

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1102656	(X3) Date Survey Completed 12/18/2020
Name of Provider or Supplier C S Sewell Md Pc	Street Address, City, State 341 West Central Ave, Jamestown, TN	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory performance in 2 out of 3 proficiency testing (PT) events for the White Blood Cell Differential (WBC Diff), resulting in the 1st unsuccessful PT occurrence for the WBC Diff. (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p>

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and American Proficiency Institute (API) evaluation report, the laboratory failed to achieve satisfactory performance for White Blood Cell Differential (WBC Diff) analyte in two out of three testing event resulting in the 1st unsuccessful PT performance in 2020. The findings include: 1. Review of the CMS 155 revealed a score of 40% for the 2nd event 2020, and a score of 60% for the 3rd event 2020 for the WBC Diff analyte. 2. Review of the laboratory's API evaluation report revealed a score of 40% for the 2nd event 2020, and a score of 60% for the 3rd event 2020 for the WBC Diff analyte.