

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0725037	<b>(X3) Date Survey Completed</b>  07/19/2018
<b>Name of Provider or Supplier</b>  Bigfork Valley Laboratory - Northome	<b>Street Address, City, State</b>  12052 Main St, Northome, 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>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 document review and interview with laboratory personnel, the laboratory failed to retain quality control and maintenance documents for a retired Hematology analyzer. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 07/19 /18 at 10:05 a..m. 2. A Sysmex KX-21N hematology analyzer was used in the laboratory until 12/01/16. 3. The discontinued Sysmex KX-21N procedure indicated three levels of quality control (QC) were performed each day of patient testing. The procedure also indicated maintenance was required daily, weekly, monthly, and quarterly. 4. QC and maintenance records for the time period of October - November 2016 were not present in laboratory documents on date of survey. The laboratory was unable to provide the missing records upon request. 5. The laboratory was given an opportunity to locate the missing QC and maintenance records and provide them to the surveyor within 7 days of the survey. 6. In an email message received on 07/24/18 at 1:12 p.m., the TC indicated the missing Sysmex KX-21N QC and maintenance records could not be located.</p>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p>

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least 2 years. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 07/19/18 at 10:05 a..m. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The API PT result documents for the 3rd Hematology event of 2016 were not present in laboratory records on date of survey. The laboratory was unable to provide these documents upon request. 4. The laboratory was given an opportunity to locate the missing original result documents and provide them to the surveyor within 7 days of the survey. 5. In an email message received on 07/25/18 at 3:02 p.m., The TC indicated the original result documents for the 2016 Hematology 3rd PT event could not be located.