

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0935548	<b>(X3) Date Survey Completed</b>  07/12/2023
<b>Name of Provider or Supplier</b>  New England Newborn Screening Program	<b>Street Address, City, State</b>  377 Plantation 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 New England Newborn Screening Program 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>D5423</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to: 1) establish performance specifications for newly implemented test procedures; and, 2) failed to perform adequate validation studies to validate all aspects of test performance as evidenced by the following: SMN2 gene copy number - Precision and Sensitivity : a) In May of 2023 the laboratory put into place a new test for the SMN2 gene copy number used in detecting spinal muscular atrophy (SMA)disease. A review of the validation study for the SMN2 gene copy test revealed that the laboratory failed to: 1) establish performance specifications for precision and sensitivity; and, 2) perform precision and sensitivity studies prior to implementing the test for patient sample testing and reporting. b) The technical supervisor confirmed in an interview on 7/12</p>

/23 at 10:53 am that the laboratory had not included precision and sensitivity as part of the validation for the test. c) The laboratory has performed a total of one (1) patient sample annually.