NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements

ISO 15189	ISO Requirement	NHS sickle cell and thalassaemia screening: laboratory quality assurance requirements	Examples of evidence to be assessed
1,2,3	Introductory sections - As ISO 15189		
4.	**MANAGEMENT REQUIREMENTS**		
4.1	**Organisation and management**		
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 sickle cell and thalassaemia screening in the event of any failures to the laboratory service.	Business continuity plan / Emergency plan / Business contingency standard operating procedure or policy.

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			Evidence that this plan has been tested.
4.1.2.1	**Management responsibility**	The laboratory must participate in the cross-organisational and multidisciplinary 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 requirements of the sickle cell and thalassaemia screening service. 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: • identifying antenatal specimens as distinct from other specimens • receiving and processing specimens to enable matching these against the cohort of women who have accepted screening • identifying and recording un-labelled or mis-labelled specimens, and specimens unsuitable for analysis, and requesting and receiving repeat	All standard operating procedures for sickle cell and thalassaemia screening undertaken within the laboratory.

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		specimens • recording and informing maternity services about missing or incomplete Family Origin Questionnaires (FOQs)	
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 England/NHS Screening Programme Managing Safety Incidents in NHS Screening Programmes • NHS service specification for SCT • NHS SCT Screening Programme. Sickle cell and thalassaemia: screening handbook • NHS SCT Screening Programme. Handbook for antenatal laboratories • NHS SCT Screening Programme. Standards • NHS Screening Programmes Key Performance Indicators (KPIs): submission guidance and data definitions document	Screenshots / evidence of listed documents within QMS.
4.4.	**Service agreements**		

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4.4.1	**Establishment of service agreements**	The 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 to other laboratories, including referral of antenatal samples for mutation analysis. For SCT, the agreements must include arrangements for: • referral and tracking the sample • monitoring turnaround time • providing data for laboratory returns required by the programme • reporting results These laboratories must be ISO 15189 accredited (or CPA accredited and working to ISO 15189), and participate in ISO 17043 accredited EQA schemes.	Service level agreements / risk assessment protocols / send away procedure document.
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**		

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	Identification and control of nonconformities	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 Programmes 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 audit programme to assess performance against screening standards and quality indicators, in line with SCT Programme requirements. This must include audit of all the quality indicators in 4.14.7.	SCT 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 SCT 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 screen positive results by clinical services. The audit must be of a randomly selected positive specimen.	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 minimise 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 SCT standards and key performance indicators. Collection of data to measure performance against programme 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 and 3 months of each quarter end. Data from prenatal diagnostic (PND) laboratories must be reported annually by the end of September.	KPI and annual data submissions.

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		The laboratory must: • meet the acceptable threshold for SCT Standard 4: Test turnaround time • submit data to maternity services for SCT Standard 2 (KPI ST2) 'Timeliness of antenatal screening test' to support maternity reporting • submit data to maternity services for SCT Standard 3 (KPI ST3) 'Completion of family origin questionnaire' to support maternity reporting • submit data for SCT Standard 6: 'Timeliness of prenatal diagnosis' (annually) (PND laboratories only) • submit data on screen positive women to the National Congenital Anomaly and Rare Diseases Register	
4.15	**Management review**		
4.15.1	**General**	The laboratory must include sickle cell and thalassaemia 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		

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5.3	Equipment, reagents & consumables – As ISO 15189		
5.4	**Pre-examination processes**		
5.4.3a.	**Request form information**	The laboratory must use paper or electronic data request fields which are compliant with the minimum data fields required for the programme, and: • the specimen must be clearly recorded as an antenatal screening specimen and matched to a specific maternity service • the specimen must include the nationally agreed dataset for the Family Origin Questionnaire (FOQ) and gestation If using an electronic FOQ (eFOQ) it must: • include the ability to select multiple family origins as required • in low prevalence sites, highlight when Hb variant testing is required and risk of Alpha zero • in high prevalence sites, highlight risk of Alpha zero	Request form (scanned paper copy or screenshot of electronic request).
5.5	**Examination processes**		

5.5.1	**Selection, verification and validation of exam processes**	The laboratory must comply with the screening programme action values and use as a minimum, the protocols and algorithms that are specified in the SCT Programme Handbook for antenatal screening. • QC for antenatal screening for sickle cell and thalassaemia	Standard operating procedures. Evidence demonstrated in the visit, for example results.
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5.6	**Ensuring quality of examination results**		
5.6.3	**Interlaboratory 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 adopt the following general principles for the standardised reporting of antenatal screening results as published in the SCT Handbook for antenatal laboratories.	Scanned / screenshot copy of report

5.8.3	**Report content**	The laboratory must issue reports in accordance with the model frameworks set out in the SCT Handbook for antenatal laboratories.	Scanned / screenshot copy of report
5.9	Release of results - As ISO 15189		
5.10	Information management - As ISO 15189		