

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0648254	(X3) Date Survey Completed 07/29/2021
Name of Provider or Supplier Kansas Health And Environmental Lab	Street Address, City, State 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the technical supervisors (TS) #2, 5, 7, 9, the laboratory failed to include reference intervals (normal values). Findings: 1. Review of the procedure manuals for newborn screening for Galactosemia, Lysosomal Storage Disorder (LSD), 17-hydroxyprogesterone (OHP), Severe Combined Immunodeficiency (SCID) showed no reference intervals. 2. Review of the serology/immunology procedure manuals for human immunodeficiency virus (HIV), rapid plasma reagin (RPR), hepatitis C (Hep C), and SARS-CoV-2 IgG, IgM antibodies showed no reference intervals. 3. Review of the</p>

	<p>virology procedure manual for Saliva Direct COVID-19 revealed a lack of reference intervals. 4. Interview with the TS #2, 5, 7, 9 on July 29, 2021 at 4:00 PM confirmed the laboratory failed to include reference intervals (normal values) for Galactosemia, LSD, OHP, SCID, HIV, RPR, Hep C, SARS-CoV-2 IgG, IgM antibodies, and Saliva Direct COVID-19.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of three of three opened bottles of Bio-Rad Lyphochek quality control (QC) for blood lead testing, review of manufacturer's inserts, patient reports, and interview with testing personnel (TP) #18, the laboratory failed to use unexpired QC material. Findings: 1. Observation of the refrigerator in the blood toxicology laboratory showed three bottles of Bio-Rad Lyphochek QC (level 1 lot number 38921, level 2 lot number 38922, level 3 lot number 38923) in use with no open date and a manufacturer non reconstituted expiration date of October 31, 2021. 2. Review of the Bio-Rad Lyphochek whole blood control for lead testing package insert revealed "14 day reconstituted stability at 2-8 degrees Celsius." 3. Approximately 3000 whole blood lead patient results were reported for 2020. 4. TP #18 stated on July 27, 2021 at 10:00 AM "the QC is good until the expiration date on the bottle." TP #18 confirmed the laboratory used QC material past the reconstituted expiration date.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation for the BioFire Respiratory Panel 2.1, Individualized Quality Control Plan (IQCP), and interview with the technical supervisor (TS) #2, the laboratory failed to perform QC as established by the laboratory. 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 QC logs revealed the laboratory failed to perform QC in November 2020, March 2021, and May 2021. 3. Interview with TS #2 confirmed the laboratory failed to perform QC monthly as specified by the laboratory.</p>
<p>D5775</p>	<p>COMPARISON OF TEST RESULTS</p>

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of 2019, 2020, and to date July 29, 2021 instrument comparisons and interview with technical supervisors (TS) #1, 2, 5, 7, 9, the laboratory failed to perform instrument comparisons two times a year. Findings: 1. The laboratory failed to perform instrument comparisons for two of two sets of Baebies analyzers, two of two Waters 2777C mass spectrophotometers, two of two Bio-Rad HPLC, and two of two PerkinElmer AutoDELPHIA for newborn screening. 2. The laboratory failed to perform instrument comparisons for three ABI Fast 7500 DX analyzers, two Quant Studio analyzers, and the Evolis and rapid plasma reagin (RPR) manual method for serology/immunology testing. 3. The laboratory failed to perform instrument comparisons for 16 7500 Fast Track PCR analyzers used for Sars COVID-2 molecular testing, 4. Interview with TS #1, 2, 5, 7, 9 on July 29, 2021 at 4:00 PM confirmed the laboratory failed to perform instrument comparisons twice a year to evaluate and define the relationship between test systems reporting the same analyte.