Methodist Health Services Corporation & UnityPoint Health Methodist|Proctor Laboratory 7000 Administration	Page # 1 of 4	Section: UPPIA LA: Regulatory & Administrative	Policy #: 02.003 Formerly: B - 3
	Approved by: see signature block at end of document		Date: 1/25/16
	Revised: 3/27/13, 8/25/11, 7/27/10, 9/1/08, 4/19/06, 10/13/04, 9/27/04, 8/18/2004, 3/03/2003, 1/3/03, 6/23/2000, 9/29/98, 1/5/96, 1/3/96		
	Reviewed:		
	Policy/Revision Submitted by: Laboratory Director		
	CAP Standard: NA		

POLICY GUIDELINE ON: **Proficiency Testing of Waived, Moderate and High Complexity Tests**

I. POLICY:

The laboratory will enroll in an approved proficiency program if available. If an approved proficiency program is not available, a defined process will be used to determine the accuracy and reliability of results.

II. PURPOSE:

To ensure that the laboratory is providing both accurate testing results and is in compliance with CLIA regulations.

III. POLICY SCOPE:

The scope of this policy applies to all Laboratory staff at Methodist and Proctor campuses performing testing.

IV. GENERAL INFORMATION:

A. The laboratory must enroll in available approved proficiency program(s) for the regulated analytes in each of the specialties and subspecialties for which it seeks certification.
   1. Proficiency testing is required for only the test assay used as the primary method for patient testing.
   2. The laboratory must participate in a proficiency testing program for a minimum of one year before it designates a different program.
   3. HCFA is to be notified of any changes in the programs.
   4. The laboratory currently uses the College of American Pathologists proficiency program, Wisconsin State Lab Hygiene and American Proficiency Institute.

B. The laboratory must test the samples in the same manner as patients' specimens.

C. The laboratory must authorize proficiency programs to release to HHS all data to determine the laboratory's compliance and to make the proficiency testing results available to the public as required.

D. The laboratory sections will not engage in any inter-laboratory or external laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report the results to the program for the testing event in which the samples were sent.
   1. The laboratory will not engage in any communication within the institution concerning duplicate proficiency samples being performed by more than one testing site.
   2. The laboratory will not send proficiency testing samples to another laboratory for analysis which they are certified to perform in their own laboratory.

E. The laboratory will document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.
    1. The laboratory will maintain a copy of all records, including a copy of the proficiency testing program report forms used the laboratory to record proficiency testing results including the attached statement, signed by each analyst and the laboratory director (designee) documenting that proficiency testing samples were tested in the same manner as patient samples.
    2. These records must be kept a minimum of two years and 5 years for blood bank.

F. If a test is not subject to proficiency testing, the laboratory must have a system for verifying the accuracy and reliability of its test results at least twice per year.

V. PROCEDURE:

A. Receipt of Survey Samples

1. Proficiency testing samples arrive in the laboratory by mail or overnight carrier. They should immediately be given to the Laboratory Manager or Coordinator, who will be responsible for seeing that the appropriate testing section receives the Survey Samples.
2. Laboratory Manager and/or Coordinator is responsible for initiating a Survey Checklist, and assigning testing of the survey specimens.

B. Testing of Survey Samples

1. Testing is to be completed within the time limits specified by the assignment notice.
2. Testing sections will document the handling, preparation, processing, examination, and testing as is appropriate for the section and as instructed by the Manager/Coordinator.
3. Proficiency testing of Waived, Moderate, and Highly Complex Tests will be performed in the same manner as patient specimens.
4. Results of all testing, recorded on the survey result form. All worksheets, printouts and corresponding QC are to be stored in the survey folder.

C. Reporting of Results

1. The Laboratory Manager or Coordinator or Team Leader will review all results and enter results electronically.
2. The completed original Survey Result form or copies of electronically entered reports will be reviewed by the team leader (as appropriate), the Laboratory Manager or Coordinator, and the Pathologist/Ph.D. These reviews are to be documented on the Survey Checklist. Testing personnel and the Pathologist/Ph.D. must also sign the attestation statement.
3. When review of results is completed, the Laboratory Manager, Coordinator or Lead will photocopy the completed original result form to be maintained in the laboratory or maintain a copy of results entered electronically.
4. The result form(s) and the documented Survey Checklist will be kept and filed for documentation.
5. The Laboratory Manager, Coordinator or Lead will either send/fax the original result form to the CAP, WSLH, or API or submit the results electronically.

D. Receipt/Review of CAP Survey Results

1. The Laboratory Manager receives in the mail survey proficiency testing results.
2. The Laboratory Manager places results in the coordinators mailbox..
3. The Laboratory Manager or Coordinator retrieves the Survey Checklist and photocopied result form from the file, placing this paper work with the survey result.
4. The results are reviewed and the review documented as indicated on the survey checklist (Coordinator or Laboratory Manager, Pathologist/Ph.D., and the Laboratory Medical Director). The Laboratory Medical Director only reviews surveys with deficiencies.
5. When the review is completed, all paperwork is filed in the Survey file cabinet or survey manuals.

E. Corrective Action

1. If the laboratory fails to participate successfully in a given specialty, subspecialty, analyte or test, immediate steps must be taken in the testing section to troubleshoot the problem.
   a. It is imperative that the problem be corrected prior to the receipt of the next proficiency testing sample(s).
   b. The remedial action must be documented on the Survey Exception Form, Linearity Survey Investigation Doc. Form, or other appropriate means.
   c. This documentation must be filed with the other survey paperwork and maintained for a minimum of two years from the date of participation in the Proficiency Testing event.
2. A separate grading formula is established for each specialty/subspecialty.
   a. All subspecialties are given an overall score, and some are also scored for each analyte or test.
   b. For most specialties/subspecialties, analytes or tests, the minimum passing score is 80%.
   c. The exceptions are ABO and D (Rho) typing and compatibility testing for which 100% is required.
3. Failure to participate in a testing event is unsatisfactory performance (with a limited number of documented exceptions) and results in a score of zero for the testing event.
4. A laboratory that fails two consecutive or two out of three testing events will be subject to sanctions for the specialty, subspecialty, analyte or test.
   1. Sanctions may include:
      a. The suspension of the laboratory's certificate and
      b. Termination of Medicare or Medicaid approval.
5. If the laboratory has proficiency testing challenges that were not graded for some reason (i.e. submitted late, etc.), then the results will be submitted and documentation made on the routing sheet. This will be communicated at the next department PI meeting. The results will be evaluated and compared to similar methods and reviewed against peer group data.

F. **Steps to be taken when the laboratory is subject to CLIA Sanctions:**

1. The laboratory must immediately contact the CAP by telephone at 800-323-4040 and by certified letter to inform them of the failure.
   a. This letter will be initiated by the Laboratory Manager, signed by the Laboratory Medical Director with a copy to the Administrative Director.

2. The laboratory must immediately take steps within the testing section to prevent the reporting of results of the failed specialty, subspecialty, or analyte.
3. The laboratory must make immediate arrangements with another certified laboratory to perform the failed testing in a timely fashion and to provide evidence on the chart as to where the results, once obtained, were performed.
   a. The Laboratory Medical Director will designate that laboratory.
4. The laboratory must amend the charting format to indicate (when needed) that the result will be forthcoming if the failed analyte is part of a profile or group test.
5. After a certificate has been withdrawn, the laboratory must demonstrate sustained satisfactory performance on two consecutive Proficiency Testing events, one of which may be on site before CAP and HCFA will consider reinstatement and Medicare or Medicaid approval in that specialty, subspecialty, or analyte.
6. The termination period for Medicare or Medicaid approval or the suspension of a certificate is for a period of not less than six months form the date of termination or suspension.
7. If the laboratory's certificate is suspended and/or Medicaid approval is terminated in gynecologic cytology, the laboratory must take corrective action and re-apply for certification.
8. Upon passing two consecutive Proficiency Testing events, another letter will be sent to CAP stating that we have passed two consecutive events and will begin, as of _____ (date), analyzing specimens and billing Medicare.

G. Analytes for which proficiency testing is unavailable

1. All test(s) performed by the Department of Pathology not included in Subpart 1, Proficiency Testing Programs of the CLIA regulations and not classified as waived testing, must be tested twice a year for accuracy and reliability.
2. Two general processes are used to determine the accuracy and reliability of analytic results for which no external proficiency testing is available.
   a. One process is split sample analysis (sample analyzed by procedure being validated and by a reference laboratory or by an established in-house method).
   b. The second process is clinical validation by a Pathologist/Ph.D. Patient results for these tests will be reviewed in conjunction with the patient chart to check to see that the results correlated with the patient's clinical picture.
3. Procedure
   a. Split sample analysis
      (i) Rubeola (split analysis with ARUP)
      (ii) Heparin Antibody
      (iii) Breath Hydrogen
      (iv) LAP
      (v) 0_2 Saturation/Oxicom (Cath Lab)
   b. Clinical validation by a Pathologist/Ph.D.
      (i) Current methodologies using the process include:
         (i) Charcoal
         (ii) Dysmorphic RBC's
      (ii) The criteria used for this process will be that the test results fall within the realm of the patient's clinical picture.

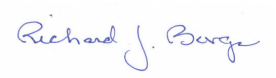
4. The split sample analysis process defined above will be exercised at least semi-annually. The clinical validation process will be exercised with each patient tested for the above mentioned tests.
5. The Laboratory Medical Director (or designee) will review the results from the sample analysis comparisons. If the sample comparison results are found to not fall within the acceptable criteria, follow-up investigation and troubleshooting will be performed until favorable comparisons are obtained. No patient results will be released until this time.
6. The Laboratory Manager or Coordinator will maintain a file of the test study results for a period of at least 2 years.

V. MAINTENANCE AND STORAGE:

A. All policies and procedures are reviewed every two years by Laboratory Administration and or the Medical Director of the Laboratory or designee.
B. The Laboratory Administration and Medical Director review policies and procedures when there are changes in practice standards, or requirements.
C. All policies and procedures are reviewed every two years by staff or at the time new or revised ones are put in effect.
D. All policies are retained 8 years after being discontinued or revised.
All procedures are retained 2 years after being discontinued or revised.

REVISION HISTORY (began tracking 2012)			
Rev	**Description of Change**	**Author**	**Effective Date**
1	System logo changed, formatting changes	T. Lanan	3/27/13

Reviewed by

Designee	Date	Laboratory Director	Date
			10/5/15