

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2007437	<b>(X3) Date Survey Completed</b>  07/21/2021
<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 July 21, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(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;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interview, the laboratory director failed to ensure all proficiency testing (PT) results are reviewed upon receipt. Findings include: 1. Review of the laboratory's PT records revealed no documentation of review on the American Academy of Physicians (AAFP) result reports for 2019 event #3, 2020 events #1, #2, and 2021 event #1. 2. Interview with staff #2 (CMS 209) on 7/21/21 in the conference room at approximately 12 PM, confirmed the missing aforementioned reviews.</p>
<b>D6019</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</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</p>

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and staff interview, the laboratory director failed to ensure the corrective action plan is followed when any proficiency testing (PT) results are found to be unacceptable or unsatisfactory. Findings include: 1. Review of the laboratory's PT records revealed no documentation of corrective action for American Academy of Family Physicians (AAFP) unacceptable or unsatisfactory results for 2019 event #3, 2020 event #3, and 2021 event #1. 2. Interview with staff #2 (CMS 209) on 7/21/21 in the conference room at approximately 12 PM, confirmed the missing aforementioned corrective actions.

**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:

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 have the appropriate education. Findings include: 1. TP document review revealed the LD/TC failed to ensure the TP had the minimal educational document on Staff #6, #7, and #8 (CMS 209) in 2019 and 2020. 2. An interview with Staff #2 (CMS 209) in the conference room on 7/21/21 at approximately 11:00 a.m. confirmed the lack of educational documents on the aforementioned TP.