

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0955466	(X3) Date Survey Completed 01/27/2023
Name of Provider or Supplier Wellspan Endocrinology	Street Address, City, State 292 St Charles Way, 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
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of quality assurance (QA) documentation and an interview with the practice manager (PM), the laboratory director (LD) failed to ensure a QA program was established and maintained to ensure the quality of services provided by the laboratory from 02/09/2021 to the date of the survey. Findings include: 1. On the date of the survey, 01/27/2023 at 10:15 am, the laboratory could not provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 02/09/2021 to 01/27/2023. 2. The laboratory performed 38 synovial fluid crystal identification in 2022 (the annual volume listed on the CMS-116 form). 3. The PM confirmed the findings above on 01/27/2023 around 10:45 am.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory competency assessment records and interview with practice manager (PM), the laboratory failed to assess the competency of 2 of 3 testing personnel (TP) who performed the testing in chemistry from 02/09/2021 to the day of survey. Findings include: 1. On the day of survey, 01/27/2023 at 09:36 am, the laboratory could not provide the annual competency assessment records for 2021 and 2022 for 2 of 3 TP (CMS 209 TP #2 and TP#3) who performed synovial fluid crystal identification. 2. PM confirmed the finding above on 01/27/2023 around 10:45 am.