

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D2050413	<b>(X3) Date Survey Completed</b> 04/02/2021
<b>Name of Provider or Supplier</b> Cook Hospital Tower Lab	<b>Street Address, City, State</b> 415 North 2nd Street Suite #2, Tower, MN	
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>D5807</b>	<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, the laboratory failed to ensure a reference interval was consistent between a Chemistry procedure and a patient test report. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 8.10 a.m. on 04/01/21. 2. An Abbott i-STAT chemistry analyzer was observed as present and available for use during the tour. 3. A reference interval listed in the i-STAT Chem8+ Cartridge Basic Metabolic Panel procedure, located in the Lab Manual, was not consistent with that included on a patient test report reviewed on date of survey, as indicated below. Patient - adult female, aged 38 yrs, tested on 1-27-20 Procedure Report Chloride 98-118 mmol/L 99-111 mmol/L 4. In an interview at 10:45 a.m., on 4/1/21, the LD confirmed the above finding. .</p>
<b>D6054</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on document review and interview with laboratory personnel, the Technical Consultant failed to evaluate the competency of 5 of 5 testing personnel in 2019. Findings are as follows: 1. The laboratory performed Mycology, Parasitology, General Immunology, Chemistry and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 8.10 a.m. on 04/01/21. 2. The Quality Assurance Plan - Laboratory procedure / Personnel Assessment section, located in the General Policies manual, indicated personnel were evaluated semi-annually during the first year of employment and annually thereafter. 3. 2019 competency assessments for TP1, TP2, TP3, TP4 and TP5 were not found during review of the laboratory's records. The laboratory was unable to provide the document upon request. 4. In an interview at 9:15 a.m. on 04/01/21, TP1 confirmed the above finding. .