Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0931219	10/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Palos Verdes Medical Group	550 Deep Valley Drive, Ste 319, Rolling Hills, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on the number and severity of the proficiency testing (PT) deficiencies The condition of proficiency testing for non-waived testing was not met. The findings included: 1) Based on review of American Proficiency Institute (API) proficiency testing (PT) documents, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte in two consecutive testing events and for two out of three consecutive proficiency testing events for the analytes: chloride and sodium leading to unsuccessful performance. See D2096 2) Based on review of the American Proficiency Institute (API) laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC) and testing personnel (TP) it

	was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for 2nd event in 2022 (Q2-2022) 2022 for the analyte chloride. D2087
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 American Proficiency Institute (API) laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC) and testing personnel (TP) it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event with unsatisfactory analyte performance for HsCRP during the third even of 2021 (Q3-2021) which is unsatisfactory. The findings included: 1) For the API (Q3-2021) the lab received an successful result of zero (0%) for Hs CRP. 2) On October 27, at approximately 1:00pm (TC) affirmed the results in 1. 3) The laboratory's testing declaration form, signed by the Lab Director (LD) on October 25, 2022, stated that the laboratory no longer performs the HsCRP test.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 American Proficiency Institute (API) laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC) and testing personnel (TP) it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event with unsatisfactory analyte performance for the testing event. The findings included: 1) For the API (Q2-2022) the lab received an unsuccessful result of 20% for Chloride. 2) On October 27, at approximately 1:00pm Technical Consultant (TC)affirmed theresults stated in 1. 3) The laboratory's testing declaration form, signed by the Lab Director (LD) on October 25, 2022, stated that the laboratory performs approximately 2,673 Chloride tests in Routine Chemistry annually: (D2016)
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) documents, it was determined that the laboratory failed to achieve satisfactory

	performance for the same analyte in two consecutive testing events and for two out of three consecutive testing events for the analytes sodium and chloride leading to unsuccessful performances. The findings include: 1. API reported two consecutive events on events Q- 2, 2022 and Q- 3, 2022 for chloride. The laboratory received unsuccessful scores of 20% on both events. 2. API reported two out of three consecutive events on events Q- 1, 2022 and Q- 3, 2022 for sodium. The laboratory received unsuccessful scores of 40% on both events. 3. On October 27,2022 at approximately 1:00pm (TC) affirmed the results in 1 and 2. 4. The accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 5. The laboratory's testing declaration form, signed by the Lab Director (LD) on October 25, 2022 stated that the laboratory performs approximately 56,324 tests in the specialty of Chemistry annually. (D2016)
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 American Proficiency Institute (API) laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC) and testing personnel (TP) it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for (Q-2 2022) for the analyte Estradiol. The findings included: 1) For the API (Q-2 2022) the lab received an usuccessful result of 60% for Estradiol. 2) On October 27, at approximately 1:00 pm (TC) affirmed the results in 1. 3) The laboratory's testing declaration form, signed by the Lab Director (LD) on October 25, 2022, stated that the laboratory performs approximately one (1) test of Estradiol in the speccialty of Endocrinology annually: (D2016)
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor's observation of the laboratory testing area and interview with Technical Consultant (TC) and testing personnel (TP); it was determined that the laboratory testing area failed to be constructed and arranged to ensure the space, necessary for conducting analytical phase of the clinical testing process. The findings included: 1. The laboratory area consisted of a small room (approximately 200-300 square feet) which serves to house the automated testing instruments as well as storage area for reagents, documents, patients' results, and data. 2. The space designated for the laboratory appears to be insufficient. The room is crowded, difficult to maintain, inappropriate for proper traffic flow, and fails to provide sample integrity and quality for testing, in addition to an increased risk of contamination of paperwork and possible cross-contamination of samples. 3. The TC affirmed on October 27, 2022, at approximately 3:00 p.m. that the laboratory failed to be constructed and

	arranged to ensure the space necessary for conducting analytical phase of the testing process. 4. Sample processing was found to be on top of the analyzer. 5. SAR-CoV -2 samples to be tested were placed on a high shelf above the head of TP while working on the computer. 6. The laboratory's testing declaration form, signed by the laboratory director on October 27, 2022, stated that the laboratory performs approximately 119,325 tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, American Proficiency Institute (API) proficiency testing (PT) records, interview with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. 1. Corrective action forms for six(6) of seven (7) unsuccessful PT testing were not located at the time of survey. 2. Partial data was presented to the surveyor by the TC for the corrections. 3. The incomplete corrective action report lacked LD signature and date signed. 4. Lab failed to follow their established policy for corrective action remediation. 5. The laboratory's testing declaration form, signed by the laboratory director on October 27, 2022, stated that the laboratory performs approximately 119,325 tests annually.