

Frequently Asked Questions (FAQs), Abbott i-STAT
Updated as of 12/08/2022

<u>FAQ #</u>	<u>Description of Change</u>
23 -24	Information added to address Abbott customer letter 11-2022-168 and CLIA enforcement discretion for the i-STAT® cTnl cartridge (list number 03P90-25), (updated 12/08/2022)

Next Steps for Laboratories

1. What does the release on January 14, 2020 of the two Abbott customer letters (APOC2020-001, APOC2020-002: see link below) related to the Abbott i-STAT cartridges [i.e., CHEM8+ (BLUE), CG4+ (BLUE), G3+ (BLUE)] mean for my laboratory?

- A.** These letters mean that the CG4+ (BLUE) and G3+ (BLUE) are now considered high complexity tests due to lack of FDA categorization. If your non-waived laboratory is using one of these (BLUE) cartridges as described by Abbott, the Laboratory Director and Technical Consultant/Technical Supervisor should take immediate action to determine if the methodologies are appropriate for their non-waived laboratory. If your laboratory holds a Certificate of Waiver (CoW) or a Certificate for Provider-performed Microscopy (PPM) Procedures, the laboratory must discontinue use of these cartridges and seek an alternative testing method that has been FDA cleared and categorized as waived. See <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf>. Alternatively, they may apply for a new CLIA certificate, that is, a Certificate of Compliance or Certificate of Accreditation or send the testing to a reference laboratory.

Update 04/29/2020: The CHEM8+ (BLUE) and the CG4+ (BLUE) cartridges were cleared by the FDA and categorized as moderate complexity for arterial or venous whole blood as of 2/28/2020 and 4/9/2020, respectively. With respect to the G3+ (BLUE) test cartridge, CMS is exercising enforcement discretion (as of 3/27/2020) to allow laboratories with a Certificate of Registration that applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance, that have the i-STAT system, to use the G3+ (BLUE) test cartridge as a moderate complexity test. ([APOC2020-001B](#) and [APOC2020-002A](#)). Enforcement discretion will continue for the duration of the declared COVID-19 public health emergency or until the FDA has cleared/approved this test cartridge, whichever comes first. Laboratories need to follow all CLIA regulations that apply to moderate complexity testing. CMS based this decision on the FDA’s determination to exercise enforcement discretion for the G3+ (BLUE) test cartridge. ([APOC2020-001B](#) and [APOC2020-002A](#))

Laboratories with a Certificate of Accreditation (CoA) are advised to contact their Accreditation Organization (AO) for specific guidance, as the AO may have more stringent requirements than those listed above.

2. Can our laboratory continue to use the CHEM8+ (BLUE), CG4+ (BLUE), G3+ (BLUE) cartridges?

- A.** Yes, facilities can continue to use the three BLUE cartridges in laboratories that have a Certificate of Registration and applied for a Certificate of Compliance, or laboratories

with a Certificate of Compliance. However, because these tests are not categorized by the FDA, the laboratory must discontinue testing and establish performance specifications as required in 42 CFR § 493.1253(b)(2) for each analyte if it chooses to continue use of the cartridges. After performance specifications have been established and meet laboratory requirements, patient testing may resume. Please note that these tests are considered high complexity, and all applicable regulations must be followed.

Laboratories with a Certificate of Accreditation (CoA) are advised to contact their Accreditation Organization (AO) for specific guidance, as the AO may have more stringent requirements.

Update 04/29/2020: See FAQ #1 update above.

3. **Which i-STAT cartridges are still cleared by the FDA for clinical chemistry and blood gas testing?**
 - A. Please see the FDA website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm> for current FDA test categorization.
4. **What does "fully characterized" mean for the laboratory as included in the Abbott statement (APOC2020-002) ("During the transition, clinicians and laboratory staff should be informed that the performance of the i-STAT G3+ (BLUE) cartridge has not been fully characterized by Abbott.")?**
 - A. We suggest contacting Abbott for clarification regarding any language contained in their statements.
5. **The language in the letter (APOC2020-001) about CHEM8+ and CG4+ states that laboratories should 'transition' to alternate methods for venous and arterial specimens, and 'discontinue' use for capillary specimens. What does this mean for my laboratory?**
 - A. We suggest contacting Abbott for clarification regarding any language contained in their statements.
6. **What should the laboratory do if they have no other method to perform this testing and the test cannot be sent to a reference laboratory?**
 - A. If no suitable alternatives are available, the facility can continue to use the CG4+ (BLUE) and G3+ (BLUE) cartridges in laboratories that have a Certificate of Registration and applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance. Because these tests are not categorized by the FDA, the laboratory must establish performance specifications as required in 42 CFR § 493.1253(b)(2) for each analyte if it chooses to continue use of the cartridges. Please note that these tests are considered high complexity, and all applicable regulations must be followed. Please see the FDA website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm> to search for possible alternatives. This FDA website allows laboratories to search for possible alternative test system.

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Update 04/29/2020: See FAQ #1 update above.

7. **What does this mean for other BLUE cartridges (e.g., troponin)?**
 - A. We suggest contacting Abbott directly for a response to your question.
8. **What are the differences between the WHITE and BLUE cartridges?**
 - A. We suggest contacting Abbott directly for a response to your question.

Test Complexity/Test Categorization/Certificate Types

9. **How do the two Abbott customer letters affect the CLIA test complexity of the CHEM8+ (BLUE), CG4+ (BLUE), G3+ (BLUE) cartridges?**
 - A. Since the FDA has not categorized the CG4+ (BLUE) and G3+ (BLUE) test cartridges, they have also not been assigned a CLIA test complexity by the FDA for CLIA purposes per 42 CFR § 493.17(c)(4). Therefore, these test cartridges default to high complexity. As such, laboratories are expected to follow the appropriate CLIA regulations for high complexity testing when using these cartridges, including, but not limited to establishing performance specifications and assessing laboratory personnel (Laboratory Director, Technical Supervisor, Clinical Consultant, General Supervisor, and Testing Personnel) qualifications. See 42 CFR § 493.1252.

Update 04/29/2020: See FAQ #1 update above.

10. **How do the two customer letters affect my laboratory's CLIA certificate?**
 - A. Laboratories who hold a Certificate of Waiver or a Certificate for PPM Procedures must discontinue use of these cartridges and seek an alternative testing method that has been FDA cleared and categorized as waived. Alternatively, they may apply for a new CLIA certificate, that is, a Certificate of Compliance or Certificate of Accreditation or send the testing to a reference laboratory. See <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>
11. **What should I do if my laboratory has a Certificate of Accreditation?**
 - A. If your laboratory has a Certificate of Accreditation, you must contact your Accreditation Organization directly for a response to your question(s) related to the Abbott i-STAT customer letters. If you contact the State Agency, you will be directed to contact your Accreditation Organization.
12. **What are the CLIA personnel requirements for high complexity testing?**
 - A. The high complexity personnel requirements can be found in subpart M of the CLIA regulations ([CLIA Regulations](#)). Because the **CHEM8+ (BLUE), CG4+ (BLUE), G3+ (BLUE) cartridges** are not categorized by the FDA, all laboratory personnel must meet high complexity personnel requirements.

B.

Position	Regulatory Citation
Laboratory Director	42 CFR §493.1443
Technical Supervisor	42 CFR §493.1449
Clinical Consultant	42 CFR §493.1455
General Supervisor	42 CFR §493.1461
Testing Personnel	42 CFR §493.1489

Update 04/29/2020: See FAQ #1 update above.

13. Will the FDA test categorization website ([FDA Database](#)) be updated to reflect the BLUE and WHITE test cartridges test categorization as waived, moderate or high complexity?

- A. Yes. The FDA has updated their database, located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>.

Performance specifications

14. Do we need to verify or establish performance specifications if we are using any of the affected cartridges?

- A. If a laboratory uses a test system that has not been cleared or approved by the FDA, they are required to establish performance specifications for the test system prior to reporting patient test results. As the **CG4+ (BLUE)** and **G3+ (BLUE)** cartridges are not cleared or approved, this CLIA requirement would apply. The establishment studies must include, as applicable: accuracy, precision, analytical sensitivity, analytical specificity (including interfering substances), reportable range, reference intervals, and any other performance characteristics required for test performance. See the CLIA State Operations Manual (SOM), Appendix C ([Interpretive Guidelines](#)) for further guidance.

Update 04/29/2020: See FAQ #1 update above. For unmodified FDA-cleared tests, the laboratory needs to verify performance specifications.

15. If a laboratory continues to use the Abbott i-STAT CHEM8+ (BLUE), CG4+ (BLUE), G3+ (BLUE) cartridges, are they required to perform additional validation studies as the cartridge is not FDA-cleared?

- A. **Updated response 04/29/2020:** The laboratory must follow 42 CFR § 493.1253(b)(2) if it:
- Continues to use the Abbott i-STAT CHEM8+ (BLUE) on fingerstick (capillary) specimens or modifies the manufacturer’s instructions;
 - Modifies the manufacturer’s instructions for the CG4+ (BLUE) cartridge; or
 - Modifies the manufacturer’s instructions for the G3+ (BLUE) cartridge.

16. What timeframe do laboratories have to perform the establishment of performance specification studies?

- A. The laboratory must immediately begin verifying or establishing performance specifications, as applicable, in accordance with 42 CFR §493.1253(b) or discontinue testing.

Miscellaneous

17. Can a laboratory develop an Individualized Quality Control Program (IQCP) for the three affected test cartridges? Or can a laboratory continue to use a current IQCP?

- A. A laboratory may develop an IQCP for the three affected test cartridges. The laboratory may use historical data. The laboratory director must determine the number of samples to use, and the IQCP must contain the three required elements (Risk Assessment, Quality Control Plan, and Quality Assessment). The following guidance, under “Downloads” is available at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP
- CLIA Individualized Quality Control Plan (IQCP) benefits
 - FAQs for IQCP
 - IQCP Workbook – Developing an IQCP. A Step-by-Step Guide
 - som107ap_c_lab (Interpretive Guidelines)
 - CLIA Brochure – CLIA IQCP, Considerations When Deciding to Develop an IQCP
 - CLIA Brochure – CLIA IQCP, What is an IQCP?

18. Does this product corrective action affect my laboratory’s enrollment and participation in proficiency testing (PT)?

- A. This may affect your laboratory’s enrollment and participation in Proficiency Testing (PT). For example, if your laboratory performs only waived glucose testing, PT enrollment and participation is not required. With this product corrective action, that same glucose test is no longer waived, and is now considered a regulated analyte (i.e., analytes listed in subpart I), so PT enrollment and participation is required. A complete listing of regulated analytes as well as PT providers can be found at [Proficiency Testing Providers](#).

19. What should laboratories do if they have both CLIA certification and State licensure?

- A. These FAQs are intended to address CLIA-specific questions. If your state has additional licensure requirement, please contact your State Agency directly.

20. If a lab has 10 handhelds and validates a blood gas cartridge, are 2 levels of QC required on each handheld each day of patient testing or are 2 levels of quality control (QC) required on the cartridge prior to patient testing using the handhelds (QC would be rotated among the cartridges)?

- A. Until the laboratory develops an IQCP, the laboratory must perform two levels of quality control each day of patient testing on each analyzer (handheld) in use. For blood gas testing, default QC is testing one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. See 42 CFR § 493.1267(b).

21. For an IQCP, the lab is planning to do a 30 day quality control (QC) study for a blood gas cartridge; the study will include rotating the QC between the 10 handhelds for 30 days. Does

each handheld require a complete set of QC for 30 days or is rotating the QC between handhelds acceptable?

- A. The laboratory must perform an IQCP for each individual instrument. Per “Developing an IQCP. A Step-by-Step Guide”, “In laboratories with multiple, identical test systems (same make and manufacturer), a single risk assessment may be performed. However, differences in testing personnel and environments where the test systems are used must be taken into consideration. Due to these differences, you should determine if you need to perform a risk assessment for each individual location and/or device.”

22. If a laboratory validated Abbott’s CG4+ cartridge for blood gases, does the laboratory have to validate the blood gases again if using another cartridge type that has blood gases (CG8+)?

- A. Yes. See 42 CFR § 493.1253.

i-STAT® cTnI cartridge (list number 03P90-25) - Updated 12/08/2022

23. What does the release of the November, 2022 Abbott Point of Care customer letter (11-2022-168) related to the Abbott i-STAT cTnI cartridge (list number 03P90-25) mean for my laboratory?

- A. No change in your current procedures is needed. With respect to the cTnI cartridge (list number 03P90-25) [ABBOTT Account Login](#), CMS is exercising enforcement discretion (as of 12/08/2022) to allow laboratories with a Certificate of Registration that applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance, that have the i-STAT system, to continue to use the cTnI test cartridge as a moderate complexity test. Enforcement discretion will continue for the duration of the declared COVID-19 public health emergency or until the FDA has cleared/approved the changes to this test cartridge, whichever comes first. Laboratories need to follow all CLIA regulations that apply to moderate complexity testing.

Laboratories with a Certificate of Accreditation (CoA) are advised to contact their Accreditation Organization (AO) for specific guidance, as the AO may have more stringent requirements than those listed above.

24. Can our laboratory continue to use the Abbott i-STAT cTnI cartridge (list number 03P90-25)?

- A. Yes, facilities can continue to use the cTnI cartridge in laboratories that have a Certificate of Registration and applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance.

Laboratories with a Certificate of Accreditation (CoA) are advised to contact their Accreditation Organization (AO) for specific guidance, as the AO may have more stringent requirements.

Please note: During a CLIA survey, if the surveyor reviews a laboratory’s i-STAT and has concerns with how a laboratory is handling the i-STAT cartridge, the surveyor will forward those concerns and a copy of the survey findings to the CMS Branch office for review before the survey report is issued to the laboratory.

Helpful Links

- Link to Abbott Login [Abbott Account Login](#)
- Link to Abbott notification related to CG4+ (BLUE) and G3+ (BLUE) test cartridges → [APOC2020-001B and APOC2020-002A](#), dated April 2020
- CLIA Regulations → [CLIA Regulations](#)
- CLIA State Operations Manual (SOM), Appendix C (Interpretive Guidelines) → [Interpretive Guidelines](#)
- CLIA Website → <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index>
- FDA CLIA Categorization Website → [FDA Test Categorization](#)
- Link to CLIA Policy Memos to States and Regions
 - QSO 20-21-CLIA: Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency → [CMS QSO-20-21-CLIA](#)
 - QSO 18-19-CLIA: Performance Specification Verification of Assays Authorized Under Emergency Use (EUA) → [CMS QSO-18-19-CLIA](#)
- Link to the FDA EUA listing → [FDA EUA COVID-19 Test List](#)