

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1078232	(X3) Date Survey Completed 09/14/2021
Name of Provider or Supplier Princeton Medicine Physicians	Street Address, City, State 5 Plainsboro Road, Plainsboro, NJ	
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
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to participate in American Proficiency Institute (API) PT for the first event of 2020 for Hematology tests. The TC confirmed on 9/14/21 at 2:00 pm that the laboratory did not participate in the first event of 2020.</p>
D5221	<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 surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to review and evaluate results when they received an unacceptable score in Hematology tests performed with the</p>

American Proficiency Institute (API) for the third event in the calendar year 2020. The findings include: 1. The laboratory received an unacceptable score for Hematocrit (Hct), Mean Corpuscular Hemoglobin Concentration (MCHC), Mean Corpuscular Volume (MCV) and Red Cell Distribution Width (RDW) for sample HEM-14. 2. There was no documented evidence that the laboratory investigated the failure. 3. The TC confirmed on 9/14/21 at 1:30 pm that the laboratory did not review and document an evaluation of unacceptable PT results.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that PT samples were tested for Hematology tests for the first event of 2020 with the American Proficiency Institute (API). The TC confirmed on 9/14/21 at 2:00 pm that the LD did not ensure that PT samples were tested.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Files (PF) and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to have appropriate education documentation for all Testing Personnel (TP) performing laboratory testing from 4/3/18 to the date of survey. The findings include: 1. The laboratory did not have education records for three out of six TP listed on the CMS form 209. 2. The TC confirmed on 9/14/21 at 1:30 pm the above records were not on file.