

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0982252	(X3) Date Survey Completed 03/25/2021
Name of Provider or Supplier Wellspan Poc Testing	Street Address, City, State 30 Monument Dr, Suite 1100, York, 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 of the istat quality control (QC) records, and interview with the manager of point of care testing, PoC team leader, testing personnel (TP) #1, TP#8 and TP#9, the laboratory failed to document QC procedures performed each day of patient testing on 2 of 12 days the Abbott istat chem 8 cartridges were in use during the month of February 2021. Findings include: 1. On the day of survey, 03/25/2021, review of the istat chem 8 cartridge QC records revealed, the laboratory did not document QC procedures performed each day of patient testing in February 2021 (2 of 12 days). 2. The laboratory was aware of the days QC was not performed, but failed to document a corrective action taken when QC was not performed on 02/05/2021 and 02/24/2021. 3. On 02/05/2021 - 1 patient was analyzed on an Abbot Istat Chem 8 cartridge. 4. On 02/24/2021 - 1 patient was analyzed on an Abbot Istat Chem 8 cartridge. 5. The manager of point of care testing confirmed the findings above on 03/25/2021 around 10:00 am.</p>