|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Laboratory Section/Department:** | | | **Instrument/Device/Tests:** | | **Date**: |
|  | **QA Process/Monitor** | **Issues Identified** | | **Actions Taken (eg, retraining, patient lookback, investigation of cause)** | |
|  | Quality Control performed appropriately and reviewed monthly | QC issues resolved? | |  | |
|  | Temperature log sheets completed and reviewed monthly | Out of range or missing temperatures resolved? | |  | |
|  | Maintenance logs completed and reviewed monthly | Incomplete data? Corrective actions recorded? | |  | |
|  | Instrument issues resolved and recorded | Instrument failures or downtime? | |  | |
|  | Proficiency testing performed and reviewed | Unsuccessful PT performance? | |  | |
|  | Sampling of personnel training/competency reviewed | Retraining needed? | |  | |
|  | Sampling of patient results reviewed | Reporting errors corrected? | |  | |
|  | Relevant quality indicators reviewed | Turnaround time, corrected reports, specimen rejection, etc.? | |  | |
|  | Laboratory occurrence reports | Corrective actions completed? | |  | |
|  | Complaint reports | Physician or care giver concerns? | |  | |
|  | IQCP reapproval by laboratory director or designee, as required | Does the IQCP need to be modified based on any issues identified? | |  | |
|  |  |  | |  | |
|  |  |  | |  | |
|  |  |  | |  | |

* Have test process failures been identified?
  1. Assess the use (eg, timely, effective) of the monthly review process of quality control, temperature, and maintenance logs to identify problems
  2. Record any corrective action for patient results affected by the testing process failure.
  3. Evaluate the effectiveness of the corrective action taken.
* Have any changes been made to the five elements of the Risk Assessment (ie, reagents, environment, specimen, testing personnel, or test system) requiring reevaluation of the Quality Control Plan?
* Have any changes been made to the Quality Control Plan?
  1. Specify any updates/modifications
* Have revisions to the Quality Control Plan been signed by the laboratory director (including signature and date)?
* Is the IQCP sufficient to mitigate risk in this laboratory? If no, explain actions to be taken.

Reviewed by:

Laboratory Director/Designee Click here to enter text. Date