

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0038621	(X3) Date Survey Completed 11/11/2020
Name of Provider or Supplier Spencer Hospital	Street Address, City, State 1200 First Avenue East, Spencer, 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 review of hematology quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 5:00 pm on 11/11/2020, the laboratory failed to retain hematology complete blood count (CBC) QC records for three out of three lot numbers of QC and 28 out of 61 days from 04/01/2020-05/31/2020. The findings include: 1. The laboratory performed three levels of CBC QC for each 24-hour period of patient testing. 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. 3. The laboratory's records indicated that QC parameters were entered into the Beckman Coulter DXH 600 hematology instrument on 04/16/2020 for the following new lot numbers: 123173100, expiration 2020-05-16 (low); 133183100, expiration 2020-05-16 (normal); and 143193100, expiration 2020-05-17 (high). 4. Review of printed QC records revealed that the laboratory did not have QC records from 04/20/2020- 05/17/2020. 5. Laboratory personnel identifier #2 stated that the QC files for lot numbers 123173100, 133183100 and 143193100 had been deleted before they could be printed and that the hematology instrument did not store more than the current and previous set of QC files. 6. At the time of the survey, the laboratory did not have additional QC records from 04/20/2020- 05/17/2020.</p>