

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1006512	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Atlantis Urgent Care	Street Address, City, State 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	A Recertification survey was conducted on March 2, 2021. Atlantis Urgent Care clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director and Testing Personnel failed to have documentation of the signed attestation form for proficiency testing (PT) for 1 (2020 1st event) of 6 (2019 1st, 2nd, 3rd & 2020 1st, 2nd, 3rd events) for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) Attestation Statement noted "Signatures Required - Testing personnel and laboratory director must physically sign an attestation statement for PT results, and retain the signed statement (or a copy) for a minimum of 2 years." Review of the API PT records showed that the signing the attestation statement for the 1st event in 2020 was missing. During an interview on 03/02/2021 at 10:50 AM, Testing Personnel B stated he was unable to locate the attestation forms for the 2020 1st event.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper</p>

use.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to label the quality control vials currently in use with the open date and expiration date. Findings: Examination of the XN-L hematology controls for the Sysmex XN-L analyzer on 03/02/2021 at 10:25 AM showed the quality control vials for level 1, 2 and 3 did not have the open date and the new expiration date for the vials currently being used. Review of the package insert for the controls noted "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2 - 8 degrees C after being re-capped." During an interview on 03/02/2021 at 10:30 AM, Testing Personnel B stated the open date and the new expiration date were not on the control vials.