Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0572581	01/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Desert Oasis Healthcare Medical Group	275 N El Cielo Rd Ste D402, Palm Springs, 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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control records and interview with the laboratory technical consultant on January 26, 2024, at 11:35 am, the laboratory failed to have control procedures that monitor the precision of the complete analytic process. The findings include: 1. The laboratory performed Troponin test using the Triage Meter instrument. The laboratory used a control procedure by running quality control materials on each day of patient testing to detect immediate errors and system failure. However, the laboratory lacked a control procedure that will monitor the precision of the test over time. Test precision is usually monitored over time by a Levey-Jennings chart of the control. The laboratory did not monitor the trend and shift of the control over time and thus failed to detect any system failure. As a result, the laboratory failed in proficiency testing in 2023 and passed after re-calibration of the instrument. Therefore, the accuracy of the Troponin test results rendered by the laboratory cannot be assured and might have had harmed patients. 2. The laboratory technical consultant on January 26, 2024, at 11:35 am, affirmed that the laboratory did not use a Levey-Jennings chart to monitor test precision. 3. The laboratory's testing

	declaration form, signed by the laboratory director on 1/15/2024 stated that the laboratory performs approximately 1,224 Troponin tests, annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patients test, quality control and quality assessment records, and interview with the laboratory technical consultant on January 26, 2024, at 11:35 am, the laboratory failed to establish the quality assessment for the analytical system. The findings include: The laboratory did not have a system in place to assess the quality of its work, see D5441. Quality assessment is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. QA of the Analytic System includes assessing: Test procedures; Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; Specimen and reagent storage condition; Equipment/instrument/test/system maintenance and function checks; Establishment and verification of method performance specifications; Calibration and calibration verification; Control procedures; Comparison of test results; Corrective actions; and Test records.
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 and procedure, patients test, quality control and quality assessment records, and interview with the laboratory technical consultant on January 26, 2024, at 11:35 am, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D5441 and D5791.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control records and interview with the laboratory technical consultant on January 26, 2024, at 11:35 am, the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided. The findings include: The laboratory failed to have control procedures that monitor the precision of the complete analytic process. So, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have had harmed patients, see D5441.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patients test, quality control and quality assessment records, and interview with the laboratory technical consultant on January 26, 2024, at 11:35 am, the laboratory director failed to ensure that the laboratory established and maintained the quality assessment programs to assess the quality of laboratory services provided. The findings include: See D5791.