

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403647	(X3) Date Survey Completed 01/15/2021
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a Chemistry procedure (performance verification) was approved, signed, and dated by the laboratory director prior to use. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 01/14/21, at 8:05 a.m. 2. An Abbott Architect C4100 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities for the analyzer (a total of 38 analytes) were acceptable and the laboratory began patient specimen testing in August 2019 as indicated in laboratory records. 4. The laboratory director did not approve, sign, or date the performance verification documents prior to use of the analyzer. 5. In an interview on 1/15/21, at 8:30 a.m., the GS confirmed the above finding. .</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel,</p>

the laboratory failed to ensure a reference interval was consistent between a Coagulation procedure and a patient test report. Findings are as follows: 1. The laboratory performed Coagulation testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 01/14/21, at 8:05 a.m. 2. An ACL Elite Coagulation analyzer was observed as present and available for use during the tour. 3. The Prothrombin Time (PT) reference intervals listed in the Prothrombin Time (PT) / INR (International Normalized Ratio) procedure, located in the on-line Lab Manual, were not consistent with those included on a patient test report reviewed on date of survey, as indicated below. Patient - adult male, aged 80 yrs, tested on 11/25/20 Procedure Report 10.5 - 15.0 seconds 7.26 - 12.96 seconds 4. In an interview on 1/15 /21, at 8:30 a.m., the GS confirmed the above finding. .