Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1022148	**(X3) Date Survey Completed** 05/24/2018
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**
D0000	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES resulting in a finding of IMMEDIATE JEOPARDY: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant D6063 - 42 C.F.R. 493.1421 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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. NOTE: THE LABORATORY WAS ASKED TO CEASE TESTING FOR GONORRHEA AND CHLAMYDIA PERFORMED ON THE GENEXPERT. THE LABORATORY COMPLIED (SEE THE LETTER DATED 05/24/2018)
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2016, 2017, and 2018, and staff interview, it was revealed the

	laboratory failed to have documentation of the laboratory director signing 1 of 6 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 (events 2 and 3), 2017 (events 1, 2, and 3) and 2018 (event 1) revealed the laboratory failed to have documentation of the laboratory director signing 1 of 6 attestation statements. The event missing the laboratory director's signature was: 2016 event 2 2. The laboratory was asked to provide documentation of the laboratory director signing the attestation statement. No documentation was provided. 3. An interview with the consultant on 05 /24/2018 at 1000 hours in the break room - after her review of the records- confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2016, 2017, and 2018 and staff interview, it was revealed the laboratory failed to have documentation of the review of 2 of 6 proficiency testing results. The finding were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing results from 2016 (events 2 and 3), 2017 (events 1, 2, and 3) and 2018 (event 1) revealed the laboratory failed to have documentation of the review of results of 2 of 6 events. The events without documentation of review were: 2017 event 1 2017 event 3 2. The laboratory was asked to provide documentation of the results being reviewed. No documentation was provided. 3. An interview with the consultant on 05/24/2018 at 1010 hours in the break room - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 09/04/2014 AND 06/03/2016.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for gonorrhea and chlamydia in 2017. The findings were: 1. A review of the laboratory's test menu revealed the laboratory started performing gonorrhea and chlamydia testing utilizing the GeneXpert analyzer in July 2017. 2. The laboratory was asked to provide documentation of performing twice annual accuracy assessments in 2017. No documentation was provided. 3. An interview with the consultant on 05/24/2018 at 1020 hours in the break room revealed the laboratory did not perform twice annual accuracy assessment for gonorrhea and chlamydia in 2017. This confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	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. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory's failed to provide overall quality in analytic systems. The findings were: 1. The laboratory failed to ensure temperatures were documented for reagents kept in the storage room (refer to D5413). Note: This is a repeat deficiency from the survey conducted 06/03/2016 2. The laboratory failed to ensure verification studies were complete (refer to D5421). 3. The laboratory failed to ensure quality control testing was performed each day of patient testing (refer to D5449). 4. The laboratory failed to ensure is quality assessment plan could identify and correct issues in analytic systems (refer to D5791). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 06/03/2016
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the GeneXpert CT/NG assay, surveyor observation, and staff interview, it was revealed the laboratory failed to have documentation of monitoring the temperature of the storage room where the assay cartridges were stored. The findings were: 1. A review of the manufacturer's instructions for the GeneXpert CT/NG assay (301-0234, Rev. G March 2018) under the section titled "Storage and Handling" revealed: "Store the Xpert CT/NG Assay cartridges and reagents at 2C - 28C." 2. Surveyor observation of reagents in a storeroom on 05/24/2018 at 1130 hours revealed 3 boxes of GeneXpert CT/NG each containing 10 assay cartridges. 3. The laboratory was asked to provide documentation of monitoring the temperature of the storage room. No documentation was provided. 4. An interview with the consultant on 05/24/2018 at 1130 hours revealed she was unaware the cartridges were kept in the storage room and that the laboratory did not monitor the temperature of the storage room. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 06/03/2016
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 verification studies performed for Gonorrhea and Chlamydia testing performed on the GeneXpert analyzer, and staff interview, it was revealed the studies were incomplete. The findings were: 1. Based on review of the laboratory's verification studies performed on the qualitative assays of Gonorrhea and Chlamydia performed on the GeneXpert analyzer done in June 2017 revealed the following: a) Accuracy 1 of 18 study samples were positive for Chlamydia 0 of 18 study samples were positive for Gonorrhea b) Precision No precision studies were performed. 2. The laboratory was asked to provide documentation of including positive samples as part of the accuracy and of performing precision studies. No documentation was provided. 3. The laboratory performed 927 Gonorrhea and Chlamydia tests from June 2017 to May 2018 (as of the day of the survey). See patient alias list. 4. An interview with the consultant on 05/24/2018 at 1200 hours in the break room - after her review of the records- 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 procedures, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing for Gonorrhea and Chlamydia testing performed on the GeneXpert analyzer. The findings were: 1. A review of the laboratory's procedure titled "Xpert CT/NG Assay" under the section titled "External Controls" revealed: "External Controls" revealed: "External controls described n Section 7.2, Materials Available but Not Provided are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable. 2. CLIA requires external control be tested each day of patient testing unless the laboratory had developed and Individualized Quality Control Plan. 3. A review of the laboratory's quality control records from June 2017 to April 2018 revealed the laboratory performed quality control testing with each new lot/shipment of reagent. The laboratory performed quality control testing the following days: 06/02/2017 06/16/2017 07/28/2017 08/18/2017 09/14/2017 10/18 /2017 11/15/2017 12/07/2017 01/11/2018 01/24/2018 02/14/2018 03/05/2018 04/20 /2018 4. The laboratory was asked to provide documentation of performing quality control testing each day of patient testing. No documentation was provided. 5. The laboratory was asked to provide documentation of developing an Individualized

	Quality Control Plan to modify the frequency of quality control testing. No documentation was provided. 6. The laboratory performed 927 Gonorrhea and Chlamydia tests from June 2017 to May 2018. 7. An interview with the consultant on 05/24/2018 at 1230 hours revealed the laboratory did not perform quality control testing each day of patient testing, nor did it develop an Individual Quality Control Plan to modify the frequency of quality control testing. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 09/04/2014
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. (c) The laboratory must document all analytic systems assessment 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's quality assessment plan failed to identify and correct issues in analytic systems. The findings were: 1. The laboratory's quality assessment plan failed to identify and correct that temperatures were not documented for reagents kept in the storage room (refer to D5413). Note: This is a repeat deficiency from the survey conducted 06/03/2016 2. The laboratory's quality assessment plan failed to identify and correct that verification studies were complete (refer to D5421). 3. The laboratory's quality assessment plan failed to identify and correct that quality control testing was not performed each day of patient testing (refer to D5449).
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION 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 provide overall management and direction for the laboratory. The findings were: 1. The laboratory director failed to ensure reagents were stored separately from items for human consumption (refer to D6010). 2. The laboratory director failed to ensure verification studies were complete (refer to D6013). 3. The laboratory director failed to ensure proficiency testing results were reviewed (refer to D6018). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 09/04/2014 AND 06/03/2016. 4. The laboratory director failed to ensure quality control was tested each day of patient testing (refer to D6020). 5. The laboratory director failed to ensure the laboratory's quality assessment plan identified and corrected issues in analytic systems (refer to D6021). 6. The laboratory director failed to ensure testing personnel had documentation of education and training to perform moderate complexity testing (refer to D6029). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 09/04/2014

D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and staff interview, it was revealed the laboratory director failed to ensure reagents were stored separately from items for human consumption. The findings were: 1. Surveyor observation of items stored in the refrigerator in the break room on 05/24/2018 at 1300 hours revealed: a) 13 bottles of Easydex 100 An oral glucose tolerance beverage - 4 bottles on the top shelf - 9 bottles on the bottom shelf b) 2 BD Affirm VPIII Microbial Identification Test kits Lot: 8024792 exp. 2018-12-13 - both kits stored on the middle shelf 2. A review of the manufacturer's instructions for the BD Affirm VPIII Microbial Identification Test kits (670160JAA(02) 2015-04) revealed the kits were determined to: - contain highly flammable liquid and vapor - be harmful if swallowed - cause skin irritation - cause serious eye irritation - cause drowsiness or dizziness 3. An interview with consultant on 05/24/2018 at 1305 hours by the front desk revealed she was unaware reagent kits were being stored with items for human consumption. She stated the reagent kits should not be stored there. 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 (refer to D5421).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were reviewed (refer to D5211). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 09/04/2014 AND 06/03/2016.
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 quality control was tested each day of patient testing (refer to D5449). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 09/04/2014
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 records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment plan could identify and correct issues in analytic systems (refer to D5791).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the

	type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to ensure 2 of 7 personnel had the appropriate education and that 3 of 7 personnel had documentation of training to perform moderate complexity testing (refer to D6065 and D6066). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 09/04/2014
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION 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 provide technical oversight for the laboratory. The findings were: 1. The technical consultant failed to ensure verification studies were complete (refer to D6040). 2. The technical consultant failed to ensure quality control was tested each day of patient testing (refer to D6042). 3. The technical consultant failed to perform competency assessments twice within the first year of employment (refer to D6053).
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 (refer to D5421).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of 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 technical consultant failed to ensure quality control was tested each day of patient testing (refer to D5449).
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 submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to have documentation of performing competency assessments twice within the first year of employment for 1 of 1 testing personnel who required it. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/23/2018) revealed the laboratory identified 7 testing personnel. 2. A review of the laboratory's personnel records revealed testing personnel #6 (as listed on Form CMS 209) was employed by the laboratory from May 2016 to September 2017. Thus, two competency assessments were required during the first year. 3. The laboratory was asked to provide documentation of the technical consultant performing competency assessments twice within the first year of employment for testing personnel #6. No documentation was provided. 4. An interview with the consultant on 05/24/2018 at 1000 hours in the break room revealed the laboratory could not provide documentation of the competency assessments being performed. This confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209 and staff interview, it was revealed the laboratory failed to ensure 2 of 7 testing personnel had documentation of education, and 3 of 7 testing personnel had documentation of training to perform moderate complexity testing (refer to D6065 and D6066). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 09/04 /2014
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a

	chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 7 testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/23/2018) revealed the laboratory identified 7 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation education for 2 of 7 testing personnel. They were (as listed on Form CMS 209): Testing personnel #4 Testing personnel #6 3. The laboratory was asked to provide documentation of education for the identified testing personnel. No documentation was provided. 4. An interview with the consultant on 05/24/2018 at 0945 hours in the break room revealed she thought the records were somewhere in the office manager's office, but was unable to locate them. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 09/04/2014
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 3 of 7 testing personnel who performed testing on the BD Affirm. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/23/2018) revealed the laboratory identified 7 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation training for 3 of 7 testing personnel. They were (as listed on Form CMS 209): Testing personnel #4 Testing personnel #5 Testing personnel #6 3. The laboratory was asked to provide documentation of training for the identified testing personnel. No documentation was provided. 4. An interview with the consultant on 05/24/2018 at 0945 hours in the break room revealed she thought the records were somewhere in the office manager's office, but was unable to locate them. This confirmed the findings.