

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0598778	(X3) Date Survey Completed 12/19/2019
Name of Provider or Supplier Palo Alto Medical Foundation	Street Address, City, State 3200 Kearney St, Bldg 1 Fl 1, Fremont, 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
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of laboratory documents for personnel competency assessment and interview with the General supervisor (GS) on 12/18/19 and 12/19/19, it was determined that the Technical Supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year. The findings included: a. The laboratory identified eight (8) testing personnel (TP) and one General Supervisor (GS) on the form CMS-209. b. The General Supervisor's start date was March of 2019. c. Although the laboratory maintained a policy for competency assessment of all lab personnel within its quality manual titled 'Quality Manual Policy, 'PAMF-QA-POL-4.4,' version 3,' the laboratory was unable to provide for review documents evaluating the competency of the General Supervisor at least semiannually during the first year for high complexity testing. d. The failure to evaluate and document the competency of the General Supervisor at least semiannually during the first year for high complexity testing, was confirmed by interview with the General Supervisor and Quality Assurance management personnel on 12/19/19 at 12.40 p.m. e. The laboratory reports performing approximately 300,000 patient tests annually.</p>