

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0038249	(X3) Date Survey Completed 12/08/2022
Name of Provider or Supplier Unitypoint Health Marshalltown	Street Address, City, State 55 Unitypoint Health-Marshalltown, Marshalltown, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Clinitek Advantus quality control and maintenance records and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 12/8/2022, the laboratory failed to retain the Clinitek Advantus quality control records and maintenance records for 31 out of 31 days in August 2022. At the time of the survey, the laboratory could not locate the Clinitek Advantus quality control records or the maintenance records from August 2022.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and the Laboratory Test List & Annual Volume form and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at approximately 9:15 am on 12/8/2022, the laboratory failed to verify the accuracy for reticulocyte count and manual white blood cell differentials twice annually for 4 out of 4 time periods from 1/1/2021 - 12/8/2022.</p>

	<p>The findings include: 1. The Laboratory Test List & Annual Volume form confirmed the laboratory performed reticulocyte counts and manual white blood cell differentials. 2. For 2021 and 2022, the laboratory did not enroll in proficiency testing for either reticulocyte counts or manual white blood cell differentials. 3. At the time of the survey, the laboratory did not have documentation that the laboratory had performed a twice annual verification for reticulocyte counts or manual white blood cell differentials.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 12/18/2022, the laboratory failed to have procedures for the following test systems and/or analytes: ABL 90 blood gas analyzer, Clinitek Advantus urinalysis analyzer, and urine sediment examination.</p>
<p>D6128</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and the Echo Lumena verification of performance specification records and confirmed by laboratory personnel identifiers #1 and #2 (refer to Laboratory Personnel Report) at approximately 11:00 am on 12/8/2022, the technical supervisor failed to document training for the Echo Lumena blood bank test system for seven out of 14 high complexity testing personnel. The findings include: 1. The laboratory started using the Echo Lumena blood bank test system to perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in September of 2021. 2. At the time of the survey, the laboratory did not have training records for high complexity testing personnel identifiers #3 - #9 for the Echo Lumena test system.</p>