SURVEYOR QUESTIONS
CERTIFICATE OF WAIVER LABORATORIES

Laboratory Name:		**Surveyor:**
CLIA#:	**State:**	**State Laboratory Licensure Program: YES ☐ NO ☐**
Type of Facility:		**Urban (= 10,000) ☐ or Rural (< 10,000) ☐**
Demographic Change in: Address ☐ Director ☐ Ownership ☐		**Survey Action: Congratulatory Letter ☐ Recommendation Letter ☐ 2567 ☐**
Estimated Annual Test Volume:		**Number of Different Tests:**
Initial Survey Date:		**Follow-up Survey Date:**

PLEASE ANSWER **EVERY** QUESTION.

	INITIAL SURVEY				FOLLOW-UP SURVEY		
	YES	**NO**	**N/A**	**COMMENTS**	**YES**	**NO**	**COMMENTS**
1. Are all tests performed classified as waived? **§§493.15(c), and 493.1775(b)(3)**				See the attached list.			
2. If the answer to #1 is NO, list the non-waived tests. **§493.1775(b)(3)**							
3. Does the laboratory operate in and perform testing in a manner that constitutes an imminent and serious risk to public health? If the answer is YES, contact the RO for further instructions (ASAP). **§493.1775(b)(1)**							

This checklist is a survey tool used to gather information on laboratories issued Certificates of Waiver (COW).

	INITIAL SURVEY				FOLLOW-UP SURVEY		
	YES	NO	N/A	COMMENTS	YES	NO	COMMENTS
4. Does the laboratory **have** the current manufacturer's instructions for all tests performed? If no, please detail in the comments section. (Please include the manufacturer's name, the package insert date, and the name of the test system in the comment section for all tests performed.) **§493.15(e)(1)**							
5. Does the laboratory **follow** the current manufacturer's instructions for all tests performed by: **§493.15(e)(1)** a) Using the appropriate specimen?							
b) Adding the required reagents in the prescribed order?							
c) Adhering to the manufacturer's storage and handling instructions?							
d) Using the proper expiration date for the storage method?							
e) Performing the quality control?							
f) Performing function checks or calibration?							
g) Performing confirmatory tests as required? If no, specify which test.							
h) Reporting the patients' test results with the terminology or in the units described in the package insert?							
i) Performing instrument maintenance?							

	INITIAL SURVEY				FOLLOW-UP SURVEY		
	YES	NO	N/A	COMMENTS	YES	NO	COMMENTS
6. Does the testing personnel understand the manufacturer's instructions for all tests performed? What part of the package insert gives the testing personnel the most difficulty? (Please answer in the comments section). If there are questions, does the testing personnel:							
a) Call the manufacturer?							
b) Ask the physician?							
c) Use the test anyway? (Send copies of problem package inserts to RO. RO will forward them to the CO.)							
7. Does the testing personnel: a) Document the name of the test, lot number, and expiration date for all tests performed?							
b) Understand what **''always"**, **"require", "shall",** and **"must"** mean?							
8. Is there training for the testing personnel? (Please note **who** provided the training.)							
a) Is the staff observed or evaluated to assure they can provide accurate and reliable testing?							
b) Are the testing personnel shown how to document the patient's test results?							
c) Are the testing personnel shown how to identify inaccurate results and/or test system or device problems?							

	INITIAL SURVEY				FOLLOW-UP SURVEY		
	YES	NO	N/A	COMMENTS	YES	NO	COMMENTS
d) Are the testing personnel shown how to handle inaccurate results or device problems?							
e) If training courses were developed for waived laboratories, would the testing personnel attend? If NO, why not?							
f) What type of training would the testing personnel find helpful? (Please describe.)							
9. Are the testing personnel informed when there's a change in the test procedure or if there's a new test kit? (If NO, note how the testing personnel learned about the new test).							
a) If YES, is training given? (Please note **who** provided the training).							
b) Has there been a change in (new) testing personnel within the last 12 months?							
c) Does the laboratory routinely check incoming package inserts to ensure there have been no changes in the product or procedure?							
d) Are all the products clearly labeled to advise of a revision?							
10. Have the testing personnel ever been asked to repeat a waived test?							
a) If YES, was the second result different than the original result?							
b) If the second result was different from the first result, what result did the physician use? (Please state in the comments section. Check N/A, if the response is NO to 10a.)							

	INITIAL SURVEY				FOLLOW-UP SURVEY		
	YES	NO	N/A	COMMENTS	YES	NO	COMMENTS
11. Does the laboratory have an understanding of good laboratory practices?							
12. Does the laboratory: a) Check patient identification?							
b) Collect the proper specimen for the test requested?							
c) Require a requisition (or patient's chart) before performing a test?							
d) Maintain a log or record of laboratory tests performed?							
e) Maintain a log or record of quality control results for each waived test instrument?							
f) Keep the patient's test report in the patient's chart?							
13. Does the laboratory use any waived test kits that require additional confirmatory procedures? (Some rapid strep kits may require a throat culture if the patient's test result is negative). List the manufacturer's name, the package insert date and the name of the test system in the comment section.							
a) If YES, does the laboratory send the specimen out to meet the additional requirement?							
b) If the specimen is sent out to meet the additional requirements, does the laboratory report results prior to receiving the confirmation report?							
c) Are the results of the confirmatory test documented in the patient's chart?							

	INITIAL SURVEY				FOLLOW-UP SURVEY		
	YES	NO	N/A	COMMENTS	YES	NO	COMMENTS
14. Is the laboratory performing diagnostic glucose testing? (e.g., GTT, 2 hour post-prandial, diagnosis of diabetes, diagnosis of gestational diabetes). If YES, please write the name of the instrument and send RO a copy of the package insert. RO will forward it to the CO.							
15. If the laboratory performs glucose, prothrombin, or any quantitative analyte waived testing when the results are outside the reportable range of the instrument, does the laboratory:							
a) Repeat the test?							
b) Notify the physician?							
c) Draws blood and send it to a reference laboratory?							
d) Send the patient to the hospital?							
16. Does the laboratory identify:							
a) Instrument or device error codes?							
b) Internal or electronic (procedural) quality control failure?							
c) External (liquid) quality control failure?							
d) Proficiency testing failure?							
e) Test results not correlating with patient's symptoms or history?							
17. Are the laboratory's results timely?							
18. Is the laboratory voluntarily enrolled in proficiency testing?							
19. Has the laboratory ever received a complaint that involved waived testing? If YES,							
a) Who submitted the complaint?							
b) Did the laboratory investigate the complaint?							

	INITIAL SURVEY				FOLLOW-UP SURVEY		
	YES	NO	N/A	COMMENTS	YES	NO	COMMENTS
c) Was the complaint resolved?							
20. Has the laboratory had another CLIA certificate prior to the current Certificate of Waiver? If YES:							
a) Indicate the certificate type in the comments section.							
b) Did the laboratory have condition level deficiencies on the inspection that caused them to change certificate types?							
21. Did you give the laboratory the 668B?							
a) Did the laboratory have any concerns about the survey? (Please state this information in the comments section.)							
b) Did the laboratory do anything to prepare for the survey? (Please state this information in the comments section.)							
22. Of the waived tests you are currently performing, would you continue using those tests if they were not waived? (If the laboratory is unsure, check N/A. If the laboratory responds YES, list the tests in the comment section.)							

	Please check all that apply.	COMMENTS	Please check all that apply.	COMMENTS
TEST PERFORMED: Cholesterol Fecal Occult Blood Glucose Hemoglobin Hemoglobin A1C Hematocrit Influenza Lyme Disease Ovulation Prothrombin Time Rapid Strep Sedimentation Rate Urinalysis Dipstick Urine Pregnancy (Please include additional tests in the comment section.)	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐		☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
TESTING 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.) Medical Laboratory Technician - MLT (A.A.) Medical Assistant Military Training High School Diploma Other (please specify)	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐		☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	

	Please check all that apply.	COMMENTS	Please check all that apply.	COMMENTS
LABORATORY DIRECTOR: 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.) Medical Laboratory Technician MLT (A.A.) Medical Assistant Military Training High School Diploma Other (please specify)	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐		☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
USE THIS SPACE TO DESCRIBE ANY SITUATIONS WHERE WAIVED TESTING CAUSED A PROBLEM WITH A PATIENT (LIST THE TYPE OF TESTING, INACCURATE RESULTS, ETC).				

INITIAL SURVEY TIME	**FOLLOW-UP SURVEY TIME**
Pre-survey: On-site: Travel: *Post-survey: Supervisory Review (if applicable): *The post survey time does not include the final report for RO and CO.	Pre-survey: On-site: Travel: *Post-survey: Supervisory Review (if applicable): *The post survey time does not include the final report for RO and CO.