

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0388341	(X3) Date Survey Completed 11/23/2022
Name of Provider or Supplier Aurora Health Center - Grafton, W Washington St	Street Address, City, State 215 W Washington St, Grafton, WI	
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:</p> <p>Item 1: Based on surveyor review of laboratory records, observation of the Alcor Mini iSED erythrocyte sedimentation rate (ESR) analyzer, and interview with the general supervisor, the laboratory did not retain the date the current lot of wash solution was put into use on the Alcor Mini iSED ESR analyzer. Findings include: 1. Review of maintenance logs for the Mini iSED ESR analyzer showed the wash lot recorded on the log is 01/2022 with an expiration date of 12/2022 in March 2022 and June 2022. Further review showed no documentation on the logs for the other nine months in 2022. 2. Observation of the wash solution on the Mini iSED ESR analyzer on November 23, 2022, at 10:45 AM showed the current lot of wash solution is 2022-05-00 and expires 2023/04. Further observation showed no documentation when new lot was started. 3. Interview with the general supervisor on November 23, 2022, at 10:48 AM confirmed the laboratory did not retain the date the current lot of wash solution was put into use on the Alcor Mini iSED ESR analyzer. Item 2: Based on surveyor review of laboratory records, observation of the hematology stain containers, and interview with the general supervisor, the laboratory did not retain the current lot and expiration date for the hematology differential stain and did not retain the date the new lot was put into use. Findings include: 1. Review of hematology logs for the differential stain showed the following: Month of record/Lot number/Expiration date January 2022/106532/May 2022 March 2022/111797/September 2022 Further review showed no documentation on the logs for the other nine months in 2022 to include new lot and expiration date after expiration of lot on September 2022. 2. Observation of the hematology stain containers on November 23, 2022, at 10:35 AM showed only</p>

an expiration date with no indication of lot number for the stain. Further observation showed the main hematology stain container in the waste bucket with a lot number of 118084, expiration of 4/2023 and did not include the date the lot was put in use. 3. Interview with the general supervisor on November 23, 2022, at 10:40 AM confirmed the laboratory did not retain the current lot and expiration date for the hematology differential stain and did not retain the date the new lot was put into use.