

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0002842	(X3) Date Survey Completed 09/05/2019
Name of Provider or Supplier University Of New Hampshire Health & Wellness	Street Address, City, State 4 Pettee Brook Ln, Durham, NH	
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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in an approved proficiency testing (PT) program for all 3 events per year in 2018 and 2019 for the subspecialties of Diagnostic Immunology, Endocrinology, and Bacteriology. Findings include: 1) Review on 9/5/2019 of the laboratory's PT order confirmations revealed the laboratory was enrolled in Medical Laboratory Evaluation (MLE) and College of American Pathologist (CAP) PT programs. The laboratory enrolled in 2 MLE "Bacteriology-1" events in 2018 and 2019. Each MLE "Bacteriology-1" event included 1 antimicrobial sensitivity testing, 1 genital culture, 2 gram stain and morphology, 3 miscellaneous cultures (sources vary between blood, cerebral spinal fluid, ear, eye, sputum, stool and wound), 1 throat culture, and 1 urine culture. The laboratory's CAP PT enrollment for 2018 and 2019 included 2 events for infectious mononucleosis (mono), 2 events for serum pregnancy (hCG), two events for gram stain, and 2 throat/urine culture testing (2 PT samples per event for the presumptive identification of Group A Streptococcus and 3 PT urine specimens for culture, 1 of which is for gram stain and morphology and antimicrobial sensitivity testing). 2) Review on 9/5/2019 of PT records from 2018 and 2019 revealed the laboratory participated in MLE events 1 and 3 for bacteriology testing and in the 1st and 3rd</p>

CAP events (events A and C) for infectious mono, serum hCG, gram stain, throat /urine culture. The record review revealed no records of the laboratory participating event 2 for MLE and event B for CAP PT during the summer months. 3) Interview on 9/5/2019 at 11:30 a.m. with Staff A (Director of Finance and Administration) and Staff B (Clinical Manager) confirmed the above findings. Staff B further revealed mono and serum hCG testing were performed all year long, including during the laboratory's summer hours.