

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1003115	(X3) Date Survey Completed 11/13/2023
Name of Provider or Supplier Singleton Health Center	Street Address, City, State 1773 Villagepark Drive, Orangeburg, 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
D0000	The following deficiencies are the result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
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: Based on a proficiency testing desk review of Certification and Survey Provider</p>

Enhanced Reporting (CASPER) 0155 report and Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing 2023 records, the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Hematology and for the Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), Platelet (PLT), and WBC Diff analytes. Refer to D2130 and D2131
Word Key: WBC Diff = White blood cell differential

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of CASPER 0155 report and WSLH Proficiency Testing 2023 records (Events 1, 2, and 3), the laboratory failed to achieve a satisfactory performance for the same analytes for two consecutive testing events for Alanine Aminotransferase (ALT), Albumin, Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), Bilirubin, Calcium (CA), Carbon dioxide (CO2), Chloride (CL), Cholesterol (HDL), Cholesterol (Total), Creatinine, Glucose, Potassium (K), Total Protein, Sodium (NA), Triglycerides (TRIG), and Urea nitrogen (BUN) chemistry analytes. Findings included: 1. Review of the CASPER 0155 report revealed the following results: Chemistry 2023-1st Event the laboratory received an unsatisfactory score of 0% for: Alanine Aminotransferase (ALT) Albumin Alkaline Phosphatase (ALP) Aspartate Aminotransferase (AST) Bilirubin Calcium (CA). Carbon Dioxide (CO2) Chloride (CL) Cholesterol (HDL) Cholesterol (Total) Creatinine Glucose Potassium (K) Total Protein Sodium (NA) Triglycerides (TRIG) Urea nitrogen (BUN) Chemistry 2023-2nd Event the laboratory received an unsatisfactory score of 0% for: Alanine Aminotransferase (ALT) Albumin Alkaline Phosphatase (ALP) Aspartate Aminotransferase (AST) Bilirubin Calcium (CA). Carbon Dioxide (CO2) Chloride (CL) Cholesterol (HDL) Cholesterol (Total) Creatinine Glucose Potassium (K) Total Protein Sodium (NA) Triglycerides (TRIG) Urea nitrogen (BUN) 2. A review of the WSLH Proficiency Testing records confirmed the laboratory received the above results.

D2097

ROUTINE CHEMISTRY
CFR(s): 493.841(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of CASPER 0155 report and WSLH Proficiency Testing 2023 records (Events 1,2, and 3), the laboratory failed to achieve an overall satisfactory performance for Routine Chemistry for two consecutive testing events. Findings included: 1. Review of the CASPER 0155 report revealed the following results: The laboratory received an unsatisfactory score of 0% for overall

Chemistry for: Routine Chemistry 2023-1st, 2nd, and 3rd Event. 2. A review of the WSLH Proficiency Testing 2023 records confirmed the laboratory received the above results.

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 testing desk review of CASPER 0155 report and WSLH Proficiency Testing 2023 records (Events 1,2 and 3), the laboratory failed to achieve a satisfactory performance (80% or better) for the same analytes for three consecutive testing events in the specialty of Hematology for the Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood cell (WBC), Platelet (PLT), and WBC Diff analytes. Findings included: 1. Review of the CASPER 0155 report revealed the following results: Hematology 2023-1st Event the laboratory received an unsatisfactory score of 0% for Red Blood Cell (RBC). Hematology 2023-1st Event the laboratory received an unsatisfactory score of 0% for Hematocrit (HCT). Hematology 2023-1st Event the laboratory received an unsatisfactory score of 0% for Hemoglobin (HGB). Hematology 2023-1st Event the laboratory received an unsatisfactory score of 0% for White Blood cell (WBC). Hematology 2023-1st Event laboratory received an unsatisfactory score of 0% for Platelet (PLT). Hematology 2023-1st Event laboratory received an unsatisfactory score of 0% for WBC Diff analytes. Hematology 2023-2nd Event the laboratory received an unsatisfactory score of 0% for Red Blood Cell (RBC). Hematology 2023-2nd Event the laboratory received an unsatisfactory score of 0% for Hematocrit (HCT). Hematology 2023-2nd Event the laboratory received an unsatisfactory score of 0% for Hemoglobin (HGB). Hematology 2023-2nd Event the laboratory received an unsatisfactory score of 0% for White Blood cell (WBC). Hematology 2023-2nd Event laboratory received an unsatisfactory score of 0% for Platelet (PLT). Hematology 2023-2nd Event laboratory received an unsatisfactory score of 0% for WBC Diff analytes. Hematology 2023-3rd Event the laboratory received an unsatisfactory score of 0% for Red Blood Cell (RBC). Hematology 2023-3rd Event the laboratory received an unsatisfactory score of 0% for Hematocrit (HCT). Hematology 2023-3rd Event the laboratory received an unsatisfactory score of 0% for Hemoglobin (HGB). Hematology 2023-3rd Event the laboratory received an unsatisfactory score of 0% for White Blood cell (WBC). Hematology 2023-3rd Event laboratory received an unsatisfactory score of 0% for Platelet (PLT). Hematology 2023-3rd Event laboratory received an unsatisfactory score of 0% for WBC Diff analytes. 2. A review of the WSLH Proficiency Testing records confirmed the laboratory received the above results.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

	<p>Based on a proficiency testing desk review of CASPER 0155 report and WSLH Proficiency Testing, the laboratory the laboratory failed to achieve an overall satisfactory performance (80% or better) for the specialty of Hematology for three consecutive testing events. Findings included: 1. A Review of the CASPER 0155 report revealed the following results: Hematology 2023-1st Event the laboratory received an unsatisfactory score of 0% for overall Hematology. Hematology 2023-2nd Event the laboratory received an unsatisfactory score of 0% for overall Hematology. Hematology 2023 3rd Event the laboratory received an unsatisfactory score of 0% for overall Hematology. 2. A review of the WSLH Proficiency Testing records confirmed the laboratory received the above results.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155 report and WSLH Proficiency Testing 2023 records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155 report and WSLH Proficiency Testing 2023 records, the laboratory director failed to ensure that the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2130 and D2131.</p>