

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0396363	<b>(X3) Date Survey Completed</b>  03/24/2022
<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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with the general supervisor, the laboratory did not have a procedure available for the Cepheid Gene Xpert 4-plex plus test process. Findings include: 1. Review of laboratory records showed the laboratory was performing the Cepheid Gene Xpert 4-plex plus test for influenza, respiratory syncytial virus (RSV) and SARS-CoV-2 (COVID-19) testing as of December 31, 2021. 2. Review of laboratory procedures showed the laboratory was using the manufacturer's standard operating procedure (SOP) template for testing performed on the Cepheid Gene Xpert. Further review showed the current approved SOP was for the 4-plex test for influenza, RSV and COVID-19 test (REF# XPCOV2/FLU/RSV-10) and no procedure was available for the 4-plex plus test (REF# XP3COV2/FLU/RSV-10). 3. Interview with the general supervisor on March 23, 2022 at 1:20 PM confirmed the laboratory was performing the 4-plex plus test for influenza, RSV and COVID-19 testing and the SOP was not available in the laboratory.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor review of laboratory procedures and interview with the general supervisor, the laboratory director did not approve, sign and date the procedure for the Cepheid Gene Xpert Chlamydia trachomatis (CT)/Neisseria gonorrhoeae(NG) test. Findings include: 1. Review of laboratory procedures revealed the laboratory was using the manufacturer's standard operating procedure (SOP) template for testing performed on the Cepheid Gene Xpert. Further review showed no documentation of approval by the laboratory director for the CT/NG procedure. 2. Interview with the general supervisor on March 23, 2022 at 1:20 PM confirmed the laboratory director did not approve, sign and date the procedure for the Cepheid Gene Xpert CT/NG test.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on survey review of laboratory records and interview with the general supervisor, the laboratory director did not review and approve the performance specification verification records on the Cepheid Gene Xpert 4-plex plus analyte prior to reporting patient results. Findings include: 1. Review of laboratory records showed the laboratory started reporting patient test results for the Cepheid Gene Xpert 4-plex plus test on December 31, 2021. Further review showed no evidence the laboratory director had reviewed and approved the performance specification verification records on the Cepheid Gene Xpert 4-plex plus test. 2. Interview with the general supervisor on March 23, 2022 at 1:20 PM confirmed the laboratory director did not review and approve the performance specification verification records on the Cepheid Gene Xpert 4-plex plus analyte prior to reporting patient results.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Individualized Quality Control Plan (IQCP), patient and quality control (QC) records and interview with the general supervisor, the

laboratory did not perform two levels of quality control on each day of patient testing and had not developed an IQCP for the Cepheid Gene Xpert 4-plex plus test cartridge. Findings include: 1. Review of the IQCP records showed an IQCP plan in place for the Cepheid Gene Xpert 4-plex test cartridge signed by the laboratory director on December 31, 2020. Further review showed no IQCP in place for the 4-plex plus test cartridge. 2. Review of patient records showed patient testing began on the Cepheid Gene Xpert 4-plex plus test cartridge on December 31, 2021. 3. Review of QC records for the Cepheid Gene Xpert 4-plex plus test cartridge showed QC was performed per the Cepheid Gene Xpert 4-plex test cartridge IQCP of monthly and with each new shipment and new lot. 4. Interview with the general supervisor on March 23, 2022, at 1:20 PM confirmed the laboratory did not perform two levels of quality control on each day of patient testing and had not developed an IQCP for the Cepheid Gene Xpert 4-plex plus test cartridge.