Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 32D2011233	**(X3) Date Survey Completed** 11/19/2025
Name of Provider or Supplier Aztec Urgent Care	**Street Address, City, State** 604 S Rio Grande Ave, Aztec, NM	
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	An onsite Initial Survey conducted on November 18, 2025, at Aztec Urgent Care found the laboratory to not be in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following conditions cited. 42 C.F.R. 493.801 PT Enrollment 42 C.F.R. 493.1403 Moderate Complexity Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's test menu, lack of documentation, and interview with testing personnel 1, the laboratory failed to enroll in an HHS (Health and Human Services) approved proficiency testing program for chlamydia and gonorrhea (CT /NG) testing performed on the Cepheid GeneXpert in 2025.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, review of manufacturer's instructions (MI), lack of documentation, and interview with Testing Personnel (TP) 1, the laboratory failed to monitor temperature in the secondary storage room in 2025. Findings include: 1. During a tour of the laboratory on 11/19/2025 at 1:14 pm, the following test kits were observed in a secondary storage room: Henry Schein OneStep + ER FOB (Fecal Occult Blood) Enhanced Readability Test Kit (FOBtk), Henry Schein OneStep+ hCG Urine Cassette Test (hCG), Henry Schein OneStep+ Strep A Dipstick (Strep A), and Henry Schein OneStep+ Ultra Mono Test Kit (Mono). 2. Review of the MIs for the listed test kits revealed the following temperature storage requirements: a. FOBtk: 15-30C b. hCG: 2-30C c. Strep A: 15-30C d. Mono: 2-30C 3. A lack of documentation identified the laboratory failed to document temperature in the secondary storage room in 2025. 4. An interview on 11/19/2025 at 1:20 with TP1 confirmed the above findings. 5. The laboratory reports performing 1600 waived tests annually.
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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and interview with testing personnel 1, the laboratory failed to establish written quality assessment policies to ensure monitoring, assessment, and correction of problems during testing in 2025. Findings included: 1. Review of the laboratory's policies and procedures revealed the laboratory failed to have policies or guidelines for an ongoing mechanism for monitoring, assessment, or correction of problems during testing. 2. An interview on 11/19/2025 at 1:40 pm with testing personnel 1 confirmed the above findings. 3. The laboratory reported performing 300 moderate complexity tests annually.
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 test menu, the laboratories policies and procedures, Centers for Medicare and Medicaid (CMS) 209 personnel form, personnel training records, lack of documentation, and interview with testing personnel 1, the Laboratory Director failed to provide overall management and direction as evidenced

	by: 1. The Laboratory Director failed to ensure the laboratory was enrolled in an HHS (Health and Human Services) approved proficiency testing program. Refer to D6015 2. The Laboratory Director failed to ensure all staff performing moderate complexity testing had documentation of initial training. Refer to D6029 3. The Laboratory Director failed to ensure policies for competency assessments were established for testing personnel. Refer to D6030
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, lack of documentation, and interview with testing personnel 1, the laboratory director failed to ensure the laboratory was enrolled in an HHS (Health and Human Services) approved proficiency testing (PT) program for chlamydia and gonorrhea (CT/NG) testing performed on the Cepheid GeneXpert in 2025. Findings included: 1. Review of the laboratory's test menu revealed the laboratory began testing for CT/NG on the Cepheid GeneXpert in May of 2025. 2. A lack of PT records identified the laboratory failed to enroll in an HHS approved proficiency testing program for CT/NG testing. 3. An interview on 11/19 /2025 at 12:30 pm with testing personnel 1 confirmed the above findings. 4. The laboratory reported performing 300 CT/NG tests annually.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 Center for Medicare and Medicaid (CMS) 209 personnel form, personnel training records, interview with the testing personnel (TP) 1, and lack of documentation, the laboratory director failed to ensure 10 of 10 testing personnel received documented training prior to performing moderate complexity testing in May of 2025. Findings include: 1. A review of the CMS 209 personnel form indicated 10 testing personnel performing moderate complexity testing. 2. A review of the personnel training and competency records indicated competency assessments were performed for 10 of 10 testing personnel for CT/NG testing in November 2025. 3. An interview on 11/19/2025 at 12:30 pm with TP1, indicated the laboratory started performing moderate complexity testing in May 2025. 4. A lack of initial training records for CT/NG testing identified the laboratory director failed to ensure that 10 of 10 testing personnel had approproate training prior to starting patient testing in May 2025. 5. The laboratory reports performing 300 moderate complexity tests annually.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)

	(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratories policies and procedures, and interview with Testing Personnel (TP) 1, the Laboratory Director failed to ensure a competency assessment policy was established for personnel performing moderate complexity testing 2025. Findings include: 1. A review of the laboratories policies and procedures indicated the laboratory failed to have a policy for assessing competency of moderate complexity testing personnel. 2. An interview on 11/19/2025 at 12:30 pm with TP1 indicated there is no competency assessment policy for moderate complexity testing. This confirms the above findings. 3. The laboratory reports performing 300 moderate complexity tests annually.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the Center for Medicare and Medicaid (CMS) 209 personnel form, personnel training records, education records, and interview with testing personnel 1, the technical consultant (TC) failed to assess personnel competency for 10 of 10 testing personnel (TP) performing moderate complexity testing in 2025. Findings include : 1. A review of the CMS 209 personnel form listed 10 testing personnel performing moderate complexity testing and one technical consultant. 2. A review of the personnel competency records revealed competency assessments were performed by TP1 for 1 of 10 testing personnel, and TP10 for 9 of 10 personnel. 3. A review of education records revealed TP1 and TP10 did not qualify as technical consultants. 4. An interview on 11/19/2025 at 12:30 pm with TP1 indicated the TC did not participate in competency assessments of testing personnel in 2025. This confirms the above findings. 5. The laboratory reports 300 moderate complexity tests annually.