

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2175386	<b>(X3) Date Survey Completed</b>  01/07/2021
<b>Name of Provider or Supplier</b>  Reveal Diagnostic Services, Inc	<b>Street Address, City, State</b>  3915 Cascade Road, Suite 355, 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>D0000</b>	On February 16, 2021, an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 the review of Proficiency Testing (PT) records and interviews with the Technical Consultant(TC) (TP#3 CMS 209) and Clinic administrator, the laboratory director failed to review and attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed the laboratory failed to provide or retain the signed attestation forms for API event #3 of 2020. 2. An interview with the TC (TP#3 CMS 209) and the clinics administrator on 01/07/2021 at approximately 12:15 pm in the review room confirmed the PT documents were not reviewed and signed by the laboratory director.</p>
<b>D5293</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on Quality Assurance (QA) document review and interviews with the Technical Consultant (TC) (TP#3 CMS 209) and the clinic administrator, the laboratory failed to document all general laboratory systems QA activities as required. Findings include: 1. QA documents review revealed there were no monthly or quarterly QA documentation available at the time of survey from August 2020 to December 2020. 2. Room temperature and refrigerator temperature logs were not reviewed by the laboratory director on a monthly or quarterly basis. 3. Interviews with the TC (TP#3 CMS 209) and the clinic administrator in the review room on 01/07/2021 at approximately 12:25 p.m. confirmed there were no QA documentation available for the aforementioned period from August to December 2020.