

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2046627	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Advanced Urgent Care Center	Street Address, City, State 1980 N Roosevelt Blvd, Key West, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209-Laboratory Personnel Report, review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (TP) A, the laboratory failed to have all testing staff rotate through the testing of PT for 1 out of 2 years reviewed (2017-2018). Findings include: -Review of the CMS 209 (signed and dated by the Laboratory Director 1/16/2018 had 6 testing TP listed (A, B, C, D, E, F). -Review of API PT records found that TP F did not performed any PT during 2018. -Interview 01/16/2019 at approximately 3:00 pm, TP A confirmed that TP F did not performed PT during 2018 even though TP F performed patient testing.</p>
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with Testing Person (TP) A the laboratory failed to adequate set up the laboratory and phlebotomy in a separate space in order that one activity does not interfere with the other. Findings include: Observation of the laboratory revealed that: - There is not enough space for the the phlebotomy area, that</p>

it is located inside the laboratory in the back of a narrow hallway. Next to the drawing chair there is a cable station that it is not properly secured which represents a potential hazard for patients and staff. -The sink with the eyewash for the laboratory and drawing station, has a printer placed just in front of it, there is a potential risk for electrical accident. During an interview on 01/16/2019 at 3:30 PM, the TP A confirmed that the location of the drawing station is not adequate.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) records and interview with Testing Person (TP) A, the laboratory failed to have attestation signed by TP B in 2 out of 6 events and for TP B in 1 out of 6 events reviewed for Hematology and Chemistry for 2 years reviewed (2017-2018). Findings include: Review of API PT reports for 2017 and 2018, revealed that : -The laboratory failed to have attestation signed by TP D for 1st event Hematology/Coagulation 2017. - The laboratory failed to have attestation signed by TP B for 2nd Event of Chemistry and Hematology for 2018. During an interview on 01/16/2019 at 2:30 PM, the TP A confirmed that the laboratory failed to have the signed attestation by TP A and D for the events of reference.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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 EasyRA quality control (QC) policy, QC record review and interview with Testing Person #A (TPA) the laboratory failed to have the 2 levels controls within acceptable range for Triglycerides (TRIG), Alanine Aminotransferase (ALT), Albumin (ALB), Aspartate Transaminase (AST), Blood Urea Nitrogen (BUN), Calcium (Ca), Alkaline Phosphatase (ALK), prior to testing patients on 1 testing date 11/15/2018. Findings included: Review of QC policy stated that for EasyRA no patient tested until two control levels are accepted. Review of QC records for EasyRA revealed that on 11/15/18 of the 2 levels controls (A, B), control A was run twice, in the 1st run was in the range, another run performed 9 minutes later the control was out of acceptable range for TRIG, ALT, ALB, AST, BUN, CA, ALK. No records of any further run for control A available. Patients tested on the day of reference. There were no records explaining why the TP ran the controls twice, and why patients tested when the control was out of range. On the day of reference, patient 1 and 2 tested and reported using EasyRA. During an interview, on 01/16/19 at 2:30 PM with the TPA, she confirmed that there were no records of a rerun for the controls out of range for analytes mentioned above, nor documentation of the review.