Turnaround Time Policy

Purpose: This policy has been developed to meet the Clinical Laboratory Improvement Amendments (CLIA) Standards 493.1249 (Standard requirements for Preanalytic Systems Quality Assessment), 493.1289 (Standard requirements for Analytic Systems Quality Assessment), and 493.1299 (Standard Requirements for Postanalytic Systems Quality Assessment).

Principle: In an effort to establish expectations on the part of Ohio Department of Health Laboratory (ODHL) testing staff as to when an assay result may be reasonably expected to be provided for a specimen/sample submitted by either an external or internal client, a turnaround time (TAT) has been established for each assay at the ODHL. In summary, the laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the preanalytic, analytic and postanalytic systems.

1. Establishing TAT

1.1. The ODHL has established acceptable turnaround times for all assay categories. The TATs are based on standard practices, clinical need, and available resources. See monthly template for current acceptable TAT values.

2. Monitoring of TAT

2.1. Turnaround times will be monitored on a monthly basis for each of the assays as indicated on the TAT template form.

2.2. A monthly summary report will be issued to the Laboratory Director by the Quality Assurance office no later than one month past the month being reported (ex. April summary report will be issued by June 1) indicating which testing met the established TAT and which testing did not meet the established TAT.

- 2.2.1. The Quality Assurance office will provide access to an electronic version of the report and accompanying documents used to determine TATs.
- 2.2.2. The TAT report will remain preliminary until the TAT for the final specimen received for that month can be reported.
- 2.2.3. Upon completion of the final TAT determination, the TAT report will be printed and provided to the Laboratory Director for review and signature.

2.3. It is the responsibility of the Quality Assurance office and Section Supervisors to ensure the TAT data is available in an accurate and timely fashion for completion of the monthly summary TAT report.

2.4. In addition to the monthly summary reports, the Quality Assurance office will provide quarterly and annual summary TAT reports to the Laboratory Director for review and approval.

3. Quality Assessment of TAT

3.1. In order to assure that the laboratory is providing timely test result reporting, TAT is monitored and evaluated on a regular basis (e.g. monthly, quarterly and annually).

3.2. The acceptable TAT monitors for each assay will be reviewed by the Laboratory Director and the appropriate Section Supervisor at least annually and adjusted as needed.

3.3. Should an assay fail TAT, the Section Supervisor is responsible for supplying an explanation for the failure and corrective actions to be taken, as applicable, to prevent the failure from occurring again. The explanations will be provided to the Quality Assurance office for inclusion with the summary report. All variables that contribute to the failed TAT (i.e., preanalytic, analytic and post-analytic) must be addressed in the explanation.

3.3.1. Staff will provide documentation through the use of email to the Quality Assurance office as soon as it is recognized that a specimen will be out of TAT. The email communication to the Quality Assurance office will be entitled "TAT Notification LITS #".

3.3.2. As necessary, the Quality Assurance office will provide notification to the testing section a list of specimens being out of TAT.

3.4. For assays that fail TAT due to the same explanation for two concurrent months, a "Request for Remedial Action Form" will be initiated by the Section Supervisor. See "Corrective Action Policy" for more information.

3.5. If trends or patterns develop that affect a specific assay or more than one testing section of the TAT report, a continuous improvement activity will be developed by the Section Supervisor(s), Quality Assurance office, and the Laboratory Director.

4. Record Retention

4.1. The TAT reports and supporting documents will be retained by the Laboratory Director or designee for a period of no less than 2 years.

5. References

5.1. CLIA Standard 493.1249; Standard requirements for Preanalytic Systems Quality Assessment)

5.2. CLIA Standard 493.1289; Standard requirements for Analytic Systems Quality Assessment)

5.3. CLIA Standard 493.1299; Standard Requirements for Postanalytic Systems Quality Assessment

Signature Approvals

_____ / 7/7/2014
QA Officer Date

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Laboratory Director Date