

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0396363	<b>(X3) Date Survey Completed</b>  11/17/2020
<b>Name of Provider or Supplier</b>  Krohn Clinic Ltd	<b>Street Address, City, State</b>  610 W Adams St, Black River Falls, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and other laboratory records and interview with the technical consultant, the laboratory did not verify the accuracy of potassium hydroxide (KOH) testing performed on dermatology samples twice annually in 2019 or 2020. Findings include: 1. Review of PT records from 2019 and 2020 showed no evidence of evaluation of KOH testing for skin samples. 2. Review of other laboratory records showed no evidence of accuracy verification of KOH testing of skin or other dermatology samples. 3. Interview with the technical consultant on November 17, 2020 at 8:30 AM confirmed the laboratory performed KOH testing of dermatology samples. Further interview confirmed the laboratory had not developed a process to verify the accuracy of this testing twice annually. This is a repeat deficiency previously cited on April 6, 2010 and March 19, 2014.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs and interview with the technical consultant, the laboratory did not document maintenance as defined by the</p>

manufacturer of the Tosoh G8 analyzer and with at least the six-month frequency specified by the manufacturer. Findings include: 1. Review of maintenance logs for the Tosoh G8 analyzer from 2020 showed the laboratory had not documented the replacement of the fluid supply line filters every six months as required. 2. Interview with the technical consultant on November 17, 2020 at 11:50 AM confirmed the laboratory had not documented performance of the six-month maintenance for the Tosoh G8 analyzer. This is a repeat deficiency previously cited on March 9, 2018.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Center for Medicare and Medicaid (CMS) Form 209, Laboratory Personnel Report (CLIA), personnel records, and interview with the Technical Consultant, the Technical Consultant failed to document the semi-annual competency evaluation for one of two new Testing Personnel. Findings include: 1. Comparison of the current CMS Form 209 with the Form 209 from the March 2018 survey showed two new Testing Personnel listed on the current form. 2. Review of personnel records for Testing Personnel, staff A, showed no documented semi-annual competency assessment. Records for staff A showed records dated May 2018 identified as initial competency and the single set of records from 2019 identified as annual competency. 3. Interview with the Technical Consultant on November 16, 2020 at 3:45 PM confirmed the Technical Consultant had not evaluated semi-annual competency for one of two new Testing Personnel in the first year. This is a repeat deficiency previously cited on March 9, 2018.