

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2136461	<b>(X3) Date Survey Completed</b>  03/14/2022
<b>Name of Provider or Supplier</b>  Aurora Health Center Oak Creek- Ryan Road	<b>Street Address, City, State</b>  200 E Ryan Road, Oak Creek, WI	
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>D6072</b>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b> CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of hematology maintenance logs, review of patient test records and quality control records, and interview with the technical consultant and testing personnel, testing personnel did not document two of five days of wright stain quality control in March 2022. Additionally, testing personnel did not document quarterly maintenance for the Sysmex pocH-100i analyzer between November 2020 and May 2021 and documented biweekly maintenance only once in three of twelve months in 2021. Findings include: 1. Review of stained slides and patient test records on March 14, 2022 showed testing personnel evaluated wright stained slides for patient one on March 9 and patient two on March 13, 2022. Review of the stain quality control records for March 2022 revealed testing personnel documented stain quality control on three days. The records showed no documented wright stain quality control on March 9 or March 13, 2022. 2. Review of the maintenance logs for the Sysmex pocH-100i analyzer showed personnel documented quarterly maintenance on November 26, 2020 and May 21, 2021. The logs showed no other documented quarterly maintenance between November 2020 and May 2021. Further review of the maintenance logs showed personnel documented biweekly maintenance only once during each of three months in 2021. In January, April and November the logs only showed documentation of biweekly maintenance on January 6, April 7, and November 16, 2021. 3. Interview with testing personnel (staff A) on March 14, 2022 at 11:05 AM confirmed wright stain quality control was not documented on March 9</p>

and 13, 2022 when they performed wright stain evaluations of patient samples. Interview with the technical consultant on March 14, 2022 at 10:30 AM confirmed quarterly and biweekly maintenance was not documented as required in 2021.