

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0202709	<b>(X3) Date Survey Completed</b> 11/06/2019
<b>Name of Provider or Supplier</b> Far Northeast Surgical Center	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the center manager and surgical center assistant, the laboratory failed to establish a complete competency assessment procedure to assess 1 of 1 technical consultant for competency from 2018 to 2019. Findings Include: 1. On the day of survey, 11/06/2019, the laboratory could not provide a complete competency assessment procedure to assess 1 of 1 technical consultant for competency in 2018 and 2019. 2. The center manager and surgical center assistant confirmed the findings above on 11/06/2019 around 9:20 am.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the review of American Association of Bioanalysts (AAB) 2018 and 2019 proficiency testing (PT) scores and interview with the center manager and surgical center assistant, the laboratory director failed to identify problems that required a corrective action for Immunohematology, ABO/RHO and D (RHO), 2nd scores in 2018. Findings Include: 1. On the day of survey, 11/06/2019, 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 2018: - AAB 2018, Event #2, ABO/RHO 80% - AAB 2018, Event #2, D (RHO) 80% 2. The center manager and surgical center assistant confirmed the findings above at 11/06/2019 around 10:00 am.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory procedure manuals and interview with the center manager and surgical center assistant, the laboratory director failed to ensure that quality assessment (QA) programs are established and maintained to assure quality of laboratory services provided from November of 2017 to October of 2019 (24 of 24 months). Findings Include: 1. On the day of survey, 11/06/2019, review of the laboratory's manuals revealed, the laboratory did not have a written QA procedure to assess the laboratory systems provided from November 2017 to October 2019 (24 of 24 months). 2. The center manager and surgical center assistant confirmed the laboratory does not a have QA procedure on 11/06/2019 around 9:50 am.

**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 review of testing personnel (TP) competency assessment records, review of American Association of Bioanalysts (AAB) 2018 proficiency testing (PT) scores and interview with the center manager and surgical center assistant, the technical consultant failed to assess the competency of 3 of 6 TP through internal blind testing samples or external PT samples in 2018. Findings Include: 1. On the day of survey, 11/06/2019, review of TP competency assessment records and AAB PT scores revealed, the laboratory did not assess the test performance of 3 of 6 TP (#3,#4 and #5) for AAB Immunohematology, ABO/RHO and D (RHO) events in 2018 or through internal blind testing samples in 2018. 2. The center manager and surgical center assistant confirmed the finding above on 11/06/2019 around 9:45 am.