

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2063559	<b>(X3) Date Survey Completed</b>  09/25/2018
<b>Name of Provider or Supplier</b>  Fasttrack Immediate Care	<b>Street Address, City, State</b>  1909 N Columbia Street, Suite D, Milledgeville, 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 September 25, 2018. 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>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Proficiency Institute (API) Performance Evaluation, and staff interview, the laboratory failed to document review of Proficiency Results for the Complete Blood Count (CBC). Findings: 1. Based on review of the API performance evaluation documents for the CBC, the laboratory failed to document review of the evaluation results for API 2016 Event #3, 2017 Event #1, Event #2, and Event #3. 2. Interview with staff #2 and #9 (CMS 209 form), on September 25, 2018 at approximately 2:40 pm in the breakroom, confirmed that the the API evaluation results were not documents as being reviewed for 2016 event #3, 2017 event #1, #2, and #3.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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</p>

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 review of Testing Personnel (TP) records, and staff interview the laboratory failed to provide documentation of initial training for TP performing testing. Findings:

1. Review of the TP records, the laboratory did not have documentaion of initial training records of 5 out of 7 new employees hired in the last two years. 2. Interview with staff #2 and #9 (CMS form 209), on September 25, 2017 at approximately 2pm in the breakroom, confirmed that there were no initial training records for the 5 new employees hired in the last two years.

**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 Testing Personnel (TP) documents and staff interview, the laboratory did not have documentation of the annual competency records for any of their TP. Findings: 1. Based on review of the TP documents, the laboratory failed to provide documentation that an annual competency assessment was performed on TP #3 (CMS form 209). 2. Interview with staff #2 and #9 (CMS 209 form) on August 25, 2018, at approximately 2:10 pm in the breakroom, confirmed that there were no annual competency records for TP#3.