Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1060672	01/23/2019
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 the Centra Specialty Hospital on January 23, 2019 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:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P) and interview, the laboratory did not have a P&P for performing competency assessments on testing personnel at the date of the survey on January 23, 2019. Findings include: 1. Review of the available P&P's revealed no policy for performing competency assessments on testing personnel performing patient testing. The inspector requested to review the P&P for competency assessments. The document was not available for review at the date of survey. 2. Interview with the primary testing personnel and laboratory quality manager at approximately 1:15 PM confirmed the above listed findings.
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 tour of the lab testing area, review of policy and procedures (P&P), manufacturer operator's guide, quality control (QC) records, and interview, the laboratory failed to: 1) ensure the laboratory director reviewed and signed P&P (Cross Reference D5407); 2) monitor and document room temperatures (Cross Reference D5413); and 3) perform QC every eight (8) hours of patient testing (Cross Reference D5537).
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: Base on the review of policy and procedures (P&P) and interview, the laboratory director did not sign and approve the P&P in use at the date of the survey on January 23, 2019. Findings include: 1. The inspector requested to review the P&P in use for the blood gas testing. Review of the P&P revealed the lack of the laboratory director's signature and approval for the following: - Point of Care Testing: I-STAT System V20 POC 7095.D.001, - Point of Care Testing: Quality Assurance V20 POC 7095.B. 001, - CMG: Proficiency Testing Policy V5 CMG.01.15.330, - Respiratory Care: Arterial Blood Sample Collection- CSH V3 CSH.RSP.01.32.02 and, - Respiratory Care: Care Critical Values- CSH V3 CSH.CLIN.RSP.32.09. 2. An interview with the laboratory quality manager and primary testing personnel at approximately 1:15 PM confirmed the above-specified findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the tour of the lab testing area, review of the manufacturer operator's guide and an interview, the laboratory failed to monitor and document the room temperature for the Abbott i-STAT C3+ and CG4+ blood gas cartridges from May 1, 2018 and up to the date of survey on January 23, 2019. Findings include: 1. Tour of the lab testing area for the Abbott i-STAT hand-held analyzer revealed that the staff store the Abbott i-STAT C3+ and CG4+ blood gas cartridges at room temperature for use. 2. Review of the manufacturer operator's guide, pg. 16, revealed the following statements: "Room Temperature Cartridges: - Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than the time frame indicated on the

	cartridge box. Deliver any expired cartridges to the i-STAT 1 System coordinator. - Verify that room temperature has not exceeded 30 C (86 F). - Document in the i-STAT QC log. Action: If the measured temperature of the room has been continuously below 30 C (86 F) use cartridges as required. Remedial Action: If the measured room temperature has exceeded 30 C (86 F) for any period of time: - Quarantine the cartridges. - Notify the i-STAT 1 System coordinator immediately. - DO NOT USE the cartridges. - Record the out-of-control event in the i-STAT QC Log and the action taken." The inspector requested to review room temperature documentation from May 1, 2018 and up to the date of survey on January 23, 2019. The documentation was not available for review. 3. An interview with the laboratory quality manager and primary testing personnel at approximately 1:15 PM confirmed the above-specified findings.
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 the review of quality control (QC) records, and an interview, the laboratory failed to perform QC materials every eight (8) hours of patient testing for the Abbott i-STAT C3+ and CG4+ blood gas cartridges from May 1, 2018 and up to the date of survey on January 23, 2019, in which seventy-six (76) patients were resulted. Findings include: 1. Review of the Abbott i-STAT hand-held analyzer blood gas RALS QC records (serial number 315896) revealed that the laboratory performed Abbott TriControl (level 1-lot number 301100 and level 3-lot number 321100) every 30 days from May 1, 2018 and up to the date of survey on January 23, 2019. Review of the blood gas RALS QC records revealed the following dates that did not have QC performed and patients were resulted: 05/17/2018- Accession number 1429, 05/18 /2018- Accession number 1429, 05/19/2018- Accession number 2238, 05/20/2018- Accession number 1242, 05/21/2018- Accession number 1429, and 2238, 05/24/2018- Accession number 1497, 05/25/2018- Accession number 1429, 05/26/2018- Accession number 1497, 05/30/2018- Accession number 1688, 05/31/2018- Accession number 1688, 06/07/2018- Accession number 1559, 06/08/2018- Accession number 1706, 06/09/2018- Accession number 0478, 06/12/2018- Accession number 1688, 06/13/2018- Accession number 1677, 06/16/2018- Accession number 1706, 06/22/2018- Accession number 2262, 06/26/2018- Accession number 1497, 06/30/2018- Accession number 1497, 07/06/2018- Accession number 0684, 07/08/2018- Accession number 1657, 07/11/2018- Accession number 2328, 07/13/2018- Accession number 1611, 07/14/2018- Accession number 2066, 07/16/2018- Accession number 1998, 07/18/2018- Accession number 1611, 08/02/2018- Accession number 2322, 08/03/2018- Accession number 1519, 08/04/2018- Accession number 1717, 08/06/2018- Accession number 2094, 08/11/2018- Accession number 1710, 08/13/2018- Accession number 2820, 08/18/2018- Accession number 2019 and 1848, 08/19/2018- Accession number 1710, 08/22/2018- Accession number 1519, 08/23/2018- Accession number 2226 and 1519, 08/28/2018- Accession number 1808, 09/13/2018- Accession number 4509, 09/14/2018- Accession number 4404, 09/27/2018- Accession number 8200, 09/28/2018- Accession number 1969, 09/29/2018-

	Accession number 1969, 10/04/2018- Accession number 2632, 10/05/2018- Accession number 3024, 10/06/2018- Accession number 9026, 10/08/2018- Accession number 6853, 10/17/2018- Accession number 3024, 10/20/2018- Accession number 6074 and 3024, 10/26/2018- Accession number 2884, 11/02/2018- Accession number 3024, 11/09/2018- Accession number 5896, 11/17/2018- Accession number 6197, 11/29/2018- Accession number 6197, 11/29/2018- Accession number 7661, 11/30/2018- Accession number 7661 and 3183, 12/01/2018- Accession number 7661, 12/03/2018- Accession number 8056, 12/04/2018- Accession number 7661 and 8056, 12/05/2018- Accession number 7661, 12/14/2018- Accession number 2943, 12/15/2018- Accession number 2943, 12/16/2018- Accession number 6317, 12/17/2018- Accession number 5050, 12/18/2018- Accession number 8056 and 6317, 12/31/2018- Accession number 8056, 01/01/2019- Accession number 8056 and 4681, 01/03/2019- Accession number 3929, 01/12/2019- Accession number 3929, 01/13/2019- Accession number 3929, and 01/23/2019- Accession number 8948. A total of 68 days with 76 patients resulted. 2. Interview with the laboratory director, laboratory quality manager and primary TP at approximately 11:30 AM confirmed the above-listed findings.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the tour of the lab testing area, review of manufacturer operator's guide, quality control (QC) records, and interview, the laboratory director failed to: 1) ensure room temperatures for the lab testing area were monitored and documented (Cross Reference D5413); and 2) ensure that QC was performed every eight (8) hours of patient testing (Cross Reference D5537).
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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records and interviews, the laboratory director failed to review and approve four (4) of four (4) new TP training and competency assessments

	documentation prior to performing patient testing procedures from May 1, 2018 and up to the date of survey on January 23, 2019. Findings include: 1. Review of CLIA CMS-209 form revealed that TP B, H, M and TP N were new TP (See attached TP Code Sheet). 2. Review of TP records revealed the lack of the laboratory director's signature of review and approval for the following TP: TP B- hired and performing testing May 9, 2018, TP H- hired and performing testing May 15, 2018, TP M- hired and performing testing May 15, 2018, TP N- hired and performing testing May 22, 2018. 3. Interview with the laboratory director, laboratory quality manager and primary TP at approximately 11:30 AM confirmed the above-listed findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records and interview, the laboratory director did not review and approve the semi-annual competency assessments of four (4) of 4 new TP in 2019 and eleven (11) of 11 TP annual competency assessments in 2018. Findings include: 1. Review of the CLIA CMS-209 Form revealed 4 new TP in 2018 and 11 TP performing patient testing in 2018. 2. Review of the TP records revealed the lack of the laboratory director's review and approval of the following competency assessments: TP B- semi-annual on January 22, 2019, TP H- semi-annual on January 9, 2019, TP M- semi-annual on January 9, 2019 and, TP N- semi-annual on January 22, 2019. And TP A- annual on August 17, 2018, TP C- annual on August 17, 2018, TP D- annual on August 21, 2018, TP E- annual on August 17, 2018, TP F- annual on August 21, 2018, TP G- annual on August 17, 2018, TP I- annual on August 17, 2018, TP J- annual on August 17, 2018, TP K- annual on August 17, 2018, TP L- annual on August 17, 2018 and TP P- annual on August 22, 2018. 3. Interview with the laboratory director, laboratory quality manager and primary TP at approximately 11: 30 AM confirmed the above-listed findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209

	Form), personnel records, and interview, testing personnel (TP) P did not have the required education elements to qualify and perform the duties of technical consultant at the date of survey on January 23, 2018 (Cross Reference D6034).
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), personnel records, and interview, testing personnel (TP) P did not have the required education elements to qualify and perform the duties of technical consultant at the date of survey on January 23, 2019. Findings include: 1. Review of the CLIA CMS-209 Form revealed that TP P was listed as the technical consultant. (See attached personnel code sheet.) 2. Review of the personnel records revealed that TP P did not possess the required education elements to qualify as technical consultant and TP P had performed and signed the training and competency assessments of fourteen (14) TP (Cross Reference D6029 and D6030). 3. An interview with the laboratory director, TP P and laboratory quality manager at approximately 11:30 AM confirmed the above findings.