Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2182434	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Stadia Labs Llc	1200 Nw 78th Ave, Unit 111, Doral, FL	

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
D0000	An initial survey was conducted from 03/20/2023 to 03/29/2023. STATLAB MOBILE LLC clinical laboratory was found not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified of the Immediate Jeopardy on 03/29/2023 at 11:00 AM. The Immediate Jeopardy was abated on 03/20 /2023. The following Conditions were cited: -D5400 Analytic Systems. -D6076 Laboratory Director.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory did not meet the condition for Analytic Systems. Findings included: -The laboratory failed to establish the performance characteristics of the INSTANT-VIEW Hepatitis C Virus Test from Alfa Scientific Designs Inc that does not have FDA approval before patient testing. Refer to D5423. -The laboratory failed to perform a positive and negative control for the INSTANT-VIEW Hepatitis C Virus Test on each day of testing. Refer to D5449.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document rotor speed, needle drops and room temperature for the Arlington Scientific Inc (ASI) Rapid Plasma Reagin (RPR) test for 3 out of 40 testing dates reviewed. Findings included: -Review of the ASI product insert revealed a requirement for: automatic mechanical rotor set up at speed of 100 5 rpm, needle drop should deliver 60 2 drops, room temperature of 20-30 Degrees Celsius (C). -Review of the "RPR QUALITY CONTROL" log records revealed that the laboratory failed to document rotor speed, needle drops and room temperature for the ASI RPR test revealed that the laboratory had no documentation for the following dates: 10/12/2022 (tested 6 patients), 02/24 /2023 (tested 3 patients) and 02/28/2023 (tested 25 patients). During an interview on 03/20/2023 at 1:30 PM the Technical Consultant confirmed that laboratory failed to document the rotor speed, needle drops and room temperature in the days listed above.
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 observation, record review and interview, the laboratory had expired hematology controls XN Check from Sysmex in use from 03/03/2023 to 03/20/2023. The laboratory tested 244 patients using the expired controls. Findings include: -During the laboratory tour on 03/20/2023 at 10:00 AM, the surveyor observed that the laboratory was using XN CHECK Cell Control with Lot number 20341103 for level L1, L2 and L3 and the vials were labeled with open date of 02/23/2023. No new expiration date was added. The open vials had been in use for 26 days. -Review of the XN-Check Cell Control user instructions revealed that the controls had an expiration date of seven days after first use. -Review of patient records revealed that the laboratory tested patients using the expired controls on the following dates: 03/03 /2023 tested 19 patients, 03/06/2023 tested 6 patients, 03/07/2023 tested 54 patients, 03/08/2023 tested 15 patients, 03/09/2023 tested 9 patients, 03/10/2023 tested 26 patients, 03/14/2023 tested 49 patients, 03/16/2023 tested 25 patients and on 03/17 /2023 tested 49 patients. In total 244 patients were tested using the expired controls. During an interview on 03/20/2023 at 12:30 PM, the Technical Consultant confirmed the use of the expired controls for the days listed above.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces

	a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to establish test performance specifications for INSTANT-VIEW Hepatitis C Virus Test from Alfa Scientific Designs Inc before testing began on 10/06/2022. The laboratory performed 338 tests. Findings included: -Review of patients testing revealed that the laboratory started testing with the INSTANT-VIEW Hepatitis C Virus Test on 10/06/2022. The laboratory tested 338 patients. -Review of the product insert revealed that this is a qualitative assay for the detection of antibody specific to Hepatitis C virus in human serum or plasma. -Review of the Food and Drug Administration (FDA) public database, revealed that this test does not have FDA approval. -Review of laboratory records revealed that the laboratory failed to establish performance specifications of the test before patient testing. During an interview on 03/20/2023 at 11:00 AM, the Technical Consultant confirmed that the laboratory failed to establish performance specifications before starting patient testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of records and interview with Technical Consultant (TC), the laboratory failed to run external positive and negative controls for 338 tests for INSTANT-VIEW Hepatitis C Virus Test at least once every day of patient testing since 10/06/2022 to present. Based on record review and interview the laboratory failed to document the reactive, weak reactive and non-reactive control for the Arlington Scientific Inc (ASI) Rapid Plasma Reagin (RPR) test for 3 out of 40 testing dates reviewed. Findings included: -The laboratory started using INSTANT-VIEW Hepatitis C Virus Test for the detection of specific antibodies to Hepatitis C on 10/06/2022. The laboratory tested 338 patients. -The laboratory had no record of performing daily positive and negative external controls before testing patients. This test is not FDA approved and the performance specifications were not established before patient testing. Refer to D5423. -Review of the "RPR QUALITY CONTROL" log records revealed that the laboratory failed to document the reactive, weak reactive and non-reactive control for the ASI RPR test for the following dates: 10/12/2022 (tested 6 patients), 02/24/2023 (tested 3 patients) and 02/28/2023 (tested 25 patients). During an interview on 03/20/2023 at 11:45 AM, the TC confirmed that no positive

	and negative controls were run before patient testing for the INSTANT-VIEW Hepatitis C Virus Test and that the laboratory failed to document the controls for the ASI RPR test on the dates listed above.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the titer of the reactive quality control for the Arlington Scientific Inc (ASI) Rapid Plasma Reagin (RPR) Syphilis test for 3 out of 40 testing dates reviewed. Findings included: - Review of procedure manual signed by the laboratory director (LD) on 09/07/2022 revealed that in policy "ASI RPR Screening test for Syphilis" the laboratory described the procedure for performing the test using the ASI RPR test. - Review of the "RPR QUALITY CONTROL" log records for October 2022, February 2023 and March 2023, revealed that the laboratory had no documentation of the titer for the reactive control for the following dates: 10/12/2022 (tested 6 patients), 02/24/2023 (tested 3 patients) and 02/28/2023 (tested 25 patients). During an interview on 03/20/2023 at 1: 30 PM the Technical Consultant confirmed that laboratory failed to document the titer of the positive control in the days listed above.
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 record review and interview, the laboratory's Quality Assessment (QA) failed to identify and correct deficient practices in syphilis serology and hepatitis C virus test, as follows: Findings included: -Review of daily quality control records for Arlington Scientific Inc (ASI) Rapid Plasma Reagin (RPR) Syphilis test revealed that the QA failed to identify and correct the lack of documentation of the of Rotor speed, needle drops, room temperature, control titer, positive and negative control for the Syphilis (RPR) tests on 10/12/2022, 02/24/2023 and 02/28/2023. The laboratory tested six patients on 10/12/2022, three patients on 02/24/2023 and twenty-five patients on 02/28/2023. Refer to D5413, D5451 and D5449 -The laboratory failed to establish the performance specifications for the INSTANT-VIEW Hepatitis C Virus Test (non-FDA approved). Refer to D5423. -The laboratory failed to perform daily a positive and negative control for the INSTANT-VIEW Hepatitis C Virus Test. Refer to D5449. During an interview on 03/20/2023 at 12:30 PM, the Technical Consultant confirmed that the QA failed to correct the deficient practices listed above.

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: Based on laboratory record review and staff interview, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445 of this subpart. Findings include: -The LD failed to ensure the laboratory established the performance specifications for the INSTANT-VIEW Hepatitis C Virus Test before patient testing. Refer to D6086. -The LD failed to ensure the Quality Assessment effectivelly detected and corrected the analytical deficiencies with the INSTANT-VIEW Hepatitis C Virus Test. Refer to D6094.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director (LD) failed to ensure the laboratory established the performance specifications for the INSTANT-VIEW Hepatitis C Virus Test for patient testing from 10/06/2022 to 03/20/2023. Refer to D5423.
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 record review and interview, the Laboratory Director failed to ensure that the Quality Assessment identified and corrected the analytical deficiencies in the use of the INSTANT-VIEW Hepatitis C Virus Test. Refer to D5791.