

State Surveyor Entry Form

Laboratory Demographics

CLIA Number:	<input style="width: 100%;" type="text"/>	
Laboratory Name:	<input style="width: 100%;" type="text"/>	
Demographic Change in:	<input type="checkbox"/> Address	<input type="checkbox"/> Telephone
Enter known changes:	<input style="width: 100%;" type="text"/>	
Estimated population base:	<input type="checkbox"/> Urban (>=10,000)	<input type="checkbox"/> Rural (<10,000)
Number of Different Tests:	<input style="width: 100%;" type="text"/>	

Initial Survey and Surveyor

Surveyor:	<input style="width: 100%;" type="text"/>	
Initial Survey Date:	<input style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" 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 style="width: 100%;" 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	<input style="width: 100%;" type="text"/>
3c) Adhering to the manufacturer's storage and handling instructions?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input style="width: 100%;" type="text"/>
3d) Using the proper expiration date for the storage method?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input style="width: 100%;" type="text"/>
3e) Performing the quality control if required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input style="width: 100%;" type="text"/>
3f) Performing function checks or calibration if required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input style="width: 100%;" type="text"/>
3g) Adhering to the manufacturer's instructions for confirmatory testing.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input style="width: 100%;" type="text"/>
3h) Reporting the patients' test results as required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input style="width: 100%;" type="text"/>
3i) Performing instrument maintenance if required by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input style="width: 100%;" type="text"/>
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	<input style="width: 100%;" type="text"/>
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 style="width: 100%;" 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?

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)

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.)

Government Performance and Results Act

Did the lab receive the "Ready, Set, Test booklet"? Yes No

Did the lab review the "Ready, Set, Test booklet"? Yes No

Did the lab find the "Ready, Set, Test" booklet helpful? Yes No

What section(s) of the booklet did they find helpful?

Select all that apply.

- Introduction - Background
- Introduction - Purpose
- READY? - Overview
- READY? - Prepare for Testing
- READY? - The Test Instructions
- READY? - Know How to Do the Test the Right Way
- READY? - Quality Control Testing
- SET? - Overview
- SET? - Test Ordering Patient Preparation
- SET? - Sample Collection
- SET? - Collection Devices
- SET? - Sample Labeling
- SET? - Safety Issues
- SET? - Biohazardous Waste
- SET? - Disinfecting Work Surfaces
- TEST! - Overview
- TEST! - Performing the Test
- TEST! - Reading the Results
- TEST! - Resolving Problems
- TEST! - Recording Results
- TEST! - Issuing Test Reports
- TEST! - Confirmatory or Supplemental Testing
- TEST! - Public Health Reporting
- TEST! - Record Keeping
- TEST! - Proficiency Testing
- Tips, Reminders, and Resources - Reminders
- Tips, Reminders, and Resources - Resources
- Tips, Reminders, and Resources - Safety Links
- Resources - Temperature Log Instruction
- Resources - Common Components of a Manufacturer's Instruction
- Resources - Quality Control Log Instructions
- Resources - Instructions for Logging or Recording Results
- Resources - Hand Hygiene Job Aid
- Resources - Blood/Body Fluid Exposure
- Resources - Glove Removal Job Aid
- Resources - Common Disinfectants and Antiseptics
- Terms and Abbreviations

Did the lab change any of their current practices based on their receipt of the "Ready, Set, Test" booklet? Yes No

Did the content and learning materials address a need or gap in knowledge or skills of the laboratory? Yes No

Does the laboratory have access to the Internet? Yes No

Overall comments on GPRA or RST booklet (optional)

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