

MODERATELY COMPLEX TESTING WITH i-STAT CARTRIDGES: YOUR TRANSITION, MADE SIMPLE

Abbott Point of Care is committed to helping support your facilities transition from waived to moderately complex testing. This document has been developed to guide you through the key steps your facility will need to take to access the benefits of moderately complex diagnostic tests.

IF YOUR FACILITY

✓ HAS AN EXISTING MODERATELY COMPLEX LICENSE:

- You can use your facility's existing CLIA certificate of compliance or accreditation to support future use of i-STAT cartridges as a moderately complex test.
- Confirm that the license includes i-STAT cartridges and extends beyond the lab to include your relevant department.

✗ DOES NOT HAVE AN EXISTING MODERATELY COMPLEX LICENSE:

- Use of i-STAT nonwaived tests requires an upgrade of your current certificate of waiver to a certificate of compliance or accreditation.*

ADDING TESTS TO MODERATELY COMPLEX TESTING¹

Steps to add tests to the facility's certificate of compliance or accreditation for moderately complex testing

1 Ensure the current certificate covers chemistry and hematology specialties

- A. If the current certificate does not cover these, a CMS-116 form will need to be submitted with the added specialties.

2 Adding test volume to a certificate of compliance or accreditation (with approval from laboratory director)

- A. Contact the state agency to add test volume to certificate of compliance.
- B. Contact the accrediting organization for certificate of accreditation.
- C. Enroll in proficiency testing.
- D. Update procedure manual.
- E. Ensure training and competency assessments are documented by technical consultant.
 - Ensure testing personnel are qualified and documents are on file.
- F. Follow QC requirements (CLIA or IQCP).

3 Patient testing can begin under the following conditions

- A. If applicable, a performance verification is performed and accepted by lab director.
- B. Quality control option is selected (CLIA or IQCP).
- C. Technical consultant has training and competency assessment documents on file.
- D. Testing personnel are qualified.
- E. Proficiency testing enrollment completed.



*If you have no alternate method and need to obtain a Certificate of Compliance/Accreditation, these materials can provide support

GETTING STARTED WITH MODERATELY COMPLEX TESTING

STEPS TO OBTAIN A CERTIFICATE OF COMPLIANCE OR ACCREDITATION FOR MODERATELY COMPLEX TESTING¹

- 1 Determine if a change to certificate is necessary**
 - A. Review usage with the lab director for any additional guidance.
- 2 Review requirements to obtain certificate of compliance for moderately complex testing**
 - A. Requires a laboratory director for your facility (can be an MD with CME).
 - B. Enroll in proficiency testing.
 - C. Technical consultant must be employed to perform competency assessment (may be outsourced).
 - D. Create procedure manual.
 - E. Review IQCP or QC requirements (CMS regulations).
 - F. Testing personnel must qualify by CMS or state regulations.
- 3 Submit CMS 116 application**
- 4 CMS fee paid/certificate received—start non-patient testing**
 - A. Performance verification is required.
 - B. Implement IQCP or QC program requirements (CMS regulations).
 - C. Technical consultant starts initial training of testing personnel and conducts competency assessments after 6 months and one year.
 - D. Proficiency testing will be shipped according to vendor's schedule.
- 5 Laboratory director accepts performance verification data—patient testing can begin**
- 6 Pass on-site inspection (state or accrediting agency) every two years**



A LIBRARY OF TOOLS AND RESOURCES

For additional support please visit:
www.pointofcare.abbott/us/en/YourGuideToNonWaivedTesting



LOOKING FOR END-TO-END SUPPORT?

Several organizations provide robust support for every stage of the transition.
Visit: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf

Reference: 1. Clinical Laboratory Improvement Amendments (CLIA) How to obtain a CLIA Certificate Brochure. www.cms.gov

If you have any questions regarding this information, please contact your local Abbott Point of Care representative.

The material contained on this flashcard is for informational purposes only and not for the purpose of providing legal or regulatory advice. Use of the information provided on this flashcard is at your own discretion. Please contact your attorney and regulatory experts to determine the best approach for your lab.

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