against the FASP standard of 8,000 samples per strategy per year as set out in the FASP Laboratory Handbook From April 2019 Laboratories must: • be able to evidence an annual throughput of 8000 samples or more for the screening strategies offered, or • be in a formal network with a minimum individual throughput of 2000 samples per screening strategy offered, or • be able to evidence active progress to formation of a formal network with named laboratory partners and with a network commencement date before March 31 2020	• Confirmation of sample throughput using DQASS laboratory summary reports. • Where laboratory networks are in operation a Memorandum of understanding confirming inclusion in such a network plus a network DQASS report confirming the overall throughput of the network plus a

		From April 1 2020 any laboratory not meeting these requirements will be issued with a non-conformity notice at UKAS assessment. All laboratories offering services as part of the NHS screening programme must be UKAS accredited.	a minimum of 2000 samples for each individual laboratory evidence of actively working towards setting up of a network – documentary evidence of planning meetings with partners by provision of minutes of meetings between laboratories and communication with the DQASS team and FASP programme notifying them of the intention to work towards set up of a formal network

4.1.1.4	**Laboratory director**	The laboratory must have a named clinical lead and management structure for screening. The clinical lead for screening must either be the Laboratory Director or directly responsible to the Laboratory Director. The clinical lead must be a Fellow of the Royal College of Pathologists.	Job description for named clinical lead and any other screening staff. Organogram showing screening roles and links to accountability / responsibility / governance structure within organisation
4.1.2.1	**Management responsibility**	The laboratory must have a viable contingency plan for screening, to continue the provision of fetal anomaly screening in the event of any failures to the laboratory service.	Business continuity plan / Emergency plan / Business contingency

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			standard operating procedure or policy Evidence that this plan was tested
4.1.2.1	**Management responsibility**	The laboratory must participate in the cross-organisational and multi-disciplinary arrangements for the governance, management, communication and development of the screening pathway. This must include: • having clear communication arrangements with users and commissioners of the service, including public health • sharing information on laboratory screening performance, quality indicators and incidents	Agenda / minutes / terms of reference / performance reports / incident outcome reports / action plans
4.2.	**Quality management system**		
4.2.1	**General requirements**	The laboratory quality management system must incorporate all the laboratory requirements for fetal anomaly screening. The laboratory must have documented standard operating procedures for the following processes, agreed with relevant services, for how screening specimens are monitored and managed. These must include identified responsibilities and failsafe arrangements for: • receiving and processing specimens to enable matching of these against the cohort of women who have accepted screening • identifying and recording un-labeled or mislabeled screening specimens, and specimens unsuitable for analysis, and requesting and receiving repeat specimens • reporting all screening results and notification by the end user of results not received • having an escalation process for where screening is incomplete	All standard operating procedures for fetal anomaly screening undertaken within the laboratory

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4.3.	**Document control**		
4.3	**Document Control**	The screening laboratory must make sure that all documents required by the quality management system, including documents of external origin are controlled to make sure that there is no unintended use of obsolete documents. The following documents are expected to be controlled, as external documents, as a minimum: • NHS England Serious Incident Framework • NHS Screening Programme Managing Safety Incidents in NHS Screening Programmes • NHS Service Specification for FASP • NHS FASP Screening Handbook • NHS FASP Ultrasound Practitioners Handbook • NHS FASP Laboratory Handbook • NHS FASP Specification for Calculation of chance results • NHS FASP Screening Standards • NHS Screening Programmes. Key Performance Indicators (KPIs): submission guidance and data definitions	Screenshots / evidence of listed documents within QMS
4.4.	**Service agreements**		
4.4.1	**Establishment of service agreements**	The screening laboratory must have documented signed and dated agreements and a risk assessed protocol that set out the responsibilities and working arrangements for screening specimens sent from other laboratories.	Service level agreements / risk assessment protocols / send away procedure document.

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4.5	Examination by referral laboratories - As ISO 15189		
4.6	External services & supplies - As ISO 15189		
4.7	Advisory services - As ISO 15189		
4.8	Resolution of complaints - As ISO 15189		
4.9	**Non-conformities**		
	Identification and control of non-conformities	The laboratory must make sure that the management of the identification and control of non-conformities includes a review process for screening-related non-conformities. Screening non-conformities must be reviewed, managed and reported according to local, NHS and PHE frameworks for screening incidents, in particular the NHS England Serious Incident Framework and NHS Screening Programme Managing Safety Incidents in NHS Screening Programmes.	Incident management / non-conformity policy demonstrating link to local, NHS and PHE frameworks for screening incidents.
4.10	Corrective action – As ISO 15189		
4.11	Preventive action - As ISO 15189		
4.12	Continual improvement - As ISO 15189		
4.13	Control of records - As ISO 15189		
4.14	**Evaluation and audit**		
4.14.1	**General**	The laboratory must have a documented evaluation and an audit programme to assess performance against screening standards and quality indicators, in line with FASP Programme requirements. This must include audit of all the quality indicators in 4.14.7.	FASP related audits. Audit programme. Minutes of meetings that audit is presented at and any associated action plans.

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4.14.3	**Assessment of user feedback**	The laboratory must make sure that there are arrangements for communicating with laboratory service users in the screening pathway and acting upon their feedback. The user group should reflect the communication pathways and multi-disciplinary team working in the FASP screening pathway.	Service user surveys / feedback analysis / action plans.
4.14.5	**Internal audit**	The laboratory must undertake an annual vertical audit of the screening pathway, from arrival of the specimen at the laboratory to receipt of higher chance results by clinical services, for both first and second trimester screening. The audit must be of randomly selected specimens with higher chance results.	Laboratory audit schedule Vertical audit. Associated action plans. Minutes of meetings that audit is presented at and any associated action plans.
4.14.6	**Risk management**	The laboratory must have a documented risk management policy for the laboratory aspects of the screening programme describing the steps in the testing pathway where errors could occur and the procedures taken to minimize the risk of the error occurring. This must be part of an overall risk management policy for the whole of the screening programme, and include the laboratory interaction with other services in the screening pathway.	Risk management policy.

4.14.7	**Quality indicators**	The laboratory must comply with requirements for meeting and reporting FASP standards and key performance indicators. Collection of data to measure performance against screening standards must be reported annually to the programme by the end of June at the latest. Key Performance Indicators (KPIs) must be reported quarterly between 2/3 months of each quarter end. The laboratory must: • Submit data annually and meet the acceptable threshold for FASP Standard 5 'Screening test turnaround time' of reports issued within 3 working days of the receipt of the specimen in the laboratory - Acceptable: ≥97% Achievable: ≥99%	KPI and annual data submissions NCARDRS DQASS

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		• submit data to maternity services for FASP Standard 6 (KPI FA1) 'Completion of the request forms to enable timely screening' to support maternity reporting • submit data to the Down's Syndrome Screening Quality Assurance Support Service (DQASS) to support audit in line with FASP requirements (FASP Laboratory Handbook) (6 monthly) • submit data on higher chance screening results to the National Congenital Anomaly and Rare Diseases Register monthly	
4.14.8	**Review by external organisations**	The laboratory must participate in the Down's Syndrome Screening Quality Assurance Support Service (DQASS), review their DQASS performance, with the lead biochemist for FASP participating in the DQASS feedback call, and evidence that they are addressing the actions indicated in the DQASS report.	Evidence of review and participation and how actions are addressed.
4.15	**Management review**		
4.15.1	**General**	The laboratory must include fetal anomaly screening as part of its management review of the quality management system.	Management review document Minutes of meetings where review presented and ratified for sign off.
5.	**TECHNICAL REQUIREMENTS**		
5.1	Personnel - As ISO 15189		
5.2	Accommodation & environment - As ISO 15189		
5.3	Equipment, reagents & consumables - As ISO 15189		
5.4	**Pre-examination processes**		
5.4.3.	**Request form information**	The laboratory paper request form or electronic data reporting must include the data fields highlighted in the FASP Laboratory Handbook.	Request form (scanned paper copy

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			or screenshot of electronic request).
5.5	**Examination processes**		
5.5.1	**Selection, verification and validation of exam processes.**	The laboratory must use the recommended combination of markers for first and second trimester testing set out in the FASP Laboratory Handbook (Section 4). These are: • first trimester combined test: Ultrasound markers of a paired CRL/NT measurement only and Biochemical markers of PAPP-A and free Beta hCG • second trimester: Biochemical markers of AFP, hCG (total, intact or free beta subunit), uE3 and Inhibin-A The chance result calculated from the first trimester combined or second trimester quadruple test must not be modified or recalculated once generated.	Test meets FASP requirements detailed in laboratory handbook.
5.5.1	**Selection, verification and validation of exam processes.**	The laboratory must use chance calculation software in compliance with the software specification developed by the FASP and set out in the FASP Laboratory Handbook. The minimum requirement includes: CE marking Configurability Audit Validation Median regression equations for gestation and weight (log cubic) • A + Bx+ C×2 +D×3 • Marker specific truncation limits for gestation and weight Adjustment Factors (number of levels and values should be configurable) • ethnicity • smoking	• software chance calculation test data report supplied to DQASS. • gap analysis of the requirements for software used in the laboratory to move from meeting minimal requirements

		• twins • diabetes • method of conception • analyser Distributional parameters • means (by gestational day), SDs and correlations • truncation limits Updates • factor updates • regression updates • testing • audit trail Previously records risks remain unchanged Recalculation of chance result • all previous information must be recorded for audit purposes Export • DQASS • NCARDRS Action plans for improvement shall be developed, documented and implemented, as appropriate in cases where the software meets the minimum requirement, but does not demonstrate compliance with the complete software specification. The effectiveness of these actions taken shall be determined through a focused review or audit (see also 4.14.5). Where a change is made to software including a factor or equation update following the DQASS feedback call, the test data supplied by DQASS must be run and a report sent to DQASS of the outcomes, including MoMs prior to use with live samples.	to the full requirements for discussion with software suppliers. • evidence of ongoing discussion with suppliers, review at management meetings, and inclusion in the technical specification of any potential procurement.
5.6	**Ensuring quality of examination results**		

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5.6.3	**Inter-laboratory comparisons.**	The laboratory must participate in ISO 17043 accredited EQA schemes, and must be prepared to share their data on EQA performance to the PHE QA Services and NHS Screening Programmes.	EQA performance data reports
5.7	Post-examination processes - As ISO 15189		
5.8	**Reporting results**		
5.8.3	**Report content**	The laboratory must make sure that reports include the data on the screening request form, and the items specified in the results report according to FASP reporting requirements in the FASP Laboratory Handbook	Scanned / screenshot copy of report
5.9	Release of results - As ISO 15189		
5.10	Information management - As ISO 15189		