Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2155295	02/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Gmi Laboratories, Llc	1278 E Colorado Blvd, Pasadena, 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
D2025	BACTERIOLOGY CFR(s): 493.823(c) 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 College of American Pathologists (CAP) proficiency testing report for the third quarter event in 2019 (Q3-2019), six (6) randomly chosen patients results, and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program which is unsatisfactory performance and results in a score of zero (0) for the testing event of the Respiratory Infectious Disease panel. The findings included: 1. CAP reported an unsatisfactory score of 0% for Q3-2019 for the Respiratory Infectious disease panel for failure to submit the proficiency testing results within the time frame specified by the program. 2. For two (2)) out of four (6) random patient test results covering period from 11/25/2019 to 12/9/2019, the laboratory analyzed and reported Respiratory Infectious Diseases panel results during the time period when the laboratory failed to submit its proficiency testing samples challenges. 3. The TS and TP affirmed on 02/03/2022 that the laboratory received the above unsatisfactory proficiency testing score of 0% for Respiratory Infectious Disease panel tests.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

	This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the technical supervisors (TS) and testing personnel (TP) on February 3, 2022 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using the COVID-19 PCR thermo-amplification kit and amplification method performed on the ABI 7900. 2. During the laboratory tour on 2/03/2022 at approximately 12:00 p.m. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same open area without unidirectional flow. 3. The TS and TP confirmed by interview on 02 /03/2022 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 2,6000 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the lack of the laboratory's standard operating procedures, proficiency testing records, and interview with the laboratory technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to verify at least twice annually, the accuracy of its Allergy Panel test for the years 2020 and 2021. The findings included: 1. The laboratory did not have any documentation showing that it had verified its Allergy Panel test accuracy for the years 2020 and 2021. Therefore, the accuracy of the laboratory's test results to the patients for Allergy Panel procedure, cannot be assured. 2. The laboratory TS and TP affirmed on 2/3/2022 at approximately 1:00 p.m. that the laboratory did not have any record to verify its Allergy Panel tests results accuracy. 3. The laboratory's testing declaration form signed by the laboratory director on 02/03/2022, stated that the laboratory performs approximately 400 Allergy Panel tests annually.
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 the lack of current laboratory written standard operating procedures (SOPs)

	and interview with the laboratory's technical supervisors (TS) and testing personnel (TP), it was determined that the laboratory failed to have available and follow written procedures for all test procedures performed in the laboratory. The findings included: 1. On the day of the survey on February 3, 2022, at approximately 2:00 p.m. the laboratory failed to provide written (SOPs) for each of the test procedures currently performed in the laboratory. 2. For six (6) out six (6) randomly chosen patient test results reviewed covering period from 11/25/2019 to 10/12/2021 all the patients had test ordered, analyzed, and reported for which the laboratory had no written SOP available for the current practice. 3. The laboratory's TS and TP confirmed on February 3, 2022, at approximately 2:30 p.m. that the laboratory did not have written SOPs available for the current tests performed in the laboratory.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyor's direct observations of the laboratory's SARS-CoV-2 PCR testing processes and interview with the laboratory's technical supervisor and testing personnel on February 3, 2022; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed. Findings include: See D3005.
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on the survey findings, the laboratory director (LD) is herein cited for deficient practice in providing overall administration to ensure proficiency testing results are returned within the timeframes established by the proficiency testing program. Findings included: See D2025.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records of personnel training, competency

	evaluation, laboratory policies and procedures, random patient testing records, and interview with the laboratory 's technical supervisor (TS) and testing personnel (TP); the laboratory failed to provide records showing that the laboratory director (LD) has authorized, delegated, and approved lab personnel of any responsibilities and duties in writing. The findings include: 1. The laboratory did not have any records of written delegation and authorization of responsibilities and duties by the LD for the laboratory's technical supervisor (TS) and testing personnel (TP). 2. On February 3, 2022, at approximately 2:00 p.m., the TS and TP affirmed that the LD did not assign, delegated, and authorized in writing duties and responsibilities to the laboratory personnel including the technical supervisor. 3. The laboratory testing declaration form, signed by the LD on 2/3/2022 stated that the laboratory performs 6,600 tests annually.