Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1022148	10/19/2020
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, 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 recertification 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.
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 CMS 209 form, review of the laboratory's policies, and staff interview, it was revealed the facility failed to have documentation of establishing written policies to assess the competency of the technical consultant. The findings were: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 1 Technical Consultant. 2. A review of the laboratory's policies revealed the facility did not have a written policy to assess the competency of the Technical Consultant. 3. The laboratory was asked to provide

	documentation of a policy. No documentation was provided. 4. An interview with the Technical Consultant on 10/19/2020 at 1000 hours in her office confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing complete verification studies. The findings were: 1. A review of the laboratory's records revealed the facility place a new BD AFFIRM VPIII instrument (serial number A5688014) into service in August 2018. 2. A review of the verification studies revealed the facility failed to have documentation of performing precision studies on the qualitative assay. 3. The laboratory was asked to provide documentation of perform precision studies. No documentation was performed. 4. An interview with the Technical Consultant on 10/19/2020 at 1130 hours in her office revealed the laboratory performed accuracy studies, but did not perform precision studies. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/14/2018
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Gene Xpert system, review of the laboratory's maintenance records from 2019 and 2020, and staff interview, it was revealed the laboratory failed to have documentation of performing required maintenance. The findings were: 1. A review of the manufacturer's instructions for the Gene Xpert system (P/N 301-0045, Rev. H) revealed the following manufacturer-required maintenance: - monthly maintenance archive tests purge tests replace fan filters - quarterly maintenance clean plunger rod and cartridge bays clean instrument surfaces 2. A review of the laboratory's maintenance records from 2019 and 2020 revealed the laboratory failed to have documentation of performing the following maintenance: a) monthly January 2020 February 2020 July 2020 September 2020 b) quarterly 1 of 4 missing in 2019 2 of 3 missing in 2020 3. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 4. An interview with the Technical Consultant on 10/19/2020 at 1130 hours in her office confirmed the findings.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, review of the laboratory's quality control records, and staff interview, it was revealed the failed to have documentation of establishing an IQCP (Individualized Quality Control Plan) for its BD AFFIRM VPIII instrument (serial number A568014). The findings were: 1. A review of the laboratory's records revealed the facility added a second BD AFFIRM VPIII instrument in August 2018 (serial number A568014). 2. A review of the laboratory's IQCP currently in place revealed the laboratory only utilized the initial BD AFFIRM instrument (serial number 402004) as part of the study. 3. The laboratory was asked to provide documentation of establishing an IQCP which included serial number A568014). No documentation was required. 4. An interview with the Technical Consultant on 10/19/2020 at 1130 hours revealed she was unaware an IQCP had to be developed per instrument. This confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) for the BD Affirm VPIII instrument, review of the laboratory's quality control records from 2019 and 2020, and staff interview, it was revealed the facility failed to have documentation of following its IQCP. The findings were: 1. A review of the laboratory's IQCP for the modification of the frequency of quality control testing (approved by the laboratory director on 06/27/2018) revealed the laboratory was to perform quality control testing with each new lot, each shipment, and at least monthly. The external controls tested were to be positive and negative control for Gonorrhea and Chlamydia. 2. A review of the laboratory's quality control records from 2019 and 2020 revealed the laboratory failed to have documentation of performing quality control testing at least monthly for the following months: - February 2019 - May 2019 (negative control not tested) - November 2019 - March 2020 - August 2020 - September 2020 (GC Positive/ CT negative not tested) 3. The laboratory was asked to

	provide documentation of performing the require quality control testing. No documentation was provided. 4. An interview with the Technical Consultant on 10/19 /2020 at 1000 in her office confirmed the findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing comparison studies between its BD AFFIRM VPIII instruments in 2019. The findings were: 1. A review of the laboratory's records revealed the facility added a second BD AFFIRM VPIII instrument in August 2018. 2. Further review of the laboratory's records revealed comparisons between the two instruments were not performed in 2019. 3. The laboratory was asked to provide documentation of performing the comparisons. No documentation was provided. 4. An interview with the Technical Consultant on 10/19 /2020 at 1130 hours in her office revealed she was not aware comparison studies were required to be performed twice annually. This confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete. The findings were: 1. The verification studies were incomplete for the BD AFFIRM VPIII (refer to D5421). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/14/2018
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality control plan was followed. The findings were: 1. The laboratory director failed to ensure an Individualized Quality Control Plan was established for the BD AFFIRM VPIII (refer to D5445). 2. The laboratory director failed to ensure the laboratory's Individualized Quality Control Plan was followed (refer to D5449). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/14/2018
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, and staff interview, it was revealed the laboratory director failed to ensure a quality assessment policy was written to monitor, assess and correct problems. The findings were: 1. A review of the laboratory's policies revealed the facility did not have a written policy quality assurance policy. 3. The laboratory was asked to provide documentation of a policy. No documentation was provided. 4. An interview with the Technical Consultant on 10/19/2020 at 1000 hours in her office confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/14/2018
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director fail to specify in writing the responsibilities of the laboratory director, clinical consultant, and technical consultant. The findings were: 1. A review of the laboratory's records revealed the laboratory director failed to have written

	responsibilities for the laboratory director, clinical consultant, and technical consultant. 2. The laboratory was asked to provide documentation of the responsibilities of each. No documentation was provided. 3. An interview with the Technical Consultant on 10/19/2020 at 1000 hours in the office confirmed the findings.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the Technical Consultant failed to ensure verification studies were complete. The findings were: 1. The verification studies were incomplete for the BD AFFIRM VPIII (refer to D5421). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/14/2018
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the Technical Consultant failed to perform semi-annual competency assessments on 1 of 1 testing personnel requiring them. The findings were: 1. A review of the laboratory's personnel records revealed testing personnel number 3 (as listed on Form CMS 209) was hired by the laboratory on 04/19/2018. Thus, two competency assessments were required to be performed by 04/19/2019. 2. Further review of the personnel records revealed the laboratory had documentation of a competency assessment being performed on 05/28/2019. 3. The laboratory was asked to provide documentation of the required competency assessments being performed prior to 04/19/2019. No documentation was provided. 4. An interview with the Technical Consultant on 10/19/2020 at 1000 hours - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 05/14/2018