

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2030855	<b>(X3) Date Survey Completed</b>  11/30/2018
<b>Name of Provider or Supplier</b>  Centers For Disease Control & Prevention Ii	<b>Street Address, City, State</b>  1600 Clifton Road Ne, Bldg 17,18, And 23, Atlanta, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's documentation of twice annual verification of accuracy (alternative assessment) for 2017 and interviews with the technical supervisors and testing personnel, the laboratory failed to verify the accuracy of the Coryne toxAB RT-PCR test twice annually. The findings include: 1. Review of the 2017 alternative assessment documentation for the Coryne toxAB RT-PCR test revealed that the laboratory failed two alternative assessments for 2017. On June 30, 2017, an alternative assessment was completed for the Coryne toxAB RT-PCR test. Test results revealed two out of two positive controls were reported as undetermined (UND) on the alternative assessment report. The alternative assessment report was reviewed and approved by Technical Supervisor #1 (TS1) and Technical Supervisor #2 (TS2). TS1 noted on the alternative assessment report that new panels should be made due to panel samples showing inhibition. On December 21, 2017, the second alternative assessment was completed by Testing Personnel #2 (TP2) using the same panels from the June 30, 2017 alternative assessment. The panel failed and was retested by TP2 on December 22, 2017. Positive controls failed and no corrective action was taken. 2. The laboratory's Alternative Assessment Procedure Doc. No.: PDL-100-P09 under Section 6.9 Investigating an Unacceptable AAP Result states, "The laboratory should systematically evaluate every aspect of the testing process in order to identify, understand, and correct any problems identified. Use the Unacceptable PT/AAP Investigation Form PDL-100-F34A to document the investigation and any outcomes resulting." The June 30, 2017 failure was identified and documented by TS1 and TS2 on the Unacceptable PT/AAP Investigation Form,</p>

but no corrective action was taken. TP2 identified the failure for the second alternative assessment on December 21, 2017 and December 22, 2017, but no corrective action was taken at the time. TP2 took corrective action on April 5, 2018 by creating and testing a new a panel for Coryne toxAB RT-PCR test and completed the Unacceptable PT/AAP Investigation Form documenting the December 22, 2017 failure. 3. The TS1 and TS2 confirmed during an interview on November 28, 2017 at 3:26 p.m. that the laboratory failed to verify accuracy of the Coryne toxAB RT-PCR test for 2017.