

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403647	(X3) Date Survey Completed 09/29/2022
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 investigate two unacceptable proficiency testing (PT) results in 2022. Findings are as follows: 1. The laboratory performed Bacteriology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 09/29/22. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The laboratory received one unacceptable PT result of 10 Gram Stain testing challenges completed to date in 2022 and one unacceptable PT result of 10 Blood Urea Nitrogen(BUN) testing challenges completed to date in 2022 as indicated in API reports. See below. 2022 1st Microbiology event Test: Gram Stain Sample: GS-02 Laboratory Result: Gram Positive API expected result: Gram Negative 2022 1st Chemistry core event Test: BUN Sample: CH-05 Laboratory Result: 21 API expected result: 14-19 4. Investigation of unacceptable PT results was required as established in the laboratory's Proficiency Testing procedure located in the General Lab Policies manual. 5. Investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 12:15 p.m. on 09/29/22, the GS confirmed the above finding. .</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without</p>

analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of a non-graded proficiency testing (PT) result from a regulated Specialty when the PT program did not evaluate or score the result in one of two events reviewed from 2022. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 09/29/22. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The following PT result from the 2022 Microbiology first event was not graded by API as indicated in the API report: Test: Gram Stain Sample: GS-05 API instructed to See Data Summary 4. The API Data Summary for the 2022 Microbiology first event was not present in laboratory records. An evaluation of the non-graded result was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 5. In an interview at 12:15 p.m. on 09/29/22, the GS confirmed the above finding. .