

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2007437	<b>(X3) Date Survey Completed</b>  01/08/2019
<b>Name of Provider or Supplier</b>  Bright Pediatrics, Pc	<b>Street Address, City, State</b>  2918 E Walnut Avenue, Dalton, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 8, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of PT samples into the patient workload as required. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed the LD failed to sign the attestation statements for the following Hematology and Bacteriology PT events: 2017 -- Events 2 and 3; 2018 -- Events 1,2, and 3. 2. An interview in the conference room on 1/8/2019 with Staff #2 (CMS 209) at approximately 3:00 p.m. confirmed the lack of LD signatures on attestation statements for the aforementioned PT events.</p>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(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</p>

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 proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed laboratory bacteriology log documents for the third PT event of 2018 were not available at the time of survey. 2. An interview with Staff #2 (CMS 209) in a conference room on 1/8 /2019 at approximately 3:00 p.m. confirmed the aforementioned PT documents were not available at the time of survey.

**D5200**

**GENERAL LABORATORY SYSTEMS**  
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on policy and procedure manual (SOP) review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems as required. Findings include: Refer to D5209

**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 review of the policy and procedure manual (SOP), the laboratory failed to establish a testing personnel (TP) competency policy as required. Findings include: 1. SOP review revealed the laboratory did not contain a TP competency for performing initial, six-month, and annual competencies. 2. An interview with Staff #2 (CMS 209) on 1/8/19 in a conference room at approximately 3:00 p.m. confirmed the laboratory SOP did not contain a competency policy. This is a REPEAT deficiency.

**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 bacteriology quality control (QC) document review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required. Findings include: Refer to D5477

**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:  
Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to include a policy and procedure for all phases of patient testing. Findings include: 1. SOP review revealed there was not a policy and procedure for specimen acceptance and rejection. 2. SOP review revealed there was not a policy and procedure for specimen collection 3. SOP review revealed there was not a step-by-step policy and procedure for the operation of the Emerald Cell-Dyn. 4. SOP review revealed there was not a policy and procedure for sterility check of microbiology media. 4. An interview with Staff #2 (CMS 209) in a conference room on 1/8/19 at approximately 3:00 p.m. confirmed the aforementioned items were not included in the laboratory SOP.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
 Based on review of calibration documents and staff interview, the laboratory failed to perform instrument calibration every six months as required. Findings include: 1. Cell-Dyn hematology analyzer calibration document review revealed calibration was performed once (3/7/18) since the last survey. 2. An interview with Staff #2 (CMS 209) in a conference room on 1/8/19 at approximately 3:00 p.m. confirmed the lack of required hematology analyzer calibrations.

**D5441**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
 Based on review on quality assurance (QA) and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. QA document review revealed the laboratory failed to produce hematology Levey-Jennings charts for 2017 and 2018. 2. An interview with Staff #2 (CMS 209) in a conference room on 1/8/19 at approximately 3:00 p.m. confirmed the lack of hematology Levey-Jennings charts for 2017 and 2018.

**D5477**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its

ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of bacteriology quality control (QC) documents and staff interview, the laboratory failed to perform QC as required. Findings include: 1. Review of bacteriology QC documents revealed sterility checks were not performed on throat and urine culture media for bacteriology. for 2017, 2018, and 2019 thus far. 2. Review of bacteriology QC documents revealed Taxo disc QC was not performed for 2017, 2018, and 2019 thus far. 3. An interview with Staff #2 (CMS 209) in a conference room on 1/8/19 at approximately 3:00 p.m. confirmed sterility checks were not performed for throat and urine culture media for the aforementioned time period. During the same interview, Staff #2 (CMS 209) confirmed Taxo disc QC was not performed for 2017, 2018, and 2019 thus far. This is a REPEAT deficiency.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on proficiency test (PT) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to review all PT reports received as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD/TC did not review the 2017 Bacteriology 2nd event report. 2. An interview with Staff #2 (CMS 209) on 1/8/2019 in the conference room at approximately 3:00 p.m. confirmed the aforementioned lack of LD/TC PT report review.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

	<p>Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to ensure that prior to testing patient's samples, all TP receive the appropriate training for the type and complexity of the services offered. Findings include: 1. TP document review revealed the LD/TC failed to perform an initial training competency on Staff #8 (CMS 209) in 2017 and Staff #12 (CMS 209) in 2018. 2. An interview with Staff #2 in a conference room on 1/8 /2019 at approximately 3:00 p.m. confirmed an initial competency was not performed for the aforementioned TP in 2017 and 2018.</p>
<p><b>D6032</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</p> <p>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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the responsibilities and duties of each individual involved in all phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to establish a duties and responsibilities policy and procedure for each person involved in all phases of laboratory testing. 2. An interview with Staff #2 (CMS 209) in a conference room on 1/8/19 at approximately 3:00 p.m. confirmed there was not a duties and responsibilities policy in the SOP.</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of testing personnel (TP) documents, quality control (QC) documents, and temperature logs, the technical consultant/laboratory director (TC /LD) failed to provide technical oversight over the laboratory. Findings include: Refer to D6049, D6053, and D6054</p>
<p><b>D6049</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p>

	<p>This STANDARD is not met as evidenced by:  Based on review of temperature logs and quality control (QC) logs, the technical consultant/laboratory director failed to perform a review as required. Finding include:  1. Temperature log and QC log review revealed the TC/LD did not perform a review in 2017 and 2018. 2. An interview with Staff #2 (CMS 209) in a conference room at approximately 3:00 p.m. on 1/8/2019 confirmed the aforementioned findings.</p>
<p><b>D6053</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:  Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. TP document review revealed the LD/TC failed to perform a six-month competency on Staff #8 (CMS 209) in 2018. 2. An interview with Staff #2 (CMS 209) in a conference room on 1/8/2019 at approximately 3:00 p.m. confirmed the aforementioned TP did not have a six-month competency performed.</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to perform annual competencies on TP as required. Findings include: 1. TP document review revealed the LD/TC failed to perform annual competencies on the following TP in 2017 and 2018: Staff #2-Staff #6, Staff #9-11 (all listed on CMS 209). 2. An interview with Staff #2 (CMS 209) in a conference room on 1/8/2019 at approximately 3:00 p.m. confirmed the failure of the LD/TC to perform competencies on the aforementioned TP.</p>