

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0892882	(X3) Date Survey Completed 02/12/2020
Name of Provider or Supplier M Health Fairview - Bethesda Hospital Laboratory	Street Address, City, State 559 Capitol Blvd, Saint Paul, MN	
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 document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2019 proficiency testing (PT) score when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed manual microscopic analysis of urine sediment testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:10 p.m. on 02/12/20. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. One urine sediment result from the first 2019 Hematology PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte US-02 Urine Sediment 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above analyte was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 5. In an interview at 2:55 p.m. on 02/12/20, the GS confirmed the above finding.</p>