Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2090034	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Diagnostic Labs Llc	11030 N Tatum Blvd, Bldg F, Ste 101b, Phoenix, AZ	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) attestation statements for 2018 and 2019 and interview with the laboratory personnel, the laboratory failed to have the director sign the attestation statements under the specialty of Chemistry. Findings include: 1. The PT attestation statements noted above consistently did not have the signature of the director. Individuals serving as technical supervisors were also serving as testing personnel for PT and had signed the testing personnel sections of the attestation statements. 2. The laboratory personnel acknowledged that the attestation statements indicated above lacked the signature of the director. 3. The laboratory's approximate annual test volume under the sub-specialty of Toxicology is 66,000.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the reagent assay sheets for the toxicology testing that was performed on the Carolina Biolis until 12/09/2019 and interview with the laboratory personnel, the laboratory failed to retain all of the assay sheets for testing performed

	for the last two years. Findings include: 1. (a) Assay sheets for Cocaine Metabolite Assay for lot numbers received prior to 08/10/2018 were not retained. (b) Assay sheets for Tramadol Urine Enzyme Immunoassay for lot numbers received prior to 01 /31/2019 were not retained. (c) Assay sheets for Ethyl Alcohol Assay for lot numbers received prior to 08/10/2018 were not retained. (d) Assay sheets for Cannabinoid Assay for lot numbers received prior to 08/10/2018 were not retained. (e) Assay sheets for Opiate Assay for lot numbers received prior to 08/10/2018 were not retained. (f) Assay sheets for Benzodiazepine Assay for lot numbers received prior to 02/05/2019 were not retained. (g) Assay sheets for Fentanyl Assay for lot numbers received prior to 08/10/2018 were not retained. 2. The previous compliance survey was conducted on 10/27/2017. 3. The laboratory personnel acknowledged that they did not know where the missing assay sheets were located. 4. The laboratory's approximate annual test volume under the sub-specialty of Toxicology is 66,000.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) records and interview with the facility personnel, the laboratory failed to perform and document quality assessment activities as indicated in laboratory policy. Findings include: 1. The laboratory's QA policy at the time of the survey included a monthly review of laboratory records including Quality Control, Calibration, Proficiency Testing, Patient Test Management, Maintenance and Personnel. 2. The monthly QA records presented for review from February 2018 through February 2020 were incomplete and missing documented evidence that the review was performed, including evidence of a patient test management audit. 3. The monthly QA records presented for review from February 2018 through February 2020 were missing the Laboratory Director's or Technical Consultant's signature and date, as indicated on the forms. 4. The facility personnel confirmed that the laboratory could not produce evidence of complete QA reviews from the time period indicated above.
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 review of the laboratory's policy and procedure manual and interview with the laboratory personnel, the laboratory failed to have a policy in place that indicated when the laboratory was to perform confirmatory testing under the subspecialty of Toxicology. Findings include: 1. There was no policy in place that indicated when to run only the toxicology screening for patient specimens performed on the Carolina

	Biolis instrument until 12/09/2019. 2. There was no policy in place that indicated when to run the confirmatory LC/MS/MS testing performed on the Agilent 6460 instrument. 3. The laboratory personnel acknowledged there was no policy in place that indicated when to run just a toxicology screen and when to run both the toxicology screen and the confirmatory toxicology testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation of quality control (QC) material for the Carolina Biolis 24i analyzer used for toxicology testing, review of QC records and interview with the facility personnel, the laboratory used QC material that exceeded the expiration date. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Toxicology, with an approximate annual test volume of 66,000. 2. During the survey conducted on 3/11/2020, direct observation of the Tramadol Urine Low Control (lot# E34715) revealed an expiration date of 9/2019. 3. During the survey conducted on 3 /11/2020, direct observation of the Tramadol Urine High Control (lot# E34716) revealed an expiration date of 9/2019. 4. Review of quality control records indicated the laboratory utilized the expired controls on the following testing dates in which patient testing was performed: 10/07/19, 11/11/19, 12/07/19, and 12/09/19. The number of patients tested during that time period could not be determined at the time of the survey. 5. The facility personnel confirmed that the Tramadol QC indicated above used by the laboratory in conjunction with patient testing from September 2019 through December 2019 was expired.
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 review of quality control (QC) records for the Carolina Biolis 24i analyzer used for toxicology testing and interview with the facility personnel, the laboratory failed to identify errors found in the analytic systems. Findings include: 1. Review of QC records (Levey-Jennings Reports) from the Biolis 24i analyzer for testing that occurred on 11/11/19 revealed the lot and expiration date of Tramadol QC as follows: Tramadol 250 High, Lot# E34716, expiration date 9/30/2020; Tramadol 150 Low, Lot# E34715, expiration date 9/30/2020. 2. Direct observation of the Tramadol QC reagents during the survey indicated the QC reagents were expired, see D5417 for findings. 3. No corrective action documentation was presented for review during the survey conducted on March 11, 2020 to indicate the laboratory identified and corrected the error of listing the wrong expiration date on the QC records for the Low and High Tramadol QC. The expiration date listed on the reagents was 9/2019, while

	the expiration date listed on the QC records indicated an expiration date of 9/30/2020. 4. The facility personnel acknowledged that the QC expiration date for each level of Tramadol QC was incorrect on the QC records indicated above.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records and quality control reagents, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5417 and D5791 for findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the facility personnel, the laboratory failed to document the competency evaluation for two out of two testing personnel for 2018 and one out of two testing personnel for 2019. Findings include: 1. No 2018 competency evaluation was presented for review for two out of two testing personnel. 2. No 2019 competency evaluation was presented for review for one out of two testing personnel. 3. The facility personnel confirmed the testing personnel indicated above were missing competency evaluations for 2018 and 2019.