Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2006340	09/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mira Dx, Inc	11601 Wilshire Blvd Ste 105, Los Angeles, 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**
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's policy & procedure, patient test record review from July 1 to July 5, 2020, and interview with the laboratory technical supervisor on September 2, 2020 at 2:00 pm, it was determined that the laboratory failed to establish and follow written policies and procedures that ensured optimum integrity of a patient's specimen from the time of collection of the specimen through completion of testing and reporting of results, causing 106 compromised samples out of 663 samples, reviewed. Findings include: 1. The laboratory received patient samples on melted ice pack, and after testing, was found that the sample integrity was compromised. So, the laboratory concluded that due to high temperature during transportation which caused ice pack to melt, the sample integrity was compromised. However, it never established any temperature effect on the sample integrity. This caused delay in sample recollection and patient management. a. On July 1-2, 2020 the laboratory collected 106 patient samples. The laboratory received the samples in the lab on July 2, 2020 on a cold pack which was warm and melted. The laboratory noted that in the collection area, the outside temperature was 100 degree F and due to the high temparature the cold pack was melted during transportation. The laboratory did not reject the sample upon received and subsequently tested the samples for SARS-CoV-2 by polymerase chain reaction. On July 5, 2020 the laboratory found compromised sample integrity based on the internal control failure. b. The laboratory's sample rejection criteria stated, "If there is evidence that the sample was not kept on ice packs or refrigerated, the sample may fail RNA isolation. For the benefit of the

	patient the sample should proceed to determine if it fails or succeeds RNA isolation based on internal controls". c. The laboratory's established optimum sample integrity time is for 72 hours after collection. The laboratory procedure recommended refrigeration of the sample after collection. 2. The laboratory technical supervisor, on 9 /2/2020 at 2:00 pm, affirmed that the laboratory did not establish and follow written policies and procedures that ensure optimum integrity of a patient's specimen at various temperatures. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/2/2020, stated that the laboratory performs 500,000 SARS-CoV-2 tests, annually.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's policy & procedure, patient test record review from July 1 to July 5, 2020, and interview with the laboratory technical supervisor on September 2, 2020 at 2:10 pm, it was determined that the laboratory failed to establish and follow written policies and procedures for specimen storage, preservation, and conditions for specimen transportation causing 106 compromised samples out of 663 samples, reviewed. Findings include: 1. The laboratory did not establish any procedure for specimen storage, preservation, and conditions for specimen transportation. Though, the laboratory procedure recommended refrigeration of the sample after collection, it accepted patient samples received on melted cold pack. a. On July 1-2, 2020 the laboratory collected 106 patient samples. The laboratory transported the samples and received in the lab on July 2, 2020 on a cold pack which was warm and melted. The laboratory noted that during transportation the cold pack was melted due to high temperature. b. The laboratory did not reject the sample because its rejection criteria stated, "If there is evidence that the sample was not kept on ice packs or refrigerated, the sample may fail RNA isolation. For the benefit of the patient the sample should proceed to determine if it fails or succeeds RNA isolation based on internal controls". 2. The laboratory technical supervisor, on 9/2/2020 at 2:10 pm, affirmed that the laboratory did not establish and follow written policies and procedures for specimen storage, preservation, and conditions for specimen transportation. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/2/2020, stated that the laboratory performs 500,000 SARS-CoV-2 tests, annually.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's policy & procedure, patient test record review from April 4 to September 1, 2020, and interview with the technical supervisor on September 2, 2020 at 2:40 pm, it was determined that the laboratory failed to notify the ordering physician of the delayed testing of 2 samples out of 14 samples, reviewed. Findings include: 1. The laboratory's calculated average turn-around-time from the sample receipt to reporting is 3 days, however, for the samples S212521 and S213507, it was determined that the turn-around-time was 6 days which was 3 days more than the laboratory's average turn-around-time. The laboratory did not notify the ordering physician regarding this delay in testing might have impacted adversely on patient management. 2. The laboratory technical supervisor, on 9/2/2020 at 2:40 pm, affirmed that the laboratory did not meet its average turn-around-time and failed to notify the delay in testing to the ordering physician. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/2/2020, stated that the laboratory performs 500,000 SARS-CoV-2 tests, annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's policy & procedure, patient test record review from April 4 to September 1, 2020, and interview with the laboratory technical supervisor on September 2, 2020, at 3:00 pm it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems of the delayed testing of 2 samples out of 14 samples, reviewed. Findings include: 1. Laboratory's patient samples testing record showed that for the samples S212521 and S213507, laboratory's turn-around-time was 6 days while laboratory's calculated average turn-around-time is 3 days. The laboratory's failure to identify problems in turn-around-time might have caused negatively on patient management. 2. The laboratory technical supervisor, on 9/2/2020 at 3:00 pm, affirmed that the laboratory did not establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/2/2020, stated that the laboratory performs 500,000 SARS-CoV-2 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 surveyor review of laboratory's policy & procedure, patient sample, quality control and proficiency testing records, and interview with the laboratory Technical Supervisor , it was determined that the laboratory director failed to ensure compliance with the applicable regulations. Findings include: See D5203, D5311, D5815 and D5891.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 surveyor review of laboratory's policy & procedure, patient sample, quality control and proficiency testing records, and interview with the laboratory technical supervisor, it was determined that the laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: See D5891.