Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0041212	08/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
St Cloud State University Medical Clinic	850 1st St S, Saint Cloud, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate 1 of 1 unacceptable Microbiology proficiency testing (PT) results in 2020. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Laboratory Director (LD)) during a tour of the laboratory at 10:10 a. m. on 08/03/21. 2. The laboratory performed PT using the American College of Physician's Medical Laboratory Evaluation (MLE) program. 3. The laboratory received an unacceptable Wet Mount Preparation (WMP) PT result in the 2020 MLE-M2 event. See below. 2020 MLE-M2 event Sample - PPM-7 Test - WMP Laboratory result - Squamous epithelial cell Expected result - Clue cell 4. Investigation of unacceptable PT results was required as established in the Proficiency Testing Policy located in the Laboratory Procedure Manual. 5. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 12: 20 p.m. on 08/03/21, the LD confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities required for a Microbiology test system. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:10 a.m. on 08/03/21. 2. A BD MicroProbe Processor - Affirm VPIII Microbial Identification System was observed as present and available for use during the tour. The LD stated DNA probe testing for Candida species, Gardnerella vaginalis, and Trichomonas vaginalis were performed on this analyzer. Laboratory records indicated the test was implemented on 08/27/19. 3. Quality control (QC) testing with Candida albicans was required with each new reagent lot as indicated in the BD Affirm VPIII Microbial ID Test procedure located in the Laboratory Procedure Manual. 4. The laboratory's Affirm VPIII QC log indicated QC was performed upon receipt of new reagent lots since implementation of the test. 5. The laboratory did not establish an Individual Quality Control Plan to reduce the amount and frequency of QC performance from 2 levels of control material each day of patient testing. 6. A total of 304 patient specimens were tested from 08/27/19 to date of survey, 08/03/21. See below Year Number tested 2019 113 2020 136 2021 55 7. In an interview at 12:45 p.m. on 08/03/21, the LD confirmed the above finding.