

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0233388	(X3) Date Survey Completed 07/24/2024
Name of Provider or Supplier Clinch Valley Physicians Associates, Llc	Street Address, City, State 398 Clinic Road, Cedar Bluff, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	<p>An announced CLIA Recertification survey was conducted at Clinch Valley Physicians Associates on July 23, 2024 & July 24, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F.R. 493-801 Condition: Enrollment and Testing of Samples. D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems. D6000 - 42 C.F.R. 493-1430 Condition: Moderate Complexity Laboratory Director.</p>
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), CASPER Survey Summary (Report 0096D), tour of the laboratory testing room, review of patient test results, proficiency testing (PT) records, and interviews, the laboratory failed to enroll in PT for the i-STAT CG4+ partial pressure carbon dioxide (pCO2), pH, and partial pressure oxygen (pO2) analytes from 01/02/24 up to the date of survey on 07/24/24. Findings include: 1. Review of the CMS 116 application revealed the laboratory performs blood gas testing. Review of the CASPER Report 0096D revealed results for the non-waived</p>

regulated pCO₂, pH and pO₂ analytes for the first and second events in 2024. 2. Tour of the laboratory testing room in the adjacent office on 07/23/24 at 1430 revealed a Siemens Rapid 500 blood gas analyzer on a table. 3. Review of three randomly selected patient records from the Athena electronic medical record (EMR), patient #1 on 02/02/24, patient #2 on 02/09/24 and patient #3 on 04/11/24, revealed blood gas results from an i-STAT hand-held analyzer (serial number 398896) using the CG4+ blood gas cartridge (pCO₂, pH, pO₂, and lactate analytes). 4. In an interview with the technical supervisor (TS) and Quality Assurance (QA) nursing manager on 07/23/24 at 1500, the surveyor asked about the use of the i-STAT analyzer with the CG4+ cartridge(s). The TS stated, "our respiratory therapist retired in December 2023 and we are currently trying to hire another therapist. We were told by the physician that is performing the respiratory assessments that the Siemens Rapid 500 was not in use for patients and that blood gases were not performed." The QA nursing manager confirmed the statement. In the same interview, the surveyor asked about the location of the analyzer and CG4+ cartridges. The TS and QA nursing manager simultaneously stated, "we are not aware of testing with the i-STAT or cartridges, and we don't know where the analyzer or cartridges are located." 5. The surveyor, TS and QA nursing manager opened the small brown refrigerator located in the testing area and discovered the following on 07/23/24 at 1545: AbbottTri-control (quality control) Level 1 (lot number 301168) - one box, Level 3 (lot number 321168) one box. CG4+ Cartridges- Lot number D24011- six cartridges, Lot number D23252- 12 cartridges and Lot number D23321- 12 cartridges. During the same time of discovery, the QA nursing manager stated, "the analyzer may be in the physician's office" and confirmed the door was locked and did not have access to the office. 6. Review of the American Proficiency Institute (API) PT chemistry results revealed the physician submitted pCO₂, pH and pO₂ blood gas results obtained from the Siemens Rapid 500 analyzer. 7. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor inquired about enrollment with API or another PT company for the blood gas testing using the i-STAT analyzer with the CG4+ cartridges. They stated, "no, we are not enrolled or have PT testing for the i-STAT. But we are enrolled and have PT testing for the Rapid 500." In the same interview, the surveyor inquired about the location of the i-STAT analyzer in use. They stated, "it's in my office." In an interview with the laboratory director, TS and QA nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of patient testing with the i-STAT. We did PT for the Rapid 500 and we are currently looking for another respiratory therapist for the blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed. 8. A call to the API technical support team on 07/25/24 at 10:00 AM revealed that the PT samples for the Siemens Rapid 500 cannot be used interchangeably with the i-STAT analyzer and CG4+ cartridge. They revealed that the lab is currently enrolled with module 111-blood gases and would need to enroll with module 145-i-STAT blood gas.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
 Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, electronic medical records (EMR), manufacturer's operator's manual, lack of documentation, and interviews, the laboratory failed to: 1- Provide a policy and procedure manual for the Abbott i-STAT hand-held analyzer and the Abbott CG4+ blood gas cartridge(s). Refer to D5401. 2. Have a laboratory director approved policy and procedure (P&P) for the use of the i-STAT hand-held analyzer and the CG4+ blood gas cartridges prior to patient testing on 01/02/24. Refer to D5407. 3. Verify the accuracy, precision, reportable range and the normal (reference) ranges of the Abbott CG4+ blood gas test system prior to patient testing on 01/02/24. Refer to D5421. 4. Provide documentation of performing the external electronic simulator and thermal probe check every six months. Refer to D5429. 5. Perform external quality control (QC) materials every eight hours of patient testing for 37 of 42 dates, reporting 49 patients. Refer to D5537. 6. Establish and follow a written policy to identify and address analytic issues in order to monitor, assess and correct problems in the specialty of chemistry. Refer to D5791. 7. Ensure the name and address of the testing facility, source of specimen, and the reference ranges were included on 49 of 49 patient final test results. Refer to D5805.

D5401

PROCEDURE MANUAL
 CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
 Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory failed to provide a policy and procedure (P&P) manual for the Abbott i-STAT hand-held analyzer and the Abbott CG4+ blood gas cartridge(s) at the date of survey, 07/24/24. Findings include: 1. Review of the CMS 116 application revealed the performs blood gas testing, non-waived regulated partial carbon dioxide (pCO₂), pH, and partial pressure oxygen (pO₂) analytes. The CMS 116 application listed "Siemens" as the analyzer used for blood gas testing. 2. Tour of the laboratory testing room in the adjacent office on 07/23/24 at 1430 revealed a Siemens Rapid 500 blood gas analyzer on a table. 3. Review of three randomly selected patient records from the Athena electronic medical record (EMR), patient #1 on 02/02/24, patient #2 on 02/09/24 and patient #3 on 04/11/24, revealed blood gas results from an i-STAT hand-held analyzer (serial number 398896) using the CG4+ blood gas cartridge (pCO₂, pH, pO₂, and lactate analytes). 4. In an interview with the Technical Supervisor (TS) and Quality Assurance (QA) nursing manager on 07/23/24 at 1500, the surveyor asked about the use of the i-STAT analyzer with the CG4+ cartridge(s). The TS stated, "our respiratory therapist retired in December 2023 and we are currently trying to hire another therapist. We were told by the physician that is performing the respiratory assessments that the Siemens Rapid 500 was not in use for patients and that blood gases were not performed." The QA nursing manager confirmed the statement. In the same interview, the surveyor asked about the location of the analyzer and CG4+

cartridges. The TS and QA nursing manager simultaneously stated, "we are not aware of testing with the i-STAT or cartridges, and we don't know where the analyzer or cartridges are located." 5. The surveyor, TS and QA nursing manager opened the small brown refrigerator located in the testing area and discovered the following on 07/23/24 at 1545: AbbottTri-control (quality control) Level 1 (lot number 301168) - one box, Level 3 (lot number 321168) one box. CG4+ Cartridges- Lot number D24011- six cartridges, Lot number D23252- 12 cartridges and Lot number D23321- 12 cartridges. During the same time of discovery, the QA nursing manager stated, "the analyzer may be in the clinician's office" and confirmed the door was locked and did not have access to the office. 6. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor asked about a P&P for the i-STAT analyzer and the CG4+ blood gas cartridges. They stated, "no there is not a policy and procedure manual. I could get the user's manual." During the same interview, the surveyor asked if there was a P&P or user's manual located on-site and where the i-STAT analyzer was currently located. They stated, "no, there isn't one on-site. The analyzer is in my office." In an interview with the laboratory director, TS and QA nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory director failed to review and approve a policy and procedures (P&P) for the use of the i-STAT hand-held analyzer and the CG4+ blood gas cartridges prior to patient testing on 01/02/24. Findings include: 1. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott i-STAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 2. In an interview with the laboratory director, Technical Supervisor (TS) and Quality Assurance nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing. I have not approved or reviewed this test system." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory failed to verify the accuracy, precision, reportable range and the normal (reference) ranges of the Abbott i-STAT CG4+ blood gas test system prior to patient testing on 01/02/24. Findings include: 1. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott i-STAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 2. The surveyor was provided a blue folder for review on 07/24/24 at 08:30 AM. The blue folder contained five days of external quality control materials assayed. The blue folder lacked documentation of the performance of initial verification records to include accuracy, precision, reportable and normal (reference) ranges for the CG4+ blood gas cartridge(s). 3. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor asked for the initial verification records for the i-STAT analyzer and the CG4+ blood gas test cartridge(s). They stated, "no, I do not have those records." During the same interview, the surveyor asked where the physician obtained the i-STAT analyzer and the cartridges. They stated, "I got it from a clinic in West Virginia." In an interview with the laboratory director, Technical Supervisor (TS) and Quality Assurance nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, manufacturer's operator's manual, lack of documentation and interviews, the laboratory failed to provide documentation of performing the external electronic simulator and thermal probe check every six months from 01/02/24 up to date of survey on 07/24/24. Findings include: 1. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott i-STAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 2. The surveyor reviewed the current Abbott i-STAT operator's manual on 07/24/24 at 07:00 AM from the website: www.globalpointofcare.abbott/content/dam/ardx/globalpointofcare/apoc/support/i-stat-1/system-manual/english-us/040353-08%2015A.pdf. The review of the Abbott i-STAT operator's manual revealed instruction for performing the external electronic simulator when the thermal probe check is verified every six months. 3. The surveyor was provided a blue folder with documents for review on 07/24/24 at 08:30 AM. The blue folder contained five days of external quality control materials assayed however, the

folder lacked documentation of the performance the external electronic simulator and thermal probe check as least every six months from 01/02/24 up to date of survey on 07/24/24. 4. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor asked for documentation of the performance of the external electronic simulator and thermal probe check every six months for the i-STAT analyzer. They stated, "No, I do not have those records." In an interview with the laboratory director, Technical Supervisor (TS) and Quality Assurance nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test 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. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory failed to perform external quality control (QC) materials every eight hours of patient testing for 39 of 42 dates, reporting 49 patients. Dates of review from 01/02/24 up to the date of survey on 07/24/24. Findings include: 1. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott i-STAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 2. The surveyor requested external QC materials performed every eight hours of patient testing from 01/02/24 up to 07/24/24. The surveyor was provided a blue folder for review on 07/24/24 at 08:30 AM. The blue folder contained five dates of instrument printouts of assayed external quality control materials: 01/26/24- 2 patients reported, 03/28/24- 1 patient reported, and 06/07/24- 1 patient reported. Note- for 01/02/24 and 05/31/24- QC materials assayed with no patient testing/resulting. The blue folder lacked documentation of external QC materials assayed for the following dates in which patient testing/resulting occurred: 1/29/24- 1 patient, 02/02/24- 2 patients, 02/06/24- 1 patient, 02/08/24- 1 patient, 02/09/24- 2 patients, 02/16/24- 2 patients, 02/19/24- 1 patient, 02/20/24- 1 patient, 02/26/24- 1 patient, 02/27/24- 1 patient, 03/01/24- 2 patients, 03/08/24- 1 patient, 03/14/24- 1 patient, 03/15/24- 1 patient, 03/18/24- 1 patient, 03/19/24- 1 patient, 03/22/24- 1 patient, 03/26/24- 1 patient, 03/29/24- 2 patients, 04/01/24- 1 patient, 04/02/24- 1 patient, 04/05/24- 2 patients, 04/11/24- 1 patient, 04/12/24- 2 patients, 04/15/24- 1 patient, 04/16/24- 1 patient, 04/19/24- 1 patient, 04/25/24- 1 patient, 04/26/24- 2 patients, 04/29/24- 1 patient, 05/03/24- 1 patient, 06/17/24- 1 patient, 06/18/24- 1 patient, 06/21/24- 2 patients, 06/24/24- 1 patient, 06/27/24- 1 patient, 06/28/24- 2 patients, 07/12/24- 1 patient, and 07/22/24- 1 patient. Dates of patient testing/resulting obtained from Athena electronic medical records (EMR). Total of 49 patients. 3. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor asked for additional documentation of the performance of the external QC materials each day patient testing/resulting occurred. They stated, "I have the printouts of the QC I performed in the blue folder." Additional documentation of

the performance of QC materials for the above-specified dates was not available for review during the survey. In an interview with the laboratory director, Technical Supervisor (TS) and Quality Assurance nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, random review of three patient test results, lack of documentation, and interviews, the laboratory failed to establish and follow a written policy to identify and address analytic issues in order to monitor, assess and correct problems in the specialty of chemistry from 01/02/24 up to the date of survey on 07/24/24. Findings include: 1. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott i-STAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 2. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor asked for an established and approved quality assurance (QA) policy to identify and address analytic issues for the Abbott CG4+ blood gas cartridge (s) assayed on the i-STAT hand-held analyzer. They stated, " I do not have a policy." In an interview with the laboratory director, Technical Supervisor (TS) and QA nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, random review of three patient test results, electronic medical records (EMR), lack of

documentation, and interviews, the laboratory failed to ensure the name and address of the testing facility, source of specimen, and the reference ranges for the partial carbon dioxide (pCO₂), pH, partial pressure oxygen (pO₂) and lactate analytes were included on 49 of 49 patient final test results from 01/26/24 up to 07/22/24. Findings include: 1. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott i-STAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 2. Patient test reports obtained from Athena EMR revealed a scanned copy of the i-STAT hand-held instrument printout of the CG4+ results. The printouts lacked documentation of the testing facility's name and address, source of specimen and the reference ranges for pCO₂, pH, pO₂ and lactate analytes. 3. In an interview with the laboratory director, Technical Supervisor (TS) and QA nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory director failed to: 1. Ensure the verification of the accuracy, precision, reportable range and the normal (reference) ranges for the Abbott CG4+ blood gas test system prior to patient testing. Refer to D6013. 2. Ensure the enrollment in PT for the i-STAT CG4+ partial pressure carbon dioxide (pCO₂), pH, and partial pressure oxygen (pO₂) analytes. Refer to D6015. 3. Ensure the establishment of quality control and quality assessment procedures to monitor, assess, and identify analytical issues for the Abbott i-STAT hand-held analyzer and Abbott CG4+ cartridges. Refer to D6022. 4. Ensure the name and address of the testing facility, source of specimen, and the reference ranges were included on 49 of 49 patient final test results. Refer to D6026. 5. Ensure that one of one testing personnel received training for the Abbott i-STAT hand-held analyzer with use of the Abbott CG4+ blood gas test system prior to patient testing. Refer to D6029.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory director failed to ensure the verification of the accuracy, precision, reportable range and the normal (reference) ranges for the Abbott CG4+ blood gas test system prior to patient testing on 01/02/24. Refer to D5421.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), CASPER Survey Summary (Report 0096D), tour of the laboratory testing room, review of patient test results, proficiency testing (PT) records, and interviews, the laboratory director failed to ensure the enrollment in PT for the i-STAT CG4+ partial pressure carbon dioxide (pCO2), pH, and partial pressure oxygen (pO2) analytes from 01/02/24 up to the date of survey on 07/24/24. Findings include: 1. Review of the CMS 116 application revealed the lab performs blood gas testing. Review of the CASPER Report 0096D revealed results for the non-waived regulated pCO2, pH and pO2 analytes for the first and second events in 2024. 2. Review of the American Proficiency Institute (API) PT chemistry results revealed the clinician submitted pCO2, pH and pO2 blood gas results obtained from the Siemens Rapid 500 analyzer. 3. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott iSTAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 4. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor asked about enrollment with API or another PT company for the blood gas testing using the i-STAT analyzer with the CG4+ cartridges. They stated, "no, we are not enrolled or have PT testing for the i-STAT. But we are enrolled and have PT testing for the Rapid 500." In the same interview, the surveyor inquired about the location of the i-STAT analyzer in use. They stated, "it's in my office." In an interview with the laboratory director, Technical Supervisor (TS) and Quality Assurance nursing manager on 07/24/24 at 11:30, the findings were presented to the laboratory director. They stated, "I was not aware of patient testing with the i-STAT. We did PT for the Rapid 500 and we are currently looking for another respiratory therapist for the blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed. 5. A call to the API technical support team on 07/25/24 at 10:00 revealed that the PT samples for the Siemens Rapid 500 cannot be used interchangeably with the i-STAT analyzer and CG4+ cartridge. They revealed that the lab is currently enrolled with module 111-blood gases and would need to enroll with module 145-i-STAT blood gas.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory director failed to ensure the establishment of quality control and quality assessment procedures to monitor, assess, and identify analytical issues for the Abbott i-STAT hand-held analyzer and Abbott CG4+ cartridges at the date of survey on 07/24/24. Refer to D5401, D5421, D5429, D5537, and D5791.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(8)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, electronic medical records (EMR), lack of documentation, and interviews, the laboratory director failed to ensure the name and address of the testing facility, source of specimen, and the reference ranges were included on 49 of 49 patient final test results from 01/26/24 up to 07/22/24. Refer to D5805.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing room, review of patient test results, lack of documentation, and interviews, the laboratory director failed to ensure that one of one testing personnel received training for the Abbott i-STAT hand-held analyzer with use of the Abbott CG4+ blood gas test system prior to patient testing on 01/02/24. Findings include: 1. Review of the CMS 116, a tour of the testing area on 7/23/24 at 1545, and review of 3 patient test results revealed non-waived blood gas testing performed on an Abbott i-STAT analyzer. Refer to D5401, findings 1-5 for details regarding discovery. 2. In an interview with the physician performing the respiratory assessments on 07/24/24 at 09:18 AM, the surveyor asked if they had documentation of training for the Abbott the i-STAT hand-held analyzer with the Abbott CG4+ blood gas cartridge(s). They stated, "I do not have training documentation or any competency assessments for the i-STAT." In an interview with the laboratory director, Technical Supervisor (TS), and Quality Assurance nursing manager on 07/24/24 at 11:30 AM, the findings were presented to the laboratory director. The director stated, "I was not aware of testing with the i-STAT analyzer or cartridges for blood gas testing." In an exit interview with the TS on 07/24/24 at 15:30, the findings were confirmed.