

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0432359	(X3) Date Survey Completed 04/17/2019
Name of Provider or Supplier Bloomington Pediatrics, Ltd	Street Address, City, State 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to ensure all testing personnel (TP), who performed proficiency testing (PT), signed the attestation statement for 5 of 6 PT events in 2017 through 2018. Findings Include: 1. Review of American Academy of Family Physicians (AAFP) PT records found for 5 of 6 events in 2017 through 2018 that the attestation statements were not signed by the personnel performing the testing. a. 2018 Event C found the attestation statement was not signed by the TP who performed the readings of urine cultures, bilirubin, and lead testing. b. 2018 Event A found the attestation statement was not signed by TP#10 who performed some of the bilirubin testing. c. 2017 Event C found the attestation statement was not signed by TP#10 who performed bilirubin testing. d. 2017 Event B found the attestation statement was not signed by TP#5 who performed the reading of urine cultures. e. 2017 Event A found the attestation statement was not signed by TP#1 who performed the bilirubin and lead testing. 2. Interview with the TC on survey date 4-17-2019, at 3:35 pm, confirmed all TP failed to sign the AAFP attestation statements for 5 of 6 PT events in 2017 through 2018.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to establish policies and procedures to assess competency of all personnel listed on the CMS-209 (Laboratory Personnel Report). Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Laboratory Personnel Competency Evaluation", which failed to address competency for the technical consultant. 2. On survey date 04-17-2019 at 03:35 pm, the TC confirmed the above findings.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to evaluate ungraded neonatal bilirubin (Direct) proficiency testing (PT) scores for 6 of 6 PT events reviewed in 2017 through 2018. Findings Include: 1. Review of American Academy of Family Physicians (AAFP) PT records found for 6 of 6 PT event in 2017 through 2018 AAFP did not grade PT results for neonatal bilirubin (Direct). 2. Review of PT documentation found no assessment of ungraded neonatal bilirubin (Direct) PT scores. 3. Review of test volume records indicate between January 5, 2018 and January 5, 2019, 208 patient test results were documented for neonatal bilirubin (Direct). 4. On survey date 4-17-2019, at 3:35 pm, the TC confirmed ungraded neonatal bilirubin (Direct) were not reviewed for 6 of 6 PT events in 2017 through 2018.

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:

A. Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to demonstrate it can obtain performance specifications for influenza A & B testing on the Cepheid GeneXpert prior to patient testing. Findings Include: 1. During tour of the laboratory facility on 4-16-2019, at 10:28 am, the TC confirmed the laboratory began influenza A & B testing using the Cepheid GeneXpert analyzer in October of 2018. 2. Review of the laboratory policy and procedure manual identified the policy, "New Tests", which states the following: "The lab will verify the

manufacture's performance specifications provided in the package insert - for accuracy, precision, reportable range, and reference ranges for each new, moderate complexity test." 3. Review of verification documentation found no data showing the accuracy, precision, and reportable range had been verified for influenza testing on the Cepheid GeneXpert analyzer for influenza A&B testing. 4. Review of the test volume worksheet indicate 2,183 patient tests were performed between January 5, 2018 to January 5, 2019 for influenza A & B. 5. On survey date 04-17-2019, at 3:35 pm, the TC confirmed no analysis had been documented to show the accuracy, precision and verification of the reportable range. B. Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to demonstrate it can obtain performance specifications for streptococcus A testing on the Cepheid GeneXpert prior to patient testing. Findings Include: 1. During tour of the laboratory facility on 4-16-2019, at 10:28 am, the TC confirmed the laboratory began streptococcus A testing using the Cepheid GeneXpert analyzer in October of 2018. 2. Review of the laboratory policy and procedure manual identified the policy, "New Tests", which states the following: "The lab will verify the manufacture's performance specifications provided in the package insert - for accuracy, precision, reportable range, and reference ranges for each new, moderate complexity test." 3. Review of verification documentation found no data showing the accuracy, precision, and reportable range had been verified for streptococcus A testing on the Cepheid GeneXpert analyzer. 4. Review of the test volume worksheet indicate 5,190 patient tests were performed between January 5, 2018 to January 5, 2019 for streptococcus A. 5. On survey date 04-17-2019, at 3:35 pm, the TC confirmed no analysis had been documented to show the accuracy, precision and verification of the reportable range.

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 review of laboratory records and interview with technical consultant (TC); the laboratory failed to develop a complete Individual Quality Control Plan (IQCP) for influenza A & B and streptococcus A testing on the Cepheid GeneXpert analyzer. Findings include: 1. Interview with the TC on 4-16-2019, at 10:28 am, confirmed the laboratory had developed an IQCP for testing on the Cepheid GeneXpert analyzer. 2. Review of the IQCP documentation for influenza A & B and streptococcus A testing on the Cepheid GeneXpert analyzer found the IQCP failed to address the following required components of an IQCP: a. Risk Assessment - Failed to address the specimens, test system, reagents, and environment and cover the entire test process from pre-analytical, analytical, and post analytical processes as well as supporting documentation. b. Quality Control Plan - No plan identified. c. Quality Assessment - No plan identified. 3. Review of the laboratory test volume worksheet indicated 7,373 patient tests were performed on the Cepheid GeneXpert for Influenza A&B and streptococcus A from January 5, 2018 through January 5, 2019. 4. On survey date 04-

17-2019, at 3:35 pm, the TC confirmed the laboratory failed to have a complete IQCP for testing on the Cepheid GeneXpert analyzer.

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 review of laboratory records and interview with the technical consultant (TC); the laboratory failed to include all the required components of a laboratory test report for 8 of 8 streptococcus A test reports reviewed for testing on the Cepheid GeneXpert. Findings Include: 1. Review of 8 of 8 patient test reports for streptococcus A testing on the Cepheid GeneXpert found the laboratory failed to clearly indicate the test result: a. Patient #: C2, Test Date: 02-14-2019 b. Patient #: C3, Test Date: 02-16-2019 c. Patient #: C5, Test Date: 11-09-2018 d. Patient #: C7, Test Date: 12-20-2018 e. Patient #: C11, Test Date: 11-10-2018 f. Patient #: C12, Test Date: 11-09-2018 g. Patient #: C14, Test Date: 12-20-2018 h. Patient #: C15, Test Date: 01-23-2019 2. On survey date 4-17-2019, at 3:35 pm, the TC 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.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
A. Based on review of laboratory records and interview with the technical consultant (TC); the TC failed to ensure annual competency assessments were completed for 5 of 5 testing personnel (TP) performing urine cultures in 2017 and 2018. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "Laboratory Personnel Competency Evaluation", which includes a competency evaluation form. 2. Review of competency assessment records for 5 of 5 TP (#1, 2, 3, 4, 5), who perform urine culture testing, failed to have competency assessment forms completed in 2017. 3. Review of competency records for 2018 found assessment of test performance documentation was documented, however 2 of 5 testing personnel miss read urine culture results and no corrective actions were noted. 4. No competency evaluation forms were completed in 2018 for 5 of 5 testing personnel for urine cultures in 2018. 5. On survey date 4-17-2019, at 3:35 pm, the TC confirmed competency assessments were not documented in 2017 and in 2018 competency assessments were incomplete for 5 of 5 TP that perform urine cultures. B. Based on

review of laboratory records and interview with the technical consultant (TC); the TC failed to ensure annual competency assessment covered all elements of competency for 2 of 2 testing personnel performing bilirubin testing in 2017 through 2019. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "Laboratory Personnel Competency Evaluation", which includes a competency evaluation form. 2. Review of competency assessment records for 2 of 2 testing personnel (TP - #1, 10) performing bilirubin testing failed to have complete competency assessments documented in 2017, 2018, and 2019. a. TP#1 - No documented competency assessments. b. TP#10 - 2017 - No competency form completed. 2018 - A note documenting PT testing was made but no form was completed and failed to cover all 6 elements of competency. 2019 - A note documented portions of competency but failed to use the laboratory form and address direct observation of patient testing, direct observation of maintenance, and assessment of test performance. 3. On survey date 4-17-2019, at 3:35 pm, the TC confirmed competency assessments were incomplete or not documented for 2 of 2 TP that perform bilirubin testing.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the technical consultant (TC); the laboratory director failed to specify, in writing, all the responsibilities and duties for 13 of 21 testing personnel (TP) listed on the CMS-209. Findings Include: 1. Review of the laboratory policy and procedure manual identified testing personnel authorizations for all 21 TP. 2. Review of TP authorizations found 13 of 21 authorizations failed to accurately reflect the testing performed by each individual. a. TP# 1, 2, 3, 4, 5, 13 - Failed to indicate Influenza A&B and Streptococcus A testing on the Cepheid GeneXpert and remove throat cultures for streptococcus, which have been discontinued by the laboratory. b. TP# 6, 7, 8, 9, 10, 11, 21 - Failed to indicate Influenza A&B and Streptococcus A testing on the Cepheid GeneXpert and remove throat cultures for streptococcus, which have been discontinued by the laboratory. 3. On survey date 04-16-2019 t 10:25 am, the technical consultant confirmed the laboratory director failed to accurately specify, in writing, the responsibilities and duties for 13 of 21 personnel listed on the CMS-209.