

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396363	(X3) Date Survey Completed 04/01/2026
Name of Provider or Supplier Krohn Clinic Ltd	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Individualized Quality Control Plans (IQCP) and procedures and interview with a technical consultant (Staff A), the laboratory did not specify the required number, type, and frequency of quality control (QC) materials in the IQCP and procedures for two of two tests performed using the Cepheid GeneXpert system. Findings include: 1. Review of the laboratory's IQCP quality control plan (QCP) for the Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) and the Covid, Flu and RSV (SARS-CoV-2 Flu RSV) panel using the Cepheid GeneXpert showed the following statement, "Based on our risk assessment and Quality Assessment, the QCP consists of following the instructions that are provided in explicit detail in the Cepheid Procedure Manual". The IQCPs did not define the number, type, or frequency of quality control testing required. 2. Review of procedures for the CT/GC and SARS-CoV-2 Flu RSV test systems showed no explicit instruction for the number, type, or frequency of control testing. 'Section 14.2 External Controls' in the SARS-CoV-2 Flu RSV procedure included the following, "External controls may be used by customers...", "External controls may be purchased from outside vendors or may be prepared from the leftover samples or by following</p>

institutional procedures", and "The external quality control materials provided by the specified vendor in Section 8.1 are an optional source." 3. Review of the laboratory's "Quality Control Management Program" policy, effective July 16, 2025, showed the required period during which the laboratory tests one control "set" of QC products for the GeneXpert instrument is once a month or every new lot number or shipment. The procedure did not define the specific control type. 4. Interview with Staff A on April 1, 2026, at 10:00 AM confirmed the IQCP QCPs did not define the number, type, and frequency of required controls for the two tests performed using the Cepheid GeneXpert test system.

D5455

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(v)(g)

(d)(3)(v) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor observation of GeneXpert instrument supplies, review of laboratory records, and interview with a technical consultant (Staff A), the laboratory did not ensure the one of two cartridge lot numbers available for Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) testing had been tested in the last month as required by the laboratory's individualized quality control plan (IQCP), an equivalent quality testing procedure. Findings include: 1. Observation in the laboratory on April 1, 2026, at 10:00 AM of cartridges available for CT/NG testing with the Cepheid GeneXpert instrument showed five cartridges of lot number 45701 available for testing. Additionally, a box of cartridges, lot number 45903, were available. 2. Review of Cepheid GeneXpert quality control (QC) test records for CT /NG cartridges showed testing personnel last tested lot number 45701 with QC samples on February 16, 2026. Records showed personnel performed QC testing on lot 45903 on March 18, 2026. 3. Interview with Staff A on April 1, 2026, at 10:00 AM confirmed the laboratory's IQCP required testing of GeneXpert cartridges monthly and with new lots and shipments. Additional interview confirmed cartridges from lot numbers 45701 and 45903 were available for patient testing and confirmed lot 45701 had not had QC testing performed in the last month.