Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2149550	09/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ahf Public Health Laboratory	750 Se 3rd Ave 1st Floor, Fort Lauderdale, 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	A recertification survey conducted on 09/07/2021 found that the AHF PUBLIC HEALTH LABORATORY clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. Cited the following Condition: - D5400 - Analytic Systems.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to report 204 out of 204 Coronavirus disease 2019 (COVID-19) negative results tests from 01/08/2021 to 09/07/2021 to the Florida Department of Health (FDOH). The laboratory used qualitative rapid real time PCR Cepheid Xpert Xpress SARS-COV-2 for detection of severe acute respiratory syndrome coronavirus 2 (SARS-COV-2). Findings include: -Review of reports submitted to the FDOH, revealed that the laboratory failed to report 204 negative cases from 01/08/2021 to 09/07/2021 of SARS-CoV-2 test results. During an interview on 09/07/2021 at 2:00 PM, the technical consultant confirmed that the laboratory failed to report 204 negative cases for qualitative rapid real time PCR Cepheid Xpert Xpress SARS-COV-2 from 01/08/2021 to 09/07/2021 to FDOH.

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 include: -Failure to run positive and negative controls every day of patient testing for Cepheid Xpert Xpress SARS CoV-2 test. Refer to D-5449.
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 review of quality control records, patient records and interview with technical consultant (TC), the laboratory failed to run positive and negative controls for 301 out of 310 tests for Qualitative Xpert Xpress SARS-CoV-2 virus detection test at least once every day of patient testing since 11/18/2020 to present. Findings include: -Review of Cepheid Xpert Xpress SARS-COV-2 virus detection kit instructions for use (IFU) under Emergency User Authorization (EUA) Only, revealed that Quality Control Procedure section 15.2 for external controls stated that external controls should be used in accordance with local, state, and federal accrediting organizations as applicable. -Laboratory testing quality control records and patient testing records review revealed that the laboratory failed to run positive and negative controls in the following days of patient testing: 1) November 2020: - 11/18/20: 7 patients. - 11/23/20: 1 patient. - 11/ 24/20: 6 patients. - 11/25/20: 2 patients. -11/ 27 /20: 1 patient. -11/30/20: 11 patients. 2) December 2020: - 12/01/20: 3 patients. - 12 /0220: 2 patients. - 12/03/20: 5 patients. - 12/07/20: 2 patients. - 12/09/20: 4 patients. - 12/10/20: 1 patient. -12/11/20: 1 patient. -12/15/20: 5 patients. - 12/16/20: 3 patients. - 12/17/20: 7 patients. -12/18/20: 2 patients. -12/21/20: 1 patient. -12/22/20: 1 patient. -12/23/20: 2 patients. -12/28/20: 1 patient. -12/29/20: 4 patients. -12/30/20: 11 patients. 3) January 2021: -01/04/21: 3 patients. -01/05/21: 3 patients. -01/06/21: 3 patients. -01/07/21: 3 patients. -01/08/21: 2 patients. -01/11/21: 2 patients. -01/13/21: 3 patients. -01/14/21: 4 patients -01/25/21: 3 patients. -01/26/21: 1 patient. -01/27/21: 3 patients. -01/28/21: 1 patient. -01/29/21: 1 patient. 4) February 2021: -02/02/21: 2 patients. -02/08/21: 1 patient. -02/09/21: 1 patient. -02/11/21: 1 patient. -02/16/21: 1 patient. -02/17/21: 3 patients. 02/18/21: 4 patients. -02/19/21: 1 patient. -02/22/21: 2 patients. -02/26/21: 3 patients. 5) March 2021: -03/02/21: 2 patients. -03/03/21: 1 patient. -03/05/21: 1 patient. -03/12/21: 2 patients. -03/16/21: 1 patient. -03/18/21: 1

	patient. -03/19/21: 6 patients. -03/22/21: 1 patient. -03/23/21: 1 patient. -03/24/21: 1 patient. -03/25/21: 1 patient. -03/26/21: 1 patient. -03/29/21: 4 patients. -03/30/21: 8 patients. 6) April 2021: -04/21/21: 5 patients. -04/23/21: 2 patients. -04/26/21: 1 patient. -04/27/21: 1 patient. -04/28/21: 1 patient. -04/29/21: 2 patients. 7) May 2021: -05/07/21: 1 patient. -05/11/21: 2 patients. -05/14/21: 1 patient. -05/19/21: 1 patient. -05/20/21: 1 patient. -05/24/21: 1 patient. -05/27/21: 6 patients. 8) June 2021: -06/01 /21: 2 patients. -06/03/21: 1 patient. -06/08/21: 1 patient. -06/09/21: 1 patient. -06/10 /21: 4 patients. -06/14/21: 1 patient. -06/15/21: 4 patients. 9) July 2021: -07/12/21: 2 patients. -07/16/21: 2 patients. -07/19/21: 2 patients. -07/23/21: 1 patient. -07/28/21: 2 patients. -07/29/21: 2 patients. -07/30/21: 1 patient. 10) August 2021: -08/02/21: 6 patients. -08/04/21: 15 patients. -08/05/21: 4 patients. -08/06/21: 5 patients. -08/09/21: 3 patients. -08/10/21: 2 patients. -08/11/21: 3 patients. -08/12/21: 3 patients. -08/16 /21: 5 patients. -08/17/21: 3 patients. -08/18/21: 2 patients. -08/19/21: 1 patient. -08/20 /21: 1 patient. -08/23/21: 3 patients. -08/24/21: 7 patients. -08/25/21: 6 patients. -08/26 /21: 4 patients. -08/27/21: 6 patients. -08/30/21: 1 patient. 11) September 2021: -09/01 /21: 4 patients. -09/02/21: 5 patients. -09/03/21: 2 patients. During an interview on 09 /07/2021 at 1:30 PM., the TC confirmed that no positive and negative controls were run on the patient testing days of reference.
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) program failed to correct the deficiency of running positive and negative controls every patient testing day for the Cepheid SARS-COV-2 virus detection test from 11/18 /2020 to present. Findings include: -Review of QA records revealed that the laboratory failed to detect and correct the deficiency of running positive and negative controls every day of patient testing. Refer to D-5449. During an interview on 09/07 /2021 at 3:30 PM, with the laboratory director confirmed that the QA program failed to correct the deficiency of running positive and negative controls every patient testing date.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure that quality control (QC) was performed correctly before patient testing and failed to

	ensure that quality assurance (QA) corrected the deficiency. Refer to D-5449 and D-5791.