Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2145763	07/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urgent Care Of The Upper Keys	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey conducted on 07/13/2020 found that Advanced Urgent Care of the Upper Keys clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were cited: -D5400 Analytical Systems -D6076 Laboratory Director -D6168 Testing Personnel
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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 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 interview with Technical Consultant B, the laboratory failed to follow manufacturer's instructions for storage temperature of the control 1 and 2 for Troponin, Myoglobin, and D-Dimer test on Alere Triage instrument (See D5413), to perform initial test verification for RightSign COVID-19 IgG/IgM Rapid Test Cassette with lot number SA200401 before started patient testing (See D5421), to perform initial test verification for Biolab Sciences COVID-19 IgG/IgM Rapid Test from Phamatech with lot number 0640 and for COVID-19 IgG/IgM Rapid test Cassette from Aurora Biomed with lot number 20200512 before started patient testing (See 5423) and to use positive and negative controls to confirm the test procedure and verify proper test performance; as per manufacturer instructions (MI); for COVID-19 IgG/IgM serology tests (See D5449).
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 observation, record review and staff interview, the laboratory failed to follow manufacturer's instructions for storage temperature of the control 1 and 2 for Troponin, Myoglobin, and D-Dimer test on Alere Triage instrument for the lot number C3551AN and C3573AN respectively. The findings include: Observation in the laboratory on 7/13/2020 at 10:00 am showed that in the freezer compartment of the refrigerator located in the laboratory revealed that there was 1 box with 2 ampoule of control 1 lot number C3551AN and 1 box of control 2 lot C3573AN with 5 ampoules of Quidel Triage 5 Total Control. Review of Manufacturer Instructions (MI) revealed that this controls must be stored at -20 C or below. Review of freezer temperature log revealed that the temperature range for this freezer did not reach the -20 C. During an interview on 7/13/2020 at 10:00 am, TP # A confirmed that the laboratory failed to store the controls with lot number listed above as per MI.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to perform initial test verification for RightSign COVID-19 IgG/IgM Rapid Test Cassette with lot number SA200401 before started patient testing after receiving the kit on 6/20/2020. The findings include: -Review of Food and Drug Administration (FDA) letter addressed to Hangzhou Biotest Biotech Co; Ltd revealed that the test RightSign COVID-19 IgG/IgM Rapid Test Cassette received an Emergency Use Authorization (EUA) on 6/4/2020. -Review of MI revealed the use of this test is limited to Moderate and High Complexity laboratories. -The laboratory failed to have documentation of the exact date, they started to use the test of reference, they provide an approximate starting date as of 6/25/2020 and failed to perform the validation before started patient testing. -The laboratory tested 64 patients with this test with lot number SA200401. During an interview on 7/13/2020 at 12:00 pm, with Technical Consultant B confirmed that the laboratory failed to document the day they started to use the test of reference and failed to perform initial test validation before starting patient testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and staff interview, the laboratory failed to perform test verification for Biolab Sciences COVID-19 IgG/IgM Rapid Test from Phamatech with lot number 0640 and for COVID-19 IgG/IgM Rapid test Cassette from Aurora Biomed with lot number 20200512 before started patient testing since 5/13/2020. The findings include: -Review of patients testing revealed that the laboratory started testing for COVID-19 serology testing since 5/13/2020. -The laboratory initially started testing with the test from Phamatech on 5/13/2020 and later they switched to the AuroaBiomed test. There is no date documented for this transition. -The laboratory failed to provide documentation of EUA approval for the Phamatech and Aurora Biomed test kits, which the FDA listed on date 5/22/2020 as: "Removed, should not be distributed". -The laboratory used the Aurora Biomed test until 6/24/2020, they tested 214 patients from 5/13/2020 to 6/24/2020. -This is a moderate complexity laboratory and because those tests had not EUA, they are classified as high complexity, and required a full validation before their use. The laboratory had no documentation of test validation for the Phamatech and Aurora Biomed test. During an interview on 7/13/2020 at 1:00 pm, with Technical Consultant B, she confirmed that the laboratory failed to have exact date of switch from Phamatech test to Aurora Biomed test and failed to perform test validation before starting patient testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and staff interview, the laboratory failed to use positive and negative controls to confirm the test procedure and test performance; as per manufacturer instructions (MI); for COVID-19 IgG/IgM serology tests kits used from 5/13/2020 to 7/13/2020. Findings include: -Review of MI for Biolab Sciences COVID-19 IgG/IgM Rapid test (Phamatech), COVID-19 IgG/IgM Rapid test Cassette (Colloidal Gold) (Aurora Biomed) and RightSign COVID-19 IgG /IgM Rapid Test Cassette (Hangzhou) Quality Control for qualitative serology tests

	revealed that: "it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance". -There is no documentation of positive and negative control run before patient testing to confirm the test procedure and verify test performance. -The laboratory tested 264 patients from 5/13/2020 to 7/13/2020. During an interview on 7 /13/2020 at 1:00 pm, with Technical Consultant B confirmed that the laboratory failed to follow MI to test a positive and negative control for the tests of references for the period of 5/13/2020 to 7/13/2020.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to have qualified Laboratory Director (LD) from 5/13/2020 to 6/24/2020 (See D6078). The LD failed to ensure test performance before patients testing for serology COVID-19 IgG/IgM (See D6086). LD failed to ensure the laboratory follow MI for COVID-19 IgG/IgM serology tests of using positive and negative control (See 6093).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be

	qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and staff interview. The laboratory failed to have qualified LD from 5/13/2020 to 6/24/2020. Findings Include: -Cross reference to D5423. -From 5/13/2020 to 6/24/2020 the laboratory performed High Complexity tests from Biolab Sciences COVID-19 IgG/IgM Rapid Test from Phamatech with lot number 0640 and for COVID-19 IgG/IgM Rapid test Cassette from Aurora Biomed with lot number 20200512 because the kits did not have FDA approval. -The laboratory failed to provide documentation that proved that the LD is qualified to be the director for a High Complexity laboratory. During an interview on 07/13/2020 at 5:30 pm with Consultant B confirmed that the laboratory do not have documentation that the LD qualified as high complexity LD.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and staff interview the LD failed to ensure that the laboratory verified tests performance for COVID-19 IgG/IgM serology tests before starting patient testing from 5/13/20 to 7/13/2020. Findings include: -See 5421 -See 5423 During an interview on 07/13/2020 at 5:30 pm with TC B confirmed that LD failed to ensure test verification for the COVID-19 IgG/IgM serology test before the laboratory started patients testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and staff interview the LD failed to ensure the laboratory follow MI for COVID-19 IgG/IgM serology tests relative to using positive and negative controls from 5/13/20 to 7/13/2020. Findings include: -See 5449 During an interview on 07/13/2020 at 5:30 pm with TC B confirmed that LD failed to follow MI of using positive and negative controls for the COVID-19 IgG/IgM serology test verification for the time mentioned above.
D6168	TESTING PERSONNEL CFR(s): 493.1487

	The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory filed to have qualified Testing Personnel for High Complexity tests (See 6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the

	factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have qualified testing personnel to perform High Complexity tests from 5/13/2020 to 6/24/2020. Findings include: -The laboratory performed High Complexity tests from 5/13/2020 to 6/24/2020. See D5423 -Review of form CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 7/13/2020 revealed that the laboratory had 3 testing personnel (TP A, TP B and TP C). -Review of academic information for 3 out of 3 revealed that they do not qualify for High Complexity testing because their highest degree of education is High School. During an interview on 07/13/2020 at 5:00 PM, with TC B confirmed that TP did not qualified for High Complexity testing.