

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1062625	<b>(X3) Date Survey Completed</b>  11/20/2020
<b>Name of Provider or Supplier</b>  Wellstar Pediatric And Adolescent Center - Smyrna	<b>Street Address, City, State</b>  4581 S Cobb Drive Se, Suite 100, Smyrna, 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 November 20, 2020. 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>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) document review and staff interview, the laboratory failed to document corrective action for unacceptable performance on a PT sample. Findings include: 1. PT document review revealed there were no corrective actions documented for PT sample # NB-2 or NB-7 for 2020 events #1 or #2. 2. An interview with staff #3 (CMS 209) in the lab director's office on 11/20/2020 at approximately 11:12 a.m. confirmed the lack corrective actions for the aforementioned PT samples.</p>
<b>D6029</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(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.</p>

This STANDARD is not met as evidenced by:  
Based on review of the staff competency documents, and staff interview, the laboratory director (LD) failed to ensure all testing personnel receive the appropriate training for the testing performed. Findings include: 1. Staff competency document review revealed the LD failed to document in writing the initial training/competency for testing personnel #2 and #4 (CMS 209). 2. An interview with Staff #3 (CMS 209) in the lab director's office on 11/20/2020 at approximately 11:30 a.m. confirmed the lack of the aforementioned initial training/competency.

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of the staff competency documents, and staff interview, the technical consultant (TC) failed to ensure semiannual competency was performed on all testing personnel. Findings include: 1. Staff competency document review revealed the TC failed to document in writing the semiannual competency for testing personnel #4 (CMS 209). 2. An interview with Staff #3 (CMS 209) in the lab director's office on 11/20/2020 at approximately 11:30 a.m. confirmed the lack of the aforementioned semiannual competency.

**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:  
Based on review of the staff competency documents, and staff interview, the technical consultant (TC) failed to ensure annual competency was performed on all testing personnel. Findings include: 1. Staff competency document review revealed the TC failed to document in writing the annual competency for testing personnel #3 (CMS 209) for the year of 2019. 2. An interview with Staff #3 (CMS 209) in the lab director's office on 11/20/2020 at approximately 11:30 a.m. confirmed the lack of the aforementioned annual competency.