

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D1056222	<b>(X3) Date Survey Completed</b>  04/12/2022
<b>Name of Provider or Supplier</b>  Ahc Waterford	<b>Street Address, City, State</b>  818 Forrest Ln, Waterford, 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>TESTING PERSONNEL RESPONSIBILITIES 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 laboratory records, observation of slides, and interview with the technical consultant, testing personnel did not document calibration every six months for the Sysmex pocH-100i analyzer B0994 from January to September 2021 and did not document quarterly maintenance from January through May 2021. Additionally, testing personnel stained slides with Wright stain and did not document stain quality on three of five days in March and April 2022. Findings include: 1. Review of calibration records from 2021 for the Sysmex pocH-100i analyzer, serial number B0994, showed no calibration completed from January to September. An incomplete calibration document was available for the B0994 analyzer; testing personnel had not included the reagent information, the date performed, and did not sign or date the document. The Sysmex pocH-100i maintenance log required semi-annual calibration of the Sysmex pocH-100i analyzer. Review of the logs from January to September 2021 showed no documented performance of calibration. 2. Review of Sysmex pocH-100i analyzer maintenance logs from January through May showed testing personnel did not document quarterly maintenance during this five month period. 3. Observation of Wright-stained slides on April 12, 2022 at 12:15 PM showed stained slides from March 24, 30, 31, and April 2, and 8, 2022. Review of the stain logs used to document stain quality showed testing personnel did not document stain quality on March 30, 31, or April 8, 2022. 4. Interview with the technical consultant on April 12, 2022 at 12:15 PM confirmed testing personnel did not document the stain quality for Wright stain each day of use. Interview at 12:30 PM confirmed testing personnel did not complete documentation of the required</p>

maintenance or semi-annual calibration of the Sysmex pocH-100i analyzer from January to September 2021.