

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0655168	(X3) Date Survey Completed 06/05/2019
Name of Provider or Supplier Unc Oral Microbiology Laboratory	Street Address, City, State 150 Dental Circle, Room 3030 First Dental Bldg, Chapel Hill, NC	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of CMS (Centers for Medicare and Medicaid Services) Casper report 155D and review of 2017, 2018 and 2019 AAB (American Association of Bioanalysts) proficiency testing records 6/5/19, the laboratory failed to successfully participate in proficiency testing for the subspecialty of bacteriology in two consecutive testing events. See the deficiency cited at D2020.</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p>

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on review of CMS (Centers for Medicare and Medicaid Services) Casper report 155D and review of 2017, 2018 and 2019 AAB (American Association of Bioanalysts) proficiency testing records 6/5/19 and review of email from AAB 7/5/19, the laboratory failed to successfully participate in proficiency testing for the subspecialty of bacteriology in two consecutive testing events. Findings: 1. On the 2018 Q3 Nonchemistry test event, the laboratory provided an incorrect response for 1 of 4 samples, resulting in a score of 75% for Bacteriology culture identification. 2. On the 2019 Q1 Nonchemistry test event, the laboratory provided an incorrect response for 1 of 4 samples, resulting in a score of 75% for Bacteriology culture identification. An AAB representative stated in email dated 7/5/19 "Each of the four samples reported were weighted 25% since they reported Extent 0 for one sample in each event."

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:

Based on procedure manual review, review of the plan of correction from the 5/25/17 recertification survey, and interview with the Laboratory Director 6/5/2019, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual contained two different procedures for use of the Taxo A disc for determining bacitracin sensitivity: "Bacitracin Susceptibility Test" and "Taxo A Disc for Differentiation of Group A Streptococci". 2. The procedure manual did not include step-by-step instructions for performance of the following procedures: a. MR(Methyl-Red); b. VP(Vogues-Proskauer); c. SPS(sodium polyanethol sulfate); d. Malonate Broth. During interview at approximately 150 pm the Laboratory Director confirmed that the laboratory still uses MR, VP, SPS, and Malonate Broth. 3. The plan of correction from the 5/25/17 recertification procedure stated the following

procedures were discontinued and removed from the procedure manual, but they were still included in the procedure manual 6/5/19: a. Urease Test; b. Fluorescence Test; c. Staph Streak; d. Carbohydrate Fermentation Broth Tests. 4. The procedure manual did not include the frequency for performing quality control testing on the following: a. 3% Catalase Test; b. 15% Catalase Test; c. Germ tube Test; d. Gram Stain; e. MIO (motility-indole-ornithine) Test; f. Citrate Agar; g. DNase Test; h. Phenylalanine Deaminase Agar; i. Cefinase; j. 6.5% Salt Tolerance; k. Lysine Decarboxylase Test; l. Oxidase; m. Indole; n. Bile Esculin; o. Triple Sugar Iron Agar. The Laboratory Director confirmed during interview at approximately 3:30pm that he realized the procedure manual was not complete or current for all testing performed. This deficiency was cited on the previous survey 5/25/17.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on review of records, observation, and interview with Laboratory Director on 6/5/2019, the laboratory failed to discard supplies that had exceeded their expiration dates. Findings: 1. Review of the laboratory's "Reagent Log" revealed several reagents had exceeded the expiration date, but the log did not indicate a new lot number was put into use. For example, MR-VP(Methyl Red-Vogues Proskauer) had an expiration date listed of 3/19, but the column for new lot number and expiration date was blank. 2. During a tour of the laboratory at approximately 3:00pm, surveyors observed the following expired supplies in the laboratory refrigerator and freezer, available for use: a. Urea Agar Slant (lot number: 16284, expiration date: 4/8/17) b. Moellers Arginine (lot number: 16300, expiration date: 10/26/17) c. TSI (Triple Sugar Iron) Slant (lot number: 17342, expiration date: 6/6/18) d. MR-VP (lot number 408040, expiration date: 1/8/19) e. Mycosel Agar (lot number: 8299698, expiration date: 2/21/19) f. BBL Enterococcosel Agar (lot number: 8299772, expiration date: 2/23/19) g. Phenylalanine Slant (lot number: 412515, expiration date: 3/15/19) h. R2A Agar (lot number: G54-429263, expiration date: 3/20/19) i. MR-VP (lot number: 412942, expiration date: 3/22/19) j. MR-VP (lot number: 415183, expiration date: 4/27/19) k. BD BBL Sensi-Disc Amoxicillin/Clavulanic Acid (lot number: 7284722, expiration date: 4/30/19) l. Sensi Disc Clindamycin (lot number: 6102849, expiration date: 4/30/19) m. MH (Mueller-Hinton) Agar with blood (lot number: A59-435647, expiration date: 6/3/19) During interview at approximately 3:30pm, the Laboratory Director stated that the Testing Personnel recently checked for and discarded expired supplies, but some must have been missed.