

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2077410	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Wayne Memorial Hamlin Laboratory	Street Address, City, State 543 Easton Turnpike Suite 105, Lake Ariel, 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 surveyor review of hCG quality control (QC) records and interview with the Technical Consultant and Laboratory Manager, the laboratory failed to perform a negative and positive control material each day of patient testing for Serum hCG from 2016 to the time of survey. Findings include: 1. At the time of survey (1/10/2018 start time of 1:00 PM)), it was discovered that the laboratory did not perform QC at least each day of patient testing for Serum hCG testing performed on Fischer Scientific Sure-View hCG Stat Urine/ Serum Kit. 2. In 2016, 20 Serum hCG tests were performed. 3. The Technical Consultant and Laboratory manager confirmed the findings above on 1/10/2018 around 2:30 PM.</p>