

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0982252	(X3) Date Survey Completed 02/03/2023
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the nurse navigator (NN) , the laboratory failed to provide 4 of 6 PT attestation statements for routine chemistry signed by the laboratory director or designee in 2021 and 2022. Findings Include: 1. On the day of the survey, 02/03/2023 at 10:15 am, The following AAB PT attestation statements were not signed by the laboratory director or designee in 2021 and 2022. - Routine Chemistry: i-STAT Chemistry : - 2021 Event #2. - 2022 Event #1 - 2022 Event # 2 - 2022 Event # 3 2. The NN confirmed the findings above on 02/03/2023 around 11:30 a.m.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the nurse navigator (NN), the laboratory failed to determine that the performance specifications for 1 of 1 Abbott iSTAT Chem 8+ Cartridges used for routine chemistry specimens from May 2021 to February 2023 were not affected by the relocation of the laboratory. Findings Include: 1. On the day of survey, 02/03/2023 at 10:00 am, the laboratory could not provide documentation showing that the performance specifications of 1 of 1 Abbot iSTAT were not affected by the relocation of the laboratory from May 2021 to February 2023. 2. From 01/01/2022 to 12/31/2022, 840 patients were analyzed on the Abbot iSTAT Chem 8+ cartridges. 3. The NN confirmed the finding above on 02/03/2023 around 11:30 am.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on lack of competency assessment (CA) records and interview with the nurse navigator (NN), the technical consultant (TC) failed to assess the competency of 4 of 5 testing personnel (TP) for routine chemistry examinations in 2022. Finding Include: 1. On the day of the survey, 02/03/2023 at 09:30 am, the NN could not provide CA records for 4 of 5 TP (CMS 209 personnel #2, #3, #4, and #6) who performed routine chemistry examinations using the iSTAT Chem 8+ cartridges in 2022. 2. The NN confirmed the findings above on 02/03/2023 around 11:30 am.