

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1022148	(X3) Date Survey Completed 05/20/2024
Name of Provider or Supplier Advanced Womens Center	Street Address, City, State 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, and staff interview, the laboratory failed to have documentation of performing verification studies on 1 of 1 Cepheid Xpert CT/GC analyzers. The findings included: 1. A review of the laboratory's instrumentation determined the laboratory placed a new Cepheid Xpert CT /GC analyzer (serial number 10019198) in use in March 2023. 2. The laboratory failed to have documentation of performing verification studies (accuracy, precision) on the new analyzer. 3. The laboratory reported performing 4600 tests annually. 4. The technical consultant confirmed the findings in an interview conducted on 05/20/2024 at 1000 hours in the break room. Key CT - chlamydia GC - gonorrhea</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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</p>

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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's instrumentation, review of the laboratory's Individualized Quality Control Plan (IQCP) for the Cepheid Xpert, and staff interview, the laboratory failed to have documentation of developing an IQCP for 1 of 1 Cepheid Xpert CT/NG analyzers. The findings included: 1. A review of the laboratory's instrumentation determined the laboratory placed a new Cepheid Xpert CT /GC analyzer (serial number 10019198) in use in March 2023. 2. The laboratory performed quality control testing with each new shipment and lot of test cartridges. 3. The laboratory failed to have documentation of developing an IQCP which included the new analyzer. 4. The laboratory reported performing 4600 tests annually. 5. On 05 /20/2024 at 1030 hours in the break room, the technical consultant stated this wasn't required according to an accrediting agency and the laboratory did not need to develop an IQCP which included the new analyzer. Key CT - chlamydia NG - gonorrhea