

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2087560	(X3) Date Survey Completed 09/04/2020
Name of Provider or Supplier Principle Labs, Llc	Street Address, City, State 2550 Brodhead Road, Suite 105, Bethlehem, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	This facility is in compliance with 42 CFR Part 493.
D2009	<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 American Proficiency Institute (API) proficiency testing (PT) records and interview with the Administrative Director (AD), the Laboratory Director (LD) and Testing Personnel (TP) failed to sign the API PT attestation statement documents from 2018, 2019, and 2020. Findings include: 1. On the day of survey, 09/04/2020, review of API PT records revealed, the following API PT attestation statement documents were not signed by the LD: - 2018, Event #3, Hematology/coagulation. - 2018, Event #3, Chemistry Core. - 2020, Event #2, Covid 19. - 2020, Event #2, Chemistry Core. 2. The following API PT attestation statement documents were not signed TP performing: - 2018, Event #3, Chemistry Core. - 2019, Event #2, Immunology/immunohematology. 3. The AD confirmed the findings above on 09/04/2020 at 10:30 am.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on review of Laboratory competency policy and interview with the Administrative Director (AD), the laboratory failed to establish a complete procedure to assess the competency of the technical consultant and general supervisor (on the CMS 209 form, listed as personnel #2) for their regulatory responsibilities in 2019 and 2020. Findings include: 1. On the day of survey, 09/04/2020, the Administrative Director (AD), could not provide a complete policy that reviews how to assess the competency for 1 of 1 technical consultant and general supervisor or their regulatory responsibilities in 2019 and 2020. 2. The AD confirmed the finding above on 09/04/2020 around 09:00 am.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on American Proficiency Institute (API) proficiency testing (PT) records and interview with the Administrative Director (AD), the Laboratory Director's (LD) failed to identify problems that required a corrective action for the Immunology /Immonohematology- 1st event in 2019. Findings include: 1. On the date of survey, 09/04/2020, the review of PT records revealed, 2019 API Immunology /Immonohematology- 1st event did not state an acceptable plan of correction for the Rheumatoid Factor (RF). The laboratory received a 40% score which was signed by the laboratory director on May 14, 2019. 2. The AD confirmed the findings above on 09/04/2020 at 10:15 am.