Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2182434	12/18/2020
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 certification survey conducted at Statlab Mobile LLC on 12/17-18/2020 found the clinical laboratory was not compliance with 42 CFR Part 493, Requirements for Laboratories.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and owner interview, the laboratory failed to document the Quality Assurance (QA) activity from 5/2020 to 11/2020. Findings include: -The laboratory failed to follow the QA policy, there were no documentation of incident reports, no corrective actions for the validation documentations failures from 5/2020 to 12/2020. During an interview on 12/18/2020 at 11:00 AM with owner, he confirmed that the laboratory failed to follow the QA policy.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with owner, the laboratory director failed to

	review and sign the procedure manual and analyzers Cepheid Gene Xpert IV and XVI (A, B, C and D) validation before the laboratory started testing patients for Polymerase Chain Reaction (PCR) COVID19 detection. Findings include: -Review of the laboratory's procedure manual revealed that the laboratory director signed and dated the procedure manual on 6/2/2020. -Procedure manual review revealed that the laboratory failed to have a protocol for instruments Gene Xpert analyzers validation. -Review of patients testing results revealed that the laboratory started testing on 5/9 /2020 with instruments A and C, on 6/20/2020 with instrument C and on 11/1/2020 with instrument D. -Instruments A, B and C validations signed on 7/19/2020 by laboratory director. During an interview on 12/18/20 at 11:15 AM, the owner acknowledged that the procedure manual was signed and dated by the laboratory director on 6/2/2020 and that the laboratory director failed to sign instruments validations before patient testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document the validation of the Gene Xpert analyzers A, B, C and D and to complete B analyzer validation before patient testing from 6/20/2020 to 6/22/2020. Findings include: -Procedure manual review revealed that the laboratory failed to have a protocol for Gene Xpert analyzers validation. -Validation records review revealed that the laboratory failed to have complete documentation of the steps followed during the analyzer's validation and result reviews. - Review of Gen Xpert instruments records revealed the following: Instruments A and C started testing on 5/9/2020. Instrument B on 6/20/2020 Instrument D on 11/1/2020 -Analyzer C validation date was 6/22/2020, the laboratory tested 362 patients from 6/20/20 to 6/22/2020 before completing validation. -Laboratory director signed analyzer A, B and C validations on 7/19/2020. During an Interview on 12/18/2020 at 11:30 am, the owner confirmed that the laboratory failed to have complete documentation of the Gene Xpert analyzers A, B , C and D and that the laboratory failed to perform analyzer C validation before starting patient testing from 6/20/2020 to 6/22/2020.