Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0432359	08/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bloomington Pediatrics, Ltd	306 St Joseph Dr, Bloomington, IL	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to test proficiency testing (PT) samples with the same methodology used for patient specimens when analyzing and reporting PT results for total bilirubin and direct bilirubin testing in 2019 through 2021. Findings Include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) attestation statements indicated the following for the handling of total and direct bilirubin samples, "have as closely as practical, performed the analyses on these specimens in the same manner as regularly performed on patient samples". 2. Review of total and direct bilirubin calibration records found each date PT samples were ran the laboratory performed a calibration of the BR-2 Bilirubin Stat-Analyzer photometer for seven of seven PT dates reviewed form 2019 through 2021. 3. Interview on 08-20-2021 with the LD at 12:35 pm confirmed the LD performed calibrations prior to running PT samples for direct and total bilirubin but this calibration is not performed each day of patient testing.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to test proficiency testing (PT) samples by personnel who routinely perform testing in the laboratory for total and direct bilirubin in 2019 through 2021. Findings Include: 1. Review of the laboratory's policy and procedure manual identified testing personnel authorizations, which documented 3 of 19 testing personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who were authorized to perform total and direct bilirubin testing. 2. Review of the American Academy of Family Physicians (AAFP) PT attestation statements for total and direct bilirubin testing from 2019 through 2021 found TP#1 performed seven of seven PT events. 3. On survey date 08-20-2021, at 12:35 pm the LD confirmed two of three TP who were authorized to perform total and direct bilirubin testing failed to participate in PT for seven of seven PT events in 2019 through 2021. B. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to test proficiency testing (PT) samples by personnel who routinely perform testing in the laboratory for throat and urine cultures in 2019 through 2021. Findings Include: 1. Review of the laboratory's policy and procedure manual identified testing personnel authorizations, which documented 4 of 19 testing personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who were authorized to perform and report test results for throat and urine cultures. 2. Review of the American Academy of Family Physicians (AAFP) PT attestation statements for throat and urine culture testing from 2019 through 2021 found TP#1 performed six of seven PT events and the other event was performed by TP#3. 3. On survey date 08-20-2021, at 12:35 pm the LD confirmed two of four TP, who were authorized to perform throat and urine testing failed to participate in PT for seven of seven PT events in 2019 through 2021. C. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to test proficiency testing (PT) samples by personnel who routinely perform testing in the laboratory for bacteriology/virology tests performed on the Cepheid GeneXpert analyzer. Findings Include: 1. Review of the laboratory's policy and procedure manual identified testing personnel authorizations, which documented 19 of 19 testing personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who were authorized to perform and report test results for testing performed on the Cepheid GeneXpert. Test Menu Chlamydia Neisseria gonorrhoeae Influenza A Influenza B Respiratory Syncytial Virus (RSV) SARS-CoV-2 Group A Streptococcus (GAS) 2. Review of the American Academy of Family Physicians (AAFP) PT attestation statements for Cepheid GeneXpert testing from 2019 through 2021 found 5 of 19 TP performed seven of seven PT events for all seven analytes identified in finding number one. 3. On survey date 08-20-2021, at 12:35 pm the LD confirmed 5 of the 19 TP, who were authorized to perform testing for all seven analytes on the Cepheid GeneXpert had participated in PT for seven of seven PT events in 2019 through 2021.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.

	The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to retain testing documentation for throat and urine cultures performed for seven of seven proficiency testing (PT) events in 2019 through 2021. Findings Include: 1. Review of the American Academy of Family Physicians (AAFP) records from 2019 through 2021 found the laboratory failed to retain any documentation related to the testing of urine and throat culture specimens for seven of seven proficiency testing events reviewed in 2019 through 2021. 2. On survey date 8-20-2021, at 12:35 pm, the LD confirmed the laboratory failed to retain any documentation related to PT for throat and urine cultures for the seven of seven PT events reviewed in 2019 through 2021.
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 review of laboratory records and interview with the laboratory director (LD); the laboratory failed to document review for four of seven proficiency testing (PT) events for all analytes in 2019 through 2021. Findings Include: 1. Review of American Academy of Family Physicians (AAFP) PT records from event B of 2019 through event B of 2021 revealed the laboratory failed to document review of PT results for all analytes for the following events: Events B & C of 2019 Events A & B of 2021 2. On survey date 8-20-2021, at 12:35 pm, the LD confirmed the laboratory failed to document review of PT results for events identified above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to outline all required components of a test procedure for throat cultures to identify Group A Streptococci performed for 57 patients in 2020. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Throat Culture Procedure" for identification of beta hemolytic Group A streptococci (GAS). 2. Review of the procedure, "Throat Culture Procedure", found the procedure failed to outline the following required components of a test procedure: a. Control procedures. The expected results for the control procedures were not defined. b. Corrective actions to take when control results fail to meet the laboratory's criteria for acceptability. 3. Review of the laboratory's non-waived CLIA test volume worksheet identified throat cultures were performed for 57 patients in 2020. 4. Interview with the LD on 8-20-2021 at 12:35 pm confirmed the above findings. B. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to outline all required components of a test procedure for urine cultures performed for 685 patients in 2020. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Urine Culture". 2. Review of the procedure, "Urine Culture", found the procedure failed to outline the following required components of a test procedure: a. Control procedures. The expected results for the control procedures were not defined. b. Corrective actions to take when control results fail to meet the laboratory's criteria for acceptability. 3. Review of the laboratory's non-waived CLIA test volume worksheet identified urine cultures were performed for 685 patients in 2020. 4. Interview with the LD on 8-20-2021 at 12:35 pm confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: A. Based on direct observation, review of laboratory records, and interview with the laboratory director (LD); the laboratory failed to perform and document maintenance for the laboratory's centrifuge to ensure accurate and reliable test performance for routine chemistry testing for 441 patient tests in 2020. Findings Include: 1. Direct observation on 08-17-2021 at 10:10 AM identified centrifuge used by the laboratory to centrifuge patient specimens. 2. Review of the laboratory's policy and procedure manual identified the preventative maintenance document, "Maintenance Schedule

	For:", which outlined the following maintenance procedures for the centrifuge: "Inspect daily for evidence of contamination with potentially infectious material. Check the timer every six months. ...A dated entry of any maintenance activity is made in the laboratory instrument maintenance log." 3. Review of the laboratory's instrument maintenance logs found the laboratory failed to document any maintenance activities in 2019 through the date of survey (8-20-2021). 4. On survey date 08-20-2021, at 12:35 pm the LD confirmed daily routine maintenance and timer checks every six months were not documented for 2019 through the date of survey in 2021. B. Based on direct observation, review of laboratory records, and interview with the laboratory director (LD); the laboratory failed to perform and document maintenance for the laboratory's pipettes to ensure accurate and reliable test performance for routine chemistry testing for 441 patient tests in 2020. Findings Include: 1. Direct observation on 08-17-2021 at 10:10 AM identified three MLA pipettes (30ul, 100ul, and 1000ul) used by the laboratory for patient testing. 2. Review of the laboratory's policy and procedure manual identified the pipette preventative maintenance document that is part of the bilirubin testing procedure which outlined the following maintenance procedures for the pipettes: "routine cleaning and lubrication should only be necessary at 6 month intervals...the nozzle, and the nozzle insert in particular should be cleaned regularly." 3. Review of the laboratory's instrument maintenance logs found the laboratory failed to document any maintenance activities in 2019 through the date of survey (8-20-2021). 4. On survey date 08-20-2021, at 12:35 pm the LD confirmed routine maintenance and six month cleanings and lubrications were not documented for 2019 through the date of survey in 2021.
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 direct observation, review of laboratory records and interview with the laboratory director (LD); the laboratory failed to follow the laboratory's throat culture procedure to identify Group A Streptococcus (GAS) for 57 cultures performed in 2020 and all throat cultures performed in 2021. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Throat Culture Procedure", which indicated the use of "Sensi-disc bacitracin discs" used in order to determine the presence of group A streptococcus (GAS). 2. Direct observation on 8-17-2021 at 10:10 am during a tour of the laboratory found the laboratory failed to have bacitracin discs as required for throat culture testing. 3. Interview with the LD at 10:10 am on 8-17-2021 confirmed the laboratory has not used bacitracin discs as indicated in the throat culture procedure since it was reinstated. 4. Review of non-waived CLIA test volume worksheet found 57 cultures were performed in 2020 when the laboratory's procedure was not performed as indicated. 5. On survey date 8-20-2021 at 12:35 pm the LD confirmed the above findings.

D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to rotate quality control testing for direct and total bilirubin testing between the three authorized testing personnel in 2019 through date of survey (8-20-2021). Findings Include: 1. Review of the laboratory's bilirubin testing log found TP1 performed all control testing for five of five patient testing dates (10-28-2019, 11-1-2019, 3-6-2021, 3-11-2021, and 8-2-2021) reviewed. 2. During survey date 8-20-2021, at 12:35 pm, the LD confirmed that TP1 performed all quality control testing for total and direct bilirubin testing in 2019 through the date of survey. B. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to rotate quality control testing for throat and urine culture plates between the four authorized testing personnel in 2019 through date of survey (8-20-2021). Findings Include: 1. Review of the laboratory's culture plate quality control records found TP1 performed all control testing for four of four lots of strep selective agar (Lot #'s -135816, 132842, 127502, 135278) reviewed as part of a patient test result look back. 2. Further review of the laboratory's culture plate quality control records found TP1 performed all control testing for four of four lots of Blood Agar /MacConkey Agar bi-plates (Lot #'s -485743, 136448, 469341, 125102) reviewed as part of a patient test result look back. 3. During survey date 8-20-2021, at 12:35 pm, the LD confirmed that TP1 performed all quality control testing for throat and urine culture plates in 2019 through the date of survey. C. Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to rotate quality control testing for all analytes (Chlamydia, Neisseria gonorrhoeae, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), SARS-CoV-2, Group A Streptococcus (GAS)) tested on the Cepheid GeneXpert between the 19 authorized testing personnel in 2019 through date of survey (8-20-2021). Findings Include: 1. Review of the laboratory's quality control testing print-outs for the Cepheid GeneXpert found TP1 performed all control testing for five of five patient testing dates (10-18-2019, 10-28-2019, 4-17-2020, 11-11-2021, and 7-13-21) and all cartridge types in use (Chlamydia, Neisseria gonorrhoeae, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), SARS-CoV-2, Group A Streptococcus (GAS)) by the laboratory. 2. During survey date 8-20-2021, at 12:35 pm, the LD confirmed that TP1 performed all quality control testing for all cartridges used on the Cepheid GeneXpert.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to establish, identify and correct problems with analytical performance for bacteriology and routine chemistry testing performed in 2019 through the date of survey in 2021 (8-20-2021). Findings Include: 1. Review of the laboratory's procedure manual identified the document, "Quality Assurance Statement", which outlines that the laboratory monitors and evaluates the ongoing and overall quality of the total testing process. The policy stated the following: "All quality assurance activities must be documented and as necessary, the laboratory will review and revise all policies and procedures." 2. Review of laboratory records found the laboratory lacked any documentation of quality assurance reviews performed in 2019 through the date of survey in 2021 for analytical performance. 3. See D5403, D5433, D5445, and D5463. 4. On survey date 08-20-2021, at 12:35 pm, the LD confirmed the laboratory failed to document and identify issues with analytical performance for bacteriology and routine chemistry testing.
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: Repeat Deficiency Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to include all the required components of a laboratory test report for four of four Group A Streptococcus (GAS) test reports reviewed for testing on the Cepheid GeneXpert analyzer. Findings Include: 1. Review of four of four patient test reports (P20, P21, P22, and P23) for Group A streptococcus (GAS) testing on the Cepheid GeneXpert found the laboratory failed to clearly indicate the test result on the laboratory's test report. The test reports 2. On survey date 8-20-2021, at 12:35 pm, the LD confirmed the patient test reports seem to indicate the result from the Preliminary Quidel Rapid Strep A test and not the result from the Cepheid GeneXpert test system.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review laboratory records and interview with the laboratory director (LD) the LD failed to ensure testing personnel are performing throat cultures for Group A Streptococcus (GAS) testing as outlined in the laboratory procedure (D6014) and

	testing personnel maintained competency to perform all authorized chemistry and microbiology tests (D6030).
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review laboratory records and interview with the laboratory director (LD); the laboratory director (LD) failed to ensure testing personnel are performing throat cultures for Group A Streptococcus (GAS) testing as required based on the laboratory's procedure in 2019 through the date of survey in 2021 (8-20-2021). Findings Include: 1. The LD failed to ensure the laboratory had all the required reagents in order to perform throat culture testing as outlined in the laboratory procedure and the procedure was followed. See D5445. 2. On survey date 08-20-2021, at 12:35 pm, the surveyor's findings were confirmed by the LD.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory director (LD); the LD failed to ensure policies and procedures were established and maintained to monitor the competency of 19 testing personnel authorized to perform microbiology and chemistry testing in 2019 through the date of survey in 2021 (08-20-2021). Findings Include: 1. Review of the laboratory's policy and procedure manual identified the competency assessment policy, "Competency Assessment Bloomington Pediatric and Allergy", which indicated "Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the lab director to perform". 2. Review of competency assessment records found the LD failed to ensure complete competency assessments were completed for 19 of 19 testing personnel identified on the CMS-209 (laboratory personnel report) for each authorized test. 3. No competency assessments were found for individuals performing the pre-analytical urine and throat culture set-ups for 15 of

	15 testing personnel authorized by the LD to set up urine and throat cultures. 4. Interview with the LD on 08-20-2021 at 12:35 pm, confirmed the laboratory failed to perform and document competency assessments for all six elements of competency for each test performed by the laboratory that an individual is authorized to perform.