Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2101752	01/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ahf Public Health Laboratory	1811 N Western Ave, Los Angeles, 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
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 reviews of the laboratory's policies and procedures manual and interview with the technical consultant (TC), it was determined; that the laboratory failed to have protocols in place when changes occurred in the laboratory and such existing policies were missing effective date and signature of approval by the laboratory director (LD). The findings included: 1. On the day of the survey 01/14/2021at approximately 11:30 a.m. the procedure manual in place had not being updated to reflect new testing performed in the laboratory: SARS-CoV-2 IgG Antibody detection test. 2. The existing protocols presented to the surveyor did not have an effective date or approval signature by the LD for all the existing procedures. 3. The TC affirmed on January 14, 2021 at approximately 12:30 p.m. that the procedure manuals were missing protocols for the current testing performed in the laboratory (SARS-CoV-2 IgG Antibody detection test) and that the effective date and the LD signature were missing. 4. The laboratory's testing declaration form, signed by the laboratory director on 01/14/2021, stated that the laboratory performs approximately 20,952 General Immunology test annually including SARS-CoV-2 IgG Antibody detection test.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the lack of laboratory personnel competency evaluations, the lack of laboratory written policies and procedures reflecting the current testing performed in the laboratory, lack of effective date and approval signatures by the laboratory director (LD) of the procedure manual, and interviews with the technical consultant and testing personnel (TP); the LD failed to ensure that policies and procedures are established and followed for all the test performed in the laboratory and competencies of TP performed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; are performed in a timely manner. See D5407 and D6053.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for competency assessments and interview with the technical consultant (TC), for two (2) out of four (4) testing personnel (TP) records reviewed for the years 2019 and 2020, it was determined that the laboratory's TC failed to perform and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The findings included: 1. There was no documentation to show that the testing personnel for two (2) out of four (4) were evaluated during the first six months and annually thereafter for General Immunology testing performed at the laboratory. 2. The TC and TP affirmed on 01/14 /2021 at approximately 1:00 p.m. that no six months and annually thereafter competency assessments were performed and documented by the laboratory's TC for two (2) out of four (4) TP. 3. Based on the laboratory's annual testing declaration submitted for 2019-2020, the laboratory analyzed and reported approximately 20,952 General Immunology tests.