|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **VERTICAL ASSESSMENT CHECKLIST** | |  | |
| DATE OF EVALUATION |  | | | |
| ASSESSOR/S &OBSERVERS |  | | | |
| LABORATORY |  | AREA/FIELD OF OPERATION |  | |
| LABORATORY REPRESENTATIVE |  |
| REPORT/TEST | Select one or more parameter and record the number and date | | | |
| Lab no. | | | | |
| **REQUIREMENTS AND COMMENTS**  conformance=c Non-conformance=N c Not applicable=NA | | | | |
| **TECHICAL RECORDS ( state which data and calculations were checked**) | | | | |
| Raw data/original observations, calculations, derivations | | | |  |
| Traceability to the performing operator | | | |  |
| Records permanent, correlations legible and authorized | | | |  |
| Appropriate calculation checks.( Randomly calculate) | | | |  |
| Randomly check correctness of data transfers. Laboratory’s control checks appropriate/effective | | | |  |
| Comments: | | | |  |
| **TRAINING: ( check training competence of identified operator)** | | | |  |
| Operator/s identified as competent for the work and is proof of competence available | | | |  |
| Appropriate method of determination of competence | | | |  |
| Comments: | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Performance capability of selected methods** |  | | | |
| Proof of confirmation of proper operation of standard methods |  | | | |
| Methods validated and availability of performance capability |  | | | |
| Proof of monitoring of trends and shifts |  | | | |
| Comments: |  | | | |
| **Assurance of validity of results** |  | | | |
| Proof of monitoring of TAT |  | | | |
| Presence of control charts that are evaluated/reviewed |  | | | |
| Effective control limits or tolerance been established |  | | | |
| Evidence of actions implemented when breaches occurred |  | | | |
| Comments: |  | | | |
| **Proficiency testing/ inter laboratory comparisons** |  | | | |
| Appropriateness for the work performed |  | | | |
| Evaluate results-action taken on anomalies or outliers |  | | | |
| Comments: | | | | |
| **Calibrations of equipment and/or standards used** | | | | |
| Appropriate of calibration and verification programmes, cover operating range calibration status | |  | | |
| Records of calibration and verification complete | |  | | |
| In house verification sufficient to ensure validity of calibration | |  | | |
| Comments: | |  | | |
| **Equipment maintenance and operation** | |  | | |
| Instructions on use and maintenance | |  | | |
| Records complete | |  | | |
| Handling /transport/storage/use to prevent contamination of equipment | |  | | |
| Comments: | | | | |
| **Accommodation and environmental conditions** | |  | | |
| Critical areas of accommodation/environmental control which would affect the performance of work(air conditioning) | |  | | |
| Evidence of cleanliness | |  | | |
| Monitored, controlled and auctioned when required | |  | | |
| Effective segregation of reagents | |  | | |
| Adequate storage areas | |  | | |
| Comments: | | | | |
| **Purchasing of supplies** | | | |  |
| Supplies verified prior to use to meet the quality criteria | | | |  |
| System to ensure supplies for the interrupted performance of work documented and effective e.g. stock control, requisitioning, ordering and storage | | | |  |
| Comments: | | | | |
| **Handling of patients samples** | | |  | |
| Uniquely identified, ensure that there can be no confusion regarding the identity at any time | | |  | |
| Condition of the item noted, where applicable | | |  | |
| System to avoid deterioration/damage during storage, handling, preparation and testing | | |  | |
| Comments: | | | | |
| **Reporting of results** | | | | |
| Results with reference ranges | | | |  |
| Results with date, and time of completion | | | |  |
| Results verified by independent technologist | | | |  |
| Results legible | | | |  |
| Comments: | | | | |
| AUDITOR: SIGNATURE: | | | | |

QUALITY OFFICER\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LAB IN CHARGE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

MEDICAL SUPERINTENDENT\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_