

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D2167587	<b>(X3) Date Survey Completed</b> 09/13/2022
<b>Name of Provider or Supplier</b> Cedx Laboratories Inc	<b>Street Address, City, State</b> 200 Innovative Way, Ste 1305, Nashua, NH	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of routine chemistry testing twice in 2021. Findings include: 1) Review of the test menu completed by the laboratory, revealed the laboratory performs testing for 11-Dehydro Thromboxane B2. The laboratory was not able to provide documentation at the time of survey that the accuracy of 11-Dehydro Thromboxane B2 testing was verified twice in 2021. 2) Interview on 9/13/2022 at 9:45 a.m. with the Technical Supervisor confirmed the laboratory did not verify accuracy of 11-Dehydro Thromboxane B2 testing in 2021.</p>
<b>D6125</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the competency assessments failed to include assessment of test performance for 1 of 1 testing personnel performing routine chemistry testing in 2021. Findings include: 1) Review on 9/13/2022 of annual training and competency assessment documentation revealed a competency assessment was completed 10/29/2021 for 1 of 1 testing personnel. Further review</p>

revealed no documentation for an assessment of test performance. 2) Interview on 9/13 /2022 at 9:45 a.m. with the Technical Supervisor confirmed no assessment of test performance had been conducted.