New York State Guidance for following Standard Practices in Laboratory Medicine
(For sites performing waived and/or provider-performed microscopy procedures under a Limited Service Laboratory Registration)

General	
What is a laboratory test?	Laboratory tests are medical procedures that involve testing samples of blood, urine, or other tissues or substances from the body. Information obtained from laboratory tests may help providers decide whether other tests or procedures are needed to make a diagnosis or to develop or revise a previous treatment plan.
What is a waived test?	The Clinical Laboratory Improvement Amendments (CLIA) defines a "waived" test as a test that is easy to perform and has a little to no risk to the patient if performed incorrectly. The kit will be clearly labeled as "waived" or information can be obtained from the manufacturer or distributor of the test kit, or from the Food and Drug Administration (FDA) website: To Search By Test System: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm To Search By Analyte: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm To Search a Particular Kit/Manufacturer.: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
What are provider-performed microscopy procedures (PPMP)?	PPMP are tests requiring use of a microscope and performed by physicians, dentists or midlevel practitioners (nurse practitioners, nurse midwives, physician's assistants) during the patient's visit. A list of PPMP tests is available at: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf
What is a laboratory?	A laboratory is any entity that performs testing on materials taken from the human body for the purpose of providing information for the diagnosis, prevention, treatment of any disease, or impairment of, or the assessment of the health of human beings.
What is a limited service laboratory?	A limited service laboratory is any facility that restricts laboratory testing to waived testing and/or PPMP. Testing is performed at the site where the patient receives care. Types of settings include community clinics, nursing homes, home health care, ambulatory surgery centers, point-of-care testing programs in hospitals or clinics, homeless shelters, ambulances and community-based organizations conducting supervised health screenings.
Who qualifies as a laboratory director of a limited services laboratory?	All limited service laboratories must have a laboratory director responsible for the testing performed. New York State licensed medical doctors, doctors of osteopathy, dentists, nurse practitioners, certified nurse midwives or physician's assistants can act as laboratory director at laboratories performing waived or PPMP testing. Ph.D.s and individuals holding a Doctor of Science may act as director at laboratories conducting waived testing only. For facilities such as hospitals and clinics that have a fully-permitted laboratory on-site, the director of the permitted laboratory must also be the director for the limited services laboratory.

What are the responsibilities of a laboratory director?	The laboratory director is responsible for: • Training of staff performing tests and annual evaluation to demonstrate continued ability and knowledge to perform the test (competency assessment); • Maintaining an up to date procedure manual for all laboratory tests performed. • Makes sure all tests are performed as written in the manufacturer's package insert or device user's guide; • Maintaining complete and accurate records of tests performed; and • Complying with other state and federal laws, including reporting of communicable diseases and other public health concerns (e.g. lead testing).
Are testing personnel trained in how to perform each test as required by the package insert or device user's guide?	Staff performing testing must receive training on how to perform the tests when new tests or devices are introduced or when newly hired. Training should be provided by a qualified person (e.g., experienced co-worker, facility expert, or outside consultant) with knowledge of how to perform the test and the ability to evaluate the effectiveness of the training (e.g., does staff understand how to perform the test and are they performing the test correctly). On-the-job training includes the following steps: For the Trainer: • provides a step by step demonstration of how the specimen is collected and the test is performed; • observes how the trainee collects and performs the test and provides feedback and additional instruction to ensure accurate and reliable test results; • documents in writing available for the department's review that the training has been completed by the trainee; • evaluates that the trainee has performed the test according to the package insert; and • educates how to identify invalid results and/or test kit or device problems. For the Trainee: • reads the package insert or device user's manual; • observes the trainer demonstrating how the test is performed; • performs the test according to the manufacturer's package insert while the trainer observes; and • correctly interprets the test result.
What is competency assessment? How is it done?	Competency assessment is a process to make sure that staff are following the proper test procedure after initial training and should be performed annually. Ways to perform competency assessment include: • Supervisor/director watching staff collect the specimen and perform testing to verify that the person is following the proper test procedure; • Having staff re-test previously tested samples to check that the same result is generated. Discrepant results are investigated.

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Pre-examination Phase (before beginning testing)	
How much space do I need to perform laboratory testing?	Testing should be conducted in an area that has enough space to lay out all materials needed. Testing may be conducted in a patient exam room or in a centralized area. It is important to make certain that there is enough space to keep patient samples separated to avoid any mix-up.
Why do I have to monitor temperature, humidity or lighting conditions for some tests?	The package insert or device user's guide may describe specific temperature, lighting and humidity requirements that are needed for proper operation of the test device or kit. There may also be specific temperature requirements for storage of the test kit. Recording and monitoring that testing is performed in the appropriate conditions is part of a comprehensive quality assurance plan.
How are provider authorizations (i.e. orders) documented?	Testing requires medical provider authorization (e.g. prescription, note in the medical record, etc.) to conduct laboratory testing.
Are patients given instructions on how to prepare for the test?	For tests requiring special preparation (e.g., a fasting glucose or cholesterol), make sure that the patient followed the instructions before collecting the specimen. If not, consult with the ordering provider to determine what to do next.
Are there procedures to ensure proper patient identification?	The patient is correctly identified before collecting the specimen.
What is proper specimen collection and labeling?	Directions for specimen collection, handling and storage are included in the package insert or device user's guide and may be different for each test. All specimens not immediately tested should be labeled with the patients name and some unique information (such as a birthdate) to avoid mixing up specimens and make finding a specimen easier if needed later.
Should lot numbers and serial numbers of the kits and devices be documented?	The Food and Drug Administration (FDA) regularly sends out notices of recalled devices and reagents and other problems. The laboratory should be able to identify which patients were tested with a specific lot number or kit in order to perform follow-up testing if a lot number is recalled. The laboratory should report and problems identified with kits and devices to the FDA.
Do test kits and materials ever expire? Can I use them after expiration?	Kits have an expiration date and should not be used for testing after that date. Always document the test name, kit lot number and expiration date before testing.
Can I combine unused parts of test kits together to use them up?	No. Components of test kits are made to work together as a unit. Mixing and matching parts may cause inaccurate tests results.

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Examination Phase (testing)	
What is calibration?	Calibration is a check to make sure a device is functioning properly. For glucose meters, for example, a check strip, chip or code number is entered into the meter. The meter will match the entry to a batch of test strips and verify that the device ready to use.
What is a function check?	A function check is a mechanism inside the device to monitor that the device is functioning correctly (e.g. electronic or color change indicators).
What is quality control (QC)?	Quality control makes sure that results generated by the test are correct. QC varies with the kit or device. The package insert or device user's manual tells you when and how often to use external QC materials. QC materials may include liquids, swabs, strips or disks purchased separately or included in the test kit. A control is tested in the same way as a patient sample with the results compared to the expected result. A device may also have an electronic control (a mechanism inside the device) to monitor that the device is functioning correctly. If either the external or internal QC does not provide the expected results, patient test results may be inaccurate and unreliable and must not be reported until the problem has been investigated and resolved. Quality control results must be documented.
What is a quality assurance system?	Quality assurance system checks the whole testing process from start to finish and includes : • the selection of a test; • proper training of all staff ; • appropriate specimen collection procedures; • monitoring of environmental conditions; • using quality control materials as required and obtaining expected results; • performing the test according to the package insert; • accurate recording and delivery of test results; and • recording and investigation of any unexpected results.
Why do I need to look at the manufacturer's package insert or device user's manual?	The package insert or device manual provides directions on how to perform the test, identifies required quality control , how often a device should be calibrated how to interpret test results, and what to do if the test kit doesn't work as expected. Always make sure you have the most recent version since changes may have been made since the last time you performed the test.

How are test results interpreted?	Results that are reported as presence/absence of something are qualitative results. This includes tests that require observing a color change or lack of color development. Examples of qualitative results are positive/negative or reactive/nonreactive. Results that indicate how much of something is present in the specimen are quantitative results. Interpretation would consist of recording the number viewed on the device. The report should include the actual number and the units of measure (e.g. mg/dL or whatever unit is applicable to the device).
What do I do if the test is inconclusive or results do not appear consist with the patient's clinical picture?	If the test result is interpreted as invalid, not consistent with the patient's clinical picture, or outside of the measuring range of the device, the results should not be reported. The source of the problem should be identified. Refer to the package insert to obtain additional information, including steps to follow in resolving the problem.

Post-examination Phase (after testing)	
How are test results reported?	Record test results according to your organization's policy. Results can be recorded directly in the patient's chart, in log books, or on a separate report form. Invalid, inconsistent or otherwise unacceptable results or repeat testing should also be recorded.
What records related to testing do I need to keep?	Recordkeeping is an important part in laboratory testing, showing that the tests were performed properly and all required steps were completed. It also helps when the laboratory needs to identify and resolve any problems. Records that should be kept include: • temperature logs for storage and testing spaces; • quality control records, including lot numbers, dates, results and staff who performed each test; • patient test results logs, including kit lot numbers, expiration dates, date patient test performed, patient result and staff who performed the test; • training and competency records for all testing staff; • maintenance records showing device maintenance or service; and • Quality Assurance reviews. Log books or electronic systems may be used for maintaining and tracking information. In some cases, records may be part of the patient's medical chart. Testing records should be maintained to facilitate retrieval of information.

What is a confirmatory test?	A confirmatory test is another, more advanced test that is performed to verify the result of a waived test. The confirmatory test is more sensitive or accurate. The package insert or device user's manual will tell you when confirmatory testing is required (e.g., lead and rapid HIV testing). The provider will need the results of the confirmatory test to decide on treatment for the patient. NYS DOH requires the confirmation of Blood Lead concentrations of greater than or equal to 8 micrograms/dL. Limited Service Laboratories must refer a properly collected venous sample to a NYS DOH laboratory permitted for blood lead confirmation testing, or refer the patient to that laboratory's patient service center for collection of a venous blood sample.
What waived tests must be reported to state and local public health agencies?	Blood lead is the only screening test with required reporting. All blood lead results must be reported to the NYS DOH or if performed on a resident of New York City, NYC Department of Health and Mental Hygiene. See the Blood Lead Standards of Practice for additional information. **Additional tests may require reporting in the future.**