

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1060672	<b>(X3) Date Survey Completed</b> 12/07/2020
<b>Name of Provider or Supplier</b> Centra Specialty Hospital	<b>Street Address, City, State</b> 3300 Rivermont Avenue - Krise 5, Lynchburg, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification on-site survey was conducted at the Centra Specialty Hospital on December 7, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory was conducted on November 12, 2020 with off-site record review of documentation on December 3, 2020 and a follow-up phone conference on December 4, 2020. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems. Specific deficiencies cited are as follows:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&amp;P), lack of documentation, and an interview, the laboratory failed to establish a written policy for the competency assessments for individuals performing the job duties of technical consultant at the date of survey on December 7, 2020. Findings include: 1. Review of the CMS-209 Form revealed three (3) technical consultants. See attached Personnel Code Sheet. 2. Review of the P&amp;P revealed the lack of documentation of an established written policy for competency assessments for the technical consultant. The surveyor requested the document and it was not available for review. 3. An interview with the primary testing personnel and technical consultant B at approximately 10:45 AM on December 7, 2020 confirmed the findings.</p>

**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 the review of the laboratory's performance verification records, Abbott i-STAT System Performance Verification Protocol, daily patient test logs, and interviews, the laboratory failed to: 1. verify the performance specifications for the i-STAT test system in the environment in which testing was performed (Refer to D5421 A), and 2. verify the performance specifications for the EG7+ Blood Gas cartridge (Refer to D5421 B).

**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:

A. Based on the review of the laboratory's performance verification records, Abbott i-STAT System Performance Verification Protocol, and interviews, the laboratory failed to verify the performance specifications for the i-STAT test system in the environment in which testing was performed on 8/28/20. Findings include: 1. Review of the laboratory's Abbott i-STAT test system's (serial number 311008, installed 8/28/20) performance verification documentation revealed the verification procedures were performed off-site at an affiliated hospital. A phone interview with the primary testing personnel, point of care coordinator and lab director on 12/04/20 at approximately 9:45 AM revealed that the performance verification studies were conducted off-site at an affiliated hospital by the point of care coordinator. The new device was re-located to the testing lab on 8/28/20. 2. The review of the "Abbott i-STAT System Performance Verification Protocol" revised 4/04/20 revealed the following statements: " OVERVIEW- A verification protocol provides an efficient means to collect statistically valid data that can be used to assess the performance of each device and each sensor type found in cartridges containing tests for chemistries, blood gases and hematocrit that will be used for i-STAT testing." "VERIFICATION OF ADDITIONAL NEW OR REPLACEMENT DEVICES- Reportable Range- Test the lowest level, the mid level and the highest level of calibration samples available for each cartridge that will be performed on a new or replacement device. Precision- Each cartridge that will be used with the new or replacement device must be included in the Precision study." 3. An interview with the primary testing personnel and point

of care coordinator at approximately 11:00 AM on 12/07/20 confirmed that the findings. B. Based on the review of the laboratory's performance verification records, Abbott i-STAT System Performance Verification Protocol, daily patient test logs, and interviews, the laboratory failed to verify the performance specifications for the EG7+ Blood Gas cartridge from 8/28/20 up to 12/01/20 while reporting twenty-seven (27) patients. Findings include: 1. Review of the laboratory's Abbott i-STAT test system's (serial number 311008, installed 8/28/20) performance verification documentation revealed the verification procedures were performed for the CG8+ blood gas cartridge. A phone interview with the primary testing personnel, point of care coordinator and lab director on 12/04/20 at approximately 9:45 AM revealed that the testing lab utilized the EG7+ blood gas cartridge for patient testing and not the CG8+ blood gas cartridge. It was stated, "Both cartridges contain the same analytes, with the CG8+ including glucose and the studies cover the EG7+ blood gas cartridge." 2. An Abbott Point of Care technical specialist stated, "Each individual test cartridge must be verified prior to patient testing" during a phone interview at approximately 9:22 AM on 12/7/20. In addition, the review of the "Abbott i-STAT System Performance Verification Protocol" revised 4/04/20 revealed the following statements: "OVERVIEW- A verification protocol provides an efficient means to collect statistically valid data that can be used to assess the performance of each device and each sensor type found in cartridges containing tests for chemistries, blood gases and hematocrit that will be used for i-STAT testing." "VERIFICATION OF ADDITIONAL NEW OR REPLACEMENT DEVICES- Reportable Range- Test the lowest level, the mid level and the highest level of calibration samples available for each cartridge that will be performed on a new or replacement device. Precision- Each cartridge that will be used with the new or replacement device must be included in the Precision study." 3. A patient query from the RALs laboratory information system (LIS) revealed 27 patients were tested and resulted with the EG7+ blood gas cartridge from 8/28/20 up to 12/01/20. 4. An interview with the primary testing personnel and point of care coordinator at approximately 11:00 AM on 12/07/20 confirmed the findings.

**D6040**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:  
 Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), performance verification records, Abbott i-STAT System Performance Verification Protocol, daily patient test logs, and interviews, the technical consultant (TC) failed to verify the performance specifications of the i-STAT test system in the environment in which testing was performed and for the EG7+ Blood Gas cartridge on 8/28/20. The review of the CMS-209 Form and interview with TC B on 12/07/20 at approximately 10:45 AM revealed TC B is the point of care coordinator for the affiliated hospital system. Refer to D5421 A and B.