

Quality Control for Level One Laboratory Tests

Test	Quality Control Frequency	Notes and Good Laboratory Practice
Chemical examination of urine by dipstick or tablet method (urinalysis)	Positive control each week of patient testing and with each new lot number.	The control should be positive for each constituent reported on the dipstick.
Specific gravity by method other than dipstick	For urinometer or refractometer, two levels of control or standard each week of patient testing.	
Whole blood fingerstick method for glucose	Two levels of liquid control each day of patient testing.	The check strip or confidence strip is not equivalent to a control and cannot be used in place of one of the two controls.
Urine pregnancy tests	Follow manufacturer's instructions.	Positive and negative external controls should be run with each new kit.
Spun microhematocrit	One level of control <i>or</i> speed and timer checks quarterly.	The procedure should be verified with controls or proficiency testing.
Hemoglobin (Hemocue)	Control cuvette each day of patient testing and one abnormal liquid control each week of patient testing.	Other hemoglobin instruments require two levels of liquid control each day of patient testing.
Sedimentation rate	Timer checked quarterly.	The procedure should be verified with controls or proficiency testing.
Fecal or gastric occult blood, non-instrumented	Follow manufacturer's instructions.	Most kits have built in controls that are run with every test.
Sickle cell tests (screening)	Follow manufacturer's instructions.	A positive and a negative external control should be run with each new kit.
Dermatophyte screening (DTM, Tzanck,)	Perform quality control for each lot and or shipment of DTM Media.	Note that DTM and Tzanck tests require a Certificate of Compliance under the CLIA regulations.
Microscopic examinations (urine microscopics; KOH preps; wet mounts, including preparations of vaginal, cervical, or skin specimens; synovial fluid; semen analysis, presence or absence; pinworm exams; nasal smears for eosinophils)	None.	Verify the accuracy of microscopic procedures performed at least two times a year using proficiency testing or split samples. Note that microscopic procedures require a Certificate for Provider Performed Microscopic Procedures and that polarized light examinations of synovial fluid requires a Certificate of Compliance under the CLIA regulations.



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DEPARTMENT OF HEALTH

GOOD LABORATORY PRACTICES

1. Keep the manufacturer's package insert for the laboratory test in use and be sure it's available to the testing personnel. Use the manufacturer's package insert for the kit currently in use; do not use old package inserts.
2. Follow the manufacturer's instructions for specimen collection and handling. Store specimens and kits at the proper temperature. Use the appropriate specimen collection containers.
3. Be sure to properly identify the patient. The name on the test requisition must match the patient's name. The name on the patient's chart must match the name on the requisition. The patient must be positively identified. You must be able to distinguish patients who may have the same first and last names.
4. The patient's specimen must be labeled with the patient's name or a unique identifier.
5. The patient must be informed of any test preparation such as fasting, clean catch urine, etc.
6. Only personnel who have been properly trained shall perform the test procedure. Manufacturer's instructions must be followed when performing the test.
7. When a new kit or lot number of reagents is opened, perform and document external quality control to be sure that the kits will provide accurate and reliable results.
8. Do not mix components of different kits. Kits must not be used if they have exceeded their expiration date.
9. Record the patients' results in the proper place, such as the patient chart or a patient test log. Record the results according to the instructions in the package insert. Test records must include the patient's name, the name of the test performed, the date the test was performed, and the identity of the testing person. If the kit or procedure has built in procedural controls, they must be documented. If the patients' charts are used as the test record and the test report, they must also include the test result with units of measure and normal ranges for the patient population. If it is a qualitative test, you must spell out positive/negative or pos/neg because symbolic representations such as (-) can be altered to a (+).
10. Perform and document any instrument maintenance as directed by the manufacturer.