

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D1028487	<b>(X3) Date Survey Completed</b>  08/07/2019
<b>Name of Provider or Supplier</b>  Wbgh Commonwealth Health Lab Svcs	<b>Street Address, City, State</b>  620 North Blakely Street, Dunmore, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> 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 of urine sediment microscopic examination quality control (QC) records, review of BioRad Quantify Plus Controls, levels 1 and 2 package inserts and interview with the Interim Director and Site Supervisor, the laboratory failed to perform QC procedures for casts on 4,285 of 4,285 patient specimens examined for urine sediment microscopic examinations from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/07/2019, a review of BioRad Quantify Plus Controls levels 1 and 2 package inserts revealed the laboratory did not perform QC procedures for casts analyzed during urine sediment microscopic examinations, performed each day of patient testing from 2017 to 08/07/2019. 2. In 2017, 1679 Urine Sediment Microscopic Examinations were analyzed. 3. In 2018, 1674 Urine Sediment Microscopic Examinations were analyzed. 4. In 2019 (01/01/2019 to 008/07/2019), 932 Urine Sediment Microscopic Examinations were analyzed. 5. The Interim Director and Site Supervisor confirmed the findings above on 08/07/2019 around 10:48 am.</p>