

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0382707	<b>(X3) Date Survey Completed</b>  05/24/2021
<b>Name of Provider or Supplier</b>  Wayne County Hospital	<b>Street Address, City, State</b>  417 South East Street, Corydon, IA	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> 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 review of hematology quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 05/24/2021, the laboratory failed to retain hematology complete blood count (CBC) QC records for 12 out of 12 lot numbers of QC and 122 out of 122 days from 08/31/2020- 12/30/2020. The findings include: 1. The laboratory performed three levels of CBC QC for each 24-hour period of patient testing on the Beckman Coulter DXH 600 hematology instrument. 2. At the end of use for each lot number, the laboratory printed the QC files stored on the hematology instrument and kept them as documentation of QC results. The laboratory also submitted QC data to Beckman Coulter's Interlaboratory Quality Assurance Program (IQAP) at the same time. 3. The laboratory's IQAP records indicated that the following lot numbers were used between 08/31/2020 and 09/27/2020: 123173290 (low); 133183290 (normal); and 143193290 (high). 4. The laboratory's IQAP records indicated that the following lot numbers were used between 09/27/2020 and 10/25/2020: 123173330 (low); 133183330 (normal); and 143193330 (high). 5. The laboratory's IQAP records indicated that the following lot numbers were used between 10/25/2020 and 11/22/2020: 123173380 (low); 133183370 (normal); and 143193380 (high). 6. The laboratory's IQAP records indicated that the following lot numbers were used between 11/22/2020 and 12/30/2020: 123173440 (low); 133183430 (normal); and 143193440 (high). 7. Review of printed QC records revealed that the laboratory did not have QC records from 08/31/2020- 12/30/2020.</p>

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:15 pm on 05/24/2021, the laboratory failed to perform a positive and negative control each day of patient testing for the Cardinal Health serum human chorionic gonadotropin (HCG) qualitative test system. The findings include: 1. The laboratory performed controls with each new lot and shipment of Cardinal Health serum HCG tests. 2. Laboratory personnel identifier #2 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the Cardinal Health serum HCG qualitative test system.