Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0910964	(X3) Date Survey Completed 09/09/2020
Name of Provider or Supplier Mankato Clinic Urgent Care	**Street Address, City, State** 1809 Adams Street, Mankato, 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
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 document review and interview with laboratory personnel, the laboratory failed to perform control procedures as indicated in the Individualized Quality Control Plan (IQCP) for an Endocrinology test. Findings are as follows: 1. The laboratory performed serum human chorionic gonadotropin (hCG) Endocrinology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 11:10 a.m. on 09/09/20. 2. Positive and negative control testing was required when opening a new kit and monthly as established in the ICON 25hCG procedure located in the Laboratory Procedures manual and indicated in the IQCP. 3. Monthly quality control testing was not performed in June 2020 as indicated on the laboratory's serum hCG quality control log. One patient was tested on 06/30/20. The most recent QC was performed on 05/11/20. 4. In an interview at 1:50 p.m., TC1 confirmed the above finding. .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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--
At least once a day patient specimens are assayed or examined perform the following
for-- Each qualitative procedure, include a negative and positive control material; (g)
The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel,
the laboratory failed to perform quality control (QC) each day of patient testing for a
Microbiology test. Findings are as follows: 1. The laboratory performed Candida,
Gardnerella, and Trichomonas Microbiology testing as confirmed by Technical
Consultant 1 (TC1) during a tour of the laboratory at 11:10 a.m. on 09/09/20. 2. A BD
Affirm VPIII Microbial Identification System (vDNA) was observed as present and
available for use during the tour. Testing for Candida, Gardnerella, and Trichomonas
using this analyzer was performed August 2018 through March 2020 as indicated in
laboratory records and confirmed by TC1. 3. QC with a Candida control was required
when opening a new kit as established in the BD Affirm VPIII procedure located in
the Laboratory Procedures manual. The vDNA quality control logs from August 2018
through March 2020 indicated QC was performed with each new kit . 4. An
Individualized Quality Control Plan (IQCP) to reduce the required daily QC
frequency for tests used in the identification of microorganisms was not found in the
laboratory's records. The laboratory was unable to provide an IQCP for this test
system upon request. 5. Laboratory monthly and yearly test count logs indicated 837
vDNA tests were performed between August 2018 and March 2020. See below Year
Number of tests 2018 221 2019 516 2020 100 6. In an interview at 1:15 p.m., TC1
confirmed the above finding.