Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1008641	02/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Flushing Road Internal Medicine & Pediatrics	1201 Flushing Road, Flint, MI	

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
D0000	. A survey for the addition of a specialty was completed on February 11, 2020. During the survey, it was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: Bacteriology- 42 CFR 493.1201
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to enroll in a proficiency testing program for C. difficile antigen and toxin testing for 2019. Findings include: 1. A record review of the laboratory's patient test log revealed the laboratory started testing patients for C. difficile antigen and toxin on 5/24/2019. 2. A record review of the laboratory's established "Proficiency Testing" policy revealed a section stating, "The lab will enroll and participate in Proficiency Testing on an annual basis." 3. A record review of the laboratory's documents revealed a lack of proficiency testing records for C. difficile antigen and toxin testing. 4. The surveyor requested proficiency testing records for 2019 on 2/11 /2020 at 10:43 am and the records were not made available. 5. An interview on 2/11 /2020 at 10:43 am with TC1 confirmed the laboratory was not enrolled in a proficiency testing program for C. difficile antigen and toxin testing for 2019.

D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on document review and interview, the laboratory failed to meet Bacteriology requirements as specified in 493.1230 through 493.1256. Findings include: 1. The laboratory failed to verify performance specifications for C. difficile antigen and toxin testing before reporting patient test results. Refer to D5421. 2. The laboratory failed to perform and document control procedures for C. difficile antigen and toxin testing each day of patient testing. Refer to D5445.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to assess employee competency for Testing Personnel #1 (TP1) in 2019. Findings include: 1. A record review of the laboratory's patient test log revealed the laboratory started testing patients for C. difficile antigen and toxin on 5/24/19 performed by TP1, a new employee. 2. A record review of the laboratory's competency assessments revealed a lack of documentation in 2019 for TP1. 3. A record review of the laboratory's established "Employee Evaluations" policy revealed a section stating, "All new laboratory employees will have a competency evaluation after their initial training, at the 6 month interval, and every year thereafter. The Competency Evaluation form will be filled-out. The monthly QA Review sheet will be followed to make sure employee evaluations are performed on time." 3. An interview on 2/11/2020 at 10:21 am with TC1 confirmed competency assessments were not performed in 2019 for TP1.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the

	laboratory failed to establish performance specifications for C. difficile antigen and toxin testing before reporting patient test results for 7 (patients #1-#7) of 7 patients receiving testing. Findings include: 1. A record review of the laboratory's patient test log revealed the following patients were tested for C. difficile antigen and toxin: a. Patient #1 performed on 5/24/19 b. Patient #2 performed on 5/24/19 c. Patient #3 performed on 8/7/19 d. Patient #4 performed on 10/16/19 e. Patient #5 performed on 11/7/19 f. Patient #6 performed on 11/6/19 g. Patient #7 performed on 1/13/2020 2. A review of the laboratory's records revealed a lack of verification of performance specifications for C. difficile antigen and toxin testing. 3. An interview on 2/11/2020 at 8:55 am with TC1 confirmed the laboratory did not verify performance specifications for the C. difficile antigen and toxin test system before testing and reporting results for patients.
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 record review and interview with Technical Consultant #1 (TC1), the laboratory failed to perform and document control procedures for C. difficile antigen and toxin testing for 6 (5/24/2019, 8/7/2019, 10/16/2019, 11/6/2019, 11/7/2019, 1/13 /2020) of 6 days patients were tested. Findings include: 1. A record review of the laboratory's patient test log revealed patient specimens were tested on the dates listed below: a. 5/24/2019 b. 8/7/2019 c. 10/16/2019 d. 11/6/2019 e. 11/7/2019 f. 1/13/2020 2. A record review of the laboratory's established "Quality Control" policy revealed a section stating, "All results must be recorded and evaluated every time they are run." 3. A record review of the laboratory's "C. DIFF QUIK CHEK COMPLETE Laboratory Procedure" signed by the laboratory director on 5/24/2019, revealed a section titled "Quality Control" stating, "The reactivity of the C. DIFF QUIK CHEK COMPLETE kit should be verified upon receipt using the Positive Control and negative control (diluent). the Positive Control is supplied with the kit (gray-capped bottle). The Positive Control confirms the reactivity of the other reagents associated with the assay, and is not intended to ensure precision at the analytical assay cut-off. Diluent is used for the negative control. Additional tests can be performed with the controls to meet the requirements for local, state and/or federal regulations and/or accrediting organizations." 4. The surveyor requested records of quality control performed for the dates listed above on 2/11/2020 at 9:02 am and they were not made available. 5. An interview on 2/11/2020 at 9:02 am with TC1 confirmed control procedures were not performed on days when patient testing was performed.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and

	assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the Technical Consultant failed to perform and document training for 1 (Testing Personnel #1) of 1 testing personnel performing C. difficile antigen and toxin testing. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of training performed for Testing Personnel #1. 2. An interview on 2 /11/2020 at 9:39 am with TC1 confirmed training documentation for Testing Personnel #1 was not available.