

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0942535	(X3) Date Survey Completed 11/28/2023
Name of Provider or Supplier Chester County Rheumatology Pc	Street Address, City, State 795 E Marshall Street Ste 101, West Chester, 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
D8103	<p>BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d)</p> <p>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic. (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the office manager (OM), the laboratory failed to have the required records accessible during the laboratory survey performed on 11/28/2023. Findings Include: 1. On the day of the survey, 11/28/2023 at 09:14 am, the laboratory could not provide the following records upon request: -Quality assessment (QA) records for 4 of 4 quarters in 2022. -Twice annual verification of accuracy records (peer review) for 2022. 2. The OM confirmed the finding above on 11/28/2023 at 10:00 am.</p>