

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 64D1048456	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier American Samoa Dept Of Health Clinical Lab	Street Address, City, State 3965 Petesa Rd Tafuna Village, Pago Pago, AS	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's standard operating procedure (SOP) for the Rapid Plasma Reagin (RPR) test, manufacturer's instructions, direct observation, and interview with testing personnel (TP) #6, the laboratory failed to perform the RPR tests following the manufacturer's instructions. The laboratory reports performing approximately 13 RPR tests annually. Findings: 1. The laboratory performs RPR tests using the Arlington Scientific RPR test kit which according to the manufacturer's instructions requires placing the test card on an automatic rotator and placing the cover to maintain humidity. 2. A review of the laboratory's SOP for the RPR testing states that the laboratory must place the test card on a rotator and cover it to maintain humidity. 3. Direct observation of the RPR testing area and mechanical rotator on August 24, 2023, at approximately 11:55 AM revealed that no rotator cover was present. 4. An interview with TP #6 on August 24, 2023, at approximately 2:10 PM confirmed that the laboratory was not utilizing the rotator cover when performing RPR testing.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a</p>

maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on direct observation, review of laboratory maintenance records, and interview with testing personnel (TP), it was determined that the laboratory failed to establish a maintenance protocol that ensures the performance of its Eppendorf pipettes used for Rapid Plasma Reagin (RPR) testing for accurate and reliable test results. The laboratory reports performing approximately 13 RPR tests annually. Findings: 1. Direct observation of three Eppendorf pipettes serial numbers P19546D, P48222H, and P47992H located in the RPR testing area on August 29, 2023, at approximately 11:55 AM revealed that no calibration sticker was present on the pipettes. 2. A review of the laboratory's maintenance records revealed that the laboratory did not perform calibrations for the three Eppendorf pipettes. 3. An interview with TP #1 on August 24, 2023, at approximately 11:55 AM confirmed that the laboratory failed to establish a maintenance protocol for the Eppendorf pipettes and did not perform calibrations to ensure accurate and reliable test results since the pipettes were acquired approximately in December of 2021.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's patient test reports and an interview with testing personnel (TP) #1, the laboratory failed to ensure that the test reports indicated the name and address of the laboratory location where the test was performed. The laboratory reported performing approximately 3,155 tests annually. Findings: 1. Upon review of patient test reports on August 24, 2023, nine of nine reports indicated the name and address of a different laboratory having performed the testing and not of the American Samoa Department of Health, Fatuna Family Health Center Laboratory. 2. An interview with TP#1 on August 24, 2023, at approximately 1:15 PM confirmed that the laboratory failed to have the correct name and address of the laboratory on its patient test reports.

D6056

CLINICAL CONSULTANT
CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

	<p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's personnel records and an interview with the testing personnel (TP) #1, the laboratory failed to ensure the Clinical Consultant (CC) met the required educational qualifications. A review of personnel records and an interview with TP #1 revealed that the CC did not possess the academic credential evaluation required to qualify as CC. (Refer to D6057).</p>
<p>D6057</p>	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417</p> <p>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and an interview with the testing personnel (TP) #1, the laboratory failed to ensure the Clinical Consultant (CC) met the required educational qualifications. Findings: 1. The laboratory could not provide foreign equivalency documentation performed by a nationally recognized organization to verify academic credentials for the CC. 2. An interview with TP#1 on August 24, 2023, at approximately 10:30 AM confirmed that the laboratory failed to have a qualified CC due to the lack of academic credential evaluation.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's personnel records and an interview with testing personnel (TP) #1, the laboratory failed to ensure TP #3 met the required educational qualifications. A review of personnel records and an interview with TP #1 revealed that one of six TP did not have the proper academic credential evaluation required to perform moderate complexity testing (Refer to D6065).</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an</p>

accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's personnel records and an interview with testing personnel (TP) #1, the laboratory failed to ensure that one of six TP had the proper academic credential evaluation to qualify as TP performing moderate complexity testing. Findings: 1. The laboratory could not provide foreign equivalency documentation performed by a nationally recognized organization to verify academic credentials for TP #3. 2. An interview with TP #1 on August 24, 2023, at approximately 2:00 PM confirmed that TP #3 did not possess the required academic credential evaluation.