Methodist Health Services Corporation & UnityPoint Methodist|Proctor Laboratory ADMINISTRATION	Page # 1 of 6	Section: Regulatory & Administrative	Policy #: 02.005 Formerly: B 05
	Approved by: see signature block at end of document		Date: 11/21/16
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	Policy/Revision Submitted by: Richard Borge		
	Standard: NA		
POLICY GUIDELINE ON: **Personnel Standards to Comply with CLIA Regulations**			

I. POLICY:
The laboratory must meet with the following personnel standards to comply with CLIA regulations.

II. PURPOSE:
The Purpose of this policy is to define the types of personnel needed for a laboratory classified as high complexity testing and the individual requirements of each type of personnel.

III. POLICY SCOPE
This policy applies to all laboratory staff.

IV. GENERAL INFORMATION:

1. Based on test volume and test mix, both Methodist Medical Center, Main Laboratory and Proctor Laboratory is classified as a highly complex laboratory

2. The policy will list the various type of personnel needed for high complexity testing, define the specific qualifications for the various positions, and define the functions and responsibilities for the individuals who fill these positions.
   - If an individual is qualified, he/she can perform the functions of more than one position in either a moderate or high complexity testing laboratory.
   - For example, the same individual may function as both the laboratory director and clinical consultant.

3. The point of care CLIA license if for moderate testing.
4. Records of qualifications, CV and license as necessary are required for all personnel.
5. Record of delegation of duties.

V. PROCEDURE:

1. Personnel requirements for moderate and high complexity laboratory are listed under Subpart M, sections 493.1441 through 493.1495.

2. Personnel required for high complexity testing laboratory.
   a. Laboratory Director
   b. Technical Supervisor
   c. Clinical consultant
   d. General Supervisor
   e. Cytology general supervisor
   f. Cytotechnologist
   g. Testing personnel

3. There are specific qualifications for the various positions in a highly complex laboratory.
   - These qualifications are listed below for each type of personnel.
     a. Laboratory Director - The director has overall responsibility of all testing functions within the Laboratory.
        - At UnityPoint Health Peoria Department of Pathology Laboratory, Methodist Campus Dr. Devendra Trivedi is designated as the Medical Director and Dr. Adam Quinn is Medical Director at Proctor Campus
        - The degree required is that of a pathologist which means no additional training or experience is required.

     b. Technical supervisor - Can be a pathologist with one year of clinical experience, a Ph.D. with one year experience, a Master's Degree person with two years of experience, a Bachelor's Degree person with four years of experience.
        - Also, that clinical experience must be within that specialty or subspecialty.
        - A medical technologist can qualify as a Technical Supervisor.
        - For cytology, to be classified as the technical supervisor, one must be at a doctoral level.
        - Performance Evalautions are conducted on the Section Medical Director every 2 years. A pathologists assigned to a new Directorship must pass a 6 month orientation period.

     c. Clinical Consultant - this person must be qualified to consult with and render opinions to the laboratory clients concerning diagnosis, treatment, and the management of patient care.
        - This particular person must be a pathologist or Ph.D.

     d. General Supervisor - In a high complexity laboratory, the degree required is Pathologist with no experience, a Ph.D. with no experience, a Master's with one year clinical experience, a Bachelor's with one year of experience, and Associate Degree with two years of clinical experience in the specialty or subspecialty.

     e. General supervisor for cytology - May be filled by a technical supervisor or by a cytologist with three years of experience in the preceding ten years.(does not apply to Proctor campus)

     f. Cytotechnologists - Individual must have either graduated from an accredited school of cytotechnology or be certified as a cytotech. (does not apply to Proctor campus)

     g. Testing personnel - Except for Histopathology, for which only board certified pathologists or pathology residents are authorized to perform testing, individuals performing high complexity testing without direct supervision must have at least an Associate's Degree in Laboratory Science or Medical Laboratory Technology. Moderate testing requires a high school diploma.

4. Listed below are the various responsibilities and functions for the individuals who fill these positions.
   A. Laboratory Director
      - Responsible for overall operations and administration of the laboratory.
      - He/she must be accessible for on-site telephone or electronic consultation and may direct no more than five certificates.
      - There are fifteen specifically outlined responsibilities for the director. These include:
        1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing;

2) Ensure that the physical plan and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

3) Ensure that -
   - the test methodologies which are selected have the capability of providing the quality of results required for patient care;
   - verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and
   - laboratory personnel are performing the test methods as required for accurate and reliable results.

4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that --
   - The proficiency testing samples are tested as required under subpart H of these rules;
   - The results are returned within the time frames established by the proficiency testing program;
   - All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require correction action; and
   - An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

8) Ensure that reports of test results include pertinent information required for interpretation;

9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 403.1489(b) (4);

11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provided appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

13) Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently and; whenever necessary, identify needs for remedial training or continuing education to improve skills;

14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, testing performance or result reporting and whether supervisor or director review is required prior to reporting patient test results. (see form 02.005.001)

B. Technical supervisor - is responsible for the technical and scientific oversight of laboratory operations.

- This individual does not have to be on-site at all times, but must be accessible for on-site, telephone, or electronic consultation.
- There are nine specifically outline responsibilities for the technical supervisor. These include.
  1) Selection of the test methodology that is appropriate for the clinical use of the test results;

  2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

  3) Enrollment and participation in an HHS approved proficient testing program commensurate with the services offered;

  4) Establishing a quality control program appropriate for the testing performed and establishing the parameter for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen through sample analysis, and reporting of test results;

  5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently;

9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semi-annually during the first year the individual tests patient specimens.
   - Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be re-evaluated to include the use of the new test methodology or instrumentation.

10) In cytology, the technical supervisor (N/A to Proctor Campus)
   - may perform the duties of the cytology general supervisor and the cytotechnologists;
   - must establish the workload limit for each individual examining slides;
   - must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;
   - must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program;
   - if responsible for screening cytology slide preparations, must document the number of cytology slides screening in 24 hours and the number of hours devoted during each 24 hour period to screening cytology slides.

C. Clinical Consultant
- This individual must be available to provide clinical consultation to the laboratory's clients, be available to assist the laboratory clients in assuring that the appropriate tests are ordered, ensure that reports of test results include pertinent information, and ensures that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation. Records of activities are available.

D. General Supervisor
- Is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.
  a. The general supervisor
     1) Must be accessible to testing personnel at all times testing is performed to provide on-site telephone or electronic consultation to resolve technical problems;

     2) Is responsible for providing day-to-day supervision of high complexity test performance by testing personnel;

     3) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

b. The director or technical supervisor may delegate to the general supervisor the responsibility for --

1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

3) Providing orientation to all testing personnel; and

4) Annually evaluating and documenting the performance of all testing personnel.

E. Cytology general supervisor

a. The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

b. The cytology general supervisor must --

1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

2) Document the slide interpretation results of each gynecologic and non-gynecologic cytology case he or she examined or reviewed;

3) For each 24 hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

4) Document the number of hours spent examining slides in each 24 hour period.

F. Testing Personel

- The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

a. Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

b. Each individual performing high complexity testing must ---

1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations, and maintenance performed;

4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and eight must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

6) Document all corrective actions taken when test systems deviated from the laboratory's established performance specifications.

V. MAINTENANCE:

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 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.
E. All procedures are retained 2 years after being discontinued or revised.

REVISION HISTORY			
Rev	**Description of Change**	**Author**	**Effective Date**
1	Updated maintenance statement & added revision history chart	R. Borge	7/11/11
2	Logo changed, policy scope added	T. Lanan	8/3/13
3	Added reference to form 02.005.001	R. Borge	8/25/16
4	Added section regarding Section Medical Review and time period of competency.	R. Borge	11/21/16

Reviewed by

Designee	**Date**	Laboratory Director	**Date**
		Richard J. Borge	1/16/16
		Richard J. Borge	8/25/16
		Richard J. Borge	11/21/16