Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1060672	09/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Centra Specialty Hospital	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Centra Specialty Hospital on September 7, 2022 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:
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of procedures, manufacturer's package insert, instrument

	calibration verification records, lack of documentation, and an interview, the laboratory failed to follow their policy to perform calibration verification for the Abbott EG7+ reagent cartridge blood gas analytes Hydrogen Ion Concentration (pH), Carbon Dioxide Partial Pressure (PCO2), Bicarbonate (HCO3), and Oxygen Partial Pressure (PO2) on the iSTAT analyzer every six months in calendar year 2021. Findings include: 1. Review of the laboratory's procedures revealed iSTAT calibration verification protocol as: "Calibration verification or the analytical measurement range will be performed every six months." 2. Review of the Abbott iSTAT EG7+ cartridge package insert revealed instructions: "Calibration verification is the procedure intended to verify the accuracy of results over the entire measurement range of at test and may be required by your regulatory agency." 3. Review of the laboratory's calibration verification records during the timeframe of January 2021 to the date of the survey on 09/07/22, revealed calibration verification records for the Abbott iSTAT EG7+ blood gas reagent cartridge tests as performed once on 09/07/21. The inspector requested to review additional documentation of the every six month calibration verification for the twenty-one month review timeframe outlined above. No other records were available. 4. An exit interview with the Lead Respiratory Therapist, Medical Laboratory Technician (MLT) Supervisor, Director of Quality Assurance, and Director of Lynchburg General Hospital (LGH) Lab on 09/07/22 at approximately 1:30 PM confirmed the above findings.
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 a review of the facility's Centers for Medicare and Medicaid Services Application for Certification (CMS 116) form, a randomly selected patient's electronic medical record (EMR) blood gas report, and interviews, the laboratory failed to correctly identify their address as the performing laboratory as reviewed on the blood gas panel on September 7, 2022. Findings include: 1. Review of the facilities CMS 116 form revealed a laboratory name and facility physical location address as: Centra Specialty Hospital 3300 Rivermont Avenue Lynchburg, Virginia 24503 2. The inspector randomly selected patient accession #1012332 from the laboratory's test logs dated 09/03/22 for review. The printed blood gas report from the laboratory's Cerner EMR revealed a testing location of: LGH Lab, Lynchburg General Hospital 1901 Tate Springs Road Lynchburg, Virginia 24501 The inspector noted that the printed blood gas report outlined above stated "this test was performed at LGH Lab, Lynchburg General Hospital, 1901 Tate Springs Road" and inquired regarding the lab name and address error. The Lead Respiratory Therapist stated on 09/07/22 at approximately 12:30 PM, "I had not noticed that the performing lab was not correct." The Medical Laboratory Technician (MLT) Supervisor stated simultaneously: "We will have to reach out to the IT department to get this fixed. We had an upgrade in the iSTAT Rals downloader this year and it is possible that our IT department may not

	have updated all test sites appropriately." 3. An exit interview with the Lead Respiratory Therapist, MLT Supervisor, Director of Quality Assurance, and Director of Lynchburg General Hospital (LGH) Lab on 09/07/22 at approximately 1:30 PM confirmed the above findings.