| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D1022148 | 07/01/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Advanced Womens Center | 13035 Nacogdoches Road, San Antonio, 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 |
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| **D0000** | The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>(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 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:<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, quality control (QC) records, patient final reports and confirmed in interview, the laboratory failed to document quality control performance every 31 days prior to patient testing for 255 out of 292 patients tested in 2025. Findings included: 1. Review of laboratory policy, "BD Affirm: IQCP Quality Control Plan" (Approved by the Laboratory Director on 07/20/2016) revealed the following: " ...Frequency: a. Quality control cannot be performed less frequently than what is required by the BD Affirm manufacturer. b. Based upon IQCP risk assessment, evaluation and mitigation details, it has been determined that the specimen based Quality Control samples will be performed at a minimum of every 31 days." 2. Review of laboratory quality control records in 2025, revealed the following dates positive QC was documented: a. 01/09/2025 b. 04/01/2025 c. 07/18/2025 d. 10 /13/2025 (Note: Negative QC was not documented. Refer to D5481 I.) The laboratory was asked to provide QC performance for the eight of twelve events not documented |

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| | above. No documentation was provided. 3. Review of patient reports in 2026 revealed the following patients tested with no quality control documented within the 31-day timeframe: a. 03/02/2025-03/31/2025 Patients tested: 60 b. 05/02/2025-07/17/2025 Patients tested: 82 c. 08/11/2025-10/12/2025 Patients tested: 75 d. 11/13/2025-12/31 /2025 Patients tested: 38 4. In an interview on 07/01/2026 at 10:35 AM in the laboratory conference room, the Technical Consultant (TC-1) confirmed the laboratory failed to document quality control performance every 31 days prior to patient testing for the laboratory failed to document quality control performance every 31 days prior to patient testing for 255 out of 292 patients tested in 2025. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of laboratory policy, quality control (QC) records, patient final reports, and confirmed in interview, the laboratory failed to document external negative control material at least once per patient testing day for the Vaginal Microbial Identification Test on the BD Affirm analyzer for 4 of 4 testing days in 2025. Findings Included: 1. Review of laboratory policy titled, "BD Affirm: IQCP Quality Control Plan" (Approved by the Laboratory Director on 07/20/2016) revealed the following: "Quality Control Documentation- Documentation of Quality Control, Maintenance, and Environmental logs must be made "real time" as part of daily responsibilities." 2. Review of laboratory BD Affirm quality control records revealed the following patient testing days external negative quality control was not documented in 2025: a. 01/09/2025 b. 04/01/2025 c. 07/18/2025 d. 10/13/2025 3. Review of laboratory final patient reports revealed the laboratory tested 292 patient specimens on the BD Affirm analyzer in 2025. 4. In an interview with the Technical Consultant (TS-1) on 07/01/2026 at 11:16 AM, TS-1 confirmed the above findings. II. Based on review of laboratory policy, quality control (QC) records, patient final reports, and confirmed in interview, the laboratory failed to document external positive control material at least once per patient testing day for the GeneXpert Dx Cepheid analyzer for 6 of 6 testing days in March 2026. Findings Included: 1. Review of laboratory policy titled, "GeneXpert Dx: IQCP Quality Control Plan" (Approved by the Laboratory Director on 07/20/2016) revealed the following: "Quality Control Documentation- Documentation of Quality Control, Maintenance, and Environmental logs must be made "real time" as part of daily responsibilities." 2. Review of laboratory GeneXpert quality control records revealed the following patient testing days external positve quality control was not documented in 2025: a. 03/12/2026 b. 03 /13/2026 c. 03/14/2026 d. 03/15/2026 e. 03/16/2026 f. 03/17/2026 3. Review of laboratory final patient reports revealed the laboratory tested 73 patients on the above testing days with no positive control documented in March 2025. 4. In an interview on 07/01/2026 at 10:30 AM in the laboratory conference room, the Technical Consultant (TC-1) confirmed the laboratory failed to document external positive control material at least once per patient testing day for the GeneXpert Dx Cepheid analyzer for 6 of 6 testing days in March 2026. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c) |

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| | (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory documentation, patient final reports and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems for 12 of 12 months in 2025 (January-December), as evidenced by: 1. The laboratory failed to document external negative control material at least once per patient testing day for the Vaginal Microbial Identification Test on the BD Affirm analyzer for 4 of 4 testing days in 2025. Refer to D5481 I. 2. The laboratory failed to document external positive control material at least once per patient testing day for the GeneXpert Dx Cepheid analyzer for 6 of 6 testing days in March 2026. Refer to D5481 II. 3. The laboratory failed to document quality control performance every 31 days prior to patient testing for 255 out of 292 patients tested in 2025. Refer to D5445. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Centers for Medicare and Medicaid (CMS)-209 form, review of the laboratory's competency documentation, and confirmed in interview, the laboratory failed to ensure two semi-annual competency assessments were documented on all instruments within the first year of training for one of one testing person performing moderate complexity testing from June 2025-June 2026. Findings included: 1. Review of the CMS-209 form determined testing person-1 (TP-1) was performing moderate complexity testing on the GeneXpert and BD Affirm analyzers, starting in June 2025. 2. Review of laboratory testing person-1 (TP-1) competency assessments in 2025 and 2026, revealed the following: a. Instrument/Procedure name: GeneXpert Date performed: 12/01/2025 b. Instrument/Procedure name: BD Affirm Date performed: 12/01/2025 The laboratory was asked to provide a second competency assessment in the first year of patient testing for TP-1 on the above instruments. No documentation was provided. 3. In an interview on 07/01/2026 at 10: 35 AM in the laboratory conference room, the Technical Consultant (TC-1) confirmed the laboratory failed to ensure two semi-annual competency assessments were documented on all instruments within the first year of training for one of one testing person performing moderate complexity testing from June 2025-June 2026. |