

Appendix C

List of non-waived tests performed at UCSF/Parnassus, and UCSF/Mount Zion

This appendix defines the testing methods, which are classified as moderate complexity, and the conditions under which they will be performed at the patient's bedside in accordance with federal law and regulations. All testing sites must get the approval of the POC Advisory Committee prior to beginning testing. The following must be in place before testing begins.

- 1) Laboratory Director must be determined and a CLIA Certificate obtained (493.1403 Condition)
- 2) Personnel (493.1407 E 11 Standard)
 - a) Identified
 - b) Qualifications Documented
 - c) Training Documented
 - d) Ongoing Competency Assessment Plan
- 3) Instrumentation
 - a) Standard Instrumentation as approved by the POCT Committee
- 4) Reagents (493.1407 E 2 Standard)
 - a) Supply Log
 - b) Storage requirements must be determined, including adequately assuring proper environmental conditions for testing.
- 5) Policy and Procedure Manual (493.1202 C 1 Standard)
 - a) Must follow manufacturers instructions for operations, preventive maintenance calibration, etc.
 - b) Written in Standard CLSI format
 - c) Signed by director with documentation of review by each person performing testing.
- 6) Patient Record System
 - a) The record system must include the identity of the personnel who performed the test (493.1107D Standard)
 - b) A test report must indicate the name and address of the laboratory location where the test was performed, the test performed, the test result and, if applicable, the units of measurement. (493.1109B Standard)
- 7) Controls
 - a) The Laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of the patient test results and reports. (493.1201-493-1221 Standards)
 - i) For all non-manual coagulation testing systems such as ACT, the laboratory must include two levels of control every eight hours of patient testing. These can be electronic controls, since two levels of liquid controls are run each day of patient testing. Liquid controls must also be run each time a change in reagents occurs. Individuals performing patient testing must be involved in performance of quality control.

- 8) Maintenance (493.1407 E 2 Standard)
 - a) Temperature Verification, as required by regulations and manufacturers recommendations.
 - b) Daily and Weekly Maintenance is documented.
- 9) Proficiency Testing (493.1709 B Standard)
 - a) The Laboratory must have a system for verifying the accuracy of its test results at least twice a year. Individuals performing patient testing must be involved in performance of proficiency testing.
- 10) Verification procedures to determine accuracy, precision and other pertinent performance characteristics of the method. (493.1407 D Standard)
- 11) Ensure that the quality control program and quality assurance programs are established and maintained to assure the quality of laboratory services. (493.1407 D Standard)

All of the above must be documented and the documentation is maintained in the department and also in the Clinical Laboratory QA & Regulatory Compliance Section.

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

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

1) UCSF POCT – Non-Waived (Moderately Complex) Test Procedures manual:

- ACT testing with Medtronic ACT PLUS™, and HEMOCHRON® *Response*
- Blood Gas, Lactate and Glucose analysis with GEM® Premier 3000
- Electrolyte and Blood Gas analysis with i-STAT 1
- Hematocrit by Conductance
- Co-oximetry