Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0885230	05/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
High Desert Medical Group	43839 15th St W, Lancaster, 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
D0000	A proficiency testing desk review survey was performed on 5/15/2024, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
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 Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and American Proficiency Institute (API) records (2023-2 and 2024-1), the laboratory failed to successfully participate in a proficiency testing

	program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the subspecialty of Hematology resulting in unsuccessful performance. Refer to D2130.
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 Surveyor review of laboratory's proficiency testing evaluation records, and interview with the laboratory technical consultant on May 15, 2024, at 1 pm, the laboratory failed to attain a score of at least 80% of acceptable responses for the HCG analyte. The findings include: 1. The laboratory received a score of 40% for the HCG analyte from the proficiency testing organization, AAB, at the M2 event in 2023. This score resulted in an unsatisfactory analyte performance for the event. Therefore, the accuracy of the laboratory's HCG results reported to the patients cannot be assured and may have potentially harmed patients. 2. The laboratory technical consultant on May 15, 2024, at 1 pm, affirmed that it received a 40% score for the HCG analyte probably due to the bad proficiency testing samples. 3. The laboratory's testing declaration form signed by the laboratory director on 5/7/2024, stated that the laboratory performed approximately 91,071 tests in chemistry, annually.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API-American Proficiency Institute (API) report, the laboratory failed to achieve satisfactory performamce for two consecutive events (2023 second testing event and 2024 first testing event) for the specialty of Hematology: The finding include: 1. Prothrombin Time (PT) - 40% 2023 second event PT - 60% 2024 first event A review of the 2023 and 2024 scores from American Proficiency Institute confirmed the above findings. Based on desk review of Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute evaluation reports, the laboratory failed to achieve satisfactory performance for two of three events proficiency events in 2023 and 2024 for analyte Prothrombin Time (PT). The finding include 1. The laboratory received the following scores: 40% on the 2023 PT second event 60% on the 2024 PT first event 2. A review of the 2023 and 2024 proficiency Testing scores from American Proficiency Institute confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, instrument print out, final report and interview with the laboratory technical consultant on May 15, 2024, at 1 pm, the laboratory failed to follow its procedure to verify the critical value by repeating the test run for 1 patient out of 5 patients, reviewed. The findings include: 1. The laboratory obtained a critical low result of potassium, 2.6 mmol/L, for the patient acc# 513188 on the Vitros 5600 chemistry analyzer. The laboratory reported this result without verifying it by repeat analysis though its procedure instructs to repeat. The laboratory redrew the patient sample 3 hours later and obtained a normal potassium result. Therefore, the accuracy of the laboratory's reported critical results cannot be assured and may have potentially harmed patients. 2. The laboratory technical consultant on May 15, 2024, at 1 pm, affirmed that the sample, # 513188, was not repeated to verify the result as per the laboratory's policy. 3. The laboratory's testing declaration form signed by the laboratory director on 5/7/2024, stated that the laboratory performed approximately 91,071 tests in chemistry, annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute records for 2023-2 and 2024-1 events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final test report, proficiency testing records and interview with

	the laboratory technical consultant on May 15, 2024, at 1 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and may have potentially harmed patients. The findings include: See D2098 and D5401.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final report and interview with the laboratory technical consultant on May 15, 2024, at 1 pm, the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: The laboratory personnel did not verify the potassium test results by repeat analysis. See D5401.
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 a proficiency testing desk review of CASPER 0155D report and American Proficiency Institute records for 2023-2 and 2024-1 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2130.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing evaluation records, and

	interview with the laboratory technical consultant on May 15, 2024, at 1 pm, the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for the analyte HCG. The findings include: The laboratory had an unsatisfactory proficiency testing performance for the HCG analyte. See D2098.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, instrument print out, final report and interview with the laboratory technical consultant on May 15, 2024, at 1 pm, the laboratory testing personnel failed to follow the laboratory's procedures for test analyses. The findings include: The laboratory testing person #1 did not verify the potassium test results by repeat analysis. See D5401.