

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1078232	(X3) Date Survey Completed 04/03/2018
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
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> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on eight out of eight TP in the calendar years 2016 and 2017. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. Assessment of problem solving skills and test performance through external or blind specimen was not documented on CA for all TP. 3. The TP # 1 listed on CMS form 209 confirmed on 4/3/18 at 1:20 pm that the CA was not performed correctly.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 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.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have training documented for four out of eight new TP from 2017. The TP # 1 listed on the CMS form 209 confirmed on 4/3/18 at 1:00 pm that new TP did not have training records.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) did not specify in writing the duties and responsibilities of TP engaged in the performance of preanalytic, analytic and post analytic phases of Complete Blood Count tests from 3/16/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 4/3/18 at 1:00 pm that the LD did not specify the duties and responsibilities of TP.