

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0983057	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Unitypoint Health Finley Hospital	Street Address, City, State 350 N Grandview Avenue, Dubuque, IA	
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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, lack of comparison activity records, observation during the survey, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 06/21/2023, the laboratory failed to perform and document comparison activities twice annually between three out of three i-STAT analyzers for the analytes: partial pressure of oxygen (PO2), partial pressure of carbon dioxide (PCO2), and pH for five out of five time periods from 01/01/2021 - 06/21/2023. The findings include: 1. The Laboratory Test List & Annual Volume form listed the laboratory as performing PO2, PCO2, and pH testing on the i-STAT analyzer. 2. During an interview with personnel identifier #2 and observations made during the survey, the laboratory revealed that it had one i-STAT analyzer in the Respiratory Care Department, one i-STAT analyzer in the Emergency Department, and one i-STAT analyzer in the Cardiac Catheterization Laboratory. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform and document comparison studies between the three i-STAT analyzers from 01/01/2021 - 06/21/2023.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</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.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:45 am on 06/21/2023, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing in the cardiac catheterization laboratory at least annually for one out of one testing personnel (identifier #17) in 2021 and 2022.