

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0652158	(X3) Date Survey Completed 05/18/2021
Name of Provider or Supplier Ste Genevieve County Memorial Hospital	Street Address, City, State 800 Ste Genevieve Drive, Sainte Genevieve, MO	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of the procedure manual, personnel documentation, and interview with the General Supervisor (GS) #1, the laboratory failed to perform competency evaluations for 2020 and to date May 18, 2021 for 2 of 2 competency assessments for the position of technical supervisor and 1 of 1 competency assessments for the position of general supervisor. Findings: 1. Review of 2020, 2021 personnel documentation revealed the laboratory failed to perform competency evaluations for the position of technical supervisor #2 and #3 and general supervisor #1. 2. Review of the procedure manual revealed a lack of written policies and procedures to assess employees in the position of technical supervisor and general supervisor. 3. Interview with the GS #1 on May 18, 2021 at 11:00 AM confirmed the laboratory failed to have written policies and perform annual competencies for 2020 and to date May 18, 2021 for the positions of technical supervisor and general supervisor.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Review of immunohematology procedures, 2019/2020/2021 blood bank refrigerator alarm checks and interview with the general supervisor (GS) #1, the laboratory failed to follow "Blood Bank Temperature Alarm Check" procedure for seven of nine quarters. Findings: 1. Review of "Blood Bank Temperature Alarm Check" procedure states "The alarms systems for the blood bank refrigerator and freezer are verified on a quarterly basis during the months of March, June, September, and December". 2. Review of 2019 blood bank temperature alarm checks showed no alarm checks for 2019. Review of 2020 blood bank temperature alarm checks showed no blood bank alarm checks in March or June 2020. 3. Review of "Blood Bank Temperature Alarm Check" procedure states "This laboratory's Alarm Settings are: High Alarm +5.5 degrees Celsius Low Alarm +1.5 degrees Celsius". 4. Review of April 2021 blood bank alarm check showed the high alarm activated at 8.1 degrees Celsius. 5. Interview with the GS #1 on May 18, 2021 at 1:00 PM confirmed the laboratory failed to follow procedure to perform blood bank alarms quarterly and failed to ensure they activate at correct temperatures.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
 Based on review of Cardinal Health blood bank saline manufacturer's package insert, observation of saline 20 Liter saline box, Biorad liquichek Lot#60272 and 60271, freezer temperature logs for 16 out of 16 months and interview with general supervisor #1, the laboratory failed to follow manufacturer's instructions for reagent handling. Findings: 1. Review of the Cardinal Health package insert for the saline indicated open stability for saline is 30 days. 2. Observation of the saline box in use indicated open date April 12, 2021 on survey date of May 18, 2021. 3. Observation of the BioRad Liquichek Lot #60272 and 60271 bottles in freezer indicated storage requirement of -20 degree Celsius to -70 degree Celsius. 4. Review of the freezer temperature logs where BioRad Liquidchek was stored for 2020 and 2021 up to date of May 18, 2021 indicated the temperature for the Cardinal Health Freezer to be continually warmer than -20 degree Celsius. 4. Interview with GS#1 on May 18, 2021 at 11:30 AM confirmed the laboratory failed to follow manufacturer's instructions for reagent handling of saline and BioRad Liquidchek controls.

D6076

LABORATORY DIRECTOR
 CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
 Based on review of performance specifications, quality control (QC) program, quality assessment programs, and chemistry QC, the laboratory director failed to provide

overall management and direction of the laboratory. The laboratory director failed to ensure performance specifications for the ABL 90 Flex Plus and the ACL Top were adequate before performing patient testing (Refer to D6086); the laboratory director failed to establish and maintain the QC program (Refer to D6093); the laboratory director failed to ensure quality assessment programs are established and maintained (Refer to D6094); and the laboratory director failed to ensure QC was within acceptable limits before reporting patients results (Refer D6097).

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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:
Review of verification of performance specifications for the ABL 90 Flex Plus blood gas analyzer, ACL Top analyzer and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure verification procedures are adequate to determine pertinent performance characteristics of the method. Findings: 1. Review of the ABL 90 Flex Plus verifications of performance specifications showed no reportable range of test results for the ABL system and no verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the analytes pH, pCO₂, pO₂, HCO₃, TCO₂, and O₂. 2. Review of the ACL Top verification of performance specifications showed no verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for the analytes prothrombin time, partial thromboplastin time, D-Dimer, fibrinogen and Anti-factor Xa. 3. Interview with the GS #1 on May 18, 2021 at 1:30 PM confirmed the LD failed to ensure verification procedures for the ABL 90 Flex Plus and the ACL Top were adequate to determine pertinent performance characteristics of the method.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Review of 2019/2020/2021 serum pregnancy kit test, medtox urine toxicology analyzer, TLIQ fetal fibronectin, Cepheid Genexpert and Amnisure ROM quality control (QC) and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure the quality control programs are established and maintained to assure the quality of laboratory services. Findings: 1. Review of the 2019/2020/2021 patient results reported and QC showed QC was not performed every day of patient testing for: Serum pregnancy kit showed 135 patients were resultated. Medtox urine toxicology showed 1061 patients were resultated. TLIQ fetal fibronectin showed 24 patients were resultated. Cepheid clostridium difficile 424 patients were resultated. Cepheid SARS CoV2 1009 patients were resultated. Cepheid CoV2/Flu AB 145 patients were resultated. Cepheid Flu AB 733 patients were resultated. Amnisure

ROM 155 patients were resulted. 2. Interview with the GS #1 on May 18, 2021 at 1:45 PM confirmed the LD failed to ensure the quality control programs are established and maintained to assure the quality of laboratory services.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Review of the quality assurance policy, the Vitros 5600 Chemistry analyzer quality control (QC), Vitros 5600 Unity peer review and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure quality assessment programs are established and maintained. Findings: 1. Review of "Quality Assurance Control Plan" states "Specific rules used to accept or reject shift and/or run quality control are found in the laboratory procedure for each specific test. Quality data will be reviewed for shift and trends by monthly monitor and review of the cumulative data by the medical director, administrative director, manager, supervisor, or designee." No documentation in the Vitros 5600 procedure could be provided for shifts and trends. 2. Review of Vitros 5600 QC showed testing personnel accepting chemistry QC in the laboratories LIS system, with no levey jennings charts or graphs reviewed. No documentation of QC shifts or trends could be provided. 3. Review of Vitros 5600 chemistry peer review showed for March 2021 the indirect bilirubin, total bilirubin, creatinine kinase and Free thyroxine (T4) values were "above -2 and below 2" for method SDI. No documentation for the discrepancies were documented on the peer review cover page. 4. Interview with the GS #1 on May 18, 2021 at 1:30 PM confirmed the LD failed to ensure chemistry quality assessment programs are established and maintained.

D6097

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(7)

The laboratory director must ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:
Review of Vitros 5600 chemistry analyzer quality control (QC), patient results, and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure the chemistry analyzer was functioning properly before patient test results were reported. Findings: 1. Review of the Vitros 5600 chemistry analyzer showed on May 6, 2021, level 2 control for total bilirubin (TBil) was not within acceptable limits. On May 6, 2021 the laboratory reported 40 TBil patient results. 2. Interview with the GS #1 on May 18, 2021 at 1:45 PM confirmed the LD failed to ensure the chemistry analyzer was functioning properly before patient test results were reported.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each

consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with General Supervisor #1, the laboratory director failed to specify, in writing, the responsibilities and duties of the technical supervisor engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing for immunohematology and failed to specifically delegate to qualified staff the competency evaluation duties being performed in immunohematology. 1. Review of the procedure manual reveal that laboratory director failed to specify in writing the responsibilities and duties for the technical supervisor of immunohematology. 2. Interview with the General Supervisor #1 on May 18, 2021 at 11:10 A.M. confirmed that the laboratory director had not specified in writing the responsibilities and duties for the technical supervisor of immunohematology.