Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2262146	07/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dialogix Laboratories	570 Nevada St Ste E, Redlands, 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
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, and interview with the Technical Supervisor (TS) on July 17, 2025, it was determined that the laboratory failed to return proficiency testing results for Routine Chemistry to the proficiency testing program within the time frame specified by the program and received a score of 0 for the testing event. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing (PT) program for Routine Chemistry testing in 2024 and 2025. According to the API evaluation report, the laboratory received a score of 0 for Q1-2025. 2. On July 17, 2025, at approximately 9:20 am, the Technical Supervisor affirmed that the laboratory did not submit PT results for Routine Chemistry tests to API within the specified time frame. 3. The laboratory's testing declaration form, signed by the laboratory director on July 10, 2025, stated that the laboratory performed approximately 50,930 Routine Chemistry tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) (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 laboratory's proficiency testing (PT) records, and interview with the Technical Supervisor (TS) on July 17, 2025, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Endocrinology analyte Estradiol. The findings included: 1. The laboratory participated in the American Proficiency Institute (API) proficiency testing (PT) program for endocrinology using the DiaSorin Liaison XL. According to the API evaluation report, the laboratory received an unsatisfactory score of 40% for Q2-2025. 2. On July 17, 2025, at approximately 9:00 am the Technical Supervisor affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory's testing declaration form, signed by the laboratory director on July 10, 2025, stated that the laboratory performed approximately 5,700 endocrinology tests annually.
D2104	ENDOCRINOLOGY CFR(s): 493.843(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, and interview with the Technical Supervisor (TS) on July 17, 2025, it was determined that the laboratory failed to return proficiency testing results endocrinology to API within the time frame specified by the program and received a score of 0 for the testing event. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing (PT) program for endocrinology testing in 2024 and 2025. According to the API evaluation report, the laboratory received a score of 0 for Q1-2025. 2. On July 17, 2025, at approximately 9:10 am, the Technical Supervisor affirmed that the laboratory did not submit PT results for endocrinology tests to API within the specified time frame. 3. The laboratory's testing declaration form, signed by the laboratory director on July 10, 2025, stated that the laboratory performed approximately 5,700 endocrinology tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.
D2121	HEMATOLOGY CFR(s): 493.851(a) (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 laboratory's proficiency testing (PT) records, and interview with the Technical Supervisor (TS) on July 17, 2025, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte for the specialty Hematology in 2025. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing (PT) program for hematology using the DxH 560 Analyzer. According to the API evaluation report, the laboratory received unsatisfactory scores in the first event of

	2025 as below: Erythrocyte Count: 60% Hematocrit: 40% Partial Thrombin Time (APTT): 40% 2. On July 17, 2025, at approximately 9:30 am the Technical Supervisor affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory's testing declaration form, signed by the laboratory director on July 10, 2025, stated that the laboratory performed approximately 14, 280 hematology tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on the review of Quality Control (QC) records of routine chemistry, endocrinology and general immunology, and an interview with the Technical Supervisor (TS) on July 17, 2025, the laboratory failed to verify the stated values of the commercially assayed QC materials prior to their use. The findings include: 1.It was the practice of the laboratory to utilize Randox QC materials for monitoring chemistry, endocrinology and general immunology tests with Beckman Coulter AU 680 and Beckman Access 2 analyzers. The 2. On July 17, 2025, at approximately 12:00 pm, the TS stated that the laboratory did not verify the stated values of the commercially assayed QC materials prior to their use. 3. The laboratory's testing declaration form, signed by the laboratory director on July 10, 2025, stated that the laboratory performed approximately 50,930 routine chemistry, 5,700 endocrinology, and 4,066 general immunology tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.
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. This STANDARD is not met as evidenced by: Based on the review of policies and procedures manuals, laboratory records, and an interview with the Technical Supervisor (TS) on July 17, 2025, at approximately 11:00 am, it was determined that the laboratory supervisor did not review the monthly maintenance checklists for laboratory instruments to verify their proper functioning and acceptable performance parameters thus failing to implement a system to ensure continuous improvement. The findings included: 1. On July 17, 2025, at approximately 11:00 am, the Technical Supervisor (TS) affirmed that the laboratory

	supervisor had not reviewed the monthly maintenance checklists for tests conducted in the laboratory. 2. The laboratory's testing declaration form, signed by the laboratory director on July 10, 2025, stated that the laboratory performed approximately 96,960 tests annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 interview with Technical Supervisor (TS), review of Proficiency Testing, Quality Assessment and QC records on July 17, 2025, the laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings included: 1. The LD failed to ensure the proficiency testing samples were tested as required under subpart H of 42 CFR 493. See D2093, D2098, D2121, D2104 2. The LD failed to ensure that quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5791 3. The LD failed to ensure the stated values of the commercially assayed Quality Control (QC) materials verified by the laboratory prior to their use. See D5469