Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0658581	03/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Scdmh Clinical Laboratory	8301 Farrow Road, Columbia, SC	

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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a proficiency test desk review conducted on 03/03/2022, review of CASPER report 155D and graded reports from American Proficiency Institute (API), it was determined that the laboratory failed to successfully participate in proficiency testing for the specialty of hematology, the analyte white blood cell differential (WBC Diff) for three out of three consecutive proficiency testing events reviewed (2021, Events 1, 2 and 3). See D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency test desk review conducted on 03/03/2022, review of CASPER report 155D and graded reports from American Proficiency Institute (API), it was determined that the laboratory failed to achieve satisfactory performance for the analyte WBC Diff for three out of three consecutive testing events reviewed (2021, Events 1, 2, and 3) resulting in unsuccessful proficiency testing performance.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency test desk review conducted on 03/03/2022, review of CASPER report 155D and graded reports from American Proficiency Institute (API), it was determined that the laboratory director failed to ensure proficiency testing for the analyte WBC Diff required by 42 CFR, Part 493.801 (see D6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency test desk review conducted on 03/03/2022, review of CASPER report 155D and graded reports from American Proficiency Institute (API), it was determined the laboratory director failed to ensure the laboratory attained a result of 80% for the analyte WBC Diff. The laboratory failed three out of three consecutive proficiency testing events reviewed for WBC Diff (2021, Events 1,2 and 3). (see D2130)