

PROFICIENCY TESTING, FACILITY ADMINISTRATION, and QUALITY SYSTEMS REQUIREMENTS

Submit all applicable items to verify that your facility meets the requirements in accordance with Business and Professions Code (BPC) Section 1220.

1. **PROFICIENCY TESTING documents:** *Reference: [BPC 1220 \(a\)\(2\)\(A\)](#)*
 - Enrollment confirmation with an approved proficiency testing provider, or a policy/procedure to verify the accuracy of those tests not specified as regulated analytes;
 - Proficiency testing policy and procedure

2. **FACILITY ADMINISTRATION documents:** *Reference: [BPC 1220 \(d\)\(2\)\(A\)](#)*
 - Fire Manual and Plan;
 - Safety Manual and Plan;
 - Biohazard/waste management Manual and Plan;
 - Safety Data Sheets;
 - Transfusion services agreements and requirements, (if applicable);
 - Retention requirements policy and procedure.

3. **QUALITY SYSTEMS documents:** *Reference: [BPC 1220 \(d\)\(2\)\(B\)](#)*
 - a. **General Laboratory Systems policies, procedures, and documentation:**
 - Confidentiality of patient information policy;
 - Specimen identification and integrity policy and procedure;
 - Complaint investigation policy and procedure;
 - Communication policy;
 - Personnel competency assessment policy, procedure and employee competency documentation;
 - Proficiency testing performance evaluation policy, procedure and documentation;
 - General laboratory systems quality assessment policy and procedure.

 - b. **Pre-Analytic Systems policies, procedures, and documentation:**
 - Test request;
 - Specimen submission, handling, and referral policy and procedure;
 - CLIA certificate of outside laboratory (if applicable);
 - Pre-analytic systems quality assessment policy and procedure;

 - c. **Analytic Systems policies, procedures, and documentation:**
 - Procedure manual for all tests, assays and examinations performed;
 - Reagent package inserts showing lot number and expiration dates, (if applicable);
 - List of all equipment or analyzers being used, include manufacturer, model number, serial numbers and initial maintenance checks and certificates;
 - Verification of performance specifications, including raw data;
 - Calibration and calibration verification policy and procedure;
 - Control policy and procedure;
 - Individualized Quality Control Plan (IQCP) test list and summary, (if applicable);
 - Comparison of test results policy and procedure;
 - Corrective action policy and procedure;
 - Analytic systems quality assessment;
 - For a laboratory using an outside service for MOHS surgery, policy and procedure manual of that service along with personnel competency is required.

 - d. **Post Analytic Systems policies, procedures, and documentation:**
 - Test report;
 - Post analytic systems quality assessment policy and procedure.