Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1006512	06/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Atlantis Urgent Care	2254 Hwy A1a, Indian Harbour Beach, FL	

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 announced CLIA recertification survey was conducted at Atlantis Urgent Care from June 11, 2025 to June 30, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 493.801 - Enrollment and Testing of Samples D5200 493.1230 - General Laboratory Systems D6000 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 procedure manual and American Proficiency Institute (API) proficiency testing records, and interview, the Laboratory Director and Testing Personnel failed to sign the attestation form for proficiency testing (PT) for five (2025 1st, 2024 1st, 2nd, 3rd, & 2023 3rd events) of seven PT events (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd events) for the specialty of hematology. (See D2009)
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 procedure manual and American Proficiency Institute (API) proficiency testing (PT) records, and interview, the Laboratory Director and Testing Personnel failed to sign the attestation form for PT for five (2025 1st, 2024 1st, 2nd, 3rd, & 2023 3rd events) of seven PT events (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd events) for the specialty of hematology. This is a repeat deficiency from 02 /06/2023 and 03/05/2021 recertification surveys. Findings: 1. Review of the procedure titled, Proficiency Testing read, "The Laboratory Director and all staff performing the testing should sign in the attestation spaces provided on the date sheet." 2. Review of the API Attestation Statement noted, "Signatures Required - For all PT results, an attestation statement must be signed by testing personnel and laboratory director and retained for a minimum of 2 years." 3. Review of the API PT records showed attestation statements for 2025 1st, 2024 1st, 2nd, and 3rd, events were not signed by the Laboratory Director or Testing Personnel. The attestation for 2023 3rd event was missing. 4. During an interview on 06/10/2023 at 10:27 AM, Technical Consultant A acknowledged attestations were not signed by the Laboratory Director or Testing Personnel.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the procedure manual and American Proficiency Institute (API) proficiency testing (PT) records, and interview, the Laboratory Director and the Technical Consultants failed to document review and evaluation of proficiency testing (PT) results for three (2024 1st, 2023 1st, 3rd) of seven (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd events) for the specialty of hematology. See D5211.
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 procedure manual and American Proficiency Institute (API) proficiency testing (PT) records, and interview, the Laboratory Director and Technical Consultants failed to document the review and evaluation of proficiency testing (PT) results for three (2024 1st, 2023 1st, 3rd) of seven (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd events) for the specialty of hematology. This is a repeat deficiency from the 02/06/2023 recertification survey. Findings: 1. Review of the procedure

	titled, Proficiency Testing, section Assessment of the Proficiency Testing Report read, "Proficiency testing results will be reviewed within 30 days of receipts of results. The procedure also noted, "Initially, both the testing personnel and the Laboratory Supervisor should review the PT scores, and if all are satisfactory, the forms are signed and dated. 2. Review of the Job Description for the Laboratory Directed included, "Ensuring that the laboratory's proficiency testing performance is evaluated and necessary corrective action identified by the appropriate personnel." 3. Review of the Job Description for the Technical Consultant included, "Reviewing worksheets, logs, quality control results, proficiency testing results, and maintenance records." 4. Review of the API PT showed the Proficiency Testing Performance Evaluation forms for the 2024 1st, 2023 1st, and 2024 3rd events were not signed by the Laboratory Director, Technical Consultant A, or Technical Consultant B. 5. During an interview on 06/10/2025 at 10:35 AM, Technical Consultant A acknowledged the performance reviews were not signed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview, review of the procedure manual, quality controls records, and patient records, the laboratory reported four patients' (#1 - #4) hematology test results when three of three levels of controls (Level 1, 2 , and 3) were out of the expected range on 09/08/2024. Findings: 1. Review of the procedure titled, Quality Control Assessment revealed instructions that included what to do if the controls were out of range. 2. Review of the XN L Check Hematology Controls for Sysmex XN-L Analyzers for lot #4180 for Level 1, 2 , and 3 (L1, L2, L3) listed the expected ranges for Lot #4180. 3. Review of the patients's test results showed the laboratory reported the following test on each patient: White Blood Cells (WBC), Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin, Concentration (MCHC), Red Cell Distribution Width-Standard Deviation (RDW-SD), Red Cell Distribution Width - Coefficient of Variation (RDW-CV), Platelets (PLT), Neutrophils percent (Neut %), Lymphocyte percent (Lymph %, Monocyte percent (Mono %), Eosinophil percent (Eos %), Basophil percent (Baso %), Immature Granulocytes percentage (IG %), Neutrophils number (Neut #), Lymphocyte number (Lymph #), Monocyte number (Mono #), Eosinophil number (Eos #), Basophil number (Baso #, and Immature Granulocytes number (IG #). Review of patient test reports revealed the above mentioned test results were reported for patients #1 - #4. 4. Review of the laboratory's XN L Check Raw Data Report Hematology Controls for lot #4180 showed the laboratory had control values outside the expected range. Review of the data for L1 showed the following analytes values were out of the expected range: WBC, RBC, HGB, HCT, RDW-CV, Neut %, Lymph %, Mono %, Eos %, Baso %, IG %, Neut #, Lymph #, Mono #, Eos #, Baso #, and IG #. Review of the data for L2 showed the following analytes value were out of the expected range: WBC, RBC, HGB, HCT, RDW-CV, Neut %, Neut #, Lymph #, Mono #, Eos #, Baso #, and IG #. Review of the data for L3 showed the following analytes value were out of the expected range: WBC, RBC, HGB, HCT, RDW-CV, PLT, Lymph %, Eos %, Neut #, Eos #, Baso #, and IG #. Review of the Raw Data Report showed each levels

	of control were run only once. 5. During an interview on 06/10/2025 at 12:10 PM, Technical Consultant A acknowledged the controls were out of range and four patients' hematology results were reported.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, interview, review of the procedure manual, package inserts, and refrigerator temperature log, the laboratory failed to document corrective action for 53 temperatures recorded that were out of acceptable range for hematology controls from 04/02/2024 to 06/04/2025. Findings: 1. During a tour of the laboratory on 06/10/2025 at 9:50 AM, XN- L Check Levels 1 , 2 and 3 hematology controls were observed in the refrigerator. 2. Review of the procedure titled, General Maintenance in the section Refrigerators/Freezer read, "Record temperatures daily. If the temperature is outside of the acceptable range, note on the daily temperature log. Complete the following corrective action . . . . " There was no corrective action documented on the temperature logs. 3. Review of the package insert of controls showed storage of 2 - 8 degrees Celsius (C). 4. Review of the Temperature and General Maintenance log showed the temperatures for the refrigerator was out of range on the following dates: 04/04/2024 recorded 8.7 degrees C 03/04/2024 recorded 1.5 degrees C 03/05/2024 recorded 1.6 degrees C 03/06/2024 recorded 1.3 degrees C 03/14/2024 recorded 1.9 degrees C 03/19/2024 recorded 1.6 degrees C 03/20/2024 recorded 1.6 degrees C 04/10/2024 recorded 1.3 degrees C 07/14/2024 recorded 23 degrees C 07/15/2024 recorded 23.1 degrees C 07/16/2024 recorded 13.6 degrees C 07/17/2024 recorded 8.9 degrees C 07/18/2024 recorded 0.8 degrees C 07/23/2024 recorded 0.4 degrees C 07/24/2024 recorded 0.8 degrees C 07/25/2024 recorded 1.0 degrees C 07/26/2024 recorded 1.0 degrees C 07/27/2024 recorded 12 degrees C 07/28/2024 recorded 0.8 degrees C 07/29/2024 recorded 0.1 degrees C 07/30/2024 recorded 0.4 degrees C 07/31/2024 recorded 1.1 degrees C 08/01/2024 recorded 0.8 degrees C 08/08/2024 recorded 1.8 degrees C 08/12/2024 recorded 0.6 degrees C 08/15/2024 recorded 1.9 degrees C 08/21/2024 recorded 1.1 degrees C 08/31/2024 recorded 0.0 degrees C 12/01/2024 recorded 0.3 degrees C 12/02/2024 recorded 1.4 degrees C 12/29/2024 recorded 0.0 degrees C 01/02/2025 recorded 1.5 degrees C 01/03/2025 recorded 1.3 degrees C 01/04/2025 recorded 1.8 degrees C 01/10/2025 recorded 1.6 degrees C 01/12/2025 recorded 0.8 degrees C 01/13/2025 recorded 1.7 degrees C 01/18/2025 recorded 1.8 degrees C 01/21/2025 recorded 1.3 degrees C 01/22/2025 recorded 1.7 degrees C 01/24/2025 recorded 1.5 degrees C 02/02/2025 recorded 1.1 degrees C 02/04/2025 recorded 0.8 degrees C 02/06/2025 recorded 1.6 degrees C 02/07/2025 recorded 1.4 degrees C 02/19/2025 recorded 0.3 degrees C 04/09/2025 recorded 1.3 degrees C 04/19/2025 recorded 1.1 degrees C 04/23/2025 recorded 1.1 degrees C 04/24/2025 recorded 1.9 degrees C 04/25/2025 recorded 1.5 degrees C 04

	/29/2025 recorded 1.2 degrees C 06/04/2025 recorded 1.4 degrees C 5. Review of the Temperature and General Maintenance log showed there was no corrective action documented for the temperatures that were out of range. 6. During an interview on 06 /10/2025 at 10:10 AM, Technical Consultant A acknowledged the temperatures were out of range and no corrective action was documented.
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 interview, review of the procedure manual and American Proficiency Institute (API) proficiency testing (PT) records, the Laboratory Director failed to ensure PT attestation forms were signed by the Laboratory Director and Testing Personnel for five (2025 1st, 2024 1st, 2nd, 3rd, & 2023 3rd events) of seven PT events (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd events) for the specialty of hematology (See D6016), and the Laboratory Director failed to ensure review and evaluation of PT results for three (2024 1st, 2023 1st, 3rd) of seven (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd) events for the specialty of hematology. (See 6018)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on interview and review of procedure manual and American Proficiency Institute (API) proficiency testing (PT) records, the Laboratory Director failed to ensure the PT attestation forms were signed by the Laboratory Director and Testing Personnel for five (2025 1st, 2024 1st, 2nd, 3rd, & 2023 3rd) events of seven PT events (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd) events for the specialty of hematology. Findings: 1. Review of the procedure titled, Proficiency Testing read, "The Laboratory Director and all staff performing the testing should sign in the attestation spaces provided on the date sheet." 2. Review of the API Attestation Statement noted, "Signatures Required - For all PT results, an attestation statement must be signed by testing personnel and laboratory director and retained for a minimum of 2 years." 3. Review of the API PT records showed the attestation statement for 2025 1st, 2024 1st, 2nd, and 3rd, events were not signed by the Laboratory Director or Testing Personnel and the attestation for 2023 3rd event was missing. 4. During an interview 06/10/2023 at 10:27 AM, Technical Consultant A acknowledged the attestations were not signed by the Laboratory Director or the Testing Personnel.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff

	to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on interview, review of the procedure manual and American Proficiency Institute (API) proficiency testing (PT) records, the Laboratory Director failed to ensure review and evaluation of PT results for three (2024 1st, 2023 1st, 3rd) of seven (2025 1st, 2024 1st, 2nd, 3rd, & 2023 1st, 2nd, 3rd) events for the specialty of hematology. Findings: 1. Review of the procedure titled, Proficiency Testing, section Assessment of the Proficiency Testing Report read, "Proficiency testing results will be reviewed within 30 days of receipts of results. The procedure also noted, "Initially, both the testing personnel and the Laboratory Supervisor should review the PT scores, and if all are satisfactory, the forms are signed and dated." 2. Review of the Job Description for the Laboratory Directed included, "Ensuring that the laboratory's proficiency testing performance is evaluated and necessary corrective action identified by the appropriate personnel." 3. Review of the API PT showed the Proficiency Testing Performance Evaluation forms for the 2024 1st, 2023 1st, and 2024 3rd events were not signed by the Laboratory Director, Technical Consultant A, or Technical Consultant B. 3. During an interview 06/10/2025 at 10:35 AM, Technical Consultant A acknowledged the performance reviews were not signed.