

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2048955	(X3) Date Survey Completed 10/03/2018
Name of Provider or Supplier Duly Health And Care - Lisle Lab	Street Address, City, State 430 Warrenville Rd - Ste 210, Lisle, IL	
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 review of laboratory records and interview with the technical supervisor (TS); the laboratory failed to verify the accuracy of ungraded proficiency testing (PT) analyte performance for the second PT event of 2018. Findings Include: 1. Review of American Proficiency Institute (API) Hematology/Coagulation PT documentation for event 2 of 2018 found that the laboratory's performance was not graded for the following analytes: Erythrocyte Count, Hematocrit, Hemoglobin, IG absolute, IG percent, Immature Platelet Fraction, INR, IRF, Leukocyte Count, MCH, MCHC, MCV, MPV, Nucleated RBCs, Partial Thromb. Time, Platelet Count, Prothrombin Time, RDW-CV, RDW-SD, Reticulocyte Count, Reticulocyte Hgb, Sedimentation Rate, White Blood Cell Differential. 2. Review of the laboratory's PT policy, "Proficiency Testing", stated on page 3 the following: "5. Evaluate all ungraded responses and perform a self-evaluation to verify the accuracy of analytes that are not graded". 3. Review of PT corrective action documentation for event 2 of 2018 failed to address the performance of the ungraded analytes. 4. On survey date 10-03-2018, at 2:45 pm, the TS confirmed that a self-evaluation was not performed for 2018 event 2, Hematology/Coagulation ungraded analytes.</p>