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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2095258 | (X3) Date Survey Completed 02/12/2020 |
| 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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| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based upon chemistry instrument records and personnel interview with the Laboratory Supervisor on the date of the survey, the laboratory failed to perform and document calibration verification at least each 6 months, for 7 of 7 analytes run on the ACE AXEL Chemistry analyzer. Findings include: 1. At the time of the survey, the laboratory failed to provide documentation of calibration verification from (01/06 /2019 through 02/12/2020), for 7 of 7 analytes (albumin, creatinine, calcium, direct</p> |

bilirubin, total bilirubin, total protein, and uric acid) run on the ACE AXEL Chemistry analyzer. 2. The last documented calibration verification for the 7 analytes run on the the ACE AXEL Chemistry analyzer, was performed on (01/05/2019). 3. During the survey (13:00 hours 02/12/2020), the Laboratory Supervisor confirmed the above findings.