

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2187802	<b>(X3) Date Survey Completed</b>  03/15/2023
<b>Name of Provider or Supplier</b>  Central Lab Partners	<b>Street Address, City, State</b>  124 West Boylston St, Worcester, MA	
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>D0000</b>	A CLIA recertification survey was conducted for the Central Lab Partners laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
<b>D6115</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by:                      . Based on record review and interview the technical supervisor failed to ensure the establishment of the laboratory's test performance characteristics and that the verification of the test procedures performed were adequate for accuracy, precision, sensitivity and specificity, when applicable, prior to patient testing and reporting for thirteen (13) of thirteen (13) toxicology and routine chemistry analytes on a newly implemented chemistry analyzer as evidenced by the following: Mindray 800 a) A review of validation studies for thirteen (13) of thirteen (13) analytes for the Mindray 800 chemistry analyzer implemented on 2/8/22 revealed no documented review and approval by the technical supervisor prior to the implementation of the analyzer for patient testing and reporting. The documented review by the technical supervisor was on 2/13/23. b) Technical supervisor number 2 confirmed in an interview on 3/15/23 at 9:39 a.m. that he had reviewed and signed off on the validation studies after the implementation of the Mindray 800 analyzer for patient testing and reporting.</p>