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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2095258 | (X3) Date Survey Completed 05/03/2022 |
| Name of Provider or Supplier Cumberland Valley Rheumatology Pc | Street Address, City, State 40 Parkwood Drive, Chambersburg, 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 |
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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on interview with Testing personnel (TP) 1 and review of the competency assesment records , the laboratory failed to assess employee competency for 1of 1 Testing Personnel (TP) for each testing perform in hematology and chemistry from 2 /12/2020 to 05/03/2022. Findings include: 1. On the day of survey 05/03/2022 at 10: 11am, review of the competency records revealed, the laboratory did not perform separate competency assessment for hematology analyzer DXH 520 and chemistry analyzer ACE Axcel for 1 of 1 TP from 02/12/2020 to 05/03/2022. 2. Testing personnel 1 confirmed the findings above on 05/03/2022 at 12:25pm.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the Testing personnel 1, the laboratory failed to establish a validation procedure for new test/ analyzer from 02 /12/2020 to 05/03/2022. Findings include: 1. On the day of survey 05/03/2022 at 11:</p> |

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| | <p>34am, the laboratory could not provide a procedure on how to validate a new analyzer. 2. The laboratory acquired a new hematology (DXH 520) analyzer in January 2020. 3. Interview with testing personnel 1 confirmed the above findings on 05/03/2022 at 12:26pm.</p> |
| <p>D5413</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, temperature record review and interview with the Testing personnel (TP) 1, the laboratory failed to document room temperature for the storage of 4 of 4 chemistry reagents from 02/12/2020 to 05/03/2022. Findings include: 1. Observation of the laboratory on 05/03/2022 at 12:18pm, showed that the following chemistry reagents (ACE- Albumin, Total bilirubin, Bilirubin, Total protein) are stored in room temperature. 2. The laboratory failed to provide room temperature record. 3. Interview with testing personnel 1 confirmed the findings above on 05/03/2022 at 12:22pm.</p> |
| <p>D5415</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with Testing personnel 1, the laboratory failed to ensure 11 of 11 bottles of reagents did not have receive and opening dates in 05/03/2022 at 12:12pm. Findings Include: 1. Observation of the laboratory on 05/03/2022 at 12:12pm, revealed that the following reagents did not have receiving and opening dates: 2 of 2 bottle of ACE Albumin 2 of 2 bottle of ACE Total bilirubin 2 of 2 bottle of ACE Bilirubin 2 of 2 bottle of ACE Calcium 3 of 3 bottle of Total protein 2. Interview with testing personnel 1 confirmed the findings above on 05/03/2022 at 12:15 am.</p> |
| <p>D5429</p> | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> |

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the testing personnel (TP) #1, the laboratory failed to perform and document maintenance on the 2 of 2 thermometer for the storing of chemistry and hematology reagents from 02/12/2020 to 05/03/2022. Findings Include: 1. Based on observation of the lab on 05/03/2022 at 11:25am, revealed that the following thermometers were expired on Nov 7, 2017. a. S/N 151885088- DXH 520 hematology reagent refrigerator. b. S/N 151885087- ACE Axcel chemistry reagent refrigerator. 2. Interview with TP #1 at 12:22pm confirmed the findings above.