| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 39D0202709 | 12/14/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Far Northeast Surgical Center | 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 |
|---|---|
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of American Association of Bioanalysts/ Medical Laboratory Evaluation (AAB/MLE) proficiency testing (PT) records and interview with the Director of Clinical Services (DCS), the laboratory director (LD)/designee and testing personnel (TP) failed to attest to the routine integration of samples into the patient workload for 1 of 3 Immunohematology PT events performed in 2023. Findings include: 1. The AAB/MLE PT Program Guide General Instructions for reporting results states, " The attestation statements must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes. In addition to the analysts' signatures, the director or the director's designee must sign only once for each reporting form." 2. On the day of survey, 12/14/2023 at 08:29 am., review of AAB/MLE PT records revealed the following attestation statement was not signed by the LD/designee or TP: -2023 Nonchemistry 3rd event - D (Rho) Typing, slide methods: RH11, RH12, RH13, RH14, RH15 3. The DCS confirmed the findings above on 12/14/2023 at 11:25 am. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedures and interview with Director of Clinical Services (DCS), the laboratory failed to ensure that 1 of 1 laboratory procedure manual in use for Immunohematology was approved, signed and dated by the current Laboratory Director (LD) from 09/07/2023 to 12/14/2023. Findings include: 1.The laboratory procedure manual in use for Immunohematology reviewed at the time of inspection on 12/14/2023 at 08:39 am, revealed the procedures were not approved, signed, and dated by the current LD. 2. The laboratory's annual volume for Immunohematology is 2,533 (CMS-116). 3. DCS confirmed the above findings on 12 /14/2023 around 11:25 am. |