Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0886945	01/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saint Joseph Health System -	5215 Holy Cross Parkway, Mishawaka, IN	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to perform quality control testing, in accordance with analytic systems requirements, for one of two qualitative tests performed (Synovasure Alpha Defensin Lateral Flow Test) from 3-3-2020 to 1-26-2021, for eleven of eleven patients reviewed (refer to D5449).
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 document review and interview, the laboratory failed to perform external quality control at least once each day of patient testing for one of two qualitative tests performed (Synovasure Alpha Defensin Lateral Flow Test) from 3-3-2020 to 1-26-

	2021, for eleven of eleven patients reviewed. Findings included: 1. Review of patient test log titled: "List of Synovasure Patients" indicated the laboratory began testing patients using the "Synovasure Alpha Defensin Lateral Flow Test Kit" (Synovasure) on 3-3-2020. The log indicated the laboratory had performed a total of 74 tests between 3-3-2020 and 1-26-2021. 2. Review of patient test reports indicated the following patients received Synovasure testing: a. Patient #1; 3-3-2020 b. Patient #2; 3-12-2020 c. Patient #3; 5-12-2020 d. Patient #4; 6-9-2020 e. Patient #5; 6-23-2020 f. Patient #6; 7-14-2020 g. Patient #7; 8-18-2020 h. Patient #8; 9-22-2020 i. Patient #9; 11-28-2020 j. Patient #10; 12-19-2020 k. Patient #11; 1-20-2021 3. Review of "Synovasure Quality Control Log - SJRMC Mishawaka - Surgery" indicated the laboratory did not perform any quality control testing. 4. In interview on 1-28-2021 at 11:30 AM, SP2, Director of Laboratory Services, confirmed the laboratory began performing Synovasure testing on 3-3-2020 and indicated the laboratory did not perform external quality control on dates of patient testing from 3-3-2020 to date of survey. 5. Review of "Test Methodology And Annual Test Volume Log" (Enclosure I), signed by the laboratory director on 1-28-2021, indicated the laboratory performed 80 Synovasure tests per year.