

Appendix B

List of waived tests performed at UCSF/Parnassus, UCSF/Mount Zion, and UCSF/China Basin

This appendix defines the testing methods that are classified as waived tests and the conditions under which they will be performed at the patient's bedside or in the Ambulatory practice setting in accordance with federal law and regulations. The following elements are defined:

1. The tests and the extent to which the test results are used in an individual's care (definitive or used only as a screen);
2. The individuals responsible for test performance;
3. The individuals responsible for direction/supervision of the testing activity;
4. Orientation and specific training, and competency testing of those individuals performing the tests;
5. Location of written policies and procedures regarding performance of the test. These policies and procedures describe specimen collection and preservation, instrument calibration, quality control and remedial action, equipment performance evaluation and test performance;
6. Quality control checks; and
7. Quality control and test record maintenance.

1. Waived Tests Performed at UCSF and UCSF/Mount Zion and Use of Results

Test	Use of result	Site
Blood glucose monitoring	Definitive	Hospital, Ambulatory practices
Urine dipstick	Screening	Hospital, Ambulatory practices
Fecal occult blood	Screening	Hospital, Ambulatory practices
Gastric occult blood	Screening	Hospital
Hemoglobin	Definitive	Hospital, Ambulatory practices
Hemoglobin A1c	Definitive	Ambulatory practices
Urine pregnancy	Definitive	Hospital, Ambulatory practices
pH determination by pH paper	Screening	Hospital, Ambulatory practices, Emergency Dept
RSV	Definitive	Hospital, Ambulatory practices
Strep A	Definitive	Ambulatory practices
Influenza	Definitive	Hospital, Ambulatory practices
Prothrombin time	Definitive	Ambulatory practices
Lipid analysis	Definitive	Ambulatory practices

2. Individuals Responsible for Test Performance

Within the hospital and the emergency room only licensed individuals (MD, CLT, RN, NP, PA, Nurse midwives, Respiratory Tech, and Perfusionists) may perform point of care testing.

Within the Ambulatory practices, Medical Assistants may perform waived point of care testing in addition to the above personnel categories.

3. Individuals Responsible for Direction/Supervision of Testing Activity:

Overall direction of waived testing activity is provided by the Clinical Laboratory QA & Regulatory Compliance Section. The QA & Regulatory Compliance Department and Laboratory Director appoints the Specialist of POC Testing. All POC testing is approved through the POCT Committee.

The Nurse Manager or Ambulatory practice Manager of each individual area is responsible for the supervision of waived testing on that unit. The actual orientation and competency monitoring may be delegated to a specially trained RN.

4. Orientation, Specific Training and Competency Testing:

- a. All appropriate staff are trained in waived test procedures at time of orientation.
- b. Staff is assessed for competency on an annual basis.
 - 1) Initial orientation and training consists of acquisition of theoretical knowledge concerning the test as demonstrated by a score of 80% or better on the post-test, and practical demonstration of technique to a authorized evaluator.
 - 2) Ongoing annual competency assessment will consist of at least two of the following: attaining a score of 80% or better on a written exam, practical demonstration of technique to a authorized evaluator, electronic documentation of successful quality control or test performance annually.
 - 3) Authorized evaluators are defined according to test complexity:
 - Waived tests: A licensed individual competent to perform the test
 - Moderate complexity: A person meeting or exceeding the CLIA '88 requirements for a Technical Supervisor (in general a licensed Clinical Laboratory Scientist)
 - 4) Physician competency:
 - Not required for: visual endpoint tests
 - Required for: device or instrument based tests
 - Required for: Physician performed microscopy (PPM)
- c. Documentation of training and competency validation is maintained in the employee's unit-based personnel file.

5. Location of Written Policies and Procedures Regarding Performance of the Test:

- a. **Procedures pertaining to waived testing are found in the following manual and on line at**

<http://manuals.ucsfmedicalcenter.org/>

1) **UCSF POCT – Waived Test Procedures manual:**

- Blood Glucose Determination Using the Accu-Check Inform Meter®
- Fecal Occult Blood (ColoScreen®)
- Gastric Occult Blood and pH (Gastrocult®)
- Urine Dipstick (Siemens Multistix & Uristix)
- Hemoglobin Determination Using the Hemocue Hemoglobin Photometer®
- Urine Pregnancy Using IM Confirm II ®
- Prothrombin time with CoaguCheck®

- Lipid analysis with Cholestech ®
- HgbA1c with DCA 2000®
- pH determination (pH paper)
- Strep A (Signify Strep®)
- Influenza (QuickVue Influenza®)
- RSV (Binax Now RSV Test®)

6. Quality Control:

Quality control requirements for each individual test are found in the individual test procedures.

7. Record Maintenance:

- a. Each unit maintains ongoing records to ensure that staff is trained and competent to do waived testing.
- b. Completed records are maintained for a minimum of 3 years.