Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396363	03/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Krohn Clinic Ltd	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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory failed to successfully participate in PT for the Activated Partial Thromboplastin Time (APTT) analyte in the Specialty of Hematology for events 2017-1, and 2017-3. Findings include: 1. Review of PT records in the federal CASPER reporting system shows that the laboratory failed two out of three PT events for the APTT analyte within the Specialty of Hematology- Event 2017-1, score 60% and Event 2017-3, score 60%. 2. Surveyor review of the API PT evaluation reports confirmed the failed 2017 PT scores which

	results in a failure to successfully participate in APTT for Hematology. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) and American Proficiency Institute (API) PT records, the laboratory failed to have successful performance in PT for the Activated Partial Thromboplastin Time (APTT) analyte in the Specialty of Hematology for events 2017-1, and 2017-3. Findings include: 1. Review of PT records in the federal CASPER reporting system shows that the laboratory failed two out of three PT events for APTT in the Specialty of Hematology- Event 2017-1, score 60% and Event 2017-3, score 60%. 2. Surveyor review of the API PT evaluation reports confirmed the failed 2017 PT scores. This results in a failure to achieve an overall testing event score of satisfactory performance for two out of three testing events which is unsuccessful PT performance.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory policies and procedures and interview with the Ancillary Services Manager, the Laboratory Director failed to approve, sign and date the new competency assessment policy that is currently in use. Findings include: 1. Review of the "Competency Assessment" policy that is currently in use shows that the policy has not been approved and signed by the Laboratory Director. 2. Interview with Ancillary Services Manager on March 8, 2018 at 11:30 AM confirmed that the competency assessment policy that was in use had not been approved, signed, and dated by the current Laboratory Director.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the manufacturer's instructions, laboratory procedures, and interview with the Ancillary Services Manager, the laboratory has not performed Immunohematology procedures according to the manufacturer's requirements when

	performing Immunohematology testing. Findings include: 1. Review of the specific manufacturer's instructions for the ABO Grouping, Anti-D, and Direct Coombs testing state that the cell suspensions should be 3-4% for ABO Grouping and Anti-D testing and 3-5% for Direct Coombs Testing. 2. Review of the laboratory "ABO Grouping", "Anti-D", and "Direct Coombs" procedures state the cell suspensions used for patient testing should be 2-4%. 3. Interview with the Ancillary Services Manager on March 8, 2018 at 2:00 PM confirms that the procedures used for Immunohematology testing do not follow manufacturer's package insert instructions for reagents used for testing. This deficiency was previously cited April 15, 2008 and April 6, 2010.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Log Checklist, laboratory procedures, and interview with Testing Personnel, the laboratory has not performed maintenance on the Mini-Vidas analyzer as required. Findings include: 1. Review of the laboratory "Mini-Vidas Assay" procedure and the Maintenance Log Checklist show that the lab is to perform weekly cleaning of external surfaces of the Mini-Vidas analyzer. 2. Review of the Maintenance Log Checklist from January through December 2017 show the lab performed the required weekly maintenance 13 out of 52 weeks in 2017. 3. Interview with Testing Personnel A on March 8, 2018 at 2:30 PM confirmed that the maintenance on the Mini-Vidas analyzer is not being performed as required by the lab procedure.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of training documentation and interview with the Ancillary Services Manager, the laboratory director did not ensure new testing personnel had received training for all non-waived testing performed in the laboratory. Findings include: 1. Review of training records for Testing Personnel (TP) B and TP C, who started in the laboratory in January 2017 and December 2016 respectively, shows that training documentation was not completed for Immunohematology, Microbiology, Provider Performed Microscopy, and Urine Microscopy non-waived testing prior to patient testing. 2. Interview with the Ancillary Services Manager on March 8, 2018 at

	11:00 AM confirms the training documentation was not completed and signed prior to TP B and TP C performing patient testing.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the Ancillary Services Manager, competency assessment of four Testing Personnel listed on the Center for Medicare and Medicaid Services (CMS) Form 209 was not performed in 2016 and 2017. Findings include: 1. Review of personnel records shows no completed competency assessments for all non-waived testing for four of four Testing Personnel (TP A, TP D, TP E, and TP F) listed on the CMS Form 209 for 2016 or 2017. 2. Interview with the Ancillary Services Manager on March 8, 2018 at 11:30 AM confirmed no 2016 or 2017 competency assessments were available for Testing Personnel.
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 Testing Personnel competency assessment records and interview with the Ancillary Services Manager, who is the Technical Consultant, the Technical Consultant failed to document the semiannual competency evaluation for two of two new Testing Personnel who performed patient testing. Findings include: 1. Review of competency assessment records for new Testing Personnel (TP) B and TP C, as listed on the identifier key, shows no semiannual competency assessment has been documented. 2. Interview with the Technical Consultant on March 8, 2018 at 11: 30 AM confirmed that new TP B and TP C have been performing patient testing for more than one year and that the semiannual competency evaluation for each TP was not documented in the first year.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) 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. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, chemistry quality control (QC) records, corrective action logs, Laboratory Information System (LIS) records, and

	interview with Testing Personnel the laboratory does not follow the procedures for when chemistry QC is out of control. Findings include: 1. During the interview with TP C for Chemistry QC on the Vitros 5600 analyzer, TP C stated that the "Out of Control (OOC) Correction Action Sheets" are used to document corrective actions taken if QC has to be repeated more than one time. Review of the "Quality Control Procedures" policy state that "All OOC results are to be recorded on the OOC Correction Action sheets form." 2. During the interview with the Technical Consultant it was stated that all TP are supposed to document when QC is out of range with a comment under the QC analyte on the Chemistry analyzer. Review of the "Quality Control Procedures" policy state "All OOC results are to be recorded on the OOC Correction Action sheets form." 3. Review of QC performed on the Calcium analyte on March 8, 2018 showed that one level of QC was out of control with the "12S" rule. The QC was repeated and was within range. No corrective action for the OOC QC result was documented on the lab OOC form, the LIS, or in the Chemistry analyzer database. 4. Interview with the Technical Consultant on March 9, 2018 at 10:45 AM confirms documentation of out of control QC on the Chemistry analyzer does not follow the laboratory procedure.