Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0442231	10/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Southeast Of Stoddard County	1200 N One Mile Rd, Dexter, 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
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on observation of urine specimens stored in the blood bank refrigerator and interview with testing personnel (TP) #1, the laboratory failed to minimize contamination of stored packed red blood cell units in the blood bank refrigerator. Finding: 1. Observation of the blood bank refrigerator revealed the laboratory failed to minimize contamination of stored blood units by storing four urine specimens with available inventory of packed red blood cell units. 2. Interview with TP #1 on October 27, 2020 at 10:30 AM confirmed the laboratory failed to minimize contamination of blood units by storing four urine specimens with packed red blood units in the blood bank refrigerator.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the blood bank department the laboratory failed to meet the

	requirements for the specialty of immunohematology. The laboratory failed to follow procedures for compatibility testing; (Refer to D5551) and failed to to perform blood bank alarm checks; (Refer to D5555).
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the transfusion service testing record, laboratory's procedure manual and interview with testing personnel (TP) #1, the laboratory failed to follow the laboratory's procedure for immediate spin crossmatch (ISC) to detect ABO blood group incompatibility. Findings: 1. Review of the transfusion service testing record for November 23, 2020 at 10:00 AM showed the laboratory failed to perform and document the ISC for compatibility testing between patient and donor sample on blood cell unit number W204020177899 that was transfused. 2. Review of the laboratory's procedure manual showed the ISC procedure is required for all patients transfusion workups. 3. Interview with TP #1 on October 27, 2020 at 10:30 AM confirmed the laboratory failed to follow the laboratory's procedure manual for ISC.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of blood bank alarm procedure, alarm checks in 2019/2020 and interview with the testing personnel #1, the laboratory failed to perform blood bank alarm checks according to blood bank procedure. Findings: 1. Review of "Policy: Blood Bank Maintenance" revealed "The alarm on the blood bank refrigerator is checked every 3 months by Clinitek BioMed". 2. Review of 2019 blood bank alarm checks showed no documentation of blood bank alarm checks for first or second quarter of 2019. 3. Interview with testing personnel #1 on October 27, 2020 at 11:00 AM confirmed the laboratory failed to follow blood bank alarm procedure.
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 quality assessment programs, general supervisor on-site supervision and interview with the general supervisor (GS) and technical consultant (TS) #2 the laboratory director failed to ensure the quality assessment programs are established and maintained (Refer to D6094) and the laboratory director failed to ensure that a general supervisor provides on-site supervision of high complexity test performance (Refer to D6100).
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 Cobas c 501 chemistry analyzer September/October 2020 quality control (QC), patient records and interview with testing personnel # 1, the laboratory director failed to ensure that the quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. On October 15, 2020 Alkaline Phosphatase level 1 QC was unacceptable and 63 patients test results were reported. 2. On October 20, 2020 Alkaline Phosphatase level 1 QC was repeated five times before QC results were acceptable, notes in laboratory reporting system stated "see corrective action log". Review of corrective action log showed lack of documentation on corrective action log for October 20, 2020. 3. Interview with testing personnel #1 on October 27, 2020 at 11:30 AM confirmed the laboratory director failed to ensure that the quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4). This STANDARD is not met as evidenced by: Based on interview with the general supervisor (GS) and technical supervisor (TS) the laboratory director failed to ensure that the GS provides on-site supervision of high complexity test performance by testing personnel. Findings: 1. Interview with GS revealed GS is onsite five to ten percent of laboratory working hours a week. 2.

	Interview with the GS and TS on October 27, 2020 at 11:45 AM confirmed the laboratory director failed to ensure that the GS provides on-site supervision of high complexity test performance by testing personnel.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of 2019/2020 hematology, coagulation and chemistry quality control (QC) and interview with the general supervisor (GS) and technical consultant (TS) #2 the TS failed to ensure acceptable levels of analytic performance and ensure that these levels are maintained throughout the testing process. Findings: 1. Review of 2020 Beckman Coulter Hematology QC showed lack of documentation for TS review of hematology QC form April to September. 2. Review of 2019 prothrombin time, partial thromboplastin time, Ddimer QC showed lack of documentation for TS review of prothrombin time, partial thromboplastin time, Ddimer QC for June, July and December. 3. Review of 2020 prothrombin time, partial thromboplastin time, Ddimer QC showed lack of documentation for TS review of prothrombin time, partial thromboplastin time, Ddimer QC for February and May. 4. Review of 2019 Cobas c 501 chemistry QC showed lack of documentation of TS review for the year. 5. Review of 2020 Cobas C 501 chemistry QC showed lack of documentation of TS review for January, February, March, April, July, August and September. 6. Interview with the GS and TS #2 on October 27, 2020 at 11:45 AM confirmed the TS failed to ensure acceptable levels of analytic performance and ensure that these levels are maintained throughout the testing process.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

	This STANDARD is not met as evidenced by: Based on review of 2019/2020 hematology, chemistry, coagulation quality control (QC), peer review, blood bank maintenance and interview with the general supervisor (GS) and technical consultant (TS) #2, the laboratory failed to have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. Findings: 1. CLIA inspectors entered the facility on October 27, 2020 at 8: 00 AM. During the laboratory survey the laboratory failed to provide: -2020 Beckman Coulter Hematology QC peer review from April to September. -2019 prothrombin time, partial thromboplastin time, Ddimer QC review for June, July and December. -2020 prothrombin time, partial thromboplastin time, Ddimer QC review for February and May. -2019 Cobas c 501 chemistry QC review for the year. -2020 Cobas C 501 chemistry QC review for January, February, March, April, July, August and September. -2019 blood bank alarm checks. 2. Observation of laboratory showed lack of GS and TS knowledge of where laboratory documentation was stored. 3. Interview with the general supervisor (GS) and technical consultant (TS) #2 on October 27, 2020 at 11:00 AM confirmed the the laboratory failed to have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.