

State Surveyor Entry Form

Laboratory Demographics

CLIA Number:	<input type="text"/>	
Laboratory Name:	<input type="text"/>	
Demographic Change in:	<input type="checkbox"/> Address	<input type="checkbox"/> Telephone
Enter known changes:	<input type="text"/>	
Estimated population base:	<input type="checkbox"/> Urban (>=10,000)	<input type="checkbox"/> Rural (<10,000)
Number of Different Tests:	<input type="text"/>	

Initial Survey and Surveyor

Surveyor:	<input type="text"/>	
Initial Survey Date:	<input type="text"/>	

Regulations

1) Are all tests performed classified as waived? 493.15(c), and 493.1775(b)(3)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
2) Does the laboratory have the current manufacturer's instructions for the tests performed? 493.15(e)(1)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
3b) Adding the required reagents in the prescribed order as required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3c) Adhering to the manufacturer's storage and handling instructions?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3d) Using the proper expiration date for the storage method?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3e) Performing the quality control if required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3f) Performing function checks or calibration if required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3g) Adhering to the manufacturer's instructions for confirmatory testing.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3h) Reporting the patients' test results as required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3i) Performing instrument maintenance if required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3j) Adhering to timing requirements for test incubation, result interpretation, or other procedural steps?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Laboratory Best Practices

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

5a) In the patients' charts?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5b) Elsewhere in the laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5c) Are laboratory personnel given training when they are newly hired?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5e) Are the testing personnel given training when new test kits or systems are introduced?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5f) Are testing personnel shown how to identify inaccurate results and/or test system or device problems?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5g) Does the laboratory staff have Internet access on-site?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5h) If web-based training courses were available at the laboratory, would the testing personnel participate?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5i) If off-site training courses were developed for waived laboratories, would the testing personnel attend?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

6) Does the laboratory:

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

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

7a) Checking patient identification?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7b) Keeping the patient's test report in the patient's chart?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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

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

Laboratory Personnel

- 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)

9) Testing Personnel
(Select all that apply)

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)

Survey Information

11) Survey Time in Hours:

11a) Pre-Survey	Hours:	<input type="text"/>	Minutes:	<input type="text"/>
11b) On-site / Telephone	Hours:	<input type="text"/>	Minutes:	<input type="text"/>
11c) Travel	Hours:	<input type="text"/>	Minutes:	<input type="text"/>
11d) Post-Survey	Hours:	<input type="text"/>	Minutes:	<input type="text"/>
11e) Supervisory Review (if applicable)	Hours:	<input type="text"/>	Minutes:	<input type="text"/>

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.)