

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	Based on a proficiency testing desk review of Certification and Survey Provider 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 Chemistry for the Alanine Aminotransferase (ALT), Albumin, Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), Bilirubin, Calcium (CA), Carbon Dioxide (CO2), Chloride (CL), Cholesterol (HDL), Total Cholesterol, Creatinine, Glucose, Potassium (K), Total Protein, Sodium (NA), Triglycerides (TRIGL), Urea nitrogen (BUN) analytes, and Hematology for the Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), Platelet (PLT), and WBC Diff analytes. Refer to 2096, D2097, D2130, D2131.
D2096	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

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

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	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.
D6000	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.
D6016	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 D2096 and D2097