Wake Forest Baptist Medical Center	Delegation of Duties in the Clinical Laboratory: Policy on CLIA/CAP Defined Delegations and Responsibilities	Dept:	Pathology
		Effective Date:	1/8/2019
		Revised Date:	New
		Contact:	Lab Compliance, QA and Safety
Name & Title: CLIA Lab Director		Date:	2/6/19
Signature: GPM			

1) **General Policy Statement:** All laboratory staff must understand the roles and responsibilities for personnel as defined by the Clinical Laboratory Improvement Amendments (CLIA) and The College of American Pathology (CAP). Although the CLIA Laboratory Director is ultimately responsible for everything that occurs within a clinical laboratory, CLIA and CAP do allow the Lab Director to delegate some of those responsibilities to other individuals as long as they meet educational, training and experience requirements and background.

Scope: The scope of this policy covers delegation of responsibility from the CLIA Laboratory Director to the following individuals:

- Medical Directors
- Pathologists
- Section Managers/Assistant Managers
- Lead or Specialist Technologists
- Compliance Specialists
- Non-laboratory professionals for Point of Care Testing

It is important to remember that CLIA and CAP role delegation do not have a direct comparison with Human Resource job titles and job descriptions for laboratory employment purposes.

The definitions used in this policy pertain to CLIA and CAP standards interpretations and laboratory structure for compliance purposes.

For purposes of this policy Technical Supervisor and Technical Consultant will be referred to as a single term although it is recognized that one specifically pertains to Moderate Complexity testing and the other to High Complexity testing as referenced under the definitions section.

Responsible Department/Party/Parties:

i. Procedure owner: Department of Pathology
ii. Procedure: Department of Pathology
iii. Supervision: Person named as CLIA Laboratory Director on the certificate for laboratory
iv. Implementation: CLIA Lab Director, Laboratory Compliance Officer, Section Medical Directors, Section Managers/Assistant Managers

2) **Definitions:**

a. **CLIA Laboratory Director (LD):** Person named on CLIA certificate as the Laboratory Director.

b. **Clinical Consultant (CC):** The laboratory must employ one or more individuals who are qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. Clinical consultant roles are provided by pathology school of medicine faculty and other selected school of medicine faculty 42 CFR 493.1455; Clinical Consultant qualifications.

c. **Technical Supervisor (TS):** The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. 42 CFR 493.1449; Technical supervisor qualifications.

d. **Technical Consultant (TC):** The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. 42 CFR 493.1411; Technical Consultant qualifications.

e. **Cytology General Supervisor (CGS):** For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of 42 CFR 493.1469, and provides supervision in accordance with 42 CFR 493.1471; Cytology General Supervisor qualifications.

f. **General Supervisor (GS):** The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provide day-to-day supervision of testing personnel and reporting of test results in which the laboratory performs high complexity tests or procedures. 42 CFR 493.1461: General supervisor qualifications.

3) **Procedure:**

- Persons chosen for delegation of CLIA/CAP responsibilities must meet the educational requirements of the role to which they are to be delegated. It is the responsibility of the CLIA Lab Director to verify education and experience of the individual before the responsibilities are delegated.

  *Human Resources or Laboratory Compliance may offer assistance in determining qualifications or educational background if needed.

  **Note: Cytotechnologist (CT) and Cytology General Supervisor (CGS) positions require American Society of Clinical Pathology (ASCP) certification, in addition to documentation of their highest level of academic achievement in education, training, and experiential requirements. The delegations in the Cytology laboratory are as follows LD => TS and CC, TS => GCS.

- CLIA/CAP responsibilities must be delegated to persons by name and in writing by the CLIA Laboratory Director.

- Use of the attached forms for:
  - Clinical Consultant (CC)
  - Technical Supervisor (TS)/Technical Consultant (TC)
  - Cytology General Supervisor (CGS) and General Supervisor (GS)
  - Technical Supervisor (TS)/General Supervisor (GS) combination should be utilized by all sections.

- Prior to implementing the delegation, persons must be made familiar with and express a general understanding of the responsibilities that they are being asked to perform. Any combination of the CLIA Lab Director, Section Medical Director or Section Manager may explain the duties and responsibilities to the staff member.

- The staff member will accept the role and the responsibilities by signing the required delegation form.

Responsibilities (and Defined Roles) That May Be Delegated by the Lab Director:

a. **Clinical Consultant (CC)** - Responsibilities:
   - Ensure that reports of test results include pertinent information required for specific patient interpretation; and
   - Ensure that consultation is available and communicated to the laboratory's clients on matters related to appropriate test selection, the quality of the test results reported and their interpretation concerning specific patient conditions.

b. **Technical Supervisor (TS)/Technical Consultant (TC)** - Responsibilities:
   - Appropriate test method selection;
   - Adequate method verification in order to determine the accuracy and precision of the test;
   - Quality assessment and quality control programs are established and maintained;
   - Acceptable analytical test performance are established and maintained for each test system;
   - Remedial actions are taken and documented when significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly;
   - Personnel have been appropriately trained and demonstrate competency prior to testing patient specimens;
   - Policies and procedures are established for monitoring personnel competency in all phases (pre-analytic, analytic, and post-analytic)

of testing to assure the ongoing competency of all individuals who perform testing;
- Remedial training or continuing education needs are identified and training provided; and
- An approved procedure manual is available to all personnel.

d. Cytology General Supervisor (CGS) - Responsibilities:

- 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.
- 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 (as specified under §493.1274(c));
    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.

e. General Supervisor (GS) - Responsibilities:

- Remedial actions are taken when test systems deviate from the laboratory's established performance specifications;
- Patient test results are not reported until all corrective actions have been taken and the test system functions properly;
- Orientation is provided to all testing personnel; and
- Annual personnel performance evaluations and documentation of testing personnel performance competency.
- Review monthly maintenance logs.

Annual Competency Assessment Requirements for Required Roles

a. Individuals in CLIA delegated positions are required to perform annual competency for the delegated supervisory responsibilities under their supervision.
b. Under CLIA/CAP standards, the only person with assigned responsibilities who does not require any kind of annual competency is the CLIA Laboratory Director. All other individuals must be assessed.

c. Clinical consultant role competency is reviewed biannually by the Department Chair through the OPPE/FPPE process and any restriction of clinical privileges will be communicated to the CLIA director.
d. Prepared Competency Assessment forms are attached for the roles of TS/TC, CGS and GS.

- Unlike testing personnel, the competency assessments used for delegations of responsibility do not have to incorporate the 6 point evaluation method.

- If an individual holds a CLIA delegated role such as CC, TS/TC, CGS, or GS and also performs patient testing, then a second competency assessment covering the aspects of the bench work will also be performed (in the form of a 6 point assessment).

- Both the testing defined competency and the CLIA role defined competency are required to be a part of the employee file in the laboratory.

Non-laboratory Personnel CLIA/CAP Assigned Roles

a. Another special category of delegated responsibilities within the organization includes those for non-laboratory personnel who are qualified to complete competencies for individuals performing point of care testing (non-waived) outside of the main core laboratories. These individuals are employed in other ancillary departments within the medical center such as Respiratory Care, Radiology, OR, and the Cardiac Cath Lab. These individuals are assigned the role of Technical Consultant (TC) responsibilities.

Non-testing Personnel within the Laboratory

a. Section managers within the laboratory who are responsible for non-testing personnel, have the authority to review, sign and maintain documentation as required by our regulatory agencies. These managers will perform training and competency assessments for their staff following the same guidance and time intervals as required for testing personnel. (6 point competency assessments are not required). Laboratory sections meeting these requirements are:
    - Inpatient Phlebotomy
    - Outpatient Phlebotomy
    - Central Processing
    - Outreach
    - Send outs
    - LIS/Beaker Team

CAP Organizational Profile/Online Roster of CLIA roles

a. The laboratory is required to maintain an up to date roster of CLIA defined roles under the CAP Organization Profile which can be found on the CAP website www.CAP.org

b. Section Managers are responsible for maintaining a current list of all persons within their section having delegations of responsibility at all times. Any changes or updates to this

list must be communicated immediately to the Laboratory Compliance office so that changes can be made to the master list on the CAP website.

c. The CLIA Laboratory Director also maintains a current listing of all individuals to whom delegations have been issued, including CC, TS, TC, GCS and GS thru-out the entire lab. Any section changes or updates must also be communicated directly the Lab Director as well.

Education Qualifications for Delegated Roles

a. Education qualifications for delegated roles can be found below or within the CLIA regulations at www.CMS.org.

COLLEGE of AMERICAN PATHOLOGISTS

CAP Personnel Requirements by Testing Complexity

Laboratory Director*

Waived Testing	Moderate Complexity Testing	High Complexity Testing
1. Qualified as a director for moderate or high complexity testing; OR 2. MD, DO, or DPM with a current medical license[1] **Exception - If** annual test volume exceeds 500,000, the CAP requires the laboratory director to meet the qualifications of Director for high complexity testing.	1. Qualified as a Director for high complexity testing; OR 2. MD, DO or DPM with a current medical license[1] and laboratory training/experience consisting of: a. 1 year experience supervising non-waived testing; OR b. 20 CME credit hours in laboratory practice commensurate with director responsibilities; OR c. Equivalent laboratory training (20 CME's) obtained during medical residency; OR 3. Doctoral degree in chemical, physical, biological or clinical laboratory science with: a. Certification by a board approved by HHS; OR b. 1 year experience supervising non-waived testing **Exception -** If annual test volume exceeds 500,000, the CAP requires the laboratory director to meet the qualifications of a Director for high complexity testing.	1. MD or DO with a current medical license[1] and board-certification in Anatomic and/or Clinical Pathology or possess equivalent qualifications as those required for certification; OR 2. MD, DO or DPM with a current medical license[1] and laboratory training/experience consisting of the following: a. 1 year laboratory training during medical residency; OR b. 2 years experience supervising high-complexity testing; OR 3. Doctoral degree in chemical, physical, biological or clinical laboratory sciences with certification by a board approved by HHS

Clinical Consultant

Waived Testing	Moderate Complexity Testing	High Complexity Testing
Not Applicable	1. MD, DO, or DPM with a current medical license[1]; OR 2. Doctoral degree in chemical, physical, biological or clinical laboratory sciences with certification by a board approved by HHS	1. MD, DO, or DPM with a current medical license[1]; OR 2. Doctoral degree in chemical, physical, biological or clinical laboratory sciences with certification by a board approved by HHS

Technical Consultant

Waived Testing	Moderate Complexity Testing	High Complexity Testing
Not Applicable	1. MD, DO, or DPM with a current medical license[1] with at least 1 year of training and/or experience in nonwaived testing in the designated specialty/subspecialty area; OR 2. Doctoral or Masters degree in a chemical, physical, biological or clinical laboratory science with at least 1 year of training and/or experience in nonwaived testing in the designated specialty/subspecialty area; OR	Not Applicable

*The Director may fulfill multiple roles. While CLIA may allow for non-physician or nondoctoral degreed individuals to direct Waived and Moderate Complexity laboratories, CAP does not.

[1] The license to practice medicine must be in the jurisdiction where the laboratory is located (if required). Military and VA personnel may be licensed in any US State.

Technical Consultant, Cont'd		
Waived Testing	**Moderate Complexity Testing**	**High Complexity Testing**
	3. Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least 2 years of experience in nonwaived testing in the designated specialty/subspecialty area	

Technical Supervisor		
Waived Testing	**Moderate Complexity Testing**	**High Complexity Testing**
Not Applicable	Not Applicable	For the specialties of Transfusion Medicine, Cytogenetics, and Histocompatibility, refer to checklist requirements TRM.50050, CYG.50000, and HSC.40000, respectively for details on educational qualifications and experience. For the specialties of Anatomic, Cytopathology and Clinical Pathology: 1. MD or DO with a current medical license[1] and board-certification in Anatomic, Cytopathology, and Clinical Pathology or possess qualifications equivalent to those required for certification; OR 2. MD or DO with a current medical license[1] and board-certification in Anatomic or Clinical Pathology or possess qualifications equivalent to those required for certification. • Technical supervisors overseeing anatomic or cytopathology services must have board-certification in anatomic pathology or equivalent qualifications. • Technical supervisors overseeing a clinical pathology specialty must have board-certification in clinical pathology or equivalent qualifications • Technical supervisors responsible for anatomic pathology, cytopathology, and clinical pathology must have board-certification in both anatomic and clinical pathology or equivalent qualifications. For other specialties, not including Anatomic Pathology and Cytopathology: 3. MD or DO with a current medical license[1] and 1 year training and experience in high-complexity testing in the respective specialty; OR 4. Doctoral degree in clinical laboratory science, chemical, physical or biological science with 1 year training and experience in the respective specialty; OR 5. Master's degree in medical technology, clinical laboratory science, or chemical, physical or biological science and 2 years training and experience in high-complexity testing in the respective specialty; OR 6. Bachelor's degree in medical technology, clinical laboratory science, or chemical, physical or biological science and 4 years training and experience in high-complexity testing in the respective specialty.

*The Director may fulfill multiple roles. While CLIA may allow for non-physician or nondoctoral degreed individuals to direct Waived and Moderate Complexity laboratories, CAP does not.

[1] The license to practice medicine must be in the jurisdiction where the laboratory is located (if required). Military and VA personnel may be licensed in any US State.

Technical Supervisor, Cont'd		
Waived Testing	**Moderate Complexity Testing**	**High Complexity Testing**
		For the specialty of Oral Pathology, the Technical Supervisor must be a physician and/or doctoral scientist and have specific training/experience. Refer to the CLIA regulation 42CFR493.1449 for additional qualifications.

General Supervisor		
Waived Testing	**Moderate Complexity Testing**	**High Complexity Testing**
Not Applicable	Not Applicable	1. Qualified as a Director for high-complexity testing; OR 2. Qualified as a Technical Supervisor for high complexity testing; OR 3. Doctoral degree in clinical laboratory science or chemical, physical or biological science with 1 year training and experience in high-complexity testing; OR 4. Master's degree in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in high-complexity testing; OR 5. Bachelor's degree in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in high-complexity testing; OR 6. Associate degree in medical laboratory technology (or pulmonary function) and 2 years laboratory (or blood gas analysis) training or experience, or both, in high complexity testing Refer to the CLIA regulation 42CFR493.1461 for additional qualifications

Testing Personnel		
Waived Testing	**Moderate Complexity Testing**	**High Complexity Testing**
No specific requirements outlined in the CAP or CLIA regulations, however each laboratory must ensure waived testing personnel meet facility-defined minimum requirements and have records of training and competency assessment	1. MD or DO with a current medical license†; OR 2. Doctoral degree in clinical laboratory science, chemical, physical or biological science; OR 3. Master's degree in medical technology, clinical laboratory, chemical, physical, or biological science; OR 4. Bachelor's degree in medical technology, clinical laboratory, chemical, physical or biological science; OR 5. Associate degree in chemical, physical or biological science or medical laboratory technology; OR 6. High school graduate or equivalent and laboratory training/experience consisting of the following: a. Successfully completed military training of 50 or more weeks and served as a medical laboratory specialist; OR b. Appropriate training/experience as specified in 42CFR493.1423	1. MD or DO with a current medical license†; OR 2. Doctoral degree in clinical laboratory science, chemical, physical or biological science; OR 3. Master's degree in medical technology, clinical laboratory, chemical, physical, or biological science; OR 4. Bachelor's degree in medical technology, clinical laboratory, chemical, physical or biological; OR 5. Associate degree in chemical, physical or biological science or medical laboratory or equivalent education and training (refer to 42CFR493.1489(b) for details on required courses and training); OR 6. Individuals performing high complexity testing on or before April 24, 1995 with a high school diploma or equivalent with documented training may continue to perform testing only on those tests for which training was documented prior to September 1, 1997 (refer to CLIA regulation 42CFR493.1489(b) for details on required training)OR Individual previously qualified or could have qualified as a technologist under CFR.493.1489 and CFR.493.1491 on or before February 28, 1992

*The Director may fulfill multiple roles. While CLIA may allow for non-physician or nondoctoral degreed individuals to direct Waived and Moderate Complexity laboratories, CAP does not.

† The license to practice medicine must be in the jurisdiction where the laboratory is located (if required). Military and VA personnel may be licensed in any US State.

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4) **Review/Revision/Implementation:**

   a. Review Cycle: Every 2 years
   b. Office of Record: Laboratory Compliance, Department of Pathology

5) **Related Policies: None**

6) **References, National Professional Organizations, etc.:**
   CLIA Brochure #7 – Laboratory Director Responsibilities

   CLIA Personnel Standards 42 CFR 493 Subpart M

   CAP Lab General Checklist

7) **Attachments:**

A. **Technical Supervisor/General Supervisor Delegation Template**: CLIA TS_GS Delegation Template

B. **General Supervisor Delegation Template**: CLIA GS Delegation Template

C. **Cytology General Supervisor Delegation Template:** CLIA CGS Delegation Template

D. **Technical Consultant Delegation Template:** CLIA TC Delegation Template

E. **Technical Supervisor Competency Assessment Template**: CLIA TS Comp Template

F. **General Supervisor Competency Assessment Template:** CLIA GS Comp Template

G. **Cytology General Supervisor Competency Assessment Template:** CLIA CGS Comp Template

H. **Technical Consultant Competency Assessment:** CLIA TC Comp Template

8) **Revised/Reviewed Dates and Signatures:**

Review Date	Revision	Signature

ATTACHMENT A
Wake Forest Baptist Health (WFBH) DATE: 12/Click here/ 2018
Pathology Laboratories
Dept. of Pathology, Click here Laboratory
Click here, NC

Delegation of Technical Supervisor and General Supervisor Responsibilities

TO: Click here
Manager, WFBH Click here Laboratory

FROM: Gregory J. Pomper, MD
Laboratory Medical Director

For the laboratory section(s) noted above, I designate your position(s) the authority to maintain oversight and documentation as required by and in accordance with Regulatory Agencies for the WFBH. Responsibilities include those of ***Technical Supervisor and General Supervisor***.

Responsibilities As Technical Supervisor:

- Appropriate test method selection;
- Adequate method verification in order to determine the accuracy and precision of the test;
- Enrollment of the laboratory in a CMS-approved proficiency testing (PT) program for the test performed;
- PT samples are tested in accordance with the CLIA requirements;
- PT results are returned within the time frames established by the PT program;
- PT reports are reviewed by the appropriate staff;
- Corrective action plans are followed when PT results are found to be unacceptable or unsatisfactory;
- Quality assessment and quality control programs are established and maintained;
- Acceptable analytical test performance are established and maintained for each test system;
- Remedial actions are taken and documented when significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly;
- Personnel have been appropriately trained and demonstrate competency prior to testing patient specimens;
- Policies and procedures are established for monitoring personnel competency in all phases (pre-analytic, analytic, and post-analytic) of testing to assure the ongoing competency of all individuals who perform testing;
- Remedial training or continuing education needs are identified and training provided; and
- An approved procedure manual is available to all personnel.

Responsibilities As General Supervisor:

- Remedial actions are taken when test systems deviate from the laboratory's established performance specifications;
- Patient test results are not reported until all corrective actions have been taken and the test system functions properly;
- Orientation is provided to all testing personnel; and
- Annual personnel performance evaluations and documentation of testing personnel performance competency.
- Review monthly maintenance logs.

_____ DATE: _____
Click here

_____ DATE: _____
Click here, Medical Director

_____ DATE: _____
Gregory J. Pomper, MD
Laboratory Medical Director

ATTACHMENT B

Wake Forest Baptist Health (WFBH) DATE: Click here to enter text.

Pathology Laboratories

Dept. of Pathology, Click here to enter text.***Laboratory***

Click here to enter text., **NC**

Delegation of General Supervisor Responsibilities

TO: Click here to enter text.
WFBH Click here to enter text. Laboratory

FROM: Click here to enter text.
WFBH, Technical Supervisor

Gregory J. Pomper, MD
CLIA Laboratory Director

For the laboratory section(s) noted above, I designate your position(s) the authority to maintain oversight and documentation as required by and in accordance with Regulatory Agencies for the WFBH. Responsibilities include those of ***General Supervisor***.

Responsibilities As General Supervisor:

- Remedial actions are taken when test systems deviate from the laboratory's established performance specifications;
- Patient test results are not reported until all corrective actions have been taken and the test system functions properly;
- Orientation is provided to all testing personnel; and
- Annual personnel performance evaluations and documentation of testing personnel performance competency.
- Review monthly maintenance logs.

_____ DATE: _____
Click here to enter text.

_____ DATE: _____
Click here to enter text., Laboratory Director

_____ DATE: _____
Gregory J. Pomper, MD
Laboratory Medical Director

ATTACHMENT C
Wake Forest Baptist Health
Pathology Laboratories
Dept. of Pathology, Wake Forest Baptist Hospital Cytology Laboratory
Winston-Salem, NC

Delegation of Cytology General Supervisor Responsibilities

TO:
Manager, Wake Forest Baptist Cytology Laboratory

FROM: Gregory J. Pomper, MD
Laboratory Medical Director

DATE:

For the laboratory section(s) noted above, I designate your position(s) the authority to maintain oversight and documentation as required by and in accordance with Regulatory Agencies for the WFBH. Responsibilities include those of ***Cytology General Supervisor***.

Responsibilities As Cytology General Supervisor:

- The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.
- Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;
- Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.
- Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;
- Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;
- Providing orientation to all testing personnel;
- Annually evaluating and documenting the performance of all testing personnel.
- 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;
- Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under §493.1274(c));
- 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;
- Document the number of hours spent examining slides in each 24-hour period.

Gregory J. Pomper, MD
Laboratory Medical Director
Laboratory

Manager, Wake Forest Baptist Cytology

ATTACHMENT D

Wake Forest Baptist Health (WFBH) DATE: Click here to enter text.
Pathology Laboratories
Dept. of Pathology, Click here to enter text. ***Laboratory***
Winston-Salem, NC

Delegation of Technical Consultant Responsibilities

TO: Click here to enter text.
WFBH Click here to enter text. Laboratory

FROM: Click here to enter text.
WFBH, Technical Supervisor

Gregory J. Pomper, MD
CLIA Laboratory Director

For the laboratory section(s) noted above, I designate your position(s) the authority to maintain oversight and documentation as required by and in accordance with Regulatory Agencies for the WFBH. Responsibilities include those of ***Technical Consultant***.

Responsibilities As Technical Consultant:

- Remedial actions are taken and documented when test systems deviate from the laboratory's established performance specifications;
- Patient test results are not reported until all corrective actions have been taken and the test system functions properly;
- Orientation and training is provided to all testing personnel; and
- Annual personnel performance evaluations and documentation of testing personnel performance competency.
- Review monthly maintenance logs.

_____ DATE: _____
Click here to enter text.

_____ DATE: _____
Click here to enter text., Laboratory Manager

_____ DATE: _____
Gregory J. Pomper, MD
CLIA Laboratory Medical Director

ATTACHMENT E

Competency Assessment for Technical Supervisors

Name: Click here to enter text. Lab Section: Click here to enter text.

Performs Testing (Yes/No)?: _____

(If yes, attach annual 6 point competency for testing; if no then NA)

Responsibility	TS	Yes/No/NA; Comments
Does the TS have an updated list documenting GS delegations?	TS	
Have delegated responsibilities been reviewed at least annually and documented?	TS	
Is the TS available to staff to provide consultation and technical oversight of laboratory personnel and testing?	TS	
Does the TS play an active role in the selection of appropriate test methodology for the patient population?	TS	
Does the TS ensure performance verification studies, including precision and accuracy, are performed and documented for each new test/test system?	TS	
Does the TS assure that performance specifications are established or verified for necessary tests.	TS	
Does the TS ensure that the laboratory unit is enrolled and participates in HHS approved proficiency testing (PT) for each test requiring PT?	TS	
Has the laboratory PT performance been acceptable?	TS	
Are the appropriate staff reviews conducted when PT results are received from the provider?	TS	

Does the TS ensure that a quality control (QC) program is in effect and adequate for the laboratory unit's testing performance?	TS	
Does the TS identify training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the tests they are performing?	TS	
Does the TS evaluate the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately and proficiently. -Using the 6 competency assessment techniques for performing competency assessment of laboratory technical personnel.	TS	
Does the TS ensure testing personnel competency and performance is evaluated and documented at least semiannually for the first year and annual thereafter? Or if delegated, ensure that a GS is available to perform these responsibilities?	TS	
Does the TS ensure that the policy and procedure manuals are approved, current, complete, and available to laboratory staff for testing?	TS	
Does the TS ensure that the laboratory unit performs and documents quality assessment activities and quality indicators for continuous improvement?	TS	
Does the TS resolve technical problems and ensure remedial actions are taken whenever	TS	

there is a test system failure? Or if delegated, ensure that a GS is available to perform these responsibilities?		
Does the TS ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly? Or if delegated, ensure that a GS is available to perform these responsibilities?	TS	

_____ DATE: _____

CLIA delegated TS
(Print name/signature)

_____ DATE: _____

Gregory J. Pomper, MD
CLIA Laboratory Director

Reference: 42 CFR 493.1451

ATTACHMENT F

Competency Assessment for General Supervisors

Name: Click here to enter text. **Lab Section:** Click here to enter text.

Performs Testing (Yes/No)?: _____

(If yes, attach annual 6 point competency for testing; if no then NA)

Responsibility	TS	Yes/No/NA; Comments
Remedial actions are taken when test systems deviate from the laboratory's established performance specifications?	GS	
Patient test results are not reported until all corrective actions have been taken and the test system functions properly?	GS	
Orientation is provided to all testing personnel?	GS	
Annual personnel performance evaluations and documentation of testing personnel performance competency?	GS	

_____ DATE: _____

CLIA delegated GS

(Print name/signature)

_____ DATE: _____

CLIA delegated TS

(Print name/signature)

Reference: 42 CFR 493.1463

ATTACHMENT G

WFBH Competency Assessment for Cytology General Supervisor (CGS)

Name:_____ Lab Section: Cytology

Responsibility: Is the CGS:	Role	Yes/No/NA; Comments
responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.	CGS	
accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;	CGS	
monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.	CGS	
Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;	CGS	
Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;	CGS	
Providing orientation to all testing personnel;	CGS	
Annually evaluating and documenting the performance of all testing personnel.	CGS	
accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the	CGS	

technical supervisor of cytology; Documenting the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under §493.1274(c));		
Documenting for each 24-hour period, 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;	CGS	
Documenting the number of hours spent examining slides in each 24-hour period.	CGS	

_____ DATE: _____

CLIA delegated CGS
(Print name/signature)

_____ DATE: _____

CLIA delegated TS
(Print name/signature)

_____ DATE: _____

Gregory J. Pomper, MD
CLIA Laboratory Medical Director

Reference: 42 CFR 493.1471

ATTACHMENT H

Competency Assessment for Technical Consultant

Name: Click here to enter text. **Lab Section:** Click here to enter text.

Performs Testing (Yes/No)?: _____

(If yes, attach annual 6 point competency for testing; if no then NA)

Responsibility	TC	Yes/No/NA; Comments
Is the TC available to staff to provide consultation and technical oversight of laboratory personnel and testing?	TC	
Does the TC play an active role in the selection of appropriate test methodology for the patient population?	TC	
Does the TC ensure performance verification studies, including precision and accuracy, are performed and documented for each new test/test system?	TC	
Does the TC assure that performance specifications are established or verified for necessary tests.	TC	
Does the TC ensure that the laboratory unit is enrolled and participates in HHS approved proficiency testing (PT) for each test requiring PT?	TC	
Has the laboratory PT performance been acceptable?	TC	
Are the appropriate staff reviews conducted when PT results are received from the provider?	TC	
Does the TC ensure that a quality control (QC) program is in effect and adequate for the laboratory unit's testing performance?	TC	
Does the TC identify training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the tests they are performing?	TC	

Does the TC evaluate the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately and proficiently. -Using the 6 competency assessment techniques for performing competency assessment of laboratory technical personnel.	TC	
Does the TC ensure testing personnel competency and performance is evaluated and documented at least semiannually for the first year and annual thereafter?	TC	
Does the TC ensure that the policy and procedure manuals are approved, current, complete, and available to laboratory staff for testing?	TC	
Does the TC ensure that the laboratory unit performs and documents quality assessment activities and quality indicators for continuous improvement?	TC	
Does the TC resolve technical problems and ensure remedial actions are taken whenever there is a test system failure?	TC	
Does the TC ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly?	TC	

_____ DATE: _____

(Name), CLIA delegated TC

_____ DATE: _____

Gregory J. Pomper, MD
CLIA Laboratory Director

Reference: 42 CFR 493.1413