State Surveyor Entry Form

Laboratory Demographics

CLIA Number:	
Laboratory Name:	
Demographic Change in:	☐ Address ☐ Telephone
Enter known changes:	
Estimated population base:	⊙ Urban (>=10,000) ⊙ Rural (<10,000)
Number of Different Tests:	

Initial Survey and Surveyor

Surveyor:	
Initial Survey Date:	

Regulations

1) Are all tests performed classified as waived? 493.15(c), and 493.1775(b)(3)	⊙ Yes ⊙ No	
2) Does the laboratory have the current manufacturer's instructions for the tests performed? 493.15(e)(1)	⊙ Yes ⊙ No	

3) Does the laboratory follow the current manufacturer's instructions for all tests performed by: 493.15(e)(1)

3a) Using the appropriate specimen as required by the manufacturer?	⊙ Yes ⊙ No	
3b) Adding the required reagents in the prescribed order as required by the manufacturer?	⊙ Yes ⊙ No ⊙ N/A	
3c) Adhering to the manufacturer's storage and handling instructions?	⊙ Yes ⊙ No	
3d) Using the proper expiration date for the storage method?	⊙ Yes ⊙ No	
3e) Performing the quality control if required by the manufacturer?	⊙ Yes ⊙ No ⊙ N/A	
3f) Performing function checks or calibration if required by the manufacturer?	⊙ Yes ⊙ No ⊙ N/A	
3g) Adhering to the manufacturer's instructions for confirmatory testing.	⊙ Yes ⊙ No ⊙ N/A	
3h) Reporting the patients' test results as required by the manufacturer?	⊙ Yes ⊙ No ⊙ N/A	
3i) Performing instrument maintenance if required by the manufacturer?	⊙ Yes ⊙ No ⊙ N/A	
3j) Adhering to timing requirements for test incubation, result interpretation, or other procedural steps?	⊙ Yes ⊙ No ⊙ N/A	
4) Does the laboratory operate or perform testing in a manner that constitutes an imminent and serious risk to public health? 493.1775(b)(1)	⊙ Yes ⊙ No	

Laboratory Best Practices

5) Do the testing personnel document the name of the test, lot number, and expiration date:

5a) In the patients' charts?	☐ Yes ☐ No	
5b) Elsewhere in the laboratory?	☐ Yes ☐ No	
5c) Are laboratory personnel given training when they are newly hired?	☐ Yes ☐ No ☐ N/A	
5d) Are laboratory personnel evaluated to ensure that they can perform each test correctly before they are allowed to report patients' test results?	☐ Yes ☐ No	
5e) Are the testing personnel given training when new test kits or systems are introduced?	☐ Yes ☐ No	
5f) Are testing personnel shown how to identify inaccurate results and/or test system or device problems?	☐ Yes ☐ No	
5g) Does the laboratory staff have Internet access on-site?	☐ Yes ☐ No	
5h) If web-based training courses were available at the laboratory, would the testing personnel participate?	☐ Yes ☐ No	
5i) If off-site training courses were developed for waived laboratories, would the testing personnel attend?	☐ Yes ☐ No	

6) Does the laboratory:

6a) Routinely review incoming package inserts for changes in the manufacturer's instructions?	☐ Yes ☐ No ☐ N/A	
6b) Provide information or training based on the change? (Answer this question ONLY if the answer to the previous question is YES).	☐ Yes ☐ No	
6c) Has there been a change in (new) testing personnel within the last 12 months?	☐ Yes ☐ No	

7) Does the laboratory have a written policy or procedure for:

7a) Checking patient identification?	☐ Yes ☐ No	
7b) Keeping the patient's test report in the patient's chart?	☐ Yes ☐ No	

8) Does the laboratory have a written policy or procedure to identify:

8a) Instrument or device error codes?	☐ Yes ☐ No ☐ N/A	
8b) Internal (procedural) quality control failure?	☐ Yes ☐ No ☐ N/A	
8c) External (liquid) quality control failure?	☐ Yes ☐ No ☐ N/A	
8d) Is the laboratory enrolled in voluntary proficiency testing?	☐ Yes ☐ No	

Laboratory Personnel

9) Testing Personnel
(Select all that apply)

- ☐ Dentist
- ☐ Physician (M.D., D.O.)
- ☐ Podiatrist (D.P.M.)
- ☐ Physician's Assistant
- ☐ Registered Nurse (R.N.)
- ☐ Nurse Practitioner
- ☐ Licensed Practical Nurse (LPN)
- ☐ Medical Technologist (B.S.)
- ☐ Pharmacist
- ☐ EMT
- ☐ Medical Laboratory Technician - MLT (A.A.)
- ☐ Medical Assistant
- ☐ Military Training
- ☐ High School Diploma
- ☐ Other (please specify) _____

Laboratory Personnel (cont'd)

10) Laboratory Director
(Select all that apply)

- ☐ Dentist
- ☐ Physician (M.D., D.O.)
- ☐ Podiatrist (D.P.M.)
- ☐ Physician's Assistant
- ☐ Registered Nurse (R.N.)
- ☐ Nurse Practitioner
- ☐ Licensed Practical Nurse (LPN)
- ☐ Medical Technologist (B.S.)
- ☐ Pharmacist
- ☐ EMT
- ☐ Medical Laboratory Technician - MLT (A.A.)
- ☐ Medical Assistant
- ☐ Military Training
- ☐ High School Diploma
- ☐ Other (please specify) [   ]

Comments

Survey Information

11) Survey Time in Hours:

11a) Pre-Survey	Hours:	Minutes:
11b) On-site / Telephone	Hours:	Minutes:
11c) Travel	Hours:	Minutes:
11d) Post-Survey	Hours:	Minutes:
11e) Supervisory Review (if applicable)	Hours:	Minutes:

Laboratory Feedback

12) Did you give the laboratory the 668B?	☐ Yes ☐ No
13) Describe any situations where waived testing caused a problem with a patient. (List the type of testing, inaccurate results, etc.)	