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| **Vertical Audit (BS EN ISO 15189:2012)** | | **Tees Valley Pathology Service** | | |
| **Audit topic:** |  | **Date of previous audit** |  | |
| **Are there outstanding non-conformances from previous audit?** |  |  | | |
| **Date** |  | **Auditor(s)** |  | |
| **ISO reference** | **Question** | **Record / procedures checked** | **Findings** | **Non conformance / observation raised** |
|  | **Request Form** |  | | |
| 5.4.3 | Is the request form available for this specimen? |  |  |  |
| 5.4.3 | Does the request form include: |  |  |  |
| a | * Patient identification including gender, DOB, location of patient, and a unique identifier |  |  |  |
| b | * Name or other unique identifier of the clinician, or other person legally authorised to request examinations or use medical information together with destination for the report and contact details |  |  |  |
| c | * Type of primary sample and where relevant site of anatomical origin |  |  |  |
| d | * Examinations requested |  |  |  |
| e | * Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes |  |  |  |
| f | * Date and where relevant, time of primary sample collection |  |  |  |
| g | * Date and time of sample receipt |  |  |  |
|  | **The specimen** |  | | |
| NA | Is the specimen(s) still available for this test(s)? |  |  |  |
| 5.7.2 | If not has it been discarded within the timeframe allowed by the procedure for control of clinical material? |  |  |  |
| 5.4.4.2c | Has the sample arrived in a container/fluid suitable for the request? |  |  |  |
| 5.4.6a | Does the patient demographics on the sample match that on the request form? |  |  |  |
| 4.5 | If the sample or sub sample was referred to another laboratory, are records in place of tests sent away? |  |  |  |
| 5.4.4.3 | If sample is high risk is it labelled according to trust labelling policy? |  |  |  |
|  | **Data entry** |  | | |
|  | Has transcription of patient demographics been done accurately? |  |  |  |
|  | **Remaining specimen** |  |  |  |
| 5.7.2 | Are remaining samples stored appropriately and for an appropriate period of time? |  |  |  |
| 5.7.2 | Is the retained material uniquely identified? |  |  |  |
| 5.7.2 | Is the storage recorded (including location and subsequent disposal)? |  |  |  |
|  | **Examination Procedure** |  |  |  |
| 5.5.3 | Is there a valid SOP for each required procedure? List those checked |  |  |  |
| 5.5 | Are records available for each stage of the procedure such that there is a complete audit trail? |  |  |  |
| 5.6.2.2 & 5.6.2.3 | Was the internal QC acceptable when this test(s) was carried out, if appropriate? |  |  |  |
| 5.6.1 | Has the laboratory designed quality control procedures that verify the attainment of the intended quality of results? |  |  |  |
| 5.3.1.5 | Is there evidence of routine maintenance of equipment used? |  |  |  |
|  | **Reporting results** |  | | |
| NA | Is it possible to generate a copy of the report? (This may be in written or electronic form e.g. ICE) |  |  |  |
| NA | Does the report match the request form with regard to patient demographics? |  |  |  |
| NA | Does the report match the request form with regard to laboratory number/s? |  |  |  |
| 5.9.1.e | Is there evidence of the result being telephoned? |  |  |  |
| 5.9.1.e | If YES, was it phoned according to the SOP? |  |  |  |
| NA | Has the report been authorised? |  |  |  |
| NA | Is the turnaround time acceptable? |  |  |  |