

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403647	(X3) Date Survey Completed 08/23/2018
Name of Provider or Supplier Cook Hospital & Care Center	Street Address, City, State 10 Fifth Street Se, Cook, MN	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to evaluate an unacceptable proficiency testing (PT) result. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/23/18 at 8:10 a.m. 2. The laboratory performed PT using the American Proficiency Institute PT provider. 3. The laboratory received an unacceptable PT result from API in the second Chemistry event of 2017 for the analyte and sample listed below. Analyte - pO2 Sample ID Lab Result API expected IB-07 126 31-82 4. An evaluation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide an evaluation upon request. 5. In an interview on 08/23/18 at 12:20 p.m., the GS confirmed a documented evaluation of the unacceptable result was not performed.</p>
D6125	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical supervisor (TS) failed to ensure competency assessments included assessment of test</p>

performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry, Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory 08/23/18 at 8:10 a.m. 2. Proficiency testing results for each of the following testing specialties /subspecialties were being used to evaluate testing personnel competency. This activity was documented on the Assessment of Proficiency Testing form. Specialty Instrument/test Microbiology (Micro) - BacT/Alert, Vitek2, Gram Stain Hematology (Heme) - Sysmex xs-100i, Excyte 10, Blood Cell ID Coagulation (Coag) - ACL Elite Chemistry (Chem) - Architect c4100, i-STAT Urinalysis (UA) - Drug Screen Endocrinology (Endo) - Serum HCG Immunohematology (BB) - Type, Antibody Screen, Crossmatch 3. The 2017 evaluations of proficiency testing did not include testing across all specialties/subspecialties for 5 of 5 testing personnel. The laboratory was unable to provide additional documented evaluations upon request. See below where "0" indicates proficiency testing evaluations were not complete. 2017 Testing Personnel 1 2 3 4 5 Micro 0 0 0 0 Heme 0 0 0 Coag 0 0 Chem 0 0 UA 0 0 0 Endo 0 0 0 BB 0 0 4. In an interview on 08/23/18 at 12:30 p.m., the GS confirmed the 2017 evaluations of proficiency testing did not include testing across all specialties /subspecialties. *This is a repeat finding - D6125 was cited during the 12/30/16 survey*