i-STAT® Waived Testing Regulatory Guide

This guide is intended to provide supplemental regulatory information for facilities that will be performing waived testing with the i-STAT® 1 System. For sample types and cartridge types approved as waived when used with the i-STAT 1 System, please see the i-STAT 1 System Manual for Waived Tests or the Technical Bulletin: "The i-STAT System and Waived Status" found in the i-STAT 1 System Manual. Facilities should review the regulations in CLIA or from their accrediting organization to gain full understanding of the requirements for Waived Testing. *(See "References" for a listing of resources for the regulations.)*

Introduction

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988. CLIA was written to provide standards to ensure that laboratory test results are accurate, reliable and timely. These standards apply no matter where the tests are performed.

CLIA recognizes two types of laboratory tests: ***waived*** and ***non-waived***.

Waived testing includes those examinations and procedures which:

1. Have been approved by the FDA for home use;
2. Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
3. Pose no reasonable risk of harm to the patient if performed incorrectly.

Non-waived tests are less simple to perform and have additional skill, knowledge and responsibility requirements. Different CLIA standards apply to waived tests and non-waived tests.

It is the responsibility of the facility performing the laboratory tests to meet the CLIA requirements. The Centers for Medicare & Medicaid Services (CMS) brochure, "How to Obtain a CLIA Certificate of Waiver," contains information on the requirements and responsibilities of a site performing waived tests. This brochure can be obtained from an Abbott Point of Care representative or on the CMS web site: https://www.cms.gov/regulations-and-guidance/legislation/clia/clia_brochures.html

Before a facility may perform laboratory tests, they must obtain a CLIA certificate from the CMS. A CLIA certificate is required whether or not patients are charged for the testing.

If a facility will perform only waived tests, they must have a CLIA Certificate of Waiver. Waived tests may also be performed under a CLIA Certificate of Provider-Performed Microscopy Procedures, a CLIA Certificate of Compliance or a CLIA Certificate of Accreditation. One of the latter two certificates is required to perform non-waived tests. See https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CLIABrochure.pdf

Obtaining a CLIA Certificate

To obtain a CLIA certificate, a facility must first enroll in the CLIA program by completing an application (Form CMS-116) available online at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf or from the local State Agency. To complete this form, laboratories must include specific information, including the laboratory director's name, the type of testing site (laboratory type), hours of operation, estimated total annual volume of waived testing, and the total number of persons involved in performing waived testing. The form must be signed by the facility owner or the facility director.

The completed application should be forwarded to the address of the local State Agency for the state in which the laboratory is located. A list of state agencies is available online at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html.

The address and phone number for a state agency can also be acquired by calling the CLIA program at 1-410-786-3531. For additional assistance, laboratories can contact the appropriate CMS regional office at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA /State_Agency_and_Regional_Office_CLIA_Contacts.html.

Individual states may have additional laws, codes, statutes or regulations for waived testing which are not addressed in this guide. Washington State is exempt from CLIA regulations. New York is also exempt from CLIA, except for physicians' office laboratories, which are required to have a CLIA certificate. Both of these states have their own requirements that meet or exceed CLIA requirements. Laboratories should refer to their local state agency for clarification on state regulations for waived testing.

Regulatory Information Contained in this Guide

i-STAT Manufacturer's Quality System Instructions (MQSI) for Waived Testing

The MQSI represent what are necessary and sufficient to ensure quality results (accurate, precise and reliable) based upon the specific characteristics of the i-STAT System.

Three key technological characteristics of the i-STAT System underlie the MQSI:

1. The unit-use cartridges are stable when stored properly.
2. The system has been designed so that any user influence on the analytical process is detected and flagged.
3. The performance of the i-STAT handheld and i-STAT cartridges are verified by a combination of monitoring of critical functions and procedural controls during each test event, supplemented by electronic quality control.

To ensure that the i-STAT System performs with expected accuracy, precision and reliability the MQSI should be followed:

1. Perform Daily Quality Control with Electronic Simulator
2. Check New or Replacement Handhelds with Electronic Simulator
3. Check Temperature Strip for a New Shipment of Cartridges
4. Ensure Proper Cartridge Storage
5. Ensure Thermal Probe Check is Performed
6. Train Staff on Avoidance of Pre- and Post-analytical Errors
7. Update Software, then Check with External Simulator
8. Test Liquid Control for a New Shipment of Cartridges
9. Ensure Proper Cartridge Storage (including Monthly Check)

Quality System Instructions for Waived Testing

1. Perform Daily Quality Control with Electronic Simulator – Check each Handheld reader with the Electronic Simulator, using either the internal or external simulator, once on each day of use.

2. Check New or Replacement Handhelds with Electronic Simulator – Use the Electronic Simulator, internal or external, to verify operation of a new or replacement Handheld reader before use.

   The internal Electronic Simulator will automatically activate the first time a new or replacement Handheld is used and after every 24 hours of use thereafter. The i-STAT 1 Handheld can be customized to remind the operator to perform the simulator test or automatically run the simulator more frequently as required or desired.

3. Check Temperature Strip for a New Shipment of Cartridges – Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container. Read the strip immediately since it will change once exposed to room temperature. Follow the instructions on the card that accompanies the temperature strip. Fill out information in "Received" section at bottom of card. Mark an "x" in each of the spaces corresponding to a red window. If the windows "3" or "4" are red, do not use the cartridges or controls. Contact Technical Support.

   Record the information on the temperature strip card on the "Receipt of New Cartridges" log. Retain logs for two years in a file for quality control records.

4. Ensure Proper Cartridge Storage – See the "Quick Reference Guide" of the "i-STAT 1 System Manual for Waived Tests" and "The i-STAT System and Waived Status" Technical Bulletin contained in the "i-STAT 1 System Manual".

   a. Ensure that refrigerator storage conditions for stored cartridges are between 2˚–8˚C (35˚–46˚F).

   b. Ensure that cartridges are not exposed to temperatures exceeding 30˚C (86˚F).

   c. Ensure that cartridges are not used after the expiration date printed on the individual package and box.

   d. Ensure that cartridges are not outside the refrigerator for longer than the time frame indicated on the cartridge box.

   e. Ensure that a cartridge is used immediately after it is removed from its package.

   f. Ensure that a cartridge taken from refrigerated storage is allowed to stand in its package at room temperature for 5 minutes before use, or that a box of cartridges stands at room temperature for one hour before use.

5. Ensure Thermal Probe Check is Performed – Ensure the thermal probe check is performed every 6 months on each Handheld reader.

   This check can be performed in conjunction with the software updates

6. Train Staff on Avoidance of Pre- and Post-analytical Errors – Ensure that users are trained to avoid pre-analytical errors such as those associated with sample collection, delays in testing, inadequate sample mixing, and post-analytical errors (results reporting and communication).

7. Update Software, then Check with External Simulator – Update the i-STAT Handheld software as provided by Abbott Point of Care (APOC). Check the handheld with the external Electronic Simulator after software updates. The thermal probe reading can also be taken from this check.

8. Test Liquid Control for a New Shipment of Cartridges – Check one cartridge from each newly received lot with liquid control as described in the "Quick Reference Guide" of the "i-STAT 1 System Manual for Waived Tests" and "The i-STAT System and Waived Status" Technical Bulletin contained in the "i-STAT 1 System Manual".

   Comment:

   The i-STAT System monitors the entire test cycle; quality checks detect operator, cartridge and analyzer error conditions as well as adverse environmental conditions. These quality checks are supplemented by the internal Electronic Simulator test, which automatically runs every 24 hours. The Electronic Simulator checks the ability of the Handheld reader to take accurate and sensitive signal readings from the cartridge. The PASS/FAIL limits for the simulator are very tight.

   We have added the liquid quality control requirement in our waived status MQSI (liquid quality control is not part of our MQSI for moderately complex users) to address the FDA's concern that management of refrigeration in a waived environment may not be as reliable as in a laboratory performing moderate complexity testing.

9. Ensure Proper Cartridge Storage (Including Monthly Check) – Verify that cartridges stored at room temperature are within expiration date and that cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which cartridges are stored is in doubt, use a liquid control to verify that the cartridges are performing properly.

   Check storage conditions monthly by testing one cartridge from refrigerated storage with the appropriate i-STAT level control as outlined in the "Quick Reference Guide" of the "i-STAT 1 System Manual for Waived Tests" and "The i-STAT System and Waived Status" Technical Bulletin contained in the "i-STAT 1 System Manual".

Comments:

While the following are not manufacturer's quality system instructions and are not FDA required activities, they are laboratory practices centered on quality and are suggested (not required) for all i-STAT tests whether they are categorized as moderate complexity or waived.

Review Interferences with Staff – Review "Factors that Affect Results" listed in the Cartridge and Test Information sheets with clinical staff. Cartridge and Test Information sheets are located in the i-STAT 1 System Manual and on the i-STAT website https://www.pointofcare.abbott/us/en/offerings/support/technical-documentation/cartridge-test-information-sheets.

Train Staff on Backup System Measures – Ensure that users are trained on the backup provisions for testing should they be unable to utilize the i-STAT 1 System in their area. (Backup provisions in many facilities include the use of a spare Handheld reader, backup lot of cartridges, sharing of the Handheld reader, or use of a laboratory system.)

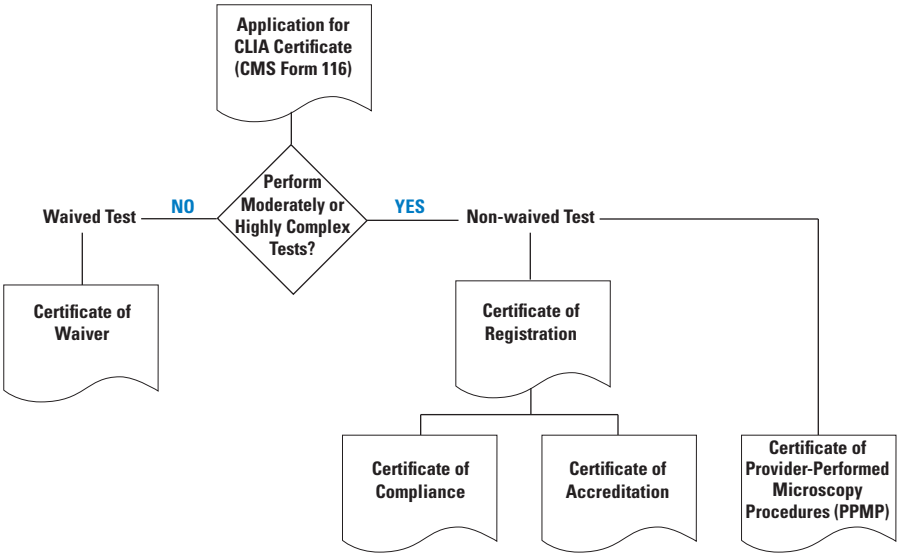
CLIA Certificates

CLIA Certificates Allowing Waived Testing

The schematic below highlights the types of certificates required for laboratory testing. Waived testing may be performed under any of the following:

1. CLIA Certificate of Waiver
2. CLIA Certificate of Provider-Performed Microscopy Procedures
3. CLIA Certificate of Compliance
4. CLIA Certificate of Accreditation

Waived testing performed under a CLIA Certificate of Waiver, a CLIA Certificate of Provider-Performed Microscopy Procedures or a CLIA Certificate of Compliance requires compliance with the same regulation (following the manufacturer's instructions). Waived testing performed under a CLIA Certificate of Accreditation may require additional testing requirements depending on the accrediting organization.



Regulations for Waived Testing Performed Under a CLIA Certificate of Waiver

Laboratories performing waived testing that is not included under any other type of CLIA certificate must obtain a CLIA Certificate of Waiver before testing patient specimens. Certain public health testing sites offering only waived testing can be included under a limited public health or mobile testing exception. A valid CLIA certificate is required for Medicare reimbursement.

Other than obtaining a Certificate of Waiver, the only other requirement for waived testing per CLIA is to:

- Follow the manufacturer's instructions for performing the test.

  It is critical that laboratories follow the manufacturer's instructions exactly as they are written. Failing to follow the instructions can potentially cause errors in testing and could cause the test to be reclassified per CLIA as high complexity, thus subjecting it to more stringent regulatory requirements.

  In order to make certain that manufacturer's instructions are followed, it is good laboratory practice to ensure that staff performing the waived testing are trained to perform the testing. APOC offers materials to assist with training staff to perform the waived cartridge testing on the i-STAT System. Additional information on Good Laboratory Practice can be found at: https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/wgoodlab.pdf.

Laboratories performing waived testing under a Certificate of Waiver must also pay required fees, make its records available to CMS, and permit announced or unannounced inspections by the CMS. Routine inspections are not performed for these laboratories. CLIA does not require Proficiency Testing (PT) for waived tests; however, laboratories performing only waived testing may voluntarily elect to participate in PT.

Individual states may have additional laws, codes, statutes, or regulations for waived testing. Laboratories should refer to their local state agency for clarification on these regulations.

Regulations for Waived Testing Performed Under a CLIA Certificate of Provider-Performed Microscopy Procedures

In performing waived testing under a Certificate of Provider-Performed Microscopy Procedures, laboratories must follow the regulations for waived testing in CLIA. These regulations include the following:

- Follow manufacturer's instructions for performing the tests.

  It is critical that laboratories follow the manufacturer's instructions implicitly as they are written. Failing to follow the instructions can potentially cause errors in testing and could cause the test to be reclassified per CLIA as high complexity, thus subjecting it to more stringent regulatory requirements.

  In order to make certain that manufacturer's instructions are followed, it is good laboratory practice to ensure that staff performing the waived testing are trained to perform the testing. APOC offers materials to assist with training staff to perform the waived cartridge testing on the i-STAT System. Additional information on Good Laboratory Practice can be found at: https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/wgoodlab.pdf.

Laboratories performing waived testing under a Certificate of Provider-Performed Microscopy Procedures must also pay required fees, make its records available to CMS, and permit announced or unannounced inspections by the CMS. Routine inspections are not performed for these laboratories. CLIA does not require Proficiency Testing (PT) for waived tests; however, laboratories performing only waived testing may voluntarily elect to participate in PT.

If the laboratory performing the testing is located in a facility accredited by The Joint Commission, they must also follow the Joint Commission Waived Testing requirements.

Individual states may have additional laws, codes, statutes, or regulations for waived testing. Laboratories should refer to their local state agency for clarification on these regulations.

Regulations for Waived Testing Performed under a CLIA Certificate of Compliance

A Certificate of Compliance also allows laboratories to perform both waived and non-waived testing. (These laboratories must first acquire a Certificate of Registration before they can acquire a Certificate of Compliance.)

In performing waived testing under a Certificate of Compliance, laboratories must follow the regulations for waived testing in CLIA. These regulations include the following:

- Follow manufacturer's instructions for performing the tests.

  It is critical that laboratories follow the manufacturer's instructions implicitly as they are written. Failing to follow the instructions can potentially cause errors in testing and could cause the test to be reclassified per CLIA as high complexity, thus subjecting it to more stringent regulatory requirements.

  In order to make certain that manufacturer's instructions are followed, it is good laboratory practice to ensure that staff performing the waived testing are trained to perform the testing. APOC offers materials to assist with training staff to perform the waived cartridge testing on the i-STAT System. Additional information on Good Laboratory Practice can be found at: https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/wgoodlab.pdf.

Laboratories performing waived testing under a Certificate of Compliance must also pay required fees, make its records available to CMS, and permit announced or unannounced inspections by the CMS. Routine inspections are performed for these laboratories as they perform non-waived testing. CLIA does not require Proficiency Testing (PT) for waived tests; however, laboratories performing only waived testing may voluntarily elect to participate in PT.

If the laboratory performing the testing is located in a healthcare facility accredited by The Joint Commission, they must **also** follow The Joint Commission Waived Testing requirements.

Individual states may have additional laws, codes, statutes, or regulations for waived testing. Laboratories should refer to their local state agency for clarification on these regulations.

Regulations for Waived Testing Performed under a CLIA Certificate of Accreditation

College of American Pathologists (CAP)

A Certificate of Accreditation allows laboratories to perform both waived and non-waived testing. (Laboratories must first acquire a Certificate of Registration before they can acquire a Certificate of Accreditation.)

In performing waived testing under a Certificate of Accreditation, laboratories must follow the regulations for waived testing. These regulations include the following:

- Follow manufacturer's instructions for performing the tests.

It is critical that laboratories follow the manufacturer's instructions implicitly as they are written. Failing to follow the instructions can potentially cause errors in testing and could cause the test to be reclassified per CLIA as high complexity, thus subjecting it to more stringent regulatory requirements.

In addition to following the manufacturer's instructions, the CAP also requires compliance with the following:

1. Competency – The competency assessment must be performed at least annually (semi-annual assessment not required). The laboratory may select which elements of competency to assess for each test system.

2. Quality Control – The laboratory follows manufacturer instructions for quality control and documents and reviews results for acceptability prior to reporting patient results.

   Quality control must be performed according to manufacturer's instructions. If control results exceed tolerance limits, corrective action must be documented. To detect problems and evaluate trends, testing personnel or supervisory staff must review quality control data on days when controls are run prior to reporting patient results. The laboratory director or designee must review QC data at least monthly or more frequently if specified in the laboratory QC policy. With respect to internal controls, acceptable control results must be documented, at a minimum once per day of patient testing for each device.*

   *Acceptable internal control results need not be documented, if (and only if) an unacceptable instrument control automatically locks the instrument and prevents release of patient results. There is evidence of corrective action when control results exceed defined acceptability limits.

3. Performance Verification – Verify the reference range.

4. Proficiency Testing – Participate in the appropriate proficiency testing (PT) program; Integrate PT samples into routine workload by personnel who routinely test patient samples using the same primary method as for patient samples; Evaluate PT results and take corrective action if results unacceptable; Laboratory director or designee must have ongoing evaluation of PT results and document it; Maintain policy that prohibits communication of PT results with other laboratories after data submitted to provider and prohibits referral of PT samples to other laboratories.

5. Maintenance and Functional Checks – For waived tests, the laboratory follows manufacturer instructions for instrument and equipment maintenance and function checks. Evidence of compliance is found in written procedures consistent with manufacturer's instructions for each waived test AND the associated instrument and equipment maintenance and function check records.

6. Personnel – The director of the POCT program is a physician or a doctoral scientist; Testing personnel have adequate, specific training to ensure competence; There is a current list of POCT personnel that delineates the specific tests that each individual is authorized to perform; There is a documented program to ensure that each person performing POCT maintains satisfactory levels of competence; POCT personnel are tested for difficulty with visual color discrimination.

7. Specimen Handling – Have documented procedure for patient identification, patient preparation, specimen collection and labeling, specimen accessioning, and specimen preservation (if applicable) before testing.

8. Results Reporting – Test results legible and retained in the permanent medical record; When applicable, all patient results reported with accompanying reference (normal) intervals or interpretive ranges; Reference intervals (normal ranges) established or verified for the population tested; Critical limits established for the results of certain tests important for prompt patient management decisions; Documentation of notification of the physician or other clinical personnel responsible for patient care of results for all critical results: Records indicate (by initials, signature, etc.) who performed each test.

9. Safety – The POCT program has a program to assure the safety of patients and health care personnel commensurate with the scope of its activities.

10. Calibration Verification – The POCT program follows manufacturer instructions for calibration, calibration verification and related functions.

11. Reagent Handling / Storage – The laboratory follows manufacturer instructions for handling and storing reagents, cartridges, test cards, etc… There is no requirement to routinely label individual containers with "date opened". A new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc… If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored and recorded daily. The identity of the individual recording the temperature(s) must be documented (recording the initials of the individual is adequate). The use of automated (including remote) temperature monitoring systems is acceptable, as long as lab personnel have ongoing, immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. Functionality of the system must first be documented daily.

12. Manufacturer's Instructions – The lab must follow manufacturer instructions or provide documentation of validation if the test has been modified – including performing quality control, calibration, calibration verification, and related functions as applicable to the scope of testing. Reagents, fluids, and disposable materials supplied by the laboratory must meet the specifications in the instructions.

If the laboratory modifies the manufacturer's instructions, the test is no longer an FDA cleared / approved test, and the modification(s) must be validated by the laboratory. **The test is no longer considered waived, and the requirements for high complexity testing apply.** Changes in the specimen type or collection device are examples of common modifications.

Laboratories performing waived testing under a Certificate of Accreditation must also pay required fees, make its records available to CMS, and permit announced or unannounced inspections by the CMS. Routine inspections are performed for these laboratories as they perform non-waived testing.

There are significant additional details for waived testing in CAP checklists. The checklist should be reviewed to endure safe practice and regulatory compliance.

The CAP requirements for waived testing are in the Point of Care checklist for testing performed with waived cartridges. The Laboratory General and Team Leader checklists should also be referenced for additional details of the regulations.

If the laboratory performing the testing is located in a facility accredited by The Joint Commission, they must **also** follow The Joint Commission Waived Testing requirements.

Information on Good Laboratory Practice can be found at:
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/wgoodlab.pdf.

Individual states may have additional laws, codes, statutes, or regulations for waived testing. Laboratories should refer to their local state agency for clarification on these regulations.

Regulations for Waived Testing Performed under a CLIA Certificate of Accreditation

COLA

A Certificate of Accreditation allows laboratories to perform non-waived testing. (Laboratories must first acquire a Certificate of Registration before they can acquire a Certificate of Accreditation.)

It is critical that laboratories follow the manufacturer's instructions implicitly as they are written. Failing to follow the instructions can potentially cause errors in testing and could cause the test to be reclassified per CLIA as high complexity, thus subjecting it to more stringent regulatory requirements.

In order to make certain that manufacturer's instructions are followed, it is good laboratory practice to ensure that staff performing the waived testing are trained to perform the testing. APOC offers materials to assist with training staff to perform the waived cartridge testing on the i-STAT System. Additional information on Good Laboratory Practice can be found at: https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/wgoodlab.pdf.

COLA requires laboratories performing waived testing to comply with requirements that are addressed in the following questions:

WAV 1 R: Are manufacturer's instructions followed in the performance of each waived testing procedure and are all kits, reagents, and controls stored according to manufacturer's recommendations?

WAV 2 R: Is all Quality Control performed per manufacturer's instructions, and are the results of QC recorded, reviewed, and found to be acceptable prior to patient result reporting?

WAV 3 R: Do the Quality Control records indicate evidence of corrective action when controls do not give the expected results?

WAV 4 R: Are the Quality Control results reviewed monthly by the Laboratory Director or designee?

WAV 5 R: Are all Quality Control results retained for two years from the date of performance?

WAV 6 R: Is employee competency assessed and documented prior to initiating testing, at six months during the first year of employment, and annually thereafter?

WAV 7 R: Is a complete, up to date and approved procedure manual readily available to all employees performing waived testing?

WAV 8 R: Are there written procedures for pre-analytic activities, such as patient identification, patient preparation, specimen collection and labeling, and accessioning?

WAV 9 R: Are all results appropriately entered into the medical record in a timely manner, and are the results retained for at least two years?

The following criterion, WAV 10, is for education purposes only. If cited during a survey, it will not count against your laboratory.

WAV 10: Is proficiency testing performed for all waived analytes, when available?

Laboratories performing waived testing under a Certificate of Accreditation must also pay required fees, make its records available to the Centers for Medicare and Medicaid Services, and permit announced or unannounced inspections by the CMS. Routine inspections are performed for these laboratories as they perform non-waived testing.

If the laboratory performing the testing is located in a healthcare facility accredited by The Joint Commission, they must **also** follow The Joint Commission Waived Testing requirements.

Individual states may have additional laws, codes, statutes, or regulations for waived testing. Please refer to your local state agency for clarification on these regulations.

Regulations for Waived Testing Performed under a CLIA Certificate of Accreditation

The Joint Commission

In addition to following the manufacturer's instructions, The Joint Commission has standards for waived testing with which laboratories and healthcare organizations accredited by The Joint Commission must comply. In summary, these are:

1. Policies and procedures for waived tests are established, current, approved and readily available.
2. The person from the organization whose name appears on the CLIA certificate identifies the staff responsible for performing and supervising waived testing.
3. Staff and licensed independent practitioners performing waived tests are competent.
4. The organization performs quality control checks for waived testing on each procedure. Note: Internal quality controls may include electronic, liquid or control zone. External quality controls may include electronic or liquid.
5. The organization maintains records for waived testing.

There are significant additional details in The Joint Commission waived testing standards that should be reviewed to ensure safe practice and regulatory compliance.

Laboratories performing waived testing under a CLIA Certificate of Accreditation must also pay required fees, make its records available to CMS, and permit announced or unannounced inspections by the CMS. Routine inspections are performed for these laboratories as they perform non-waived testing. Additional information on Good Laboratory Practice can be found at: https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/wgoodlab.pdf.

Individual states may have additional laws, codes, statutes, or regulations for waived testing. Laboratories should refer to their local state agency for clarification on these regulations.

Frequently Asked Questions for Waived Testing

What is "CLIA"?

"CLIA" is an acronym for the Clinical Laboratory Improvement Amendments of 1988. These are amendments to the federal Clinical Laboratory Improvement Act.

What is a Laboratory?

Per CLIA, a laboratory is defined as a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.

Why is CLIA important?

CLIA is intended to ensure quality laboratory testing no matter where the testing is performed and no matter how complex or simple the testing is. Patients and their providers trust and rely on the accuracy and precision of laboratory tests for screening, diagnosis and treatment of illness. Incorrectly performed tests can lead to inaccurate results which in some cases are a life or death matter for patients.

What is waived testing?

Per CLIA, waived tests are those tests that are determined by the FDA to be so simple that there is little risk of error.

Is a CLIA Certificate required to perform waived testing?

Waived testing must be performed under a CLIA certificate.

- If only waived testing is performed, it is performed under a CLIA Certificate of Waiver.
- If non-waived testing and waived testing are performed, the tests can be performed under a CLIA Certificate of Compliance or a CLIA Certificate of Accreditation.
- If Provider-Performed Microscopy Procedures and waived testing are performed, they can be performed under a CLIA Certificate of Provider-Performed Microscopy Procedures.

In general, what is necessary to be able to perform waived testing?

In order to perform waived testing, laboratories must enroll in the CLIA program and have a CLIA certificate, pay applicable certificate fees biennially, and follow manufacturers' test instructions. Additionally, if a laboratory has a Certificate of Accreditation they also have to follow the accrediting organizations regulations.

What does it mean to follow the manufacturer's instructions?

Laboratories must follow the manufacturer's instructions as they are written in the i-STAT labeling (system manual, quick reference guide, and product carton.) All instructions in the "i STAT System Manual for Waived Tests" must be followed. Particular attention should be paid to the section called "The Quick Reference Guide".

Laboratories may not make changes to the current instructions provided in the System Manual and they must follow the instructions without omission.

Frequently Asked Questions for Waived Testing *(continued)*

What should be considered before making the decision to perform waived testing?

The following are some of the items which should be considered before making the decision to perform waived testing:

- Quality Assurance:
  - Who will oversee the testing?
  - How will this person be trained on the testing?
  - What is the plan to maintain quality of the testing?
- Safety:
  - What safety factors have to be considered for those individuals who will be responsible for performing the testing?
  - How can the facility be made physically (lighting, workspace) and environmentally (humidity, temperature) ready to perform the testing?
- Regulatory Requirements:
  - What regulations apply to the testing from the federal government, state and/or accrediting organizations?
  - How will the laboratory prepare to comply with all regulations?
- Staff Competency:
  - How will staff be trained and maintain their competency to perform the testing?
  - Will all staff be trained or will only a portion of the staff be expected to perform the testing?
  - How will staff be trained on back up measures when the Point of Care System is unavailable?
- Record Keeping and Documentation:
  - What written records need to be maintained?
  - How will patient and quality control test results be recorded and maintained?
- Privacy and Confidentiality:
  - How will privacy and confidentiality of the patient results be maintained?
  - What will be done to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA)?

References

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