TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/29/2019
Department:	Mgmt & QA	**Due Date:**	8/31/2019
		Implementation:	**8/5/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

CLIA Personnel Qualification Requirements and Documentation SGMC.QA3004 v1

Description of change(s):

This is a 'new' SOP that replaces 2 previous corporate policies:

- *Policy for the Documentation of Testing Personnel Qualifications in PeopleSoft*
- *Policy for CLIA Personnel Qualification Requirements*

It is very similar to the old SOPs but has been converted to our local SOP format and info that did not pertain to our labs was deleted.

This SOP will be implemented on August 5, 2019

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**CLIA Personnel Qualification Requirements and Documentation**
Prepared by	Leslie Barrett Date: 7/5/2019
Owner	Cynthia Bowman Gholston, Robert SanLuis Date: 7/5/2019

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

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1. PURPOSE

This document

a. outlines the requirements per the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regarding the personnel qualifications for laboratory director, clinical consultant, technical consultant, technical supervisor, general supervisor, and testing personnel engaged in non-waived testing and,
b. contains the process for documentation in PeopleSoft™ of licensure, certification, academic education, specialized training and continuing education of personnel directing, supervising, consulting or performing analytic elements of laboratory tests

2. SCOPE

This policy applies to all clinical testing departments in the laboratory sites.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director (CLIA Laboratory Director)	• Approving this document and any subsequent revisions. • Ensuring that all applicable personnel meet regulatory (CLIA, CAP, stare) education, training, experience and certification requirements.
Laboratory Director / Designee	• Periodic review of this document. • The management and oversight of the process in place to ensure all applicable personnel meet their respective CLIA qualification requirements. • Generating the CLIA/CAP Personnel Evaluation Report, as needed
Department Manager or Supervisor	• Ensuring compliance with this policy in his/her department • Reviewing and approving their direct reports' information and attached supporting documents which were entered into ESS, as applicable • Ensuring that the required information for newly hired or transferred testing personnel is appropriately entered into ESS, reviewed and approved
CLIA Defined Personnel	• Providing required documentation of licensure, certification, academic education, specialized training and continuing education, as appropriate • Entering required information into the PeopleSoft™ Licensure Qualifications program using the Employee Self Service (ESS) function • Maintaining in PeopleSoft™ the records for required licensure, certification, specialized training, academic and continuing education as required by regulatory and certifying agencies • Updating the information in ESS, as applicable

4. DEFINITIONS

Academic Education: The completion of formal schooling which results in documentation of one having met or achieved defined academic standards. For purposes of this document, academic education is the highest level of education achieved that is related to the practice of laboratory medicine.
Examples:

- High school diploma or GED
- Transcript of college credits, without degree, to qualify as testing personnel
- College degree(s) (Associate, Bachelor, Masters, PhD)
- Medical degree (M.D., D.O.)
- Fellowships
- Specialized training (physician residency, other physician specialty or sub-specialty training, technologist/technician training program)

Certification: A document providing evidence of status or qualifications. Certification is often, but not always, provided by some form of external review, education, or assessment. For purposes of this document certification applies to a professional certification, where a person is certified as being able to competently complete a job or task, usually by the passing of an examination given by an agency or professional association.

Examples:

- Physician and/or Ph.D. board certifications or board eligibility
- Technicians/Technologists' certifications (i.e., ASCP, AAB, ABCC)
- Technologist/Pathologist methodology certifications - ThinPrep®, SurePath™
- Other organizational certification (i.e., ASQ)

CLIA: Clinical Laboratory Improvement Amendments of 1988

CLIA Defined Personnel:

- **Clinical Consultant:** Individual qualified to provide consultation regarding the appropriateness of tests ordered and interpretation of test results (moderate and high complexity testing). (42 CFR §493.1417 and §493.1455)

- **General Supervisor:** Individual who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results (high complexity testing). (42 CFR §493.1461)

- **Laboratory Director:** Individual qualified to manage and direct the laboratory personnel and the performance of moderate or high complexity testing. (42 CFR §493.1405 and §493.1443)

- **Technical Consultant:** Individual qualified to provide technical and scientific oversight for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity testing. (42 CFR §493.1409 and §493.1411)

- **Testing Personnel:** Individual qualified to perform and report test results for moderate and/or high complexity testing. (42 CFR §493.1423 and §493.1489)

- **Technical Supervisor:** Individual qualified to provide technical and scientific oversight for each of the specialties and subspecialties of service in which the laboratory performs high complexity testing. (42 CFR § 493.1449)

CLIA Test Complexity:

- **Moderate and High Complexity (non-waived)**: The category assigned to a specific test system or assay by evaluating specific criteria and obtaining a composite complexity score. This numerical score determines the assignment *of moderate test complexity* or *high test complexity*. The seven criteria include knowledge; training and experience; reagents and materials preparation; characteristics of operational steps; calibration, quality control, and proficiency testing materials; test system troubleshooting and equipment maintenance; and interpretation and judgment. Test systems not yet

classified are considered *high complexity*. These tests require a higher degree of skill and present a more significant opportunity for patient harm from an incorrect test result and are therefore subject to greater levels of regulation. (42 CFR §493.17)

- **Waived Tests**: Test systems that are simple laboratory examinations and procedures which are cleared by the FDA for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly. (42 CFR §493.15)

CLIA Test Specialty and Subspecialty: The category assigned in the CLIA regulations to describe related fields of laboratory medicine. Laboratories must be licensed in the specialty or sub-specialty for every test performed in the laboratory. Personnel must be qualified in order to perform testing in specialty or sub-specialty disciplines.

Continuing Education: Those courses or credit hours obtained to meet regulatory or internal requirements needed to maintain licensure or certification. Examples:

- Physician course credit hours to maintain state medical licensure
- Technologist/technician course credit hours to maintain state licensure
- Technologist/technician course credit hours to maintain ASCP certification via the Certificate Maintenance Program (CMP)
- Any course credit hours to meet internal requirements or other certifying entities

Department Manager / Supervisor: For purposes of this document, this is the person who is responsible for the hiring, termination and work assignments of staff in a department.

Employee Self Service (ESS): Employee Self Service is a PeopleSoft ™ web-based system that provides employees online access to view their personal, payroll, compensation, and benefits information. With implementation of this policy, licensure, certification, academic education, specialized training and continuing education is added to ESS in the Licensure Qualifications module.

Licensure: The granting of a license, which gives a permission to practice granted through a professional body or a licensing board. For purposes of this document, licensure applies to a license in a healthcare field that is issued by a State agency.
Examples:

- Physician/Pathologist Medical License - all applicable states
- Technologist/Technician state license, as applicable
- Laboratory director or supervisory state license, as applicable

Manager Self Service (MSS): Manager Self Service is a PeopleSoft ™ web-based system that provides managers online access to view their employees' payroll, compensation and in addition, with the implementation of this policy, their licensure and qualifications information.

5. POLICY

Step	Action
1.	This policy requires the Laboratory Director to ensure that personnel engaged in the analytic phase of non-waived testing meet the minimum personnel qualifications as required by CLIA regulations.
2.	The laboratory must maintain documentation to confirm that each employee's qualifications meet CLIA regulatory requirements. For testing personnel, documentation is maintained in PeopleSoft™.
3.	Laboratories accredited by the College of American Pathologists (CAP) must maintain documentation to confirm that laboratory personnel meet CAP personnel standards.
4.	Qualifications must be evaluated at the highest level of academic achievement related to the practice of laboratory medicine.
5.	Refer to Appendix A for specific CLIA personnel requirements based on testing complexity and laboratory positions.
6.	All of the above minimum personnel qualifications must be reviewed and re-approved whenever a change in position or job classification occurs.

6. PROCEDURE

6.1 CLIA-Defined Testing Personnel

Step	Action
1.	Provide documents supporting the qualifications as required by regulations and by this policy. Store hard copy documents in a read-only electronic file format (pdf, tif, or jpg)
2.	Enter qualifications information into PeopleSoft™: Licensure Qualifications a. LOG into ESS >Licensure Qualifications > Employee Profile b. ENTER the following information into the following sections and SAVE after entries are made in each section <u>LICENSURE</u>: Maryland does not require a license, this section may be skipped <u>CERTIFICATIONS</u>: • Type of certification, specific to specialty and certifying entity • Effective date • Status: Active or Inactive • Certification number, as applicable • Issued by <u>CLIA POSITION HELD</u> • CLIA position held (Laboratory Director, Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, or Testing Personnel) • Effective date • Status: Active or Inactive <u>CLIA TESTING COMPLEXITY</u> • Level of testing complexity - the highest level for which qualified (High,

Step	Action
	Moderate or Waived) • Effective date <u>JOB SPECIALTY</u> • Specialty/sub-specialty areas in which qualified to perform testing (i.e., Microbiology, Chemistry, Hematology) • Effective date • Status: Active or Inactive <u>ACADEMIC EDUCATION</u> • Level of academic achievement – highest level related to laboratory medicine • Physician boards • Specialized training program (i.e., Medical Technology); use OTHER category and provide details in S section • Effective date • Issued by/Institution • Course/hours, if no degree held – for Testing Personnel minimum requirements <u>CONTINUING EDUCATION</u> (optional) – fields may be completed if desired c. SAVE all entries in PeopleSoft™
3.	Attach documents into PeopleSoft™: Licensure Qualifications a. ATTACH directly or coordinate with manager the attaching of documents into each section listed above. b. If employee attaches own documents then it can be done as information for each section is entered and not as a separate step c. SAVE attachments in each section d. SUBMIT to manager for review/approval e. SIGN OUT of ESS
4.	Update qualifications information in PeopleSoft™: Licensure Qualifications a. LOG into ESS>Licensure Qualifications>Employee Profile b. UPDATE new information (i.e., new effective/expiration dates, continuing education courses/credits, CLIA position held), attach updated documents c. Update new information when transferring to a different department where testing specialties and/or qualifications may differ, attach documents d. SAVE updates e. SUBMIT to manager for review/approval and SIGN OUT
5.	Print own attached qualifications documents from PeopleSoft™, as needed a. LOG into ESS>Licensure Qualifications b. PRINT own attached qualifications documents, as needed c. SIGN OUT of ESS

6.2 Department Manager or Supervisor

For new personnel:

Requirement	Action
Review submitted qualifications and attached documents from direct reports who perform testing	1. LOG into MSS>Licensure Qualifications>Approve Profiles 2. SELECT the direct report for which qualifications have been submitted for approval 3. REVIEW qualifications information entered in all four sections (Licensure, Certifications, Academic Education, Continuing Education) 4. REVIEW the associated attached documents in each section
Approve all qualifications information and attachments	APPROVE or DENY the reviewed information and attachments. NOTE: No manager approval is required for Continuing Education however Manager must review this information.

If….	Then….
Employee does not meet all regulatory and/or internal requirements for level and area of testing performed	Notify HR and the Laboratory Director for further follow-up. Note: HR performs background check before hire and will provide guidance if requirements are not met.

For transfer of existing employee into department:

Requirement	Action
Review submitted qualifications and attached documents from direct reports who perform testing and who have transferred into department	1. LOG into MSS>Licensure Qualifications>Approve Profiles 2. SELECT the direct report for which qualifications were submitted for approval 3. Review any changed or updated qualifications information in all four sections (Licensure, Certifications, Academic Education, Continuing Education) 4. Review the new/updated associated attached documents in each section
Approve all qualifications information and attachments	APPROVE or DENY the reviewed information and attachments
Print individual direct reports' attached qualifications documents from PeopleSoft™, as needed	1. LOG into MSS>Licensure Qualifications>Team Person Profiles 2. PRINT individual's attached qualifications documents, as needed

If….	Then….
The Department Manager makes edits or attaches documents into their direct report's Employee Profile, on their behalf	The Department Manager must submit these updates to *their* Manager/Director for approval.

6.3 Human Resources

Requirement	Action
Hiring process and New Employee Orientation Program for newly hired testing personnel	1. Inform hiring candidates and newly hired testing personnel of the requirement to provide to their manager documents that support Licensure, Certification, Academic Education and specialized training 2. Inform the hiring manager when the new employee is set up in PeopleSoft™
Maintain credentialing and background check records	1. Maintain pre-hire background check records in personnel files in HR 2. Maintain International Education Research Foundation (IERF) Equivalency Report or other equivalency evaluation agency reports that verify credentials of foreign-trained testing personnel files in HR
Print individuals' attached qualifications documents from PeopleSoft™, on an as needed basis *only*, in the absence of both the manager and employee	1. LOG into MSS>Licensure Qualifications>Team Person Profiles 2. PRINT individual's(s') attached qualifications documents, as needed, *only* when employee or employee's manager is unavailable

6.4 Lab Service Director/Designee

Requirement	Action
Maintain local security access to: • run PeopleSoft™ Reports	1. Submit a formal request to the Corporate Licensing Administrator of any needed modifications for local security access to run the *CLIA/CAP Personnel Evaluation Report*

6.5 Corporate Licensing Administrator (Medical Regulatory Affairs)

Requirement	Action
Maintain security for access to PeopleSoft™ Licensing Qualifications Reports	1. Review and approve or deny formal requests from corporate staff or local Personnel Licensing Coordinator to modify security access to generate ad hoc reports, *CLIA/CAP Personnel Evaluation Report* and the *State License Report*

	2. LOG into secure Administrator's site in PeopleSoft™ to make modifications to security access list to generate the ad hoc reports, 3. Notify the requesting local Personnel Licensing Coordinator or corporate staff when access modification is complete 4. Maintain current list of all security access privileges for these Reports NOTE: Access is limited and is granted on a need-to-know basis (i.e., local CLIA Laboratory Director, Lab Services Director, local QA manager or designee and corporate staff)

6.6 Laboratory Director

Requirement	Action
Ensure that that all testing personnel meet regulatory (CLIA, CAP, State) and internal licensure, certification, education, and training requirements	1. Review for accuracy and sign the *CLIA/CAP Personnel Evaluation Report*, as needed, for o CAP accreditation re-application process o CLIA licensure/certification process o State licensure application or renewal process o Regulatory inspection process 2. Review and sign, at least annually, *CLIA/CAP Personnel Evaluation Report* to verify all that information is current and that all testing personnel meet the minimum regulatory and internal requirements

6.7 Laboratory Director/Qualified Designee

Requirement	Action
Generate the *CLIA/CAP Personnel Evaluation Report*, as needed (Designee may be local Personnel Licensing Coordinator)	1. LOG into MSS>Licensure Qualifications>CLIA/CAP Personnel Evaluation Report 2. ENTER valid CLIA or CAP number specific to site for which the report is needed 3. Review on screen or print for the Laboratory Director's signature, as needed

7. RELATED DOCUMENTS

- College of American Pathologists (CAP) Terms of Accreditation, QA procedure
- CLIA waived test list available at http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp

8. REFERENCES

1. Code of Federal Regulations, Title 42, Part 493 (Laboratory Requirements), Subpart A – General Provisions
2. Code of Federal Regulations, Title 42, Part 493 (Laboratory Requirements), Subpart M – Personnel for Moderate and High Complexity Testing
3. Federal Register, Friday, January 24, 2003 (42 CFR Part 493), Subpart M – Personnel for Non-Waived Testing
4. Quest Diagnostics *Policy for CLIA Personnel Qualification Requirements* QDNQA725
5. Quest Diagnostics *Policy for the Documentation of Testing Personnel Qualifications in PeopleSoft* QDMED717

9. DOCUMENT HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA725v2.1 and SGAHQDMED717v1.2		

10. APPENDICES

APPENDICES	Title
A	Summary of CLIA Qualifications For Moderate Complexity Testing
B	Summary of CLIA Qualifications For High Complexity Testing

APPENDIX A: Summary of CLIA Qualifications for Moderate Complexity Testing

Laboratory Director (42 CFR 493.1405)		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
MD or DO or DPM and Licensed **in the State in which the laboratory is located**	N/A	Certified in Anatomic or Clinical Pathology or both by: • American Board of Pathology • American Osteopathic Board of Pathology or Equivalent Qualifications
	1 year directing or supervising non-waived testing	N/A
	20 CME in Laboratory Practice OR Lab Training in Residency equivalent to 20 CME	N/A
Doctoral*	N/A	American Board of Medical Microbiology American Board of Clinical Chemistry American Board of Bioanalysts or American Board of Medical Laboratory Immunology
	1 year supervising or directing non-waived testing	N/A
Masters**	Must have: - At least one year of laboratory training or experience, or both in non-waived testing - And at least one year of supervisory laboratory experience in non-waived testing.	N/A
Bachelors**	Must have: - At least 2 years of laboratory training or experience, or both in non-waived testing - And at least 2 years of supervisory laboratory experience in non-waived testing	N/A
Previously Qualified under 42 CFR 493.1406	N/A	N/A
Qualified under State law on or before 02/28/92	N/A	N/A

APPENDIX A: Summary of CLIA Qualifications for Moderate Complexity Testing

Technical Consultant 42 CFR 493.1411		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
Licensed MD, DO, or DPM	N/A	Certified in Anatomic or Clinical Pathology or both by: • American Board of Pathology • American Osteopathic Board of Pathology or • Equivalent Qualifications
	1 Year in Specialty/Subspecialty	N/A
Doctoral* or Masters**	1 Year in Specialty/Subspecialty	N/A
Bachelors**	2 Years in Specialty/Subspecialty	N/A

Clinical Consultant (Moderate Complexity) 42 CFR 493.1417		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
Qualified as Lab Director under 493.1405 (b) (1), (2), or (3)(i)	N/A	N/A
Licensed MD, DO, DPM		

Testing Personnel (Moderate Complexity) 42 CFR 493.1423		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
Licensed MD, DO, or Doctoral*, Masters*, Bachelors** or Associate ***	N/A	N/A
H.S. Graduate or Equivalent	50 week Military Training with position of Medical Lab Specialist	N/A
H.S. Graduate or Equivalent	Documentation of Training	N/A

LEGEND:

* Doctoral degree in a chemical, physical, biological or clinical laboratory science.

** Masters or Bachelors degree in a chemical, physical, biological or clinical laboratory science from an accredited institution, medical laboratory technology.

*** Associate Degree in a chemical, physical, biological science or medical laboratory technology.

APPENDIX B: Summary of CLIA Qualifications for High Complexity Testing

LABORATORY DIRECTOR (42 CFR 493.1443)		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
MD or DO Licensed in the State in which the laboratory is located	N/A	Certified in Anatomic or Clinical Pathology or both by: • American Board of Pathology • American Osteopathic Board of Pathology or • Equivalent Qualifications For Oral Pathology only, be certified by: • American Board of Oral Pathology • American Board of Pathology • American Osteopathic Board of Pathology or Equivalent Qualifications
MD, DO, DPM Licensed in the State in which the laboratory is located	Must have: • 1 year lab training during medical residency or 2 years of experience directing or supervising High Complexity Testing	N/A
Doctoral*	N/A	Certified by: • American Board of Medical Microbiology • American Board of Clinical Chemistry • American Board of Bioanalysts • American Board of Medical Laboratory Immunology or • Other board deemed comparable by HHS
Doctoral*	Before February 24, 2003: • Must have served or be serving as a Laboratory Director for a laboratory performing high complexity testing; and must have at least: • 2 years lab training or experience or both • 2 years directing or supervising high complexity testing	N/A
N/A	Previously Qualified on or before 02/28/1992, under 55 FR 9538, March 14, 1990, 493.1415 OR Qualified under State Law on or before 2/28/1992	N/A

APPENDIX B: Summary of CLIA Qualifications for High Complexity Testing (continued)

TECHNICAL SUPERVISOR (42 CFR 493.1449)		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
MD, DO Licensed in the State in which the laboratory is located	N/A	For all clinical specialties and subspecialties except Histocompatibility and Cytogenetics: Certified in Clinical Pathology or Anatomic and Clinical Pathology by: • American Board of Pathology • American Osteopathic Board of Pathology or • Equivalent Qualifications
MD, DO Licensed in the State in which the laboratory is located	For Immunohematology: 1 year of training/experience in high complexity testing for Immunohematology	
MD, DO Licensed in the State in which the laboratory is located	N/A	For Cytology: Be certified in Anatomic Pathology by: • American Board of Pathology • American Osteopathic Board of Pathology or • Equivalent Qualifications or Be certified to practice cytopathology by: • American Society of Cytology or • Equivalent Qualifications
MD, DO Licensed in the State in which the laboratory is located	N/A	For Histopathology: Be certified in Anatomic Pathology by: • American Board of Pathology • American Osteopathic Board of Pathology or • Equivalent Qualifications
MD, DO Licensed in the State in which the laboratory is located	N/A	For Dermatopathology: Be certified in Anatomic Pathology by: • American Board of Pathology • American Osteopathic Board of Pathology or • Equivalent Qualifications or Be certified in Dermatopathology by: • American Board of Dermatology and American Board of Pathology or • Equivalent Qualifications or Be certified in dermatology by: • American Board of Dermatology Equivalent Qualifications

TECHNICAL SUPERVISOR (42 CFR 493.1449)		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
MD, DO Licensed in the State in which the laboratory is located	N/A	For Oral Pathology: Be certified in Anatomic Pathology by: • American Board of Pathology • American Osteopathic Board of Pathology or • Equivalent Qualifications or Be certified in Oral Pathology by: • American Board of Oral Pathology • Equivalent Qualifications or Be certified in dermatology by: • American Board of Dermatology or Equivalent Qualifications
MD, DO, DPM Licensed in the State in which the laboratory is located Doctoral*	For Histocompatibility must have: - 4 years training/experience in histocompatibility - Or 2 years training/experience in general immunology and 2 years training/experience in histocompatibility For Cytogenetics, must have: - 4 years training/experience in genetics including 2 years in clinical cytogenetics	N/A
Licensed MD, DO, DPM Licensed in the State in which the laboratory is located Doctoral* Masters** Bachelors**	MD/DO/DPM---- 1 year **** Doctoral---------- 1 year **** Masters---------- 2 years **** Bachelors---------- 4 years ****	N/A

APPENDIX B: Summary of CLIA Qualifications for High Complexity Testing (continued)

CLINICAL CONSULTANT (42 CFR493.1455)		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
MD, DO, DPM Licensed in the State in which the laboratory is located	N/A	N/A
Qualifies as Director for Oral Pathology	N/A	N/A
Doctoral*	NA	American Board of Medical Microbiology American Board of Clinical Chemistry American Board of Bioanalysts or American Board of Medical Laboratory Immunology

GENERAL SUPERVISOR (42 CFR 493.1461)		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
Qualified as high complexity Lab Director	N/A	N/A
Qualified as Technical Supervisor	N/A	N/A
Licensed MD, DO, DPM, or Doctoral*, Masters**, Bachelors**	1 year training/experience in high complexity testing	N/A
Associate Degree*** or equivalent semester hours	2 years training/experience in high complexity testing	N/A
Previously Qualified under 42 CFR 493.1462 on or before 02/28/92*****	N/A	N/A
On or before 09/01/1992, have served as General Supervisor of high complexity testing and	As of 04/24/1995 meet one of the following: • Graduate of ABHES, CAHEA or other HHS approved program or • High School graduate or equivalent with 50 week Military Training with position of • Medical Laboratory Specialist or have 2 yrs. training or experience in high complexity testing	N/A
On or before 09/01/1992, have served as General Supervisor of high complexity testing and be a H.S. graduate or equivalent	Between 09/01/1982 and 09/01/1992, have 10 years of lab training or experience in high complexity testing including 6 years of supervisory experience.	N/A

APPENDIX B: Summary of CLIA Qualifications for High Complexity Testing (continued)

TESTING PERSONNEL (High Complexity) 42 CFR 493.1489		
EDUCATION	**TRAINING/EXPERIENCE**	**BOARD CERTIFICATION OR ELIGIBILITY**
Licensed MD, DO, DPM or Doctoral*, Masters**, Bachelors** Associate Degree***	N/A	N/A
60 Semester Hours with specified distribution requirements	ABHES, CAHEA or other HHS approved program or 3 months training in high complexity testing in applicable specialty/subspecialty	N/A
On or before 02/28/1992, previously qualified under 42 CFR 493.1491	N/A	N/A
H.S. graduate or equivalent on or before 4/24/1995	ABHES/CAHEA or other HHS approved program or 50 week Military Training with position as Medical Laboratory Specialist	N/A
Until 9/1/1997, be a high school graduate or equivalent	Documentation of Skills	N/A

LEGEND:

* Doctoral degree in a chemical, physical, biological or clinical laboratory science.

** Masters or Bachelors degree in a chemical, physical, biological or clinical laboratory science from an accredited institution, medical laboratory technology or cytotechnology.

*** Associate Degree in a chemical, physical, biological science or medical laboratory technology.

**** Experience in High Complexity Testing within each Specialty or Subspecialty with the exception of those with special requirements.

***** Individuals who successfully passed the HHS proficiency examination given between 03/01/1986 and 12/31/1987, qualify if requirements of 42 CFR 493.1462, were met on or before 01/01/1994

The above summarization of the CLIA 88 personnel regulations does not include special provisions for Blood Gas Analysis.