

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0648254	<b>(X3) Date Survey Completed</b>  08/22/2019
<b>Name of Provider or Supplier</b>  Kansas Health And Environmental Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and confirmed by interview, the laboratory failed to have a procedure approved and signed by the laboratory director prior to reporting patient results for Cadmium and Mercury. Findings include: 1. Review of five patient reports from 2/21/19, for the analyte blood lead revealed that the analytes cadmium and mercury were being reported. 2. Interview with Technical Supervisor #2 (on CMS 209 form) on 8/21/19 at approximately 1:10 pm confirmed that patients results were being reported and that there was no procedure available. This is a repeat deficiency.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of five patient reports for the analyte Blood Lead, lack of procedures for Cadmium and Mercury testing, and interview of Technical Supervisor, the</p>

laboratory did not verify the performance specifications for Cadmium and Mercury testing prior to reporting patient results. Findings include: 1. Five patient reports from 2/21/19 were reviewed, blood lead, cadmium, and mercury results were reported. 2. There was no approved procedure for the cadmium and mercury testing available. 3. Interview on 8/21/19 at approximately 1:10 pm with Technical Supervisor #2 (on the form CMS 209) confirmed that there was no verification of performance specifications performed and patient specimens are being analyzed and reported for cadmium and mercury.