Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2033427	11/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ms Diagnostic Laboratory	128 W Olive Ave, Monrovia, 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**
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 American Association of Bioanalysts (AAB) proficiency testing records and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Ammonia, Serum, Glycohemoglobin, Parathyroid Hormone (PTH), and Uric Acid in 2020. The finding included: 1. Based on review of PT records for Q1-2020, AAB reported an unsatisfactory score of 50% for the Ammonia, Serum test. The laboratory failed to report an acceptable test value for one (1) out of two (2) tested samples: Sample # Reported Intended range 1 46 21-41 2 256 232-283 2. Based on review of PT records for Q3-2020, AAB reported an unsatisfactory score of 0 % for the Glycohemoglobin test. The laboratory failed to report an acceptable test value for one (2) out of two (2) tested samples: Sample # Reported Intended range 1 6.2 6.3 - 8.3 2 7.6 5.1 - 7.1 3. Based on review of PT records for Q3-2020, AAB reported an unsatisfactory score of 60 % for the Uric Acid test. The laboratory failed to report an acceptable test value for one (2) out of two (5) tested samples: Sample # Reported Intended range 1 8.3 7.0 - 9.9 2 4.4 3.0 - 4.2 3 3.7 2.2 - 3.1 4 8.5 7.3 - 10.3 5 6.8 5.5 - 7.7 4. Based on review of PT records for Q3-2020, AAB reported an unsatisfactory score of 0 % for the PTH test. The laboratory failed to report an acceptable test value for one (2) out of two (2) tested samples: Sample # Reported Intended range 1 387.1 228.1 - 380.1 2 165.8 97.6 - 162.7 5. Based on the laboratory testing declaration submitted at the time of the survey on 11/25/2020 the laboratory analyzed and reported approximately 117,188 routine chemistry tests during the time the laboratory

	had unsatisfactory proficiency testing results. 6. The TS affirmed 11/25/2020 at approximately 11:00 a.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D2121	HEMATOLOGY CFR(s): 493.851(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 records, random patient sampling, and interview with the technical supervisors, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology with Differential analyte. The findings included: 1. The American Association of Bioanalysts (AAB) proficiency program gave an unsatisfactory score of 40% each for each analyte Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, and Platelets for the Hematology with Differential Module G for event 3 (Q3) 2018. 2. Based on the laboratory's annual testing declaration submitted on the day of the survey 11/25/2020, the laboratory analyzed and reported 103,100 Complete Blood Count (CBC) which included the hematology with differential analyte. 3. The technical supervisors confirmed on 11/25/2020 at approximately 1:00 p.m. that the laboratory received the above proficiency score of 40% for Hematology with Differential analytes described in 1.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on the review of deficiencies cited for Hematology (D2121 and D2130), lack of laboratory documentation, and interview with the technical supervisor; it was determined that the laboratory failed to provide documentation for remedial actions taken for improvement of proficiency testing peformance, including appropriate additional training and technical assistance. Findings included: 1. Review of proficiency testing records revealed the lack of documentation for remedial activities. See D2121 and D2130. 2. The technical supervisor confirmed the lack of documentation of corrective actions reports for proficiency testing failures.
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 laboratory's proficiency testing (PT) result reports and interview with the technical supervisor, it was determined that the laboratory failed to achieve satisfactory score in two out of three events (first and third PT events of 2019) for Blood Cell Identification. The findings included: 1. On the day of the Survey 11/25 /2020 based on PT review of the American Association of Bioanalysts (AAB) reports the laboratory obtained a score of 60% on the Blood Cell Identification analyte for the following events: a. Q1-2019: Sample Reported ID Intended ID 1 PMN, poly Macrocyte 2 Platelet, normal Platelet, normal 3 Tear drop cell Tear drop cell 4 PMN, poly PMN, poly 5 Teardrop cell Schistocyte b. Q3-2019 : Sample Reported ID Intended ID 1 Target cell Target cell 2 PMN, poly PMN, poly 3 Reticulocyte Platelet giant 4 Monocyte Monocyte 5 Nucleated RBC Howell-Jolly bodies 2. According to the test declaration on the day of the survey the laboratory performed cell identification testing in approximately 8,592 patient samples monthly. 3. The technical supervisor affirmed on 11/25/2020 at approximately 2:00 p.m. that the laboratory attained overall scores of 60% for the first and third AAB PT events (Q1-2019 and Q3-2019) which were unsatisfactory performance.
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on surveyor observation during the laboratory tour and interview the technical supervisor (TS) and testing personnel (TP) on November 25, 2020 it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen receiving and processing. Findings include: 1. During the laboratory tour at approximately 12:00 p.m. the surveyor observed the area assigned for sample receiving and processing to take place over a liquid absorbent wood table containing various cracks and openings. 2. During an interview on November 25, 2020 at approximately 1:45 p.m. the TS confirmed the laboratory failed to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies when processing samples over a wooden liquid absorbent table. 3. The laboratory's testing declaration form, signed by the TS on stated that the laboratory performs 338,067 tests annually.
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 the lack of documentation and interview with the technical supervisor (TS) on November 25, 2020, as specified in the personnel requirements in subpart M, the

	laboratory failed to establish and follow written policies and procedures to assess all testing personnel competency. Findings include: 1. The laboratory had three (3) testing personnel. 2. One out of three of the testing personnel listed on the CMS-209 Form, did not have documentation of training or competency for the tests performed at the laboratory. 3. This deficient practice was affirmed by interview with the TS on November 25, 2020 at approximately 11:00 a.m. 4. The laboratory reportedly performs approximately 338,067 tests annually.
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 the surveyors' observation, examination of laboratory reagents, and interview with the technical supervisor (TS) and testing personnel (TP), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, 11/25/2020 at approximately 1:00 p.m., the examiner found the following Bacteriology reagents currently being used beyond its expiration date: Reagent Lot # Exp. Date Manufacturer Gram stain iodine 9934-00 1/31/2020 MCC Immersion oil 2019 3/22 /2019 ATCC Culti-Loops 534307 11/12/2020 Thermo Scientific Enterobacter cloacae ATCC Culti-Loops 534215 11/11/2020 Thermo Scientific Pseudomonas aeruginosa 2. The TS and TP affirmed on 11/25/2020 at approximately 2:00 p.m. using the reagents listed in (1) beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 31,952 Bacteriology tests annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, lack of maintenance protocol, and interview with the laboratory technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to establish a maintenance protocol for the Sysmex coagulation instrument that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. The laboratory uses two Sysmex instruments for performing hematology coagulations tests; PT and PTT. 2. Based on surveyor observation during tour of the laboratory on November, 2020 at approximately 12:00 p.m. the second coagulation instrument used had no records of preventive maintence documentation for 2018, 2019, and 2020. 3. The TS and TP

	confirmed on an interview on November 25, 2020 at approximately 4:00 p.m. that the laboratory failed to establish a maintenance protocol for the second Sysmex instrument used in hematology-coagulation testing. 4. Based on the laboratory's monthly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 103,100 hematology samples annually.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, random patient sampling, and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to use the approved quality control organisms on the Kirby-Bauer (KB) antimicrobial susceptibility testing method each day the test was performed. The findings included: 1. On the day of the survey, November 25, 2020, the laboratory lacked the documentation for KB antimicrobial susceptibility use of control organisms for each day the KB antimicrobial susceptibility test was performed. a. The laboratory had developed an Individualized Quality Control Program for E-Test susceptibility testing; a procedure which was not used in the laboratory for the antimicrobial susceptibility testing method. 2. For three (3) out of ten (10) random patient sampling test results reviewed, covering period 8/22/2018 to 10/13/2020, the laboratory analyzed and reported patient test results for KB antimicrobial susceptibility during the time when the laboratory did not use control organisms for each day the KB antimicrobial susceptibility tests method was performed. 3. The TS and TP affirmed on 11/25/2020 at approximately 3:00 p.m. that the laboratory was not using control organisms for each day the KB antimicrobial susceptibility test was performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts proficiency failures (D2087, D2121, D2128, and D2130) failure to minimize contamination of patient samples, equipment, and materials (D3003), failure not to use reagents when they have exceeded their expiration date (D5417), failure to use the approved quality control organisms on Kirby-Bauer antimicrobial susceptibility testing method each day of the test is performed, and interview with the TP; it was determined that the

	laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies & procedures, testing personnel qualifications & training records, competency evaluations, and interview with the Laboratory Technical Supervisor and testing personnel; it was determined that the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate competency assessment and experience to provide and report accurate results. See D5209.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on D2128, D5209 and D5433 deficiencies cited, the Technical Supervisor is herein cited for deficient practice in his responsibilities for resolving technical problems and take remedial action revealed at the time of the survey on 11/25/2020.