

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2105179	(X3) Date Survey Completed 06/18/2024
Name of Provider or Supplier Specialty Laboratories	Street Address, City, State 13530 Michigan Ave Suite L11, Dearborn, MI	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor, the laboratory failed to follow the laboratory policy in evaluating ungraded proficiency testing results for 1 (2022 Hematology Coagulation 3rd Event) of 12 events reviewed. Findings include: 1. A record review of the laboratory's proficiency testing for the 2022 Hematology Coagulation 3rd Event lacked evaluation of ungraded results that were outside of the expected results as follows: a. 2022 Hematology / Coagulation - 3rd Event: i. Platelet Estimate Expected Result was "Adequate / Normal" and the laboratory's result was "Increased." ii. Blood Cell ID - ECI - 13 Expected Result was "See Commentary" and the laboratory's result was "Macrocytic red blood cell." 2. The laboratory failed to document corrective action according to laboratory policy under "Proficiency Testing", - #1, "Corrective action is required whenever an unacceptable response is obtained." - #2, "Investigation and evaluation is required whenever a test result is ungraded due to the non-consensus." - #5, "The supervisor will review the written guidelines with testing personnel." - #9, "The corrective action report will be attached to and filed with the proficiency test report." 3. An interview with the General Supervisor on 6/17/2024 at 10:47am confirmed evaluation of ungraded results was not performed and documented according to laboratory policy.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the laboratory failed to establish performance specifications for the stability of specimens stored for 2 (June 2022 to June 2024) of 2 years reviewed. Findings include: 1. A review of patient test records revealed Patient #2 had a specimen collected urine quantitative toxicology testing on 11/10/22 and testing was performed on 11/25/22, a total of 15 days from collection to results. 2. The surveyor observed patient urine specimens in the freezer on 6/18/24 at 2:09 pm. 3. A review of the laboratory's establishment of performance specification data for its urine quantitative toxicology testing revealed a lack of information for how the laboratory determined patient specimen stability. 4. An interview on 6/18/24 at 2:36 pm with the General Supervisor revealed the laboratory stores urine specimens at room temperature before performing screening testing, then freezes the specimen until the confirmation can be performed. The General Supervisor confirmed the laboratory had not established performance specifications for urine specimen storage to ensure analyte stability over time prior to testing and reporting patient results.