

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0185673	<b>(X3) Date Survey Completed</b> 12/22/2021
<b>Name of Provider or Supplier</b> Wellspan Internal Medicine - Wilson Street	<b>Street Address, City, State</b> 220 Wilson Street Suite 109, Carlisle, 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>D2015</b>	<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 Proficiency Institute (API) proficiency testing (PT) records and interview with Technical Consultant (TC) , the laboratory failed to provide the PT attestation statements signed by the analyst and the laboratory director /designee in 2020 and 2021. Findings Include: 1. On the day of survey, 12/22/2021, the following API PT attestation statements were not signed by the analyst and the laboratory director/designee in 2020 and 2021: a. Chemistry Core: - 2020 Event #1. - 2020 Event #3. b. Immunology/Immunochemistry: - 2021 Event #1. - 2021 Event #2. 2. The following API PT attestation statements were not signed by the laboratory director/designee in 2020 and 2021. a. Hematology/Coagulation: - 2020 Event #3. - 2021 Event #1. b. Chemistry Miscellaneous: - 2020 Event #1. - 2020 Event #2. - 2021 Event #1. - 2021 Event #2. c. Chemistry Core: - 2021 Event #1. d. Immunology /Immunochemistry: - 2020 Event #3. 3. TC confirmed the findings above on 12/22 /2021 around 10:50 a.m.</p>
<b>D5209</b>	PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the competency assessment records and interview with the Technical Consultant (TC), the Laboratory failed to have a complete policy to assess the competency of 4 of 4 testing personnel (TP) and 1 of 1 TC who performed Chemistry, Hematology, Mycology, Parasitology, and Urinalysis testing in 2020 and 2021. Findings Include: 1. On the day of survey, 12/22/2021, the TC could not provide a complete policy that reviews how to assess the competency for 1 of 1 TC (CMS 209 personnel #2) for their supervisory responsibilities in 2020 and 2021. 2. The Laboratory director did not assess the competency for 1 of 1 TC for their supervisory responsibilities in 2020. 3. The TC could not provide a complete competency assessment policy to assess 4 of 4 TP for the six points of CLIA in 2020 and 2021. 4. The TC could not provide competency assessment records for 2 of 4 TP (CMS 209 personnel #2 and #4) who performed Chemistry, Hematology, Mycology, Parasitology, and Urinalysis testing in 2020 and 2021. 5. The TC could not provide competency assessment records for 2 of 4 TP (CMS 209 personnel #3 and #5) who performed Hematology, Mycology, Parasitology, and Urinalysis testing in 2020 and 2021. 6. The TC could not provide semiannual competency assessment records for 1 of 4 TP (CMS 209 personnel #5) during their first year of employment. 7. The TC confirmed the findings above on 12/22/2021 at 12:00 p.m