# NHS Infectious Diseases in Pregnancy Screening Programme: laboratory quality assurance evidence requirements

| ISO 15189 | ISO Requirement | NHS Infectious diseases in pregnancy 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** | **General** | The initial screening tests for all 3 infections must be performed in a single laboratory or within a single multidisciplinary pathology department. | Laboratory / department structure |
| **4.1.1.4** | **Laboratory director** | The laboratory must have robust oversight and leadership of screening, including:<br>• senior leadership for screening in the laboratory with a named clinical lead, senior member of staff at consultant level (medical or clinical scientist) accountable for the IDPS screening service<br>• there should also be management structure for screening that includes a named senior biomedical scientist | 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 infectious diseases in pregnancy screening in the event of any failures to the laboratory service. | Business continuity plan / Emergency plan / Business contingency |

| ISO 15189 | ISO Requirement | NHS Infectious diseases in pregnancy screening: laboratory quality assurance requirements | Examples of evidence to be assessed |
|---|---|---|---|
| | | | standard operating procedure or policy<br>Evidence that this plan was 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:<br>• having clear communication arrangements with users and commissioners of the service, including public health<br>• 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 infectious diseases in pregnancy screening laboratory service.<br><br>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:<br><br>• receiving and processing specimens to enable matching of these against the cohort of women who have accepted screening<br>• identifying and recording un-labeled or mislabeled specimens, and specimens unsuitable for analysis (including inadequate specimens), and requesting and receiving repeat specimens<br>• making sure that screen positive or inconclusive results in written or electronic form are not reported to the maternity service (for example | All standard operating procedures for infectious diseases in pregnancy screening undertaken within the laboratory |

| ISO 15189 | ISO Requirement | NHS Infectious diseases in pregnancy screening: laboratory quality assurance requirements | Examples of evidence to be assessed |
|---|---|---|---|
| | | screening coordinator/specialist midwife/clinical nurse specialist) until confirmatory tests are completed on the screening specimen<br>• making sure the laboratory directly informs the lead within the IDPS multidisciplinary team/screening midwifery team of a confirmed screen positive result and records when and to whom the result was communicated to<br>• making sure there is a process between the laboratory and the screening coordinator/specialist midwife to alert them to an inconclusive result - laboratories require a sample 2 weeks later | |

| | | | |
|---|---|---|---|
| **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.<br><br>The following documents are expected to be controlled, as external documents, as a minimum:<br>• NHS England Serious Incident Framework<br>• NHS Screening Programme Managing Safety Incidents in NHS Screening Programmes<br>• NHS service specification for IDPS<br>• NHS IDPS Screening Programme. Handbook<br>• NHS IDPS Screening Programme. Laboratory Handbook<br>• NHS IDPS Screening Programme. Standards<br>• NHS Screening Programmes. Key Performance Indicators (KPIs): submission guidance and data definitions | Screenshots / evidence of listed documents within QMS |
| **4.4.** | **Service agreements** | | |

| ISO 15189 | ISO Requirement | NHS Infectious diseases in pregnancy screening: laboratory quality assurance requirements | Examples of evidence to be assessed |
|---|---|---|---|
| **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.<br><br>For IDPS the agreements must include arrangements for:<br>• confirming specimen receipt<br>• managing missing or inadequate information and repeat specimens<br>• meeting the laboratory test turnaround time<br>• making sure that screening results are sent back to the requestor as specified in the service level agreement<br>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** | | |

| | | | |
|---|---|---|---|
| | **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 nonconformities.<br><br>Screening non-conformities must be reviewed, managed and reported where appropriate according to local, NHS and PHE frameworks for screening incidents, in particular the NHS England Serious Incident Framework and NHS | Incident management / non-conformity policy demonstrating link to local, NHS and PHE frameworks for screening incidents. |

| ISO 15189 | ISO Requirement | NHS Infectious diseases in pregnancy screening: laboratory quality assurance requirements | Examples of evidence to be assessed |
|---|---|---|---|
| | | Screening Programme Managing Safety Incidents in NHS Screening Programmes. | |
| 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 IDPS programme requirements. This must include audit of all the quality indicators in 4.14.7. | IDPS related audits.<br>Audit programme.<br>Minutes of meetings that audit is presented at and any associated action plans. |

| | | | |
|---|---|---|---|
| **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 IDPS 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 screen positive specimen. | Vertical audit. Associated action plans.<br>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 | Risk management policy. |

| ISO 15189 | ISO Requirement | NHS Infectious diseases in pregnancy screening: laboratory quality assurance requirements | Examples of evidence to be assessed |
|---|---|---|---|
| | | testing pathway where errors could occur and the procedures taken to minimize the risk of the error occurring.<br><br>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. | |

| | | | |
|---|---|---|---|
| **4.14.7** | **Quality indicators** | The laboratory must comply with requirements for meeting and reporting IDPS screening standards and key performance indicators.<br>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.<br><br>The laboratory must:<br>• meet the acceptable threshold for IDPS Standard 4 'Testturnaround time (HIV, hepatitis B, syphilis)' The proportion of antenatal screening samples for HIV, hepatitis B and syphilis where a result is available (confirmed screen positive or negative) and reported to maternity services within 8 working days of sample receipt - Acceptable: ≥ 95.0% Achievable: ≥ 97.0%<br>• submit data to maternity services for IDPS screening standards for ', to support maternity reporting Standard 1 'HIV coverage', Standard 2 'hepatitis B coverage and Standard 3 'syphilis coverage' | KPI and annual data submissions |
| **4.15** | **Management review** | | |
| **4.15.1** | **General** | The laboratory must include infectious diseases in pregnancy screening as part of its management review of the quality management system. | Management review document<br>Minutes of meetings where review presented and ratified for sign off. |

| ISO 15189 | ISO Requirement | NHS Infectious diseases in pregnancy screening: laboratory quality assurance requirements | Examples of evidence to be assessed |
|---|---|---|---|
| **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** | | |
| **5.4.3a.** | **Request form information** | The laboratory must use paper or electronic data request fields that are compliant with the minimum data fields set out in the IDPS Programme Laboratory Handbook<br>The specimen must be clearly identified as an antenatal screening specimen, and assigned a laboratory accession number on receipt of the specimen, on the form and on the laboratory management system. | 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 adopt the screening algorithms and protocols as defined by the national screening programme. These define the conditions to be tested and the analytical methods that must be used, together with any national action limits and the diagnostic sensitivity and specificity that must be achieved. The laboratory must submit its assays on the UKAS Accreditation Category (AC) form and be UKAS accredited for those assays. | |
| **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** | | |
| **ISO 15189** | **ISO Requirement** | **NHS Infectious diseases in pregnancy screening: laboratory quality assurance requirements** | **Examples of evidence to be assessed** |
| 5.7.2 | **Storage, retention and disposal of clinical specimens** | When the screening tests are complete an aliquot (a suggested minimum volume of 300 microliters) from the screening specimen must be stored frozen at a minimum temperature of -20 degrees Celsius for at least 2 years.<br>If cases where there is insufficient volume to store an aliquot of the screening specimen then a local process should be in place to document, monitor and manage this, for example by requesting a second sample and informing the women of the reason. Laboratories should consider reporting the proportion of samples where it is not possible to store an aliquot of the screening specimen to maternity services.<br><br>. | Storage of samples SoP / process document<br>Copy of anonymised log if appropriate |
| **5.8** | **Reporting results** | | |
| | | The laboratory must not communicate results either in written or electronic form to the maternity service until confirmatory testing is completed on the screening sample. | Scanned / screenshot copy of report |
| 5.9 | Release of results - As ISO 15189 | | |

| | | |
|---|---|---|
| 5.10 | Information management - As ISO 15189 | |