

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1022148	<b>(X3) Date Survey Completed</b>  04/21/2022
<b>Name of Provider or Supplier</b>  Advanced Womens Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plans (IQCP) for the Cepheid Gene Xpert and the BD Affirm VPIII, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to follow its IQCPs for the frequency of control testing. The findings include: 1. A review of the laboratory's Individualized Quality Control Plan for the Cepheid Gene Xpert system (approved 6/27/2018) revealed the laboratory modified the frequency of required quality control testing to each new lot, new shipment or at least every 30 days. 2. A</p>

review of the laboratory Individualized Quality Control Plan for the BD Affirm VPIII assay revealed the laboratory modified the frequency of the required quality control testing to at least every 31 days. 3. A review of the laboratory's Cepheid Gene Xpert quality control records from January 2021 to December 2021 identified the following times quality control was tested more than 30 days since the previous control runs: a) April 13, 2021 May 14, 2021 elapsed time: 31 days b) May 14, 2021 June 15, 2021 elapsed time: 32 days c) July 13, 2021 September 21, 2021 elapsed time: 69 days d) October 14, 2021 November 15, 2021 elapsed time: 32 days 4. Further review of the laboratory's Cepheid Gene Xpert quality control records from March 2021 to July 2021 identified the following new lots were placed into use without quality control being performed prior: a) Lot: 10002702777 In use: 07/12/2021 Quality control: 07/13/2021 b) Lot: 1000257663 In use: 06/03/2021 Quality control: 06/15/2021 c) Lot: 1000253783 In use: 04/28/2021 Quality control: 05/14/2021 d) Lot: 1000245954 In use: 03/16/2021 Quality control: 04/13/2021 5. A review of the laboratory's BD Affirm VPIII quality control testing from January 2021 to December 2021 identified the following times quality control testing exceeded 31 days as required by the laboratory's IQCP: a) March 1, 2021 April 8, 2021 elapsed time: 38 days b) April 8, 2021 May 21, 2021 elapsed time: 43 days c) September 1, 2021 October 29, 2021 elapsed time: 58 days 6. The laboratory was asked to provide documentation of performing quality control testing as required by its IQCPs. No documentation was provided. 7. An interview with the technical consultant on 04/21/2022 at 1100 hours in her office - after her review of the records- confirmed the findings.