

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0870514	(X3) Date Survey Completed 01/26/2018
Name of Provider or Supplier Wsu Student Health Center	Street Address, City, State 3885 W Campus Dr Ssc Rm 190, Ogden, UT	
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 quality control record (QC) review, procedure manual review, Individualized Quality Control Plan Review, and interview with staff, the laboratory procedure for media quality control failed to include step by step instructions for performing and recording media QC for one of two media types reviewed, Selective Strep Agar (SSA) and for bacitracin antibiotic disk new lot number checks. Findings include: 1. Quality control records review included documentation for positive and negative control results for new lot numbers of SSA agar written in the quality control log column for Bacitracin disk quality control checks for media received from 06/08</p>

/2017 to 01/23/2018. 2. Quality control record review failed to include documentation for the lot number, expiration date, and positive and negative test results for Bacitracin (A) disks received after lot number 6356539. 3. IQCP and procedure manual review failed to include step by step instructions for where and how to record media and A Disk quality control for new media lot number quality control and quality control for antibiotic (A) disk. 4. In an interview with staff on 01/26/2018 at approximately 4:00 P.M. staff confirmed, the documentation recorded as A disks was in fact for SSA agar media new lot numbers.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on quality control records review, lack of documentation and confirmation by staff, the laboratory failed to include in the Individualized Quality Control Plan the extent of quality control needed for each new lot number of Selective Strep Agar Media received for media shipments reviewed from January 26, 2016 to January 26, 2108. Findings include: 1. The IQCP review included instructions for positive and negative evaluation of Bacitracin disks. The IQCP failed to include media quality control determination that the selective 'strep' media supported, growth, inhibited non strep organisms, and was sterile upon receipt. 2. Quality control documentation review failed to include inhibition control. The laboratory lacked a "non strep" quality control organism for culture growth inhibition of species other than Streptococci. 3. The IQCP failed to include media inhibition risk assessment and failed to include the control plan or quality assessment for media inhibition of non strep organisms. 4. In an interview conducted on 01/26/2018 at approximately 3:30 P.M. staff confirmed they did not have a QC or QA check stated in the IQCP or that they checked each new lot number or shipment for growth inhibition.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on lack of training documentation and confirmation by staff, the laboratory

director failed to ensure one of one new technical consultant/testing person had documentation they received the appropriate training to perform and provide technical oversight for 4 of 4 moderate complexity tests reviewed , prior to patient testing (microscopic urinalysis, Group A Streptococci confirmation cultures. Vaginal wet (saline) and Potassium Hydroxide (KOH) preparations and have documented they could perform all testing operation reliably to provide and report accurate results. Findings include: 1. The laboratory director failed to document an evaluation of test performance by the new testing person for each laboratory procedure prior to performing and reporting patient tests. 2. The laboratory failed to document competency evaluations semiannually the first year of testing. 3. In an interview with staff on 01/26/2018 at approximately 4:00 P.M., staff confirmed training and evaluations were not documented for the new testing person prior to reporting patient test results.