Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2123338	12/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Signaturecare -College Station	1512 S Texas Ave, Suite # 500, College Station, TX	

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	An onsite validation survey conducted 12/11/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation, laboratory policy, quality control (QC) documentation (2022-2023), and confirmed in interview, the laboratory failed to retain QC documentation for 12 of 12 months in 2022 and 6 of 11 months in 2023 (January-November). Findings included: 1. During a tour of the laboratory on 12/11/2023 at 01: 05 p.m., the surveyor observed a Medonic M-Series Hematology Analyzer (Serial Number: 27011) in the patient test area. 2. Review of laboratory policy, "Quality Control Guidelines" (Approved by the Laboratory Director on 01/07/2014) revealed the following: "Medonic M-Series External Quality Control ...Quality Control Failure ...Document all troubleshooting failures on the appropriate form for later reference." 3. Review of laboratory hematology QC documentation for 2022 and 2023 (January-November), revealed multiple QC failures in February and March 2023. The surveyor requested corrective action/troubleshooting documentation for these failures, and none was provided. 4. During an interview on 12/11/2023 at 11:05 a.m. with the Director of Laboratory Services, in the facility conference room, the Director stated the "individual QC printouts" containing the corrective action documentation were previously shredded for all of 2022 and 6 months of 2023. This confirmed the laboratory failed to retain QC documentation for 12 of 12 months in 2022 and 6 of 11 months in 2023 (January-November).

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: I. Based on review of CMS-116 form, manufacturer's instructions, laboratory documentation (2022-2023) and confirmed in interview, the laboratory failed to have documentation of performing calibration verifications for CKMB, Troponin, and Myoglobin every six months for 2 of 2 events in 2022 and 1 of 1 event in 2023. Findings Included: 1. Review of CMS-116 form submitted at time of survey revealed the laboratory performed the Triage Cardiac Panel (CKMB, Troponin, and Myoglobin) on the Quidel Triage analyzer. 2. Review of the Alere Triage Cardiac Panel Quick Reference Guide (02/2018) revealed the following: "QC Panel ... Cal Ver Controls (5) - Run every 6 months." 3. Review of laboratory Quidel Triage documentation revealed the laboratory failed to have documentation of performing calibration verification for CKMB, Troponin, and Myoglobin in 2022 and 2023. The surveyor requested the above documentation, and none was provided. 4. During an interview on 12/11/2023 at 12:11 p.m., in the facility conference room, the Director of lab services confirmed the laboratory failed to have documentation of performing calibration verifications for CKMB, Troponin, and Myoglobin every six months for 2 of 2 events in 2022 and 1 of 1 event in 2023. II. Based on review of CMS-116 form, manufacturer's instructions, laboratory documentation (2022-2023) and confirmed in interview, the laboratory failed to have documentation of performing calibration verifications for chemistry analytes on the i-STAT analyzer every six months for 2 of 2 events in 2022 and 1 of 1 event in 2023. Findings Included: 1. Review of CMS-116 form submitted at time of survey, revealed the laboratory performed the following analytes on the i-STAT analyzer: Sodium (Na); Potassium (K); Chloride (Cl); Total Carbon Dioxide (TCO2); Ionized Calcium (iCa); Glucose (Glu); Urea Nitrogen (BUN) /Urea; Lactate; potential of hydrogen (pH); partial pressure of carbon dioxide (pCO2) and partial pressure of oxygen (PO2). 2. Review of the i-STAT Operators Manual (Revision: 07-March-13) revealed the following: "Calibration Verification Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals

	may be required by regulatory or accreditation bodies." 3. Review of laboratory i-STAT documentation revealed the laboratory failed to have documentation of performing calibration verification in 2022 and 2023. The surveyor requested the above documentation, and none was provided. 4. During an interview on 12/11/2023 at 12:11 p.m., in the facility conference room, the Director of Laboratory Services confirmed the laboratory failed to have documentation of performing calibration verifications for chemistry analytes on the i-STAT analyzer every six months for 2 of 2 events in 2022 and 1 of 1 event in 2023.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of CMS-116 form, laboratory documentation and confirmed in interview, the laboratory failed to perform twice annual comparisons between two analyzers reporting the same analyte for 1 of 2 events in 2022. Findings included: 1. Review of CMS-116 form submitted at time of survey, revealed the laboratory reported hematocrit and hemoglobin on the Medonic M-Series Hematology Analyzer (Serial Number: 27011) and an i-STAT analyzer (Serial Number: (21) 405901). 2. Review of laboratory documentation revealed the laboratory performed 1 comparison study in October 2022 between the Medonic M-Series and i-STAT. The surveyor requested a second comparison for 2022 and none was provided. 3. During an interview on 12/11/2023 at 11:14 a.m., in the facility conference room, the Director of Laboratory Services confirmed the laboratory failed to perform twice annual comparisons between two analyzers reporting the same analyte for 1 of 2 events in 2022.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of CMS (Center for Medicaid and Medicare Services)-209 form, laboratory policy, personnel documentation, and confirmed in interview, the technical consultant failed to perform 14 of 14 competency assessments in 2022 and 2023. Findings Included: 1. Review of CMS-209 form submitted at time of survey, revealed 12 Testing Personnel (TP-1 through TP-12) performing moderate complexity testing. 2. Review of laboratory policy, "Lab Testing Personnel Competency Assessment" (Approved by the Laboratory Director on 01/07/2014) revealed the following: "Description The focus of competency assessment is to carefully evaluate the individual's ability to perform assigned tasks according to the defined process and procedure- to assure accurate and reliable laboratory results. Competency shall be

	assessment completed by the Facility Manager, Lab Director, Lab Champion, or Director of Lab Services each six months for the first year of employment and annually thereafter. Procedure Direct Observation of Test Performance Observe the performance of routine patient testing to make sure that the test is being performed according to your standard procedures for the test. Direct observation can be documented on the competency assessment by noting the date of the observation for each test. Document that each step in the testing process is observed. ...Monitor the Recording and Reporting of Test Results ... ...Review of Intermediate Test Results or Worksheets ...Instrument Maintenance and Function Checks Observe the performance of instrument maintenance (if applicable) to make sure that the maintenance is being performed correctly. Direct observation can be documented on the competency assessment by noting the date of the observation of specific maintenance procedures that were observed ... ...Assessment of Test Performance Through Blind Testing Each testing personnel needs to run blind samples as part of the competency evaluation for each test that they perform. Evaluate results to make sure that they achieve acceptable results. ...Assessment of Problem-Solving Skills You can assess problem solving skills via retrospective review of problem logs or QA activities." 3. Review of personnel competency documentation for 2022 and 2023, revealed the following 14 of 14 competency assessments performed by TP-3 and TP-9: 2022 Laboratory Competency Assessment 1. Name: TP-3 Reviewer: TP-9; Date: 02/10/2022 2. Name: TP-4 Reviewer: TP-9; Date: 02/08/2022 3. Name: TP-6 Reviewer: TP-9; Date: 03/12 /2022 4. Name: TP-1 Reviewer: TP-9; Date: 07/05/2022 5. Name: TP-3 Reviewer: TP-9; Date: 08/01/2022 6. Name: TP-1 Reviewer: TP-9; Date: 10/18/2022 7. Name: TP-5 Reviewer: TP-9; Date: 11/11/2022 2023 Laboratory Competency Assessment 8. Name: TP-6 Reviewer: TP-9; Date: 02/06/2023 9. Name: TP-4 Reviewer: TP-9; Date: 02/17/2023 10. Name: TP-3 Reviewer: TP-9; Date: 02/17/2023 11. Name: TP-2 Reviewer: TP-9; Date: 02/20/2023 12. Name: TP-2 Reviewer: TP-9; Date: 06/11/2023 13. Name: TP-1 Reviewer: TP-3; Date: 10/01/2023 14. Name: TP-5 Reviewer: TP-3; Date: 11/02/2023 4. During an interview on 12/11/2023 at 10:24 a.m., in the facility conference room, the Director of Laboratory Services stated the Technical Consultant (also the Laboratory Director) would review the competency assessment but did NOT perform the competency assessments of testing personnel. This confirmed the technical consultant failed to perform 14 of 14 competency assessments in 2022 and 2023.