

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0919863	(X3) Date Survey Completed 03/15/2019
Name of Provider or Supplier Dr Prabhjit S Purewal Md Inc	Street Address, City, State 165 St Dominics Dr Ste 120, Manteca, CA	
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 laboratory policy and procedure, personnel training & competency evaluation records, and interview with the laboratory staff, the laboratory failed to evaluate competency of its testing personnel. The findings include: a. The laboratory has 2 testing personnel who performs testing in hematology. However, the laboratory did not have any training and competency evaluation records for any of the testing person. b. On March 15, 2019 at 11:40 am laboratory testing personnel affirmed that the laboratory did not have any training & competency evaluation records. c. The laboratory's testing declaration form, signed by the laboratory Director on March 2, 2019, stated that the laboratory performs 2,000 tests annually in hematology.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of proficiency testing and patient test records, lack of documentation of evaluation of proficiency testing performance, and interview with the laboratory testing personnel, the laboratory failed to evaluate proficiency testing</p>

performance of the 3rd event in 2018 for lymphocyte %. The findings include: a. The laboratory obtained a 60% score for the lymphocyte % at the 3rd event of 2018 AAB proficiency testing. b. The laboratory failed to provide any documentation showing that it had evaluated the proficiency testing performance and made any corrective action for the failure. c. On March 15, 2019 at 11:50 am laboratory testing personnel affirmed that the laboratory did not evaluate its proficiency testing performance of lymphocyte % for the 3rd event of 2018. d. The laboratory's testing declaration form, signed by the laboratory Director on March 2, 2019, stated that the laboratory performs 2,000 tests annually in hematology.

D6018

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

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on Surveyor review of proficiency testing policy, procedure and records, and interview with the laboratory staff, the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: See D5211

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 laboratory policy and procedure, personnel training & competency evaluation records, and interview with the laboratory staff, the laboratory director failed to 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. The findings include: See D5209