

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0202709	(X3) Date Survey Completed 03/17/2022
Name of Provider or Supplier Far Northeast Surgical Center	Street Address, City, State 2751 Comly Road, Philadelphia, PA	
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
D2154	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and the interview with the Center Manager (CM), the laboratory failed to obtain a 100 percent score in 1 of 3 PT events for Immunohematology in 2020. Findings Include: 1. On the day of survey, 03/17/2022 at 09:50 a.m., review of AAB PT records revealed, the laboratory received a score of 60% for D (Rho) Typing Event 2 in 2020. 2. The CM confirmed the finding above on 03/17/2022 at 12:00 p.m.</p>
D2159	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and the interview with the Center Manager (CM), the laboratory failed to submit proficiency testing results within the appropriate time frame for 1 of 3 PT events for Immunohematology in 2021. Findings Include: 1. On the day of survey, 03/17/2022 at 09:50 a.m., review of AAB PT records revealed, the laboratory received a score of 0% for D (Rho)Typing Event 3 in 2021. 2. The CM confirmed the finding above on 03/17/2022 at 12:00 p.m.</p>

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on the review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and the interview with the center manager (CM), the laboratory director failed to identify problems that required a corrective action for 2 of 6 Immunohematology events in 2020 and 2021. Findings include: 1. On the day of survey, 03/17/2022 at 09:50 a.m., review of AAB PT records revealed, the laboratory did not document corrective actions for the following AAB immunohematology PT scores that were less than 100% in 2020 and 2021: - AAB 2020 Event 2, D (Rho) typing 60%. - AAB 2021 Event 3, D (Rho) typing 0%. 2. The CM confirmed the findings above at 03/17/2022 at 12:00 a.m. * Repeated deficiency.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on the review of testing personnel (TP) competency assessment records, review of American Association of Bioanalysts (AAB) 2020 and 2021 proficiency testing (PT) attestation records and interview with the Center Manager (CM), the Technical Consultant (TC) failed to assess the competency of 2 of 6 TP through internal blind samples or external PT samples in 2020 and 2021. Findings Include: 1. On the day of survey, 03/17/2022 at 9:35 a.m., review of TP competency assessment records and AAB PT attestation records revealed, the TC did not assess 2 of 6 TP (CMS 209 personnel #5 and #7) for D (Rho) typing through internal blind samples or external PT samples in 2020 and 2021. 2. The CM confirmed the finding above on 03/17/2022 at 12:00 p.m. * Repeated deficiency.