

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 65D2137459	(X3) Date Survey Completed 03/26/2019
Name of Provider or Supplier Diagnostic Laboratory Services, Inc - Amc-2	Street Address, City, State 263 Vietnam Veterans Hwy, Mangilao, GU	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual on March 26, 2019 the procedure manual failed to include all the required elements as specified: Findings Included: a. The laboratory is an ancillary site to multisite healthcare laboratory network. Upon review of the laboratories policy's and procedures manual, the procedures for the analyzers and testing kits were available, but did not include all the elements required under 493.125(b)for this laboratory site. The elements missing were; (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen</p>

acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. . b. The Technical supervisor affirmed by interview on March 26, 2019 at approximately 2:30 pm the lack of a complete procedure manual. c. The laboratory reports performing approximately 34,515 test annually.

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 review of the laboratory's patient test reports on March 26, 2019, the laboratory failed to ensure that the test report indicated the following: (c)(2) The name and address of the laboratory location where the test was performed. Findings included. a. The laboratory is an one of four facilities in a healthcare laboratory network located on Guam. All four facilities use the same LIS server. b. Upon review of the patient test reports it was noted that 8/8 of the patient reports reviewed indicated that the tests had been performed at the main lab ITC. 01/28/2019-YD20843216 CBC 01/29/2018-YC83453014-CBC 02/20/2018-YC85158931-CBC 04/10/2018-YC89021591-CBC 04/26/2018-YC90295941-CBC 12/31/2018-YC18654819-CBC & UA 12/31/2018-YD18657613-CBC 11/28/2018-YD16286553-CBC c. The laboratory Technical supervisor affirmed this discrepant reporting of testing location by interview on March 26, 2019 at approximately 2:00 pm. d. The laboratory reportedly performs approximately 34,515 tests annually.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on review of the laboratory procedure manual and interview with the laboratory technical supervisors on March 26, 2019, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings Include: a. The laboratory's approved procedure manual did not include (10) of the (14) required elements listed in the 42 CFR 493.1251(b). See D5403.