Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0672706	08/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Fulton Reception & Diagnostic Center	1393 Highway O, Po Box 190, Fulton, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) and interview with the general supervisor (GS) #1, the laboratory failed to retain QC for human immunodeficiency virus (HIV) and syphilis for 2019, 2020 to August 16, 2021. Findings: 1. Review of chemistry QC for the two BioRad BioPlex 2200 analyzers showed the laboratory could not provide HIV or syphilis QC for 2019, 2020 to August 1, 2021 on the analyzer serial number (SN)2200-0808, and the analyzer SN 2200-0522. 2. Interview with the GS #1 on August 24, 2021 at 1:00 PM confirmed the laboratory could not provided QC for the two BioRad BioPlex 2200 analyzer's.
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 BioRad BioPlex 2200 analyzer procedure, 2020/2021 calibrations and interview with the general supervisor (GS) #1 the laboratory failed to follow "BioRad" procedure. Findings: 1. Review of BioRad BioPlex 2200 analyzer

	procedure states "Calibration is recommended every 14 to 30 days". 2. Review of human immunodeficiency virus (HIV) and syphilis calibrations showed: July 2021 calibration performed at 33 days April 2021 calibration performed at 36 days March 2021 calibration performed at 32 days January 2021 calibration performed at 32 days December 2020 calibration performed at 45 days November 2020 calibration performed at 31 days September 2020 calibration performed at 34 days August 2020 calibration performed at 31 days July 2020 calibration performed at 34 days June 2020 calibration performed at 31 days January 2020 calibration performed at 31 days 3. Interview with the GS #1 on August 24, 2021 at 11:00 AM confirmed the laboratory failed to follow BioRad procedure for calibrations.
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 review of the BioRad BioPlex 2200 operator's guide, the BioRad Evolis operator's guide, temperature logs and interview with the general supervisor (GS) #1, the laboratory failed to follow manufacturer's instructions for monitoring and documenting humidity. Findings: 1. Review of the BioRad BioPlex 2200 operator's guide for environmental requirements states "Relative Humidity 10 - 90%, non-condensing, actively controlled." 2. Review of the BioRad Evolis operator's guide for environmental requirements states "Relative Humidity 10 - 90%, non-condensing." 3. Review of temperature logs showed no documentation for humidity in 2019, 2020 and to date August 24, 2021. 4. Interview with GS #1 on August 24, 2021 at 12:00 PM confirmed the laboratory failed to follow manufacturer's instructions for monitoring and documenting humidity.
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 review of calibration records for the BioRad BioPlex 2200 chemistry analyzers and interview with the general supervisor (GS) #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of the calibration records for 2019, 2020 and to date August 24, 2021 for human immunodeficiency virus (HIV) showed the laboratory did not perform calibration verification that included at least a minimal value, a mid-point value and a maximum value near the upper limit every six months for BioRad BioPlex 2200 serial number (SN) 2200-0808 and SN 2200-0522. 2. Interview with the GS #1 on August 24, 2021 at 11:00 AM confirmed the laboratory failed to include a midpoint calibrator in the calibration verification procedure for HIV at least once every six months.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the 2019/2020/2021 proficiency testing (PT) records and interview with the general supervisor (GS) #1, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the 2019 chemistry core- third event PT records showed the laboratory obtained a not graded result for troponin I (qualitative), sample CM-15. The laboratory could not provide documentation to show appropriate staff evaluated the not graded result to identify any problems that may require corrective action. 2. Review of the 2020 chemistry core- second event PT records showed the laboratory obtained a not graded result for troponin I (qualitative), sample CM-10. The laboratory could not provide documentation to show appropriate staff evaluated the not graded result to identify any problems that may require corrective action. 3. Review of the 2021 chemistry core- first event PT records showed the laboratory obtained a not graded result for troponin I (qualitative), sample CM-04. The laboratory could not provide documentation to show appropriate staff evaluated the not graded result to identify any problems that may require corrective action. 4. Interview with the GS #1 on August 24, 2021 at 11:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)

	The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the 2019/2020/2021 proficiency testing (PT) records and interview with the general supervisor (GS) #1, the laboratory director failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Findings: 1. Review of 2021 chemistry core- first event PT record showed the laboratory obtained an unacceptable result for specimen: CM-01 Tropinin I (qualitative) 2. No corrective action documentation was available to show the laboratory investigated the unacceptable PT result. 5. Interview with the GS #1 on August 24, 2021 at 11:00 AM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.