

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2292355	(X3) Date Survey Completed 01/14/2026
Name of Provider or Supplier Advanced Ambulatory Surgery Center Of	Street Address, City, State 1619 Skyline Circle Ste B, Carlsbad, NM	
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	Based on an on-site revisit survey conducted on April 8, 2026 for Advanced Ambulatory Surgery Center of Carlsbad NM. The laboratory was found to be in compliance with 42 CFR Part 493, Laboratory Requirements. No additional deficiencies were identified. 51996 Based on a Recertification survey performed on January 14, 2026, the laboratory was found to be out of compliance with the following CONDITION LEVEL DEFICENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plans (IQCP), Quality Control (QC) Logs, and Patient Test Report, the laboratory failed to follow established QC procedures for the Abbott i-STAT CHEM8+ (CHEM8) and i-STAT Kaolin Activated Clotting Time (ACT) assays in 2025. Refer to D5445</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless</p>

otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Individualized Quality Control Plans (IQCP), Quality Control (QC) Logs, and Patient Test List, the laboratory failed to perform QC at the frequency specified in the laboratory's IQCPs for 41 of 77 Abbott i-STAT CHEM8+ (CHEM8) and 4 of 6 i-STAT Kaolin Activated Clotting Time (ACT) tests performed in 2025. Findings include: 1. Review of the IQCPs for CHEM8 and ACT indicated QC must be performed for each assay: a. Each new lot b. Each new shipment c. Every 30 days after the lot/shipment is in use d. After system maintenance and Software Upgrades 2. Review of the CHEM8 and ACT QC Logs revealed QC was performed the following Days: a. CHEM8: 01/28/2025 05/07/2025 08/11/2025 08/27/2025 b. ACT: 01/28/2025 05/07/2025 08/26/2025 3. Review of the Patient Test List revealed patient results were reported the following dates: a. CHEM8: MM/DD/YYYY (number patient results reported) 01/07/2025 (1), 01/08/2025 (2), 01/09/2025 (4), 01/14/2025 (5), 01/22/2025 (3) 02/28/2025 (1) 03/05/2025 (1), 03/11/2025 (2), 03/12/2025 (1), 03/25/2025 (3), 03/26/2025 (1) 04/15/2025 (2), 04/19/2025 (1), 04/22/2025 (1), 04/30/2025 (1) 06/10/2025 (1), 06/17/2025 (1) 07/15/2025 (2), 07/30/2025 (1) 10/03/2025 (1), 10/21/2025 (1), 10/29/2025 (1) 11/18/2025 (1), 11/26/2025 (1) 12/09/2025 (1), 12/16/2025 (1) b. ACT: MM/DD/YYYY (number patient results reported) 03/26/2025 (2) 10/31/2025 (1) 12/17/2025 (1) 4. The laboratory reported 77 CHEM8 and 6 ACT tests in 2025.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) 2025 Hematology/Coagulation - 2nd Event Performance Summary (HemePS) and interview with testing personnel 2(TP2), the laboratory failed to perform corrective action after the i-STAT Kaolin Activated Clotting Time (ACT) assay performed outside of spec on the API Hematology/Coagulation - 2nd event. Findings include: 1. Review of the API HemePS listed a score of "50%" for the analyte ACT for 2025 Event 2, and indicated no corrective actions were taken. 2. During an interview on 01/14/2026 at 10:04 am

with TP2, TP2 confirmed no corrective actions were taken following failed participation in the API Hematology/Coagulation -2nd event for ACT analyte. 3. The laboratory reports 7 ACT tests annually.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Individualized Quality Control Plans (IQCP), Quality Control (QC) Logs, and Patient Test Report, the laboratory director failed to ensure QC was performed prior to patient testing for 41 of 77 Abbott i-STAT CHEM8+ (CHEM8) and 4 of 6 i-STAT Kaolin Activated Clotting Time (ACT) tests performed in 2025. Findings include: 1. Review of the IQCPs for CHEM8 and ACT indicated QC must be performed for each assay: a. Each new lot b. Each new shipment c. Every 30 days after the lot/shipment is in use d. After system maintenance and Software Upgrades 2. Review of the CHEM8 and ACT QC Logs revealed QC was performed the following Days: a. CHEM8: 01/28/2025 05/07/2025 08/11/2025 08/27/2025 b. ACT: 01/28/2025 05/07/2025 08/26/2025 3. Review of the Patient Report revealed patient results were reported without QC the following dates: a. CHEM8: MM/DD/YYYY (number patient results reported) 01/07/2025 (1), 01/08/2025 (2), 01/09/2025 (4), 01/14/2025 (5), 01/22/2025 (3) 02/28/2025 (1) 03/05/2025 (1), 03/11/2025 (2), 03/12/2025 (1), 03/25/2025 (3), 03/26/2025 (1) 04/15/2025 (2), 04/19/2025 (1), 04/22/2025 (1), 04/30/2025 (1) 06/10/2025 (1), 06/17/2025 (1) 07/15/2025 (2), 07/30/2025 (1) 10/03/2025 (1), 10/21/2025 (1), 10/29/2025(1) 11/18/2025 (1), 11/26/2025 (1) 12/09/2025 (1), 12/16/2025 (1) b. ACT: MM/DD/YYYY (number patient results reported) 03/26/2025 (2) 10/31/2025 (1) 12/17/2025 (1) 4. The laboratory reported 77 CHEM8 and 6 ACT tests in 2025.