

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0182840	(X3) Date Survey Completed 02/06/2019
Name of Provider or Supplier Ellwood City Medical Center	Street Address, City, State 724 Pershing St, Ellwood City, 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 quality control record review and interview with the Laboratory Manager and Laboratory Assistant Manager on (02/06/2019), the laboratory failed to include a positive and negative control each day of patient testing for Wet Prep and Urine Sediment examination. Findings include: 1.The laboratory did not include a negative and positive control material at least once a day patients specimens were examined for , Wet Prep, and Urine Sediment Examination for tests preformed from (01/01/2019) through the date of survey (02/06/2019). 2. During the survey, the Laboratory Manager, confirmed that positive and negative controls are not documented each day of patient testing for Wet Prep, and Urine Sediment Examination.</p>