Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0251888	07/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lake City Community Hospital	258 North Ron Mcnair Blvd, Lake City, SC	

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
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: During an onsite recertification on 7/20/22, review of policy and procedure manual, personnel interview, and observation, the lab failed to follow the policy that ensures positive identification for blood and blood products. Findings include: 1. Review of blood bank Quality Assurance (QA) manual (Amended on 01/20/2004) reveals that that the chart of the patient must be brought to the lab by nursing before blood or blood products can be signed out. Title "Signing out a unit of blood or blood product". Under subject "Blood bank signing out a unit of blood or blood product". Approved 11 /20/1997. The procedure states "The chart of the patient shall be brought to the laboratory by nursing personnel, ward secretaries, or nursing assistants. The chart shall be checked against the sign out book and the blood bank requisitions for the medical record number of the patient and the type of product ordered by the physician and the consent form. Any discrepency must be cleared up before the blood unit can be issued. " 2. Demonstration by testing personnel # 13 on CMS form 209 showed that only blood product requisition form and patient consent form were reviewed for identification.When asked, the testing person stated that patient charts are not used for positive identification but requisitions and patient consent forms are now used. 3. During an interview with lab supervisor at 12:30pm, it was confirmed that the lab no longer follows its procedure of reviewing patient charts to confirm patient identity before signing out blood and blood products. Only an order for blood products and patient consent is reviewed. Review of the blood issuance log from May to July 2022 revealed 11 units of blood were issued.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a lab tour, personnel interview, and lack of documentation, the lab failed to have a policy for outside submissions. Findings Include: 1. During a lab tour at 11am (7/20/22) , the question was asked if specimens were recieved from outside the facility and the response from lab supervisor was yes. A request was made for the procedure and it was revealed that the facility did not have a policy for it. 2.In an interview with the lab supervisor at 1:18pm (7/20/22) in the break room confirmed the findings.
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 Laboratory Quality Assurance (QA) manual, record review of Quality Control (QC) results, and confirmed with interview with lab personnel, the lab failed to follow its own policy for documenting corrective action. 1. Review of the lab QA policy section Corrective Action for QC (effective date 9/26/96) states that all repeats and corrective action must be documented in a corrective action log. 2. .A sampling of QC results were taken from March of 2020 and May of 2021 and identified three analytes with flags that had no documentation of corrective action. They were: a) Test date: 03/03/2020 Analyte Name: Albumin Flags: +3s b) Test date: 03/03/2020 Analyte Name: Calcium Flags: +3s c) Test date: 05/30/2021 Analyte Name: Lipase Flags: +3s 3.In an interview with lab personnel #2 (refer to CMS 209) at 2:40pm, it was confirmed that the lab did not follow its procedure for logging all failed QC with a corresponding action that was taken to correct.
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 BD Macrovue Rapid Plasma Reagin (RPR) package insert, laboratory RPR test procedure, laboratory room temperature record review, and testing personnel interview, it was determined that the laboratory failed to maintain acceptable room temperatures for a total of 45 days between January 2021 through July 2022. Findings include: 1. Review of the BD Macrovue RPR package insert revealed that with each test run, the testing environment should be verified to be between 23 and 29 degrees Celsius. 2. Review of the laboratory RPR test procedure revealed that with each test run and on a daily basis, the testing environment should be verified to be between 23 and 29 degrees Celsius. 3. Review of the laboratory's room temperature logs revealed temperatures were recorded as less than 23 degrees Celsius for a total of 45 days between January 2021 through July 2022. There was no corrective action for the out of range temperatures available for review on the day of the survey. 4. Testing personnel confirmed during an onsite interview on 07/21/2022 at 3:30 pm that the documented room temperatures were outside of the acceptable ranges.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Cepheid Gene Expert Assay implementation strategy, lack of documentation, and testing personnel interview, the laboratory failed to establish the number, type and frequency of testing control materials for the Cepheid Gene Expert SARS/COV 2 test procedure. Findings include: 1. Review of the the Cepheid Gene Expert Assay implementation strategy revealed that the laboratory director should determine the frequency of quality control (QC) testing, which might include; every test run, one time per week, one time per month, only when new reagents are received, and/or when lot numbers changed. 2. There was not an established or approved policy for the number, type and frequency of testing control materials available for review for the Cepheid Gene Expert SARS/COV 2 test procedure on the day of the survey. There was also not an established or approved Individualized Quality Control Procedure (IQCP) available for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 07/21/2022 at 3:30 PM, that the laboratory failed to establish the number, type and frequency of testing control materials for the Cepheid Gene Expert SARS/COV 2 test procedure.