

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2049939	(X3) Date Survey Completed 10/16/2024
Name of Provider or Supplier Duly Health & Care - Plainfield Lab	Street Address, City, State 12004 S Route 59, Ste 100, Plainfield, 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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical consultant (TC); the TC failed to ensure 11 of 11 testing personnel (TP) received training on the Sysmex XN - 450 (SN: 12918) hematology analyzer prior to testing hematology analytes (Hematocrit, Hemoglobin, Platelet Count, Red Blood Cell Count, White Blood Cell Count (WBC), WBC Automated Differential) from 12/06 /2022 to 10/17/2024, affecting more than 2099 patient tests (Refer to D6045). The TC failed to provide hematology competency assessment documentation for 11 of 11 testing personnel in 2022 and 2023 (Refer to D6046).</p>
D6045	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical consultant (TC); the TC failed to ensure 11 of 11 testing personnel (TP) could perform and provide accurate test results for hematology analytes (Hematocrit,</p>

Hemoglobin, Platelet Count, Red Blood Cell Count, White Blood Cell Count (WBC), WBC Automated Differential) utilizing the Sysmex XN - 450 (Serial Number: 12918) prior to patient testing from 12/06/2022 to 10/17/2024, affecting more than 2099 patient tests. Findings include: 1. Review of laboratory records revealed the laboratory began to perform hematology testing on the Sysmex XN - 450 (Serial Number: 12918) on 12/06/2022 for the following analytes; Hematocrit, Hemoglobin, Platelet Count, Red Blood Cell Count, White Blood Cell Count (WBC), WBC Automated Differential. 2. Review of laboratory personnel records and lack of documentation of training revealed the TC failed to ensure 11 of 11 TP received training on the Sysmex XN - 450 (SN: 12918) hematology analyzer prior to patient testing, affecting more than 2099 patient tests. 3. On 10/16/2024, at 12:20 p.m., the TC confirmed they failed to provide training on the Sysmex XN - 450 analyzer.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the technical consultant (TC); the TC failed to perform competency assessments for hematology testing performed for 11 of 11 testing personnel (TP) in 2022 and 2023. Findings include: 1. Review of laboratory records revealed no hematology (Hematocrit, Hemoglobin, Platelet Count, Red Blood Cell Count, White Blood Cell Count (WBC), WBC Automated Differential) competency assessments were documented for 11 of 11 testing personnel (TP) in 2022 and 2023. 2. On 10/16/2024, at 12:15 p.m., an interview with the TC stated the 2022 and 2023 competency records were disposed of by the moving company.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of laboratory records, lack of documentation, CMS-209 (Laboratory Personnel Report) and interview with the technical consultant (TC); 1 of 11 testing personnel (TP 6) failed to meet the qualification requirements for moderate complexity hematology testing (Refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology

from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation, CMS-209 (Laboratory Personnel Report) and interview with the technical consultant (TC); 1 of 11 testing personnel (TP 6) failed to meet the qualification requirements for moderate complexity hematology testing. Findings include: 1. Review of the CMS-209 and laboratory records revealed no education documentation for 1 of 11 TP, TP 6. 2. On 10/16/2024, at 11:46 a.m., the TC confirmed the laboratory had no education documentation for TP 6.