

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2145763	<b>(X3) Date Survey Completed</b>  05/31/2022
<b>Name of Provider or Supplier</b>  Advanced Urgent Care Of The Upper Keys	<b>Street Address, City, State</b>  100460 Overseas Hwy, Key Largo, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted from 05/23/2022 to 05/31/2022 found the ADVANCED URGENT CARE OF THE UPPER KEYS clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition was cited: -D5400 Analytic Systems.
<b>D2093</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and Technical Consultant (TC) #A interview, the laboratory failed to submit proficiency testing (PT) results for one out of six events reviewed for Routine Chemistry (first event 2021). Findings include: -Review of American Proficiency Institute (API) PT results revealed a score of 0% for B-type Natriuretic Peptide (BNP), D-Dimer, Myoglobin, Creatine Kinase and Troponin, resulting in a overall score of 0% for Routine Chemistry for the first event of 2021. During an interview on 05/23/2022 at 2:30 PM, the TC # A confirmed that the laboratory failed to submit the results to the proficiency testing agency within the timeframe for the event of reference.</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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</p>

overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory did not meet the condition for analytic systems. Findings include: -Failed to store the controls 1 and 2 for Troponin, Myoglobin, D-Dimer and B-type Natriuretic Peptide (BNP) tests of Alere Triage instrument at acceptable temperature range. Refer to D5413. This is a repeated deficiency from the 2020 survey.

**D5413**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 record review and staff interview, the laboratory failed to follow manufacturer's instructions for storage temperature of the controls 1 and 2 for Troponin, Myoglobin, D-Dimer and B-type Natriuretic Peptide (BNP) tests of Alere Triage instrument for 169 days out of 191 days from October 2021 to May 2022. This is a repeated deficiency from the 2020 survey. The findings include: Review of Manufacturer Instructions (MI) for controls 1 and 2 for Creatine Kinase (CK), Troponin, Myoglobin, D-Dimer and B-type Natriuretic Peptide (BNP) tests of Alere Triage instrument revealed that this controls must be stored at -20 C or below. Review of freezer temperature log revealed that the temperature records for the freezer did not reach the -20 C requirement for the following days: 10/13/2021, 10/19/2021, 10/20/2021, 10/21/2021, 10/22/2021, 10/26/2021, 10/27/2021, 10/28/2021, 10/29/2021, 10/30/2021, 11/01/2021, 11/08/2021, 11/09/2021, 11/11/2021, 11/12/2021, 11/13/2021, 11/15/2021, 11/16/2021, 11/17/2021, 11/18/2021, 11/19/2021, 11/20/2021, 11/22/2021, 11/23/2022, 11/24/2021, 11/26/2021, 11/27/2021, 11/29/2021, 11/30/2021, 12/01/2021, 12/02/2021, 12/03/2021, 12/04/2021, 12/06/2021, 12/07/2021, 12/08/2021, 12/09/2021, 12/10/2021, 12/13/2021, 12/14/2021, 12/15/2021, 12/16/2021, 12/18/2021, 12/20/2021, 12/21/2021 12/22/2021, 12/23/2021, 12/24/2021, 12/26/2021, 12/27/2021, 12/28/2021, 12/29/2021, 12/30/2021, 12/31/2021, 01/01/2022, 01/02/2022, 01/03/2022, 01/04/2022, 01/05/2022, 01/06/2022, 01/07/2022, 01/08/2022, 10/10/2022, 01/11/2022, 01/12/2022, 01/13/2022, 01/14/2022, 01/15/2022, 01/17/2022, 01/18/2022, 01/19/2022, 01/20/2022, 01/21/2022, 01/22/2022, 01/24/2022, 01/25/2022, 01/26/2022, 01/27/2022, 01/28/2022, 01/29/2022, 01/31/2022, 02/01/2022, 02/03/2022, 02/04/2022, 02/05/2022, 02/07/2022, 02/09/2022, 02/10/2022, 02/11/2022, 02/12/2022, 02/14/2022, 02/15/2022, 02/16/2022, 02/17/2022, 02/19/2022, 02/21/2022, 02/22/2022, 02/23/2022, 02/24/2022, 02/25/2022, 02/26/2022, 02/28/2022, 03/01/2022, 03/02/2022, 03/04/2022, 03/05/2022, 03/07/2022, 03/08/2022, 03/09/2022, 03/10/2022, 03/11/2022, 02/12/2022, 03/14/2022, 03/15/2022, 0316/2022, 03/17/2022, 03/18/2022, 03/19/2022, 03/21/2022, 03/22/2022, 03/23/2022, 03/24/2022, 03/25/2022, 03/26/2022, 03/28/2022, 03/30/2022, 04/01/2022, 04/02/2022, 04/04/2022, 04

/05/2022, 04/06/2022, 04/07/2022, 04/08/2022, 04/09/2022, 04/11/2022, 04/12/2022, 04/13/2022, 04/14/2022, 04/15/2022, 04/16/2022, 04/18/2022, 04/19/2022, 04/20/2022, 04/21/2022, 04/22/2022, 04/23/2022, 04/25/2022, 04/26/2022, 04/27/2022, 04/28/2022, 04/29/2022, 04/30/2022, 05/02/2022, 05/03/2022, 05/04/2022, 05/05/2022, 05/06/2022, 05/07/2022, 05/09/2022, 05/10/2022, 05/11/2022, 05/12/2022, 05/13/2022, 05/14/2022, 05/17/2022, 05/18/2022, 05/19/2022, 05/20/2022, 05/23/2022 -In this period the laboratory performed the following tests: 105 CK, 105 Myoglobin, 15 BNP, 107 Troponin and 31 D-Dimer. During an interview on 05/23/2022 at 12:00 PM, Technical Consultant # A confirmed that the temperature records for the freezer were out of the acceptable range for the days of reference.