**Proficiency Testing**

**Purpose**

This policy and procedure provides written guidelines for the processes and procedures to effectively perform and monitor proficiency testing.

**Policy**:

Hanover Hospital Laboratory participates in external proficiency testing (PT) programs through CAP or CAP accepted alternate provider programs for most testing performed. For those analytes not covered by the external PT programs; testing is monitored twice yearly by alternate testing.

PT Samples, records and reports are handled as outlined in this procedure.

The laboratory’s current CAP Activity Menu is continuously updated when procedures are removed or added and accurately reflects testing performed.

**Responsibility**:

 The Medical Director is responsible for:

* Providing oversight for proficiency testing issues.
* Reviewing and signing of all proficiency testing results.
* Ensuring follow-up and corrective action is adequately performed for discrepancies.
* Reviewing and signing discrepancy follow-up and corrective action documentation.

The Laboratory Administrative Director is responsible for:

* Ensuring appropriate proficiency testing material is acquired.
* Ensuring proficiency testing is performed, reported, and monitored by all laboratory departments.

The Laboratory Technical Supervisors are responsible for:

* Ensuring proficiency testing specimens are received according to the survey schedule.
* Ensuring proficiency testing specimens are not damaged or missing and to arrange for any replacements if necessary.
* Ensuring that staff integrate proficiency testing into the routine workload and that the testing is performed by personnel who routinely test samples using the same primary method systems as for patient samples.
* Reviewing PT results, signing the evaluation submission forms, and reporting the results to the external PT provider in a timely manner before submission deadlines.
* Reviewing all proficiency testing evaluation results.
* Investigating unacceptable or otherwise discrepant results and performing the appropriate follow-up, correction action, and documentation.

The laboratory staff is responsible for:

* Performing and documenting proficiency tests as directed.

**Selection of Assessment**

**Products:**

The laboratory utilizes proficiency testing products from the College of American Pathologists (CAP), Pennsylvania Department of Health State Bureau of Laboratories, and other CAP accepted alternate providers.

**Receipt:**

1. Proficiency testing is received by mail. If the survey kits are not received within 72 hours of the anticipated arrival date; the technical supervisor contacts the PT program provider.

2. Staff receiving the PT material determine whether it needs to be test immediately or stored at package instruction temperature. If uncertain, the appropriate laboratory technical supervisor or key operator is consulted.

3. The kit is then distributed to the appropriate laboratory testing department or storage location.

**Preparation, Handling,**

**and Testing:**

1. Proficiency testing material is stored at the temperature specified in the kit instructions until testing is performed.

2. Laboratory testing staff prepare samples and perform testing per kit instructions.

3. When reconstitution is required; proficiency products are reconstituted using certified volumetric or calibrated automatic pipets.

4. Specimens are integrated into the normal workload and processed by testing personnel who routinely perform patient testing and using the primary test system method.

5. PT specimens are treated and tested in the same manner as patient samples.

6. Replicate analysis of PT is performed only when patient samples are analyzed in the same manner for the test.

7. There is no interlaboratory communication on PT data before results have been reported *unless* this is routinely performed for patient samples for the test.

8. Communication, consultation, or referral of PT samples to another laboratory is prohibited. Nor does our laboratory accept, communicate, or consult with another laboratory about PT samples.

**Documentation and**

**Reporting:**

Care must be taken when preparing the report for submission to CAP as clerical documentation or entry errors are just as critical as testing errors.

The laboratory staff documents the results of the proficiency tests on the data submission forms. The attestation statement must be signed by the individuals involved in the testing process. A printed or typed listing of names on the attestation statement is not acceptable.

The supervisor reviews the data submission forms or entry prior to submission of results to very test performance and ensure method codes are present and correct.

The Medical Director has designated that the technical supervisors may review and sign the data submission forms prior to transmission to CAP or alternate providers.

Data is submitted via mail, fax, or on-line prior to deadline to the appropriate external organization for evaluation and comparative analysis with other laboratories.

**Evaluation Review:**

PT evaluation results are reviewed by the technical supervisor and by the Laboratory Medical Director. Each of these individuals records this reviewing by signing and dating the evaluation report.

The reports are reviewed for unacceptable results and also for other discrepancies such as trends, bias, and marginal values (SDI>1.5). When deficiencies/discrepancies are noted for any test; investigation is conducted to determine the cause. This investigation includes but is not limited to:

* Reviewing survey specimen handling and preparation for testing.
* Reviewing result documentation for clerical errors.
* Reviewing quality control results.
* Reviewing calibration.
* Repeat testing (if applicable and available)
* Procedural errors.
* Staffing competency.

The form entitled Proficiency Testing Discrepancy Documentation (LAB #997) is used to document the investigation and follow-up documentation.

Results of this investigation follow-up, and corrective action are documented and reviewed and approved by the Laboratory Medical Director by signing and dating the documentation.

The PT participant summary report is used to compare our results against peer results when PT challenges are not graded due to lack of consensus or because the laboratory submitted results after the deadline for submission, failed to submit results, or made an error in result entry. This comparison review is documented and kept with the PT results.

**Files:**

The laboratory files all documents and records related to proficiency testing for a minimum of 2 years (Blood Bank 5 years). This includes instrument printouts, original report forms, discrepant result investigations, etc.

**Policy Note**:

If the laboratory is instructed by the CAP to cease patient testing for an analyte or subspecialty due to repeated unsuccessful proficiency testing; the laboratory will discontinue testing immediately and retain records that demonstrate that no patient testing results are released until after the laboratory receives approval from the CAP to resume patient testing. Such records would include: communications notifying providers that the test is suspended for the required time, LIS reports that can be run to verify no patient results were reported for the affected analyte, and a send out log or electronic trail indicating testing has been sent to a reference laboratory in the interim until testing can once again be performed in-house.

**References and**

**Supporting Documents:**

College of American Pathologists, Laboratory All Common Checklist, COM.01000, COM.01100, COM.01200, COM.01300, COM.01400, COM.01600, COM.01700, COM.01800, COM.01900, COM.01950, Waukegan Road, Northfield, IL 60093-2750, 7/29/2013.

Hanover Hospital Laboratory Administrative Manual, Proficiency Testing – Alternate Performance Assessment.

Hanover Hospital Laboratory, Proficiency Testing Discrepancy Documentation Form (LAB #997).

**Review and**

**Update**

 Prepared By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Laboratory Administrative Director

 Approved By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Laboratory Medical Director

**Replaces**

**Procedure**: \_\_\_\_\_ADM 7002.01 Proficiency Testing (7/4/2007)

Reviewed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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