Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0689489	08/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kern Valley Healthcare District	6412 Laurel Ave, Lake Isabella, 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 review of the first Immunohematology event of 2021 (Q1-2021) and second Immunology event of 2021 (Q2-2021) of the American Proficiency Institute (API) proficiency testing (PT) records, random patient sampling test results, and interview with the technical supervisor (TS) and testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 100 percent of acceptable responses for D (Rho) type and Compatibility Testing respectively. 1. The API reported for Immunohematology Q1-2021 D (Rho) type event unacceptable performance score of 80% 2. The API reported for Immunohematology Q2-2021 Compatibility Testing event unacceptable performance score of 80% 3. The laboratory analyzed and

	reported D (Rho) type and Compatibility Testing during the period wherein the laboratory received unsuccessful proficiency testing scores, and patients results could not be assured. 3. The TS and TP affirmed on August 2, 2023, at approximately 12:30 p.m. that the laboratory received the above unsatisfactory proficiency testing score. 4. Based on the laboratory testing declaration signed by the laboratory director on February 14, 2023, the laboratory tests 211 (Rho) type samples and 142 Compatibility Testing samples annually.
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records for Microbiology first event of 2023 (Q1-2023) six (6) randomly selected patients from 2/15/2021 to 8/2/2023, and interview with the technical supervisor (TS); it was determined that the laboratory failed to participate the testing event which is unsatisfactory performance and resulted with a score of 0 for the testing event. The findings included: 1. Laboratory proficiency testing records showed the laboratory attained a score of 0% for Bacteriology, Virology, and other Microbiology testing during the Q1-2023 for the following analytes: C. difficile Toxin, Gram stain, Gram stain morphology, Group A Strep antigen, Legionella antigen, MRSA culture, S. pneumoniae antigen, Rapid Urease, Influenza A, Influenza B, SARS-CoV-2 Antigen, SARS-CoV-2 liquid (molecular), and SARS-CoV-2 swab (molecular). 2. The TS affirmed on August 2, 2023, at approximately 1:00 p.m. the unsatisfactory score of 0% obtained by the laboratory for Bacteriology, Virology, and other microbiology analytes Q1-2023. 3. Based on the annual test volume reported for 2023, the laboratory performed and reported approximately 138 Microbiology analytes.
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) proficiency testing (PT) records, random patient sampling test results, and interview with the technical supervisor (TS) and laboratory testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Free T4 and TSH for the first event of 2022 (Q1-2022). The findings included: 1. Analyte Event Performance Free T4 Q1-2022 20% TSH Q1-2022 40% 2. The

	laboratory analyzed and reported test results for approximately 580 Free T4 and 1,357 TSH annually. 3. The TS and TP confirmed on August 2, 2023, at approximately 2:00 p.m. during the survey that the laboratory received the above unsatisfactory proficiency testing scores for Free T4 and TSH stated in 1.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test 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) of the laboratory proficiency testing (PT) result reports for the first Immunohematology event of 2021 and interview with the laboratory technical supervisor (TS), it was determined that the laboratory failed to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event was unsatisfactory analyte performance for the testing event. The findings included: 1. API reported a score of 80 % for ABO group and Rh (D) type in the 2021 first event (Q1-2021) which was unsatisfactory analyte performance for the testing event. 2. The laboratory TS affirmed that the laboratory attained a score of 80 % for ABO group and Rh (D) type for Q1-2021 event which was unsatisfactory analyte performance for the testing event. 3. The laboratory performed ABO group and Rh (D) type in approximately 50 patient samples monthly.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the first quarter of 2021 (Q1-2021) of the American Proficiency Institute (API) proficiency testing (PT) records, random patient sampling test results, and interview with the technical supervisor and testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 100 percent of acceptable responses for Compatibility Testing. 1. The API reported for Immunohematology Q1-2021 event unacceptable performance score of 80% for Compatibility Testing. 2. The laboratory analyzed and reported compatibility testing during the period wherein the laboratory received an unsuccessful proficiency testing score, and patients results could not be assured. 3. The TS and TP affirmed on August 2, 2023, at approximately 12:30 p.m. that the laboratory received the above unsatisfactory proficiency testing score. 3. Based on the laboratory testing declaration signed by the laboratory director on February 16, 2023, the laboratory tests 142 samples for Compatibility Testing.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyors' interviews with the laboratory's technical supervisor (TP) and testing personnel (TP) and record review of pre-analytic, analytic, and postanalytic remedial action records on August 2, 2023, the laboratory failed to establish written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's systems. Findings included: 1. According to laboratory's TS, during preanalytic, analytic, and postanalytic review of patients' test results, if a patient specimen was received or a report was issued that did not meet the laboratory's criteria for acceptability, a description as to why the specimen or report did not meet the laboratory's criteria for acceptability would be documented, appropriate corrective actions would be taken and noted, and the incident would be captured for quality assessment review. 2. Based on surveyor review of policies and procedures on 8/2/2023 at approximately 3:00 p.m.; it was determined that the laboratory failed to maintain written policies and procedures detailing the quality assessment process described for all phases of laboratory testing performed. 3. According to the laboratory testing declaration of tests volume, the laboratory performed approximately 181,138 patient tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's records for policies and procedures, patients' test results records, proficiency testing reports, direct observation by the surveyors during the lab tour, and interviews with the technical supervisor and testing personnel on August 2, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D2021, D2098, D2153, D2173, and D5391.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of personnel training and interview with the technical supervisor (TS) on August 2, 2023 (survey date), the TS failed to identifying training needs for

	the Immunohematology testing person and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed. The findings included: See D2153 and D2173.