Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1067205	(X3) Date Survey Completed 06/20/2018
Name of Provider or Supplier Palo Alto Medical Foundation For Health,	**Street Address, City, State** 701 E El Camino Real, 2nd Fl, Mountain View, 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
D2047	PARASITOLOGY CFR(s): 493.829(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent was unsatisfactory performance. The findings included as follows: a. The laboratory performed parasitology in house for their patients. b. In order to ensure and verify the accuracy of the testing procedures, the laboratory enrolled its proficiency testing with CAP (College of American Pathologists) PT program. c. The laboratory attained a score of 75 % for parasitology testing in the 3 rd 2016 PT event was unsatisfactory performance. d. The laboratory performed parasitology in approximately 13 patient samples monthly. e. The laboratory staff affirmed (6/20/18 @ 14:05) that the laboratory failed to attain an overall testing event score of 75% for parasitology in the 3 rd 2016 PT event was unsatisfactory performance.
D2066	SYPHILIS SEROLOGY CFR(s): 493.835(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to

	attain an overall testing event score of at least 80 percent was unsatisfactory performance. The findings included as follows: a. The laboratory performed syphilis serology (RPR) by SureVue in house for their patients. b. In order to ensure and verify the accuracy of the testing procedures, the laboratory enrolled its proficiency testing with CAP (College of American Pathologists) PT program. c. The laboratory attained a score of 0 % for RPR testing in the 3 rd 2016 PT event was unsatisfactory performance. d. The laboratory performed RPR in approximately 928 patient samples monthly. e. The laboratory staff affirmed (6/20/18 @ 14:05) that the laboratory attained a score of 0 % for RPR testing in the 3 rd 2016 PT event was unsatisfactory performance.
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to attain al testing event score of at least 80 percent of acceptable responses each each analyte in each testing event was unsatisfactory performance. The findings included as follows: a. The laboratory performed Rubella in house for their patients. b. In order to ensure and verify the accuracy of the testing procedures, the laboratory enrolled its proficiency testing with CAP (College of American Pathologists) PT program. c. The laboratory attained a score of 20 % for Rubella testing in the 2 nd 2017 PT event was unsatisfactory performance. d. The laboratory performed Rubella in approximately patient samples monthly. e. The laboratory staff affirmed (6/20/18 @ 14:15) that the laboratory attained a score of 20 % for Rubella in the 2 nd 2017 PT event was unsatisfactory performance.
D2109	TOXICOLOGY CFR(s): 493.845(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included as follows: a. The laboratory performed Phenobarbital in house for their patients. b. In order to ensure and verify the accuracy of the testing procedures, the laboratory enrolled its proficiency testing with CAP (College of American Pathologists) PT program. c. The laboratory attained a score of 60 % for Phenobarbital testing in the 1st 2017 PT event was unsatisfactory performance. d. The laboratory performed Phenobarbital in approximately 22 patient samples monthly. e. The laboratory staff affirmed (6/20/18 @ 14:25) that the laboratory attained a score of 60% for Phenobarbital in the 2 nd 2017 PT event was unsatisfactory performance.

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 review of the laboratory proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to be responsible for the overall operation and failed to ensure that the proficiency testing samples are tested as required. The findings included as follows; See D-2047, D-2066, D-2075, and D-2109