The following self-assessment checklist emphasizes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. It can be used as a voluntary tool to help assure good testing practices and reliable, high quality test results.

Sites that perform testing under a CLIA Certificate of Waiver must meet the following requirements: enroll in the CLIA program; pay applicable certificate fees biennially; and follow the current manufacturer’s instructions provided with the test.

Resources that can be used to supplement this checklist include:

http://wwwn.cdc.gov/clia/Resources/WaivedTests/

DISCLAIMER
Although some of the recommendations in this self-assessment checklist exceed CLIA requirements for waived testing, following these good testing practices will likely lead to reliable, high quality test results and will enhance patient safety.
### REGULATORY REQUIREMENTS

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Do you have a current CLIA Certificate of Waiver (CW)?</td>
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<tr>
<td>Do you renew the Certificate of Waiver every 2 years?</td>
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<tr>
<td>Do you perform only CLIA waived tests?</td>
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<tr>
<td>Do you follow any additional testing requirements for your state?</td>
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<tr>
<td>Do you follow Occupational Safety and Health Administration (OSHA) safety regulations for occupational exposure to bloodborne pathogens?</td>
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</tbody>
</table>

### SELF-ASSESSMENT

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Do you clean work surfaces before and after testing?</td>
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<tr>
<td>Do you perform testing in a well-lighted area?</td>
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<tr>
<td>Do you check and record temperatures of the testing and reagent storage areas daily?</td>
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<tr>
<td>Do you check inventory regularly to ensure you will have enough reagents and supplies on hand for testing?</td>
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<tr>
<td>Do you store all reagents and media as recommended by the manufacturer?</td>
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<tr>
<td>Do you document expiration dates of reagents/kits, and discard any reagents or tests that have expired?</td>
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<tr>
<td>Do you ensure that reagents from different lot numbers are not mixed together?</td>
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<tr>
<td>Do you inspect reagents for damage, discoloration, or contamination and discard if found?</td>
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<tr>
<td>Do you prepare reagents according to manufacturer’s instructions?</td>
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<tr>
<td>Do you allow time for refrigerated reagents/samples to come to room temperature prior to testing if required by the manufacturer’s instructions?</td>
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<tr>
<td>Do you inspect equipment and electrical connections to be sure they are safe and working properly?</td>
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<tr>
<td>Do you perform equipment calibration checks, as needed, following the manufacturer’s instructions?</td>
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<tr>
<td>Do you check the manufacturer’s instructions with each new lot and shipment of test kits to make sure there are no changes from the test kits being used?</td>
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<tr>
<td>Do you file the old manufacturer’s instructions and replace with the new copy if there are changes?</td>
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<tr>
<td>Do you communicate all changes in the manufacturer’s instructions to other testing personnel and to the person who directs or supervises testing?</td>
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<tr>
<td>Do you treat and test quality control (QC) samples the same as patient samples?</td>
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<tr>
<td>Do you perform QC as recommended in the manufacturer’s instructions?</td>
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<tr>
<td>Do you make sure your QC results are as expected before performing patient testing?</td>
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<tr>
<td>Do you identify and correct problems if QC results are not as expected?</td>
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</tbody>
</table>
### Do you follow the manufacturer’s instructions for use of the appropriate collection device and sample volume needed for testing?

- **SET**
- **YES**
- **NO**
- **N/A**

### Do you follow instructions for samples that need special timing for collection?

- **YES**
- **NO**
- **N/A**

### Do you only use unprocessed samples for performing waived test?

- **YES**
- **NO**
- **N/A**

### Do you check patient identification with test orders?

- **YES**
- **NO**
- **N/A**

### Do you positively identify the patient before collecting a sample?

- **YES**
- **NO**
- **N/A**

### Do you discuss any preparation, pretest instructions, and counseling needs with the patient before collecting the sample?

- **YES**
- **NO**
- **N/A**

### Do you wear appropriate personal protective equipment (PPE) such as gloves when collecting the sample and testing?

- **YES**
- **NO**
- **N/A**

### Do you properly label the sample collection device?

- **YES**
- **NO**
- **N/A**

### Do you follow all test requisition, sample collection and handling specifications of the referral laboratory if applicable?

- **YES**
- **NO**
- **N/A**

### Do you clean your hands and change gloves between patients?

- **YES**
- **NO**
- **N/A**

### Do you keep disinfectants nearby for sanitizing bench tops and treating spills?

- **YES**
- **NO**
- **N/A**

### Does your testing site have established criteria for sample rejection?

- **YES**
- **NO**
- **N/A**

### Do you use the proper biohazard containers to dispose of waste and sharps?

- **YES**
- **NO**
- **N/A**

### Do you document that all staff have satisfactorily completed initial training before performing temperature checks, blood collection, sample testing, and reporting patient results?

- **YES**
- **NO**
- **N/A**

### Do you test samples that are properly collected or handled?

- **YES**
- **NO**
- **N/A**

### Do you have the current manufacturer’s instructions or a quick reference guide at the work station?

- **YES**
- **NO**
- **N/A**

### Do you follow the manufacturer’s instructions in the exact order?

- **YES**
- **NO**
- **N/A**

### Do you use timers and follow the required timing intervals before reading test results?

- **YES**
- **NO**
- **N/A**

### Do you detect, identify, and correct laboratory errors before reporting test results?

- **YES**
- **NO**
- **N/A**

### Do you identify and document critical results?

- **YES**
- **NO**
- **N/A**

### Do you know who to contact if you need to report a critical test result?

- **YES**
- **NO**
- **N/A**

### Do you make sure patient reports are legible and reported in a timely manner?

- **YES**
- **NO**
- **N/A**

### Do you report patient test results only to authorized persons?

- **YES**
- **NO**
- **N/A**

### Do you document verbal reports followed by a written test report?

- **YES**
- **NO**
- **N/A**

### Do you make sure reports are standardized and easily distinguishable from referral laboratory test reports?

- **YES**
- **NO**
- **N/A**

### Do you have written site specific policies and procedures to ensure confirmatory or additional testing is performed or referred, when needed?

- **YES**
- **NO**
- **N/A**

### Do you have a procedure to detect test result errors, so that you promptly notify the responsible clinical personnel or reference laboratory and issue a corrected report?

- **YES**
- **NO**
- **N/A**

### Do you keep records of testing, including equipment logs, maintenance records, QC documents, and test results?

- **YES**
- **NO**
- **N/A**
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<thead>
<tr>
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<tr>
<td>Do you have a regular schedule for maintaining testing equipment?</td>
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<td>Do you have instructions for troubleshooting testing problems?</td>
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<tr>
<td>Do you dispose of biohazardous waste and sharps containers safely?</td>
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<td>Do you report confirmed positive infectious disease test results to public health agencies?</td>
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<td>Do you voluntarily participate in proficiency testing?</td>
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<tr>
<td>Do you monitor and evaluate your testing process to identify areas for improvement?</td>
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