USCENTCOM LABORATORY QUALITY PROGRAM

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☐ Minor Changes (or)	■ New document that requires a thorough reading
☐ Significant Changes	OPR: CCSG

1. **PURPOSE**

To provide essential details on the appropriate management of Clinical Laboratory Improvement Program (CLIP) procedures in a deployment environment in the U.S. Central Command (USCENTCOM) Area of Operation (AO). This policy assigns responsibilities and provides standards and procedures for managing the CLIP. This policy states minimal conditions that all laboratories must meet to perform testing on human specimens under the CLIP.

2. APPLICABILITY

This policy applies to Non-Fixed Medical Treatment Facilities performing laboratory testing within the USCENTCOM AO for field services, such as aid stations, clearing stations, and division, field and force combat support and evacuation hospitals; medical facilities afloat, such as hospital ships and sick bays aboard ships; and tactical casualty staging facilities and medical advance base components contained within mobile-type units.

3. REFERENCES

a. DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended.

b. DoD Instruction 6440.02, "Clinical Laboratory Improvement Program (CLIP)," May 29, 2014, as amended.

c. DoD Manual 6440.02, "Clinical Laboratory Improvement Program (CLIP) Procedures," May 29, 2014, as amended.

d. Memorandum of Agreement between the Department of Defense and Department of Health and Human Services on the Clinical Laboratory Improvement Amendments of 1988 within DoD, January 14, 2009.

e. Public Law 100-578, "Clinical Laboratory Improvement Amendments of 1988," October 31, 1988.

f. Title 42, Code of Federal Regulations.

g. Title 10, United States Code.

h. DoD Instruction 1010.16, “Technical Procedures for the Military Personnel Drug Abuse Testing Program (MPDATP),” June 15, 2020.

i. Appendix C of Centers for Medicare & Medicaid Service (CMS) Publication 100- 07, Medicare State Operations Manual, 1 June 2004.

4. RESPONSIBILITIES

Refer to Appendix A for USCENTCOM CLIP organizational structure.

a. USCENTCOM Command Surgeon will:

(1) Establish and maintain the USCENTCOM CLIP policy consistent with DoD directives, instructions, and policies.

(2) Appoint the USCENTCOM Laboratory Consultant in writing.

b. USCENTCOM Chief of Clinical Operations, component Chief of Clinical Operations, or Designees will oversee USCENTCOM clinical lab program.

(1) Will coordinate with designated USCENTCOM Laboratory Medical Directors, USCENTCOM Laboratory Consultant, and component command surgeons on laboratory policy and necessary interventions

(2) Will designate laboratory inspectors, if required, to evaluate theater laboratories

(3) Designate or supply qualified laboratory medical directors in coordination with component command surgeons for theater laboratories

c. USCENTCOM Laboratory Medical Directors are individuals who meets the Laboratory Director requirements of DoDM6440.02 and will:

(1) Function as the USCENTCOM Command Surgeon’s manager for ensuring compliance with regulations defined by the DoDM 6440.02 and DoD’s Center for Laboratory Medicine Services (CLMS) for laboratories under their supervision

(2) Confirm and support CLIP registration of all medical labs under their management.

(3) Review and approve validation studies required for high complexity and moderate complexity tests as required by the regulations and approve each test for clinical use.

(4) Conduct quarterly staff assisted visit (SAVs) to inspect for quality of spokes within their network. If possible, the lab officer will physically visit spokes. If physical visits are not possible, the lab officer will coordinate with other lab officers within CENTCOM to conduct on-site visits. When neither option is available, the lab officer will conduct virtual SAVs (refer to appendix B for inspection checklist).

(5) Submit to the USCENTCOM Chief of Clinical Operations and their respective component chief of clinical operations an annual calendar year assessment of section QA/PI activities, to include (as applicable): clinical indicators, PI initiatives; occurrence reports (errors/variances); point-of-care

(POC) testing; competency assessment and staff training; personnel staffing, equipment/supplies; and major improvements/accomplishments (to include copies) for which the section has proprietary responsibility.

(6) Serve as a member of the USCENTCOM Laboratory Committee meeting.

(7) Laboratory Medical Director qualifications are listed below but refer to CLMS to ensure individuals meets the exact qualifications.

a) Waived testing: Laboratory Director should be a Medical Doctor (MD), Doctor of Osteopathy (DO), Doctor of Podiatric Medicine (DPM), PhD, Master's or Bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and with appropriate clinical laboratory experience.

b) Moderate Testing: Laboratory Director must be a Medical Doctor (MD), Doctor of Osteopathy (DO), Doctor of Podiatric Medicine (DPM) with either appropriate years' training/experience directing or supervising non-waived lab testing or completion of the 20 CME course; OR a PhD from an accrediting institution with a chemical, physical, biological science, or clinical lab science AND be either certified from a board approved by Human Health Service (HHS) or have appropriate years' experience directing or supervising non-waived lab testing; OR hold a Master's or Bachelor's degree from an accrediting institution in chemical, physical, biological science or clinical lab science/medical technology AND both appropriate years' training AND supervising non-waived lab testing. For information on the applicable Laboratory Director 20 CME Course for providers contact CLMS.

c) High Complexity Testing: Laboratory Director must be an MD/DO with at least 1 year of lab training during residency or 2 years of experience directing and supervising high complexity testing OR have a PhD from an accredited institution with a chemical, physical, biological science, or clinical lab science AND be certified from a board approved by Human Health Service (HHS).

d. USCENTCOM Laboratory Consultant (Clinical Laboratory Officer in Theater) will:

(1) Enforce the standards established by the USCENTCOM Laboratory Medical Director.

(2) Establish hub and spoke model with consensus from USCENTCOM and component Clinical Operations personnel in order to execute the CLIP policy in the USCENTCOM AO and advise on designation of appropriate USCENTCOM Laboratory Medical Directors

(3) Advise the USCENTCOM Laboratory Medical Directors, USCENTCOM and Component Chiefs of Clinical Operations regarding current military and civilian laboratory regulations and policies.

(4) Inspect or facilitate inspections of laboratories

(5) Conduct the USCENTCOM Lab Committee biweekly meeting and cover the required clinical lab quality pieces.

(6) Guide USCENTCOM hubs and spokes on appropriate Quality Assessment plans and report to the laboratory director about any concerning findings or trends

(7) Serve as a clinical laboratory liaison for laboratories when needed.

(8) Ensure laboratory directors are reviewing all existing policies and procedures for the laboratory biannually or with change of directorship.

(9) Ensure laboratories are performing self-inspections, receive results of laboratory self-inspections and report and on any concerning findings

e. USCENTCOM Service Component Laboratories will:

(1) Follow USCENTCOM CCOP for clinical laboratory testing operations to include sick call and other lab testing conducted in the AOR.

(2) Implement requirements IAW CLIP regulations within their respective Commands Active and Reserve Components and facilities under their supervision.

f. USCENTCOM Clinical Consultant is performed by Pathology Service Consultant or Specialty Leader and will be available for consultation on laboratory test needs and requirements.

g. USCENTCOM Technical Supervisors, USCENTCOM General Supervisors, and USCENTCOM Technical Consultants must meet requirements in the DODM 6440.02 and will provide technical and scientific oversight of USCENTCOM clinical laboratories. The assigned medical director will designate or serve as the technical supervisor/consultant and may assign a general supervisor if required.

h. USCENTCOM Laboratory hubs are the highest-level laboratory facility in a network, headed by a commissioned clinical laboratory officer from either the Army, Navy or Air Force. The USCENTCOM hubs will:

(1) Provide regular communication with all spokes within their network to provide best practices and policies and procedure assistance; advice and mentorship; error correction and troubleshooting guidance.

(2) Provide oversight and support to their assigned spokes to ensure accurate lab results for quality patient care.

(3) Will be responsible for overseeing of a Quality Assessment plan for their spokes and notify their USCENTOM Laboratory Director and USCENTCOM Laboratory Consultant of any concerning findings and trends.

(4) Ensure an appropriate level of CLIP certificate is obtained and maintained by all labs in their network.

(5) Will designate a qualified moderate complexity laboratory director for their respective spokes if able.

i. USCENTCOM Laboratory spokes will:

(1) Maintain regular communication with their hubs.

(2) Provide documentation as requested to their hubs.

(3) Institute a Quality Assessment plan and discuss challenges, opportunities, and suspected errors with their hubs.

(4) Notify hubs immediately if new testing or instrumentation is being considered at their site and request approval.

(5) Comply with assignments and requirements as determined by their hub lab officer and if unable to comply discuss options to mitigate risk.

j. USCENTCOM Non-Fixed Medical Treatment Facilities (MTFs) will:

(1) Identify equipment critical for laboratory testing services and ensures calibration, maintenance, and system monitoring conform to the manufacturer standards and other specified requirements.

(2) Provide adequate resources to perform, verify, and manage all activities in the laboratory.

(3) Maintain certification of compliance for the appropriate complexity of clinical laboratory testing.

(4) Comply with all provisions of this policy except where exemption is specified herein (e.g., USCENTCOM Non-Fixed MTF Laboratories are exempt from mandatory external PT).

(5) Participate in continuing education when available.

(6) Participate in lab committee meetings. The meeting will identify, evaluate, and propose solutions to QA/PI related issues and problems, to ensure the highest quality services, along with opportunities for program performance and process improvement. Receive/evaluate reports all laboratory-related QA/PI issues. (i.e. clinical indicators, PI initiatives, errors/variances (Occurrence reports), quality control, process/system problems, patient safety, etc.).

(7) Ensure all laboratory staff are appropriately trained and competency assessed on clinical laboratory testing being performed and maintain appropriate documentation of it as required.

(8) Follow manufacturer’s instructions and ensure all laboratory equipment is functioning properly.

k. Clinical Laboratory Officer in Charge (OIC) will:

(1) Continuously self-assess section operations; evaluate received comments/complaints; review laboratory-related professional literature to identify potentially problematic procedures/processes and any opportunities to improve overall patient care, and develop/implement functional procedures/processes to address known or suspected problems.

(2) Establish and maintain document control for all policies, procedures, and forms.

(3) Submit to their USCENTCOM Laboratory Medical Director a monthly assessment of section QA/PI activities, to include (as applicable): clinical indicators, PI initiatives; occurrence reports (errors/variances); point-of-care (POC) testing; competency assessment and staff training; personnel staffing, equipment/supplies; and major improvements/accomplishments (to include copies) for which the section has proprietary responsibility.

5. PROCEDURES

a. CLIP CERTIFICATE APPLICATION

(1) All clinical laboratories should apply for CLIP Certificates and have a CLIP Certificate prior to any patient testing.

(2) Apply for a CLIP Certificate on the portal to gain access: https://info.health.mil/hco/clinicsup/hsd/hs/clms/SitePages/Home.aspx; click on the icon labeled "CLIP Portal," and follow submission procedures. CLIP Certificates Types:

(a) Registration Certificate allows moderate or high complexity labs to start patient testing. Must be inspected to determine compliance within one year.

(b) Certificate of Compliance allows deployed MTF's to conduct laboratory testing. A compliance inspection is performed by CLMS or the USCENTCOM Laboratory Consultant or designee. The certificate is valid for no more than two years. Most laboratories in USCENTCOM fall under a Certificate of Compliance.

(c) Certificate of Waiver is issued to labs performing waived complexity category of testing.

(d) Certificate of provider-performed microscopy (PPM) procedures is issued to sections with providers performing PPM during patient's visit

(e) Certificate of Accreditation is issued to labs performing Moderate or High complexity testing, and it requires a compliance inspection by a deemed accrediting agency. A laboratory will not apply for a certificate of accreditation without USCENTCOM approval.

b. TRAINING AND COMPETENCY OF PERSONNEL.

(1) Under the provisions of DoDM 6440.02, the DoD Clinical Laboratory Improvement Program (CLIP) requires the laboratory to establish and follow written policies and procedures to assess employee competence.

(2) Job descriptions define appropriate qualifications (i.e., education, training, and experience) for each position are updated as necessary.

(3) All laboratory sections maintain competency assessment folders (CAF) for their personnel.

(4) Initial and every 6 months as tour allows.

(5) Competency Assessment Folders are initiated within 30 days of new personnel arriving in the Theater.

(6) Testing personnel requirements are listed below:

(a) Waived Testing: No defined federal requirements – individuals must be trained appropriately in clinical lab testing to perform waived testing.

(b) Moderate Complexity Testing: Testing personnel need at least a high school diploma (or

equivalent) and appropriate training/experience with clinical lab testing. While this is the minimum, it is strongly recommended that personnel have a laboratory background due to the complexity of clinical lab testing.

(c) High Complexity Testing: Testing personnel must have an associate's degree or higher in laboratory science or medical laboratory technology AND be certified by ASCP, AMT, or other board deemed comparable OR have successfully completed a military medical lab course of at least 50 weeks and currently hold the military occupational specialty of Medical Lab Specialist. Appropriate training and ongoing competency is required.

c. STANDARD OPERATING PROCEDURE (SOP) OR OPERATING INSTRUCTION (OI) FOR EACH TEST PERFORMED.

(1) A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

(2) The procedure manual must include the following when applicable to the test procedure.

(a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection.

(b) Microscopic examination, including the detection of inadequately prepared slides.

(c) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(d) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

(e) Calibration and calibration verification procedures.

(f) The reportable range for test results for the test system as established or verified.

(g) Control procedures.

(h) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

(i) Limitations in the test methodology, including interfering substances.

(j) Reference intervals (normal values).

(k) Imminently life-threatening test results or critical or alert values.

(l) Pertinent literature references.

(m) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening

results, or critical or alert values.

(n) Description of the course of action to take if a test system becomes inoperable.

(3) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of this section.

(4) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. For USCENTCOM Laboratories expired reagents may be used only when delivery of new shipments of reagents is delayed through causes not under the control of the laboratory. The laboratory must document validation of the performance of expired reagents in accordance with a written laboratory policy.

(5) Patient forms and documents will be scanned into the applicable electronic medical record or Theater Medical Data Store (TMDS). Paper records after inclusion, may be destroyed.

d. **MAINTENANCE PROGRAM**

(1) All devices and equipment are qualified/validated for its' intended use before implementation.

(2) Modified FDA-cleared/approved tests or LDTs, the summary must address analytical sensitivity, analytical specificity, and any other parameter that is considered necessary, to assure that the analytical performance (e.g. specimen stability, reagent stability, linearity, carryover, and cross-contamination, etc.), as appropriate and applicable.

(3) Critical equipment is calibrated and adjusted: before use; after activities that may affect the calibration; and, at prescribed intervals.

(4) In conjunction with Medical Maintenance, the Laboratory maintains section-specific procedures and schedules for equipment monitoring and maintenance that include: frequency of checks, check methods, acceptance criteria, and action(s) to be taken for unsatisfactory results.

(5) The Laboratory maintains a process to investigate and follow up equipment malfunctions, failures, or adverse events.

(6) The laboratory and Medical Maintenance retain all required records for the life of the equipment. The records are stored in both section specific areas and the Medical Maintenance department. Records include:

(a) Equipment identification

(b) Results of calibrations and follow-up actions

(c) Results of maintenance and follow-up actions

(d) Temperatures of heat-regulated equipment

(e) Fulfillment of applicable life-cycle requirements

(f) Numerical designation of equipment versions (where applicable) with inclusive dates of use

e. VALIDATION, CALIBRATION, CALIBRATION VERIFICATION, AND CORRELATION OF TESTS

(1) Before initial test implementation a completed, Laboratory Director signed and approved validation studies for clinical use, per the regulations, for all non-waived complexity tests are required.

(2) Before reporting test results of an unmodified FDA cleared or approve test or method, the lab must:

(a) Demonstrate reproducibility of manufacturer performance characteristics as they pertain to accuracy, precision and the reportable range for the test system.

(b) Verify the reference intervals are appropriate for the labs' patient population.

NOTE: Modifying lab tests or not following the manufacturer's instructions per the FDA approved test is considered off-label use and raises the lab test complexity to a high complexity test. It also requires a validation study to verify the lab test for that intended use.

(2) Calibration and Calibration Verification may be required on tests. Always refer the manufacturer's instructions. If unable to get the material in theater to conduct, document appropriately and work with Clinical Lab Officer to meet the requirement, if applicable.

(3) Correlation between similar instruments may be required on a regular occurring interval, refer to the Clinical Lab Officer to verify. Utilizing a supporting USCENTCOM Non-Fixed MTF laboratory.

f. CONTINUING EDUCATION PROGRAM.

(1) Education/training is an ongoing process designed to ensure all personnel performing laboratory testing are knowledgeable in the principles and competent in the required procedures for each laboratory test they are expected to perform, including those subject areas relevant to their duties and responsibilities as laboratory scientists, technologists, and technicians.

(2) In-service classes/presentations are designed to assist the staff in acquiring, maintaining, and increasing their level of technical and administrative competence in meeting the requirements of their assigned duties and responsibilities.

(3) Continuing education provides professional learning knowledge and experience designed to enhance an individual's contributions to the organization and assist in the achievement of their professional career goals. The purpose of continuing education is not to replace basic skills or bench-level competency training or local policy/administrative procedures training within the organization.

(4) The Laboratory Non-Commissioned Officer ensures education level in-service education/training classes are scheduled, conducted, and documented for attendance and content. The Lab NCO inspects training and competency files for compliance and completeness.

g. PATIENT SAFETY REPORTS

(1) Laboratories will use the Patient Safety Report (PSR) system to capture and report all occurrences where a process or procedure does not have the expected outcome. At a minimum labs, should be in communication with the technical and clinical supervisors with quality concerns.

(2) Occurrences fall into one of three categories: Pre-analytical (e.g., specimen labeling errors, patient identification errors), Analytical (e.g., test result errors, delays in testing, and errors in data entry), and Post-Analytical (e.g., safety violations, critical results not called). Investigation and documentation of these incidents are mandatory.

(3) Laboratories will evaluate their Occurrence Reports to identify any patterns or trends adversely impacting the quality of laboratory testing.

(4) Device-Related Adverse Patient Events

(a). Personnel are to report, through the CENTCOM lab consultant to the laboratory director, device-related adverse patient events when information reasonably suggests a laboratory instrument, reagent, or other devices (e.g. an accessory device used for phlebotomy or specimen collection) caused or contributed to patient death or severe patient injury. Laboratory supervisory staff will report the event to the Chief, Logistics Division and the Chief, Medical Maintenance Branch (problem involved laboratory instruments or equipment) or the Chief, Supply Chain Management Branch (problem involved laboratory reagents or supplies). Suppose the event is to be reported directly to the FDA and device manufacturer, the report will be submitted on FDA Form 3500A (Medication and Device Experience Report) as soon as practical but no later than 10-days from the date medical personnel become aware of the event.

(b) In addition to submitting a report, the laboratory will prepare a Patient Safety Report (PSR) to report the event to the USCENTCOM MTF Patient Safety Office. A copy of the Medical Material Complaint or FDA Form 3500A, if submitted, will be included with the completed Patient Safety Report as an attachment. The Laboratory Manager will process the Patient Safety Report and report the issue to the USCENTCOM Quality Management Working Group.

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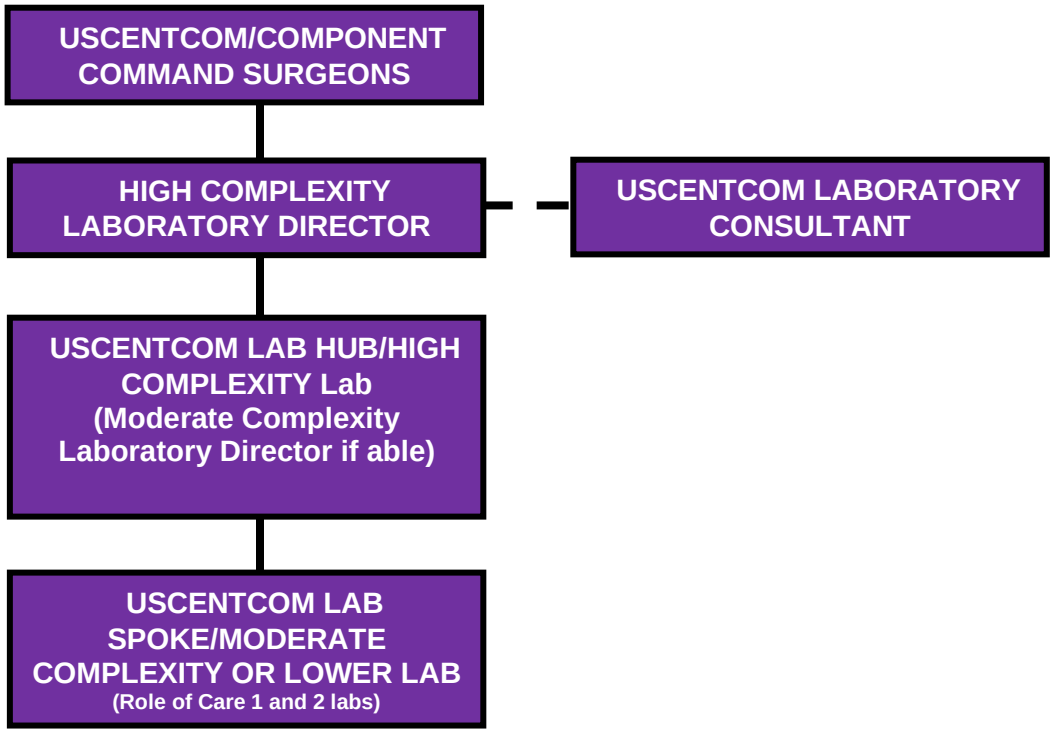
APPENDIX A, CLIP ORGANIZATIONAL STRUCTURE



- **USCENTCOM COMMAND SURGEON**: establishes and maintains the CLIP policy consistent with DoD directives, instructions, and policies.
- **USCENTCOM LABORATORY MEDICAL DIRECTOR**: (licensed physician(s), board certified) is the USCENTCOM Command Surgeon'smanager for ensuring compliance with regulations defined by the Department of Defense (DoD) Center for Laboratory Medicine Services (CLMS)and confirms CLIP registration of all medical labs under their supervision.
- **USCENTCOM LABORATORY CONSULTANT**: Consultant (Laboratory Officer in Theater) enforces the standards in coordination with USCENTCOM and Component Surgeon Offices established by the USCENTCOM Laboratory Directors.
- **USCENTOCM LAB HUB**: Hubs will be the high complexity Laboratory facilities in a network, headed by a clinical laboratory officer from either the Army, Navy, or Air Force. Laboratory officers may serve as moderate complexity laboratory directors for spokes under their supervision.
- **USCENTCOM LAB SPOKE**: Spokes will stay in regular communication with their hubs; Spokes will discuss challenges, opportunities, and suspected errors with their hubs; Spokes will immediately notify hubs if new testing or instrumentation is being considered at their site

APPENDIX B, LABORATORY INSPECTION CHECKLIST

Checklist for CLIP Registration And Compliance Certification

Laboratory Demographics
Laboratory Name:
Estimated population base:
Number of Different Tests:
OIC/NCOIC Name:
Laboratory Director Name:
Survey and Surveyor(s)
Surveyor(s):
Survey Date:
Notes: For deployed labs, this is necessary for >180 day rotation.

Use this survey during lab hand-off (L-R seat), up to initial 30 days IOT apply for Certificate of Registration (OIC2OIC)

Use this survey within initial 90 days IOT apply for Certificate of Compliance when registration certificate already in place (performed by an independent auditor i.e. DCCS, Lab Director, Blood Officer etc.)

I. General Administrative & Personnel	**Yes**	**No**	**N/A**	**Comments**
1. What is the laboratory's complexity? (WAIVED-PPM-MOD-HIGH)				
2. Are all personnel qualified by CLIP regulations for the duties they perform in the laboratory? (Lab Director has to be NP, PA, MD*)				
3. Is documentation available/verifiable for education, experience and l training for all positions covered by the CLIP?				
4. Is there a job description detailing the responsibilities of all personnel in the laboratory?				
5. Are there sufficient appropriate personnel to perform the testing workload?				
6. Is a system in place and a written procedure available for initial and continued evaluation of the competence of laboratory personnel?				
7. Are the Director and Technical Consultant(LabOIC) available as required for consultation?				
II. Facility and Safety	**Yes**	**No**	**N/A**	**Comments**
8. Is the size and location of the area used for testing appropriate to the testing being done?				
9. Is there sufficient work and storage areas for testing to be performed properly and safely?				
10. Is there an Exposure Plan for Bloodborne Pathogens for the laboratory?				
11. Is it readily available to employees and have they been familiarized with its contents?				
12. Are universal precautions used in the laboratory?				
13. Is appropriate personal protective equipment readily available?				
14. Have the staff been trained in their application and use?				
15. Is there a Chemical Hygiene Plan for hazardous materials, if needed?				
16. Is it readily available to employees and have they been familiarized with its contents?				

II. Facility and Safety (con't)	Yes	No	N/A	Comments
17. Are Material Safety Data Sheets available for all hazardous materials used in the laboratory?				
18. Are all hazardous materials stored appropriately e.g. flammables cabinets, acids and alkali stored separately, etc. and labeled properly?				
19. Are all disposable sharps discarded in an appropriate sharps container?				
20. Are "red-bag" containers and sharps containers readily available?				
21. Is eating, drinking, smoking, application of cosmetics and handling of contact lenses strictly forbidden in laboratory areas?				
22. Are pipetting devices available to avoid mouth pipetting?				
23. Are refrigerators used for food separate and apart from those used for specimens i.e. no storage of food in laboratory refrigerators or refrigerators marked for food use only?				
24. Are all electrical equipment or appliances up to generally accepted standards of electrical safety?				
25. Are fire extinguishers available and in proper working order?				
26. Do staff personnel know how to use them?				
27. Are laboratory personnel familiar with alternate routes of escape?				
III. Patient Test Management	**Yes**	**No**	**N/A**	**Comments**
28. Are all tests requested in writing?				
29. If a test is ordered orally, is it followed with a written request within 24 hours?				
Does the written requisition contain:				
30. the patient's name and/or other unique identifier?				
31. the name or other identifier of the person requesting the test?				
32. the test to be performed?				
33. the date (and time, if appropriate) of specimen collection?				
34. any additional information to assure accurate and timely testing and reporting of results?				
Does the laboratory have and follow written distributed/educated procedures for:				
35. preparation of the patient?				
36. collection of the specimen?				
37. labeling of the specimen?				
38. preservation and/or transportation of the specimen?				
39. processing of the specimen?				
Do laboratory records show:				
40. patient's name or other unique identifier through all phases of testing?				
41. date and time specimen was received in the laboratory?				
42. condition of unacceptable specimen and disposition thereof?				
43. date that all testing was performed?				
44. identity of all personnel performing testing?				

III. Patient Test Management (con't)	Yes	No	N/A	Comments
Are the results of laboratory testing:				
45. released only to authorized persons?				
46. reported in timely fashion?				
Does the laboratory report contain:				
47. the name and address of the laboratory?				
48. the test performed?				
49. the result?				
50. the unit of measurement?				
51. the pertinent "normal range" for the test?				
52. Does the laboratory have and follow written procedures for reporting imminently life-threatening results?				
53. Does laboratory policy prohibit reporting results which exceed the reportable range for the instrument or system?				
54. Are test reports maintained in a manner which permits ready identification and timely accessibility?				
55. Does the laboratory notify the appropriate person of any errors and				
is a corrected report issued?				
Are the following records maintained for two years:				
56. test requisitions?				
57. test reports, including instrument printouts and worksheets, and reports from reference laboratories?				
58. corrected reports?				
59. documentation of all quality control activities?				
60. documentation of all quality assurance activities?				
61. Are immunohematology reports (including those from reference laboratories) maintained for five years?				
62. If applicable: are pathology and Pap smear reports (including those from reference laboratories) maintained for ten years?				
IV. Proficiency Testing	**Yes**	**No**	**N/A**	**Comments**
63. Is the laboratory registered with an approved PT provider?				
64. Are all regulated assays proficiency tested?				
Are PT specimens handled exactly the same way as patient specimens:				
65. introduced into the normal work flow?				
66. assayed same number of replicates as patients?				
67. assayed by same testing personnel as patients?				
68. reported in the same manner as patient specimens i.e. > or < etc.				
69. Are copies of PT submissions filed together with applicable instrument printouts to facilitate QA followup?				
70. Are PT results reviewed by the director?				
71. Are deficiencies investigated and remediation instituted if indicated based on this review?				

V. Instrument Maintenance	Yes	No	N/A	Comments
72. Is an instrument log maintained for each instrument used in the laboratory?				
Is the following recorded in the instrument log:				
73. daily and periodic maintenance: procedure and log?				
74. function checks: procedure and log?				
75. scheduled and unscheduled manufacturer's preventive maintenance?				
76. instrument problems and attempts to rectify?				
77. Are automatic or semi-automatic pipets checked regularly for accuracy?				
78. Are all non-waived complexity procedures calibrated or calibration verified every six months?				
Is recalibration performed:				
79. when quality control shows out of control values, shifts or trends?				
80. when a complete change of reagents occurs?				
81. after major preventive maintenance procedures?				
82. after a critical part of the instrument is changed?				
83. more often than every six months if required by the manufacturer?				
VI. Procedure Manual	**Yes**	**No**	**N/A**	**Comments**
84. Does the laboratory have a procedure manual for each test performed?				
85. Does it contain all procedures performed in the laboratory?				
86. Is it accessible and understandable to testing personnel?				
87. Do procedures accurately reflect actual laboratory practice?				
88. Is the procedure manual also reviewed and signed by the director?				
89. Are all new procedures or changes in procedure also signed by the director?				
Does each procedure contain:				
90. procedure for obtaining specimens for the test?				
91. any special instructions to the patient which may be required?				
92. procedure for handling, preservation and storage?				
93. criteria for rejection of unacceptable specimens?				
94. directions for preparation of reagents, standards, controls, etc. for the test?				
95. directions for storing and storage stability of these prepared components?				
96. directions for performing the test?				
97. special procedural notes or cautions?				
98. calculations or other manipulations necessary to obtain the result?				
99. normal or expected ranges for the test, panic values, etc.?				
100. procedure to follow if quality control is out of range?				
101. limits of the procedure, including hemolysis, lipemia, and other preanalytical variables such as drug or disease interferences?				
102. linearity or calibration limits?				
103. procedure to follow if linearity is exceeded?				
104. lowest detectable concentration?				

VI. Procedure Manual (Con't)	Yes	No	N/A	Comments
Does each procedure contain (con't)				
105. literature references?				
106. sample handling in the event of instrument or system malfunction?				
107. Is each procedure reviewed and signed by each rotation director				
108. Are discontinued procedures maintained for two years?				
VII. Quality Control	**Yes**	**No**	**N/A**	**Comments**
109. Is a quality control program maintained for all analytes?				
Does the QC program specify:				
110. which controls to assay and				
how often the controls are run?				
111. how acceptable limits are derived?				
112. procedures to follow if limits are exceeded?				
113. Are temperature controlled spaces monitored each day of use?				
114. For room temperature tests, is room temperature monitored?				
115. Are acceptable ranges defined for temperature controlled spaces?				
116. Are acceptable ranges defined for room temperature?				
117. Are thermometers checked regularly for accuracy?				
118. Are timers checked regularly for accuracy?				
119. Are controls run in the same manner as patients?				
120. Are control values verified as in range prior to commencing patient testing?				
121. If not, are patient specimens since the last successful control rerun in case of control failure?				
122. Are quality control results reviewed by the director?				
123. Are mean, standard deviation and coefficient of variation calculated regularly for quantitative assays?				
124. Are Levy-Jennings or other graphs generated regularly for quantitative assays?				
125. Are prepared controls, standards, reagents, stains, etc, labeled as to content, preparation date, storage requirements and expiration date?				
126. Are all expired materials discarded on or before the expiration date? (as possible; exceptions due to optempo clearly annotate process for assuring acceptability of material/risk)				
Hematology:				
127. Are two levels of controls run every eight hours for automated hematology assays?/manufacturers/IQCP guidelines				
128. For automated differential counts, have criteria been established for determining when a manual count must be performed?				
129. Are these criteria followed by the staff?				
For sedimentation rates:				
130. Are ESR's set up within two hours of blood being drawn?				
131. If not, is the blood refrigerated and then brought to room temperature before setting up?				
132. Is the rack set up in a place free of vibration/other disturbances?				
133. Is the rack leveled before use?				

VII. Quality Control (con't)	Yes	No	N/A	Comments
For coagulation:				
134. Are two levels of controls run every eight hours?/manuf./IQCP				
135. Are two levels of controls run with change of reagents?				
136. If coagulation is run manually, are they run in duplicate?				
137. If automated, has the validity of running single testing been verified statistically?				
Serology:				
138. Are positive and negative controls assayed for each patient run?				
139. Is each new lot of reagent checked for reactivity against previous lots?				
140. Is the speed of the rotator monitored for each day of use?				
Microbiology:				
141. Are media inspected visually for defects before use?				
142. Are sterility and growth support checks performed?				
143. If performed by manufacturer to NCCLS standards, are these checks documented for each batch of media? (as possible due to supply limitations & optempo considerations)				
144. Are results of cultures reported only according to the manufacturer's directions?				
145. If identification (definitive) is performed, are catalase, coagulase, oxidase, etc. reagents checked daily for positive and negative reactivity with appropriate control organisms?				
For antibiotic sensitivity testing:				
146. Is the concentration of organisms in the inoculum standardized?				
147. Is each new batch of media or discs checked for reactivity prior to use?				
148. Are zones of inhibition sizes checked each day with appropriate control organisms?				
VIII. Quality Assurance	**Yes**	**No**	**N/A**	**Comments**
149. Does the laboratory have a written quality assurance program?				
150. Are the effectiveness of policies and procedures periodically evaluated?				
151. Does the evaluation identify problems and suggest solutions?				
152. Are the solutions monitored to ensure their effectiveness?				
153. Are the results of the evaluations discussed with the laboratory staff?				
154. Are breakdowns in communications between physicians and laboratory personnel recorded?				
155. Are corrective actions taken to remedy these breakdowns?				
156. Does the laboratory have a procedure for documenting, investigating and correcting complaints about the laboratory?				
157. Are regular QA meetings held with laboratory staff?				
158. When tests are run on more than one system, is a system in place to evaluate their correlation twice yearly?				

*** CLMS recommends the incoming Lab Director complete the COLA Resource Inc. Lab Director (20) CME Program online prior to deployment (at unit cost ~$525), or another comparable 20 CME Lab Director program.**
https://labuniversity.org/lab-director-cme-program/

Send questions and completed applications to your CLIP Program Manager, Center for Laboratory Medicine Services, DHA, Falls Church, VA, or email the CLMS org box: dha.ncr.clinic-support.mbx.clms@mail.mil

References: DODM 6440.02, CLIP Procedures, v May 29 2014
CLMS CLIP Checklist Version 20200710

Laboratory Testing Personnel	***(Select all that apply)***
	Dentist
	Physician (M.D., D.O.)
	Podiatrist (D.P.M.)
	Registered Nurse (R.N.)
	Nurse Practitioner
	Licensed Practical Nurse (LPN)
	Medical Technologist (B.S.)
	Pharmacist
	EMT
	Medical Laboratory Technician - MLT (A.A.) Medical Assistant
	Military Training
	High School Diploma
	Other (please specify)
	Comments:

Laboratory Director	***(Select all that apply)***
	Dentist
	Physician (M.D., D.O.)
	Podiatrist (D.P.M.)
	Registered Nurse (R.N.)
	Nurse Practitioner
	Licensed Practical Nurse (LPN)
	Medical Technologist (B.S.)
	Pharmacist
	EMT
	Medical Laboratory Technician - MLT (A.A.) Medical Assistant
	Military Training
	High School Diploma
	Other (please specify)
	Comments:

Lab Equipment	Quantity