

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2116986	(X3) Date Survey Completed 03/15/2019
Name of Provider or Supplier Universal Clinical Laboratories	Street Address, City, State 2550 Brodhead Rd, Suite 201, Bethlehem, PA	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review pf quality control records, and interview with testing personnel (TP) #1 and #2, the laboratory failed include a complete quality control (QC) procedure each day of patient testing for the urine microscopic examination performed from November 2017 to October 2018. Findings Include: 1. The Urine Microscopic QC logs listed 2 levels of QC (high and low) to be performed for white blood cells (WBS), red blood cells (RBC), crystals and casts. 2. On the Day of survey, 03/15 /2019, review of Urine Microscopic examination QC logs revealed, the laboratory did not perform and document each day of patient testing QC procedures for WBS, crystals and casts from November 17th, 2017 to October 19th, 2018. 3. From November 17, 2017 to December 31, 2018, 188 Urine Microscopic examinations were analyzed. 4. From January 1, 2018 to October 19th, 2018, 154 Urine Microscopic examinations were analyzed 5. TP #1 and 2 confirmed the findings above on 03/15 /2019 around 10:15 am.</p>