Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2318147	10/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Oceanside Diagnostics Llc	2821 Oceanside Blvd, Ste F, Oceanside, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of personnel competency assessment records and an interview with laboratory staff on October 27, 2025, it was determined that the laboratory failed to follow policies and procedures to assess competency of 1 out of 1 general supervisor (GS) and 1 out of 2 testing personnel (TP) for 20 days in June 2025. The findings included: 1. It was the practice of the laboratory to perform high complexity toxicology testing. The Clinical Laboratory Scientist (CLS) were responsible for analyzing and reporting results of the screening and confirmation test for pain panel medications and the drugs or abuse analytes. 2. The laboratory hired TP#2 on 4/15 /2025. TP#2 received training from TP#1, and her competency assessment was signed and reviewed by the laboratory director on 6/6/2025. The six-month competency assessment for TP#1, who also served as a general supervisor, occurred on 06/05 /2025. TP#2, who has not yet been qualified as competent, conducted this assessment. Additionally, the laboratory director did not sign and approve the competency assessment of TP#1. TP#1 continued as general supervisor and testing personnel until 06/24/2025 without the director's approval. 3. On October 27, 2025, at approximately 11:00 a.m., the laboratory staff confirmed that TP#1, who also served as GS, did not have competency assessments for 20 days. 4. The laboratory's testing declaration form, signed by the laboratory director on October 20, 2025, stated that the laboratory performed approximately 420,348 tests annually. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(10) (e)(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(5); This STANDARD is not met as evidenced by: Based on the review of the laboratory personnel records and an interview with laboratory staff on October 27, 2025, it was determined that the laboratory director failed to ensure that laboratory have at least one general supervisor to provide day-to-day supervision of high complexity tests performed by the TP for a period of 59 days in 2025. See D6142.
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on the review of personnel qualification records and an interview with laboratory staff on October 27, 2025, it was determined that the laboratory failed to have at least one general supervisor to provide day-to-day supervision of testing personnel and reporting of test results for a period of 59 days in 2025. The findings included: 1. It was the practice of the laboratory to perform high complexity toxicology testing. The laboratory must have at least one on-site general supervisor for daily supervision of testing personnel and the reporting process. 2. On October 27, 2025, at approximately 11:30 a.m., the laboratory staff confirmed that the previous general supervisor quit on June 24, 2025. A new supervisor was hired on August 11, 2025, and officially became the general supervisor on August 22, 2025, after completing competency training. The laboratory did not have a general supervisor between these two dates. 3. The laboratory's testing declaration form, signed by the laboratory director on October 20, 2025, stated that the laboratory performed approximately 420,348 tests annually. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients.