Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2180356	06/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urgent Care Of The Middle Keys	13365 Overseas Hwy Ste 102, Marathon, 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 conducted on 06/06/2022 to 06/13/2022 found the ADVANCED URGENT CARE OF THE MIDDLE KEYS clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory quality assesment (QA) activities failed to ensure the enrollment in proficiency testing (PT) for two out of three events for Hematology specialty and one out of three events in Chemistry specialty. Findings include: -Review of PT American Proficiency Institute (API) records in 2021 (three events) revealed that the laboratory had no results in first and second events of Hematology and first event of Chemistry. -Review of the 2021 Renewal Order Form received from API revealed that the laboratory received the renewal notification on 09/08/2020. No confirmation order found for this renewal order form. -The laboratory Quality Assurance Plan defined that quarterly the laboratory will review PT performance. Review of "Proficiency Testing Review Documentation" form for November 2020, revealed that the QA failed to monitor the status of enrollment for year 2021. During an interview on 06/06/2022 at 11:45 AM, the Technical Consultant A confirmed that the laboratory QA failed to ensure that the laboratory enrolled in PT for year 2021 for the events of reference.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with Technical Consultant (TC), the laboratory director (LD) failed to ensure that the facility enrolled in a PT program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for two out of three events of Hematology and one out of three events of Chemistry. Findings include: -Review of American proficiency Institute (API) PT records for 2021 revealed: no results for Hematology first and second events and No results for Chemistry first event. -The laboratory was performing the following tests: Cell Identification, Red Blood Cell Count, Hematocrit, Hemoglobin, White Blood Cell Count, and Platelets. The laboratory performed 560 tests from January to August 2021. b) No results for Chemistry first event. The laboratory was performing the following tests: B-Type Natriuretic Peptide, Creatine Kinase MB and Myogloblin. The laboratory performed 88 tests from January to May 2021. During an Interview on 06/06/2022 at 12.30 PM, the TC confirmed that the LD failed to ensure that the facility enrolled in a PT program for Hematology and Chemistry in 2021 for the events of reference.