Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2122216	06/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Premier Lab Solutions	3440 N 16th Ste 102a, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of established policies and procedures for review, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct problems identified with complaint investigations and communications, see D5205 and D5207 for findings.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on lack of policies and procedures submitted for review and documentation received by the State Agency related to multiple complaints against Premier Lab Solutions (CLIA# 03D2122216), the laboratory failed to have a system in place to ensure that it documents and investigates all complaints and problems reported to the laboratory. Findings include: 1. The Arizona State Agency, CLIA Program received

	multiple complaints against Premier Lab Solutions (CLIA# 03D2122216) during the timeframe of June 1, 2020 through June 10, 2020, related to the delay of reported test results for SARS-CoV-2 testing and a lack of communication regarding the delay of test results for SARS-CoV-2 testing. 2. The laboratory submitted evidence of a phone text received by laboratory staff on June 7, 2020 from a client inquiring about the status of SARS-CoV-2 test results from specimens that were collected during the timeframe of May 26, 2020 through June 5, 2020. The text from the client stated, "No new results since 5/27. Missing at least 50". 3. On June 1, 2020 the Arizona State Agency, CLIA Program received documentation from another client inquiring about the status of SARS-CoV-2 test results from specimens that were collected on May 27, 2020 and the laboratory's response was vague and did not include any indication of when the test results would be received and did not offer any other type of resolution. 4. No documentation was submitted by the laboratory that indicated the laboratory has a system in place to document all complaints and problems reported to the laboratory. 5. No documentation was submitted by the laboratory that indicated the laboratory conducted investigations of the complaints or problems in order to resolve the issues that were communicated to laboratory staff.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on lack of established policies and procedures submitted for review, the laboratory failed to have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Findings include: 1. The Arizona State Agency, CLIA Program received multiple complaints against Premier Lab Solutions (CLIA# 03D2122216) during the timeframe of June 1, 2020 through June 10, 2020 related to the delay of reported test results for SARS-CoV-2 testing and lack of communication regarding the delay of test results for SARS-CoV-2 testing. 2. On June 11, 2020 the Arizona State Agency, CLIA Program requested electronic documentation from the lab specific to established policies and procedures regarding communication between the laboratory and the laboratory's clients. 3. No documentation was submitted by the laboratory that indicated the laboratory has a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.
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 lack of Quality Assessment documentation submitted for review, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the laboratory with regard to complaint investigations and communication. Findings include: 1. No documentation was submitted for review to indicate that the laboratory established policies and procedures to monitor, assess and resolve complaints received by the laboratory for the delay in SARS-CoV-2 testing. See D5205 for findings. 2. No documentation was submitted for review to indicate that the laboratory established policies and procedures to monitor, assess and resolve communication issues related to the delay in SARS-CoV-2 testing. See D5207 for findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on lack of policies and procedures submitted for review, the laboratory's test procedure for SARS-CoV-2 testing failed to include a description of the course of action to take if the test system becomes inoperable. Findings include: 1. On June 11-12, 2020, the Arizona State Agency, CLIA Program requested electronic documentation of the laboratory's established policies and procedures, including but not limited to, the test procedure for SARS-CoV-2 testing. 2. The SARS-CoV-2 test procedure submitted by the laboratory on June 12, 2020 failed to include information regarding the course of action to take if the test system becomes inoperable, including notification requirements for delayed testing. 3. No other documentation was submitted for review that indicated the process the laboratory should follow in the event that the test system becomes inoperable and the specimens cannot be tested within the laboratory's established timeframe.
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 review of patient test reports, the laboratory failed to notify the appropriate individual(s) of delayed SARS-CoV-2 testing. Findings include: 1. Review of patient test reports for SARS-CoV-2 testing submitted by the laboratory on 6/16/20 indicated the following specimen collection dates and test report dates: Accession# 100060, collected on 5/27/20 and reported on 6/08/20; Accession# 98162, collected on 5/27/20 and reported on 6/06/20; Accession# 98510, collected on 5/27/20 with no final test report to date; Accession# 97856, collected on 5/27/20 and reported on 6/04/20; Accession# 106787, collected on 6/08/20 with no final test report to date. 2. No documentation was submitted to indicate the laboratory contacted the appropriate individual(s) to notify them of delayed testing. 3. The laboratory's website states, "COVID-19 Test Results In As Little As 72 hours". 4. On February 4, 2020 the U.S. Department of Health and Human Services (HHS) declared that SARS-CoV-2 testing was deemed urgent as a result of the Public Health Emergency in response to the threat of 2019 Novel Coronavirus (COVID-19).
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 lack of a written policy and/or procedure for review, the laboratory failed to establish a policy and/or procedure that indicated the Turn Around Time (TAT) for SARS-CoV-2 testing. Findings include: 1. No documentation was submitted that indicated a policy and/or procedure was established with regard to the TAT for SARS-CoV-2 tests performed by the laboratory. 2. The laboratory's website states, "COVID-19 Test Results In As Little As 72 hours".
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The Condition of Laboratory Director is not met as evidenced by D6094 - failure to establish and maintain a quality assessment program to identify and correct errors as they occur.
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 lack of quality assessment (QA) documentation, the laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291 and D5891 for findings.