Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0955358	01/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laurentian Medical Clinic	8373 Unity Drive, Virginia, MN	

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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to check each lot and shipment of Microbiology media for appearance, sterility and ability to support growth prior to or concurrent with use. Findings are as follows: 1. The laboratory performed Bacteriology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 01/10/19 at 9:10 a.m. The TC stated the laboratory performed Throat Cultures for Streptococcus A using Streptococcus Select Agar media and Taxo A discs. 2. The Throat Culture procedure, located in the intranet based procedure files, indicated media was obtained from the health system's central laboratory location. The procedure did not indicate documentation of the central laboratory's quality control (QC) activities were provided with each shipment of media. Requirements to check each shipment of media for appearance, sterility or its ability to support growth were not included in the procedure. 3. Documentation of the central laboratory's QC activities was not found in laboratory records. Documentation of media appearance, sterility and growth checks performed prior to use at the Laurentian Medical Clinic laboratory was not found in laboratory records. The laboratory was unable to provide either type of documentation upon request. 4. An Individualized Quality Control Plan (IQCP) to reduce the media QC requirements was not established prior to the 11/16/18 COLA survey date. An

	IQCP, approved by the Laboratory Director on 12/03/18, was found on date of survey, 5. In an interview on 01/10/19 at 12:15 p.m., the TC confirmed the above finding.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between a Hematology procedure and a patient test report. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 01/10/19 at 9:10 a.m. 2. An Abbott Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour. 3. Two hematology reference intervals listed on the reference range table were not consistent with those included on the patient test report reviewed on date of survey. See below. Patient #4002268 - adult male tested on 08/14/18 Analyte* Table Report MCHC 32.0-36.0 32.2-36.5 RDW 11.5-16.0 11.5-14.5 4. In an interview on 01/10/19 at 1:00 p.m., the TC confirmed the discrepancies between the reference range table and the patient test report. *Note MCHC Mean Corpuscular Hemoglobin Concentration RDW Red Blood Cell Distribution Width
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 document review and interview with laboratory personnel, the technical consultant (TC) failed to evaluate required Microbiology, Hematology and Chemistry competency assessment elements for all testing personnel (TP) in 2017. Required elements include; 1) Direct observation of test performance, 2) Monitoring the recording and reporting of test results, 3) Review of intermediate test results or worksheets and records, 4) Direct observation of instrument maintenance, 5) Assessment of test performance with previously analyzed specimens, and 6) Assessment of problem solving skills. Findings are as follows: The laboratory performed Microbiology, Hematology and Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 01/10/19 at 9:10 a.m. A. Microbiology 1. The laboratory performed Throat Cultures and KOH microscopic examinations under the Microbiology specialty. 2. The 2017 Microbiology competency assessment records for 1 of 5 tenured TP reviewed on date of survey were incomplete. See below. Throat Culture TP Missing elements TP3 5 TP7 5 KOH Microscopic examinations TP Missing elements TP7 5 3. In an interview on 01/10/19 at 10:25 a.m., the TC confirmed the 2017 Microbiology competency assessments were incomplete for TP3 and TP7. B. Hematology 1. The laboratory performed Complete Blood Count (CBC) using the Abbott Cell-Dyn Emerald hematology analyzer under

	the Hematology specialty. In addition, the laboratory performed Post-Vasectomy microscopic examinations. 2. The 2017 Hematology competency assessment records for 3 of 5 tenured TP reviewed on date of survey were incomplete. See below. Abbott Cell-Dyn Emerald TP Missing elements TP7 5 Post-Vasectomy TP Missing elements TP1 5 TP3 1, 2, 3, 4, 5,6 TP7 1, 2, 3, 4, 6 3. In an interview on 01/10/19 at 10:25 a.m., the TC confirmed the 2017 Hematology competency assessments were incomplete for TP1, TP3 and TP7. C. Chemistry 1. The laboratory performed Urine Sediment microscopic examinations under the Chemistry specialty. 2. The 2017 Chemistry competency assessment record for 1 of 5 tenured TP reviewed on date of survey was incomplete. See below. Urine Sediment TP Missing elements TP3 5 3. In an interview on 01/10/19 at 10:25 a.m., the TC confirmed the 2017 Chemistry competency assessment was incomplete for TP3.