Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0648254	06/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kansas Health And Environmental Lab	6810 Se Dwight Street, Topeka, KS	

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
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 the Individualized Quality Control Plan (IQCP) for the BioFire Respiratory Panel 2.1, review of BioFire Respiratory Panel 2.1 quality control (QC) documentation, patient reports, and interview with the technical supervisor (TS) #1, the laboratory failed to follow the procedure for QC frequency. Findings: 1. Review of the BioFire Respiratory Panel 2.1 IQCP showed "the laboratory will run a positive and negative control with each lot/shipment of reagents and monthly thereafter." 2. Review of the BioFire Respiratory Panel 2.1 QC logs revealed the laboratory failed to perform QC in December 2021, May 2022, and December 2022. 3. The laboratory reported one Respiratory Panel patient result in December 2021, five Respiratory Panel patient results in May 2022, and four Respiratory Panel patient results in December 2022. 4. Interview with TS #1 confirmed the laboratory failed to follow the procedure for performing QC monthly for Respiratory Panels.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256

	(g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of titered Rapid Plasma Reagin (RPR) quality control (QC) logs, RPR patient reports, and interview with the technical supervisor (TS) #1, the laboratory failed to perform a positive titered control for Syphilis testing. Findings: 1. Review of 2022 to date June 21, 2023 RPR QC logs showed the laboratory failed to include a positive titered control at least once a day for Syphilis testing. 2. The laboratory resulted 1800 titered RPR patient reports for 2022 and to date June 21, 2023. 3. Interview with TS #1 on June 21, 2023 at 11:00 AM confirmed the laboratory failed to perform a known titered RPR control material each day of patient testing.
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 D-B 2022 Bacteriology Proficiency Testing (PT) results for bacteria identification and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure all PT results are evaluated to identify any problems that require corrective action. Findings: 1. Review of D-B 2022 Bacteriology PT revealed an unacceptable result for specimen D-09 for bacteria identification with no evaluation. 2. Interview with the TS #2 on June 23, 2023 at 9:00 AM confirmed the LD failed to ensure all PT results were evaluated to identify any problems that require corrective action.
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 Newborn Screening quality control (QC) records for 2023 and interview with the technical supervisor (TS) #3, the TS #3 failed to ensure the establishment of acceptable levels of analytical performance for QC. 1. Review of the RNaseP control SCID0001 for Severe Combined Immunodeficiency (SCID) revealed a range of 22.36-26.60 entered for the RNaseP control. 2. Review of the Levey-Jennings (LJ) graphs for RNaseP control SCID0001 for SCID showed an acceptable range of 23.5-26.50. 3. Review of the QC documents for June 20, 2023, showed the SCIDB0001 QC result was 22.83. TP #1 and TP #2 approved the SCIDB0001 QC result. 4. Review of the QC document worksheet showed TP #3 approved the daily LJ

	graph for June 20, 2023. 5. The laboratory reported 153 SCID patient reports on June 20, 2023. 6. Interview with TS #3 confirmed TS #3 failed to establish parameters for acceptable levels of analytic performance.