

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0362833	(X3) Date Survey Completed 06/27/2019
Name of Provider or Supplier Bloom Pediatrics	Street Address, City, State 2055 E 14 Mile Road, Birmingham, 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	D0000 A recertification survey was completed on June 27, 2019. During the survey, it was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: Bacteriology- 42 CFR 493.1201
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>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.</p> <p>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 establish performance specifications for the modified bacteriology FDA approved OSOM Strep A Test kit. Refer to D5423. 2. The laboratory failed to accurately perform the OSOM Strep A Test with an acceptable specimen source and accurately report out patient specimen source on throat culture reports. Refer to D5805.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv)</p>

Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

. Based on document review, manufacturer's instruction review, and interview with the Laboratory Director (LD) and Testing Personnel #1 (TP1), the laboratory failed to establish performance specifications for the modified bacteriology FDA approved OSOM Strep A Test kit for 26 (#1 - #26) of 34 patient charts audited by using specimen sources (vaginal and anal/rectal) outside the scope of the manufacturer's instructions from June 2017 to present date. Findings include: 1. Document review for 26 of 34 patient charts audited revealed on the "Rapid Strep and Throat Cultures Log Sheet" under the section "Patient Name" documentation of vaginal or anal/rectal written on the log. 2. When queried on June 27, 2019 at approximately 12:00 pm, TP1 acknowledged the specimen source written on the log were the actual specimen used for the waived OSOM Strep A Test kit. 3. The manufacturer's package instructions state "The OSOM Strep A Test should be used only with throat swabs or colonies taken directly from a plate. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established. The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained". 4. When queried on June 27, 2019 at approximately 12:00 pm, TP1 was not able to provide the surveyor documentation to demonstrate the laboratory had established performance specifications for the modification of the strep kit for using specimens outside of the manufacturer's instructions. 5. During the interview on June 27, 2019 at approximately 12:45 pm, the Laboratory Director acknowledged the laboratory had modified the procedure and did not establish performance specifications.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on document review, patient final electronic medical record (EMR) reports, manufacturer's instructions review, and interview with the Laboratory Director (LD) and Testing Personnel #1 (TP1), the laboratory failed to accurately report out the specimen source for the OSOM Strep A Test for 27 (#1 - #27) of 35 patient specimens reviewed and 2) accurately report out patient specimen source for 14 (#1 - #2, #5, #8 - #10, #12 - #13, #17 - #18, #21 - #23, and #26) of 35 specimen samples reviewed for the throat culture testing. Findings include: 1. Document review of the "Rapid Strep and Throat Culture Log Sheet" revealed for 27 of 35 patient specimens reviewed, the specimen source reported out on the patient's final report for the OSOM Strep A Test did not match the source written on the testing log sheet as follows: a. vaginal - #5 -

#8, #10, #14 - #15, #17 - #18, #21 - #22, #25, and #27 b. anal/rectal - #1 - #4, #9, #11 - #13, #16, #19 - #20, #23 - #24, and #26 2. Document review for 14 of 34 patient's final test report in the EMR reported the result as a Throat Culture. The specimen source reported did not match the source written on the "Rapid Strep and Throat Culture Log Sheet" as follows: a. vaginal - #5, #8, #10, #17 - #18, and #21 - #22 b. anal/rectal - #1 - #2, #9, #12 - #13, #23, and #26 3. During the interview on June 27, 2019 at approximately 2:55 pm, the LD acknowledged the OSOM Strep A Test and the final throat culture report in the patient's chart did not match the specimen source recorded on the patient log sheet.