

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2235281	(X3) Date Survey Completed 09/20/2023
Name of Provider or Supplier New Vision Therapy Llc Lab	Street Address, City, State 1100 Revolution Mill Drive, Greensboro, NC	
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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE 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 upon review of records to establish the performance specifications of urine toxicology performed on the LC/MS instrument and interview with TP (Testing Personnel) #1 on 9/20/2023, the laboratory failed to perform a study to assess the storage requirements and stability of urine toxicology specimens. Findings: The review of records to establish the performance specifications of urine toxicology on the LC/MS instrument revealed the absence of documentation assessing the storage requirements and stability of urine. During interview at approximately 3:15 p.m., TP #1 stated she was in the process of performing studies to assess the storage requirements and stability of urine toxicology samples.</p>