Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	64D1048456	11/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
American Samoa Dept Of Health Clinical Lab	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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's testing menu and interview with the laboratory Manager, the laboratory failed to enroll in an approved proficiency testing (PT) program or programs for each of the specialties and subspecialties for which it seeks certification. Findings included: a. The laboratory was certified in 2017 for moderate complexity testing for the specialty/subspecialty of Microbiology/Mycobacteriology. b. The laboratory failed to enroll for PT for event 1 of 2018 for Mycobacteriology (MTB). c. Review of the laboratory testing menu on November 14, 2019, revealed the addition of subspecialty bacteriology (C. trachomatis, N.gonorrhoeae) testing on the GeneXpert analyzer. d. The laboratory had added the subspecialty to the tesing menu in 2019, but had failed to notify CMS of the addition of this subspecialty to the CLIA certificate, and designate to the PT organization API and CAP to report the results to CMS. e. Tour of the laboratory on November 14, 2019, revealed two Sysmex XP 300 automated hematology analyzers. By interview with the testing personnel and laboratory manager, the staff confirmed that the laboratory had initiated patient testing and release of patient results for complete blood counts (CBC), Hemaglobin (Hgb) and Hematocrit (HCT), on July 1, 2019. e. The laboratory validation records were completed and signed by the laboratory director in February of 2019, but the did not

	have evidence of enrollment or performance of proficiency testing for automated CBC, or H&H for 2019. f. The laboratory testing personnel and laboratory manager confirmed by interview on November 14, 2019, at approximately 11:00 a.m., that the laboratory had not enrolled or performed proficiency testing for automated CBC, Hgb /Hct (H&H) for 2019, and for event (1) 2018 for MTB. g. The laboratory tested and released approximately (187) H&H, (77) CBC , and (100) patient results between July 1, 2019 to November 14, 2019.
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on review of the CMS QIES CASPER 155D, the laboratory proficiency testing records and interview with the laboratory technical consultant on November 14, 2019, the laboratory failed to (1) notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart, and (2)(i) failed to designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS. The findings included: a. The laboratory was certified in 2017 for subspecialty of mycobacteriology (MTB) testing on the GeneXpert PCR moderate complexity testing. The laboratory had enrolled in with American Proficiency Institute (API) and College of American Pathologists (CAP) in 2018 for MTB and NG/CL PT in 2019 and 2019, but had neglected to ensure that the PT organizations were submitting data to HHS. b. Upon review of the CMS QIES CASPER 155D report, and the PT testing in the CMS- web 116, the laboratory still has not indicated to their PT organizations to transmit their PT results HHS. c. The laboratory technical supervisor confirmed by interview on November 14, 2019, that the laboratory failed to notify CMS of the addition of new testing specialties/subspecialties and the PT programs to which they would be enrolled.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records (PT), and interview with the laboraotry Technical Consultant (TC) on November 14, 2019, the laboratory director failed to document and attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. The Findings included: a. The laboratory is enrolled for proficiency testing with American Proficency Institure (API) and College of American Pathologists (CAP) for mycobacteriology and

	bacteriology. b. The laboratory director failed to document the attestation signature forms of PT testing for proficiency testing provided by the API organization Event (2) and event (3) in 2019 and attestation form provided by CAP event (2) 2019. c. The laboratory manager confirmed the lack of laboratory director review by interview on November 14, 2019 at approximately 11:15 a.m. d. The laboratory performs approximately 500 moderate complexity patient tests annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 testing personnel form, maintenance logs and interview with testing personnel on November 14, 2019, the laboratory failed as specified in the personnel requirements in subpart M, to establish and follow written policies and procedures to assess employees and, if applicable, consultant competency. The findings included: a. The laboratory's CMS-209 testing personnel form lists three testing personnel (TP-1), (TP-2), (TP-3). TP (1) and (2) both perform patient testing on the GeneXpert for mycobacterology and bacterology, as well as hematology on the Sysmex XP 300. TP (3) performs patient testing on the Sysmex XP 300. b. For the year 2019, the laboratory did not have training and competency assessments for (TP -3) for hematology testing using the new methodology of the automated Sysmex XP300 analyzer. c. For the laboratory Technical Consultant (TP-1), the laboratory did not have documentation of annual competency for 2018 or 2019 as a testing personnel or as a technical consultant. d. The laboratory did not have competency assessments for 6 months competency for all three testing personnel for 2019 for the new methodology of automated hematology being performed on the Sysmex hemotology analyzer which was initiated in February of 2019 with releasing of patient test results on July 1, 2019. e. The laboratory manager confirmed by interview the lack of competency testing policys and procedures and proformance of initial, (6) month and annual competency's for testing personnel. f. The laboratory reports performing approximately (275) hematology, 200 mycobacteriology and (100) bacterology patient specimens annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on interview with testing personnel and record review of the laboratory's hematology calibration and verification logs on November 14, 2019, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, and differant instruments. The

	findings included: a. The laboratory currently performs hemoglobin and hematocrit (H&H) manually, and through automatic means on two sysmex hematology analyzers. b. The laboratory does not have documentation of comparing the results between the manual testing system and the automated testing systems. c. The laboratory does not have documentation of comparing the results between the two automated hematology analyzers for performing H&H and Complete Blood Counts. d. The laboratory testing personnel and the laboratory manager confirmed by interview on November 14, 2019 at approximately 12:00 p.m., the lack of performing and documentation of comparison testing between manual and automated testing methods and comparison of results between the two automated hematology analyzers twice annually. e. The laboratory reports performing approximately 275 hematology patient tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the systemic nature of deficienies cited and the lack of oversight for profiency testing enrollment and reporting, lack of training and competency of staff upon initiation of new testing methodologies, and annual competency of testing personnel and consultants, the laboratory director failed to provide the overall management and direction with 493.1407 of this subpart. The findings included: a. The laboratory director failed to ensure that laboratory enrolled and participates in an HHS approved proficiency testing program prior to testing and releasing patient speciems. See D2000, D2001 b. The Laboratory director failed to attest that proficiency testing is tested in the same manner as patient testing, that interlaboratory communication did not occurr. See D2009 c. The laboratory director failed to ensure that policy's and procedures are established for monitoring competency of all personnel engaged in preanalytic, analytic and postanalytic testing, and consultant competency. See D5209, D6055
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the laboratory testing records, proficiency testing (PT) enrollment records and interview with the laboratory manager on November 14, 2019, the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. The findings included: a. The laboratory testing menu reports performing Complete Blood Counts (CBC), Hemoglobin & Hematocrit (H&H), Bacteriology and Mycobacteriology patient

	specimens. b. The laboratory records PT enrollment with (CAP) and (API) in 2018 for Mycobacterium (MTB) and in 2019 for Mycobacterium identification and resistance; N. gonorrhea, C. trachomatis (NG/CL) identification. c. The laboratory had no documentation of enrollment for MTB, or NG/CL for event (1) of 2019. d. The laboratory reports initiating patient testing and reporting of patient hematology specimens on July 1, 2019. The laboratory has no documentation of enrollment or testing of PT samples for 2019. e. The laboratory manager and testing personnel confirmed by interview on November 14, 2019 at approximately 12:00 p.m. the lack of enrollment and testing of PT for event 1 of 2019 for mycobacterium and NC/CL, and the lack of enrollment and testing of PT prior to initiating and reporting patient samples in 2019. f. The laboratory reports performing approximately 200 Mycobacterium, 100 NG/CL, and 275 Hematology patient specimens annually.
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 review of the laboratory's testing methodology's and interview with the technical consultant on November 14, 2019, the laboratory director failed to 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. The findings included: a. The laboratory director must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency see D5209
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's training and competency records and personnel interview on November 14,2019, the laboratory director failed to identify and specify in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. The findings included: a. The laboratory CMS-209 identifies (3) testing personnel who perform moderate complexity testing, and (2) phlebotomists who perform preanalytic testing activities and waived testing. b. The laboratory does not have documentation of training and competency for (2) of (3) of the moderate complexity testing personnel and no documentation of training and competency for the (2) preanalytic- waived testing personnel. c. The three moderate testing personnel all perform Complete Blood Counts (CBC) on the Sysmex hematology analyzers. There was no writted documentation as to the responsibilities and authorizations as to the authorization for release of patient results of those performing the hematology testing. There was no documentation of degree of review that is required prior to reporting of patient test results for waived testing. d. The laboratory manager and testing personnel confirmed by interview that the laboratory did not have written documentation specifying the responsibilities and duties of each testing personnel, and the degree of review requirements prior to releasing of patient test results. e. The laboratory reports performing approximately 275 hematology, and approximately 200 MTB, and approximately 1000 waived tests performed annually.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 testing personnel, maintenance logs and interview with testing personnel on November 14, 2019, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results: a. The laboratory's CMS-209 testing personnel form lists three testing personnel (TP-1), (TP-2), (TP-3). d. In 2018 the laboratory added the subspecialty bacteriology for N. gonorrheae and C. trachomatis to their testing menu, the laboratory did not have documentation of competency assessments for TP-1 or TP-2 for initial, (6) month or annual competency performance for 2018. e. The laboratory did not have competency assessments for initial competency for all three testing personnel for 2019 after implementing the new Sysmex XP 300 hematology analyzers in July of 2019. f. The laboratory technical consultant confirmed by interview the lack of competency testing policies and procedures and documentation of performance for initial, (6) month and

	annual competency's for testing personnel. g. The laboratory reports performing approximately (275) hematology, 200 mycobacteriology and (100) bacteriology patient specimens annually.