Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0251405	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Colleton Medical Center	501 Robertson Boulevard, Walterboro, 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	An on-site validation survey was completed on June 24, 2026, with the following standard level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, lack of supervisory competency assessment records, review of laboratory policies and interview with the Technical Supervisor (TS) #1, the laboratory failed to establish written policies and procedures to assess Technical and General supervisor competency for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's Form CMS 209 revealed 3 TSs and 5 General Supervisors (GS) listed. 2) The laboratory was unable to provide competency assessment records for the supervisors listed on the Form CMS 209 for 2 years (2024 and 2025). 3) Review of the laboratory's policy titled 'HCA Healthcare Lab General - Competency Assessment' revealed instruction on conducting and retaining competency assessments for testing personnel (TP), but not for consultants and/or supervisors. 4) In an interview on 6/23/2026, at 11:53 AM, TS#1 confirmed the laboratory conducted TP competencies, but was not conducting competency assessments for consultants and/or supervisors.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or

	procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of laboratory records and interviews with the laboratory director (LD) and Vice Presidency (VP) of Quality, the laboratory failed to perform twice-annual verification of accuracy for testing performed under the specialty of Histopathology in 2025 (1 of 2 years). Findings Included: 1. In the Histopathology specialty, the laboratory performed grossing of the specimen and microscopic examination of frozen sections in 2025. 2. The laboratory did not have policies or procedures in place for the performance of twice-annual verification of accuracy or PT for the testing performed in the specialty of Histopathology. 3. Review of the Histotechnician Testing Personnel (TP) competency assessment records revealed PT/ annual verification of accuracy was performed for grossing of specimens during the tech's annual competency assessment on June 6, 2025. 4. The laboratory was unable to provide documentation of the twice-annual verification of accuracy for testing performed for grossing of specimens in 2025. 5. The laboratory was unable to provide twice-annual verification of accuracy for microscopic examination of frozen sections in 2025 (1 of 2 years). 6. Review of the laboratory's test records provided revealed the following volumes: a. grossing procedures performed in-house: 2025 - 646 2026 - 381 b. two Frozen Section procedures examined: 2025 - 1 (Date: 2/11/2025) Surgical Pathology Specimen Number SR25:DAB:164, Source: Uterine Contents) 2026 - 1 (Date: 3/23/26, Surgical Pathology Specimen Number SR26:DAB:318, Source: Left Breast Cavity) 7. In an interview on June 24, 2026, at 3:00 PM, the Vice Presidency (VP) of Quality stated "the previous pathologist performed blinded verifications of accuracy twice a year, but the laboratory did not perform them that way any longer". In addition, the LD confirmed that, grossing procedures as well as Frozen Section examinations of tissue were tested within the laboratory, but twice a year, accuracy verifications were not performed.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies, test records, and interview with the Technical Supervisor (TS) #1, according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to establish and follow written policies and procedures for conditions of specimen transportation for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's policies did not reveal defined conditions of specimen preservation and transportation (i.e. temperatures), and the Clinical Laboratory Services Agreement with surrounding facilities the laboratory provided stated the following on page 4 of 10: "10. Specimen Transport & Courier Service; Phlebotomy Services A. Transport. Under normal conditions, LAB will be responsible for transport of all specimens. Transported specimens must be packaged and handled by GROUP and LAB according to OSHA guidelines. B. Courier. Courier service may

	be provided by LAB to GROUP's office at no charge if provided exclusively in conjunction with ordering and testing of laboratory services provided by LAB. LAB may also provide regular, periodic courier services to pick up and deliver specimens, reports, and supplies for the GROUP on schedules determined by LAB." 2) Review of the laboratory's test records revealed the following number of specimens from each facility received via courier from January 1 to May 30, 2026: a) Veteran Victory House Nursing Home - 213 patient specimens b) Pruitt Health Nursing Home - 82 patient specimens c) Davita Dialysis - 55 patient specimens 3) In an interview on 6/23 /2026 at 2:56 PM, TS#1 confirmed the laboratory lacked specimen preservation and transportation criteria within their policies and provided to all clinics and couriers whom they accepted specimens from for testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: I. Based on direct observation, review of Digi SmartSense temperature records, laboratory policies and procedures, and interview with the Technical Supervisor (TS) #1 according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to set room temperature ranges appropriate for blood product storage condition requirements of platelets for 2 of 2 years. Findings Included: 1) In direct observation on 6/23/2026 at 1:58 PM in the blood bank section of the laboratory, a designated platelet agitation area was observed with a temperature log taken every 4 hours, and an acceptable temperature range of 20 to 24 degrees Celsius. 2) Review of the blood bank's room temperature Digi SmartSense settings revealed an acceptable range of 19 to 25 degrees Celsius before alerting the laboratory, and the following days when room temperatures exceeded 24 degrees Celsius in January (Random review): 1/19/2026, 1/20/2026, 1/21/2026, 1/23/2026. 3) Review of the laboratory's blood product issuance logs revealed 1 irradiated platelet unit #W121625348408 issued on 1/21/2026 at 4:18 AM. However, the platelets were agitated and issued prior to when the room temperature range exceeded 24 degrees Celsius, according to the Digi SmartSense continuous temperature monitoring system. Further review of blood product issuances revealed 14 units of platelets issued to patients in 2025 and 4 units in 2026 up until May. 4) Review of the laboratory's policy titled 'HCA Healthcare: Platelet Preparation for Infusion' stated the following: "Thermometer (room temperature should be maintained between 20 to 24 degrees Celsius)". 5) In an interview on 6/23/2025 at 2:30 PM, TS#1 confirmed the room temperature acceptable range before alarming exceeded the mandatory maximum for platelets by 1 degree Celsius. II. Based on direct observation, review of Digi SmartSense temperature settings, and interview with the Technical Supervisor (TS) #1, according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to ensure storage of Fresh Frozen Plasma (FFP) with an adequate temperature threshold to alarm for temperatures above the upper limit for 2 of 2 years (2024 and 2025). Findings Included: 1) In direct observation on 6/23/2026 at 2:01 PM, one blood bank freezer was observed for the storage of FFP with Digi Smart Sense (Sensor #11666000000215955140) acceptable temperature range of -45 degrees Celsius to

	-17.7 degrees Celsius. No temperatures were observed exceeding -45 degrees Celsius to -18 degrees Celsius. Due to maintenance, all FFP had been moved from the Blood Bank Freezer to the Ultra Cold Freezer with settings of -40 degrees Celsius and colder. 2) Review of regulatory clinical guidelines the laboratory followed for FFP stated -18 degrees Celsius and colder requirements. 3) In an interview on 6/23/2025 at 2:30 PM, TS#1 confirmed the high temperature alarm threshold was not within acceptable range.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on direct observation, review of quality control (QC) records, laboratory test records, review of laboratory policy, and confirmed in interview with the General Supervisor #1 according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to take corrective action by evaluating patient test results obtained since the last acceptable test run after QC failures required recalibration on the Beckman Coulter UniCel Dxl 600 analyzer, for 2 of 58 days (January 1, 2026 - February 28, 2026 random review). Findings Included: 1) During a laboratory tour on 6/23/2026 at 11:00AM, a Beckman Coulter UniCel DXL 600 (Serial Number 901851) analyzer was observed in use within the Chemistry section. 2) Review of QC records from January to February 2026 (Random review) revealed control failures and subsequent recalibrations performed for Ferritin on 1/07/2026 and Cholesterol on 2/24 /2026, with no patient evaluation performed to the last acceptable test run. 3) Review of laboratory test records revealed the following 4 patient samples run for Ferritin on 1 /06/2026 and 4 patient samples run for Cholesterol on 2/23/2026, for which patient evaluations were not performed: 1/06/2026 - Specimens IDs: 0106: DAB: C00059S, 0106: DAB: C00092R, 0106: DAB: C00098R, 0106: DAB: C00128R 2/23/2026 - Specimens IDs: 0223: DAB: C00028R, 0223: DAB: C00077R, 0223: DAB: C00082R, 0223: DAB: C00086R. 4) Review of the laboratory's policy titled 'HCA Healthcare: Chemistry Quality Control Corrective Action', did not contain instructions to conduct patient evaluations after recalibrating due to QC failures. 5) In an interview on 6/23/2026 at 12:01 PM, TS#1 confirmed the laboratory did not perform corrective actions by evaluating patient test results obtained since the last acceptable test run after QC failures requiring recalibration.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities

	to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, lack of position delegation records, review of laboratory policy, and interview with the Technical Supervisor (TS) #1, the laboratory director failed to delegate, in writing, the duties and responsibilities for individuals reapportioned to Technical Supervisor (TS) and General Supervisor (GS) roles for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's Form CMS 209 revealed 3 TSs and 5 GSs listed. 2) The laboratory was unable to provide role delegations signed by the Laboratory Director (LD) for the supervisors listed for 2 years (2024 and 2025). 3) Review of the laboratory's policy titled 'HCA Healthcare Laboratory Medical Director Delegation' stated the following: "The Laboratory Medical Director is responsible for delegating duties to the appropriate members to assure high quality of patient care and in compliance with accreditation standards." 4) In an interview on 6/23/2026 at 11:53 AM, TS#1 confirmed the laboratory TSs and GSs did not have supervisory position delegations of reapportioned responsibilities signed by the LD.