Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2118976	05/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care Of Oconee - Watkinsville	2061 Experiment Station Road, Suite 505, Watkinsville, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 21, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. An immediate jeopardy situation was identified due to the laboratory's inability to demonstrate compliance in the speciality of Chemistry which resulted in Immediate Jeopardy. The following deficiencies were cited:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and a laboratory specialist consultant interview, the laboratory director (LD) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed the LD failed to attest to the routine integration of the Hematology PT samples into the patient workload for the following PT events: 2017 Hematology Events 2 and 3 due to the inability to produce the documentation at the time of survey. 2. An interview with the laboratory specialist consultant on 5/21/18 in a conference room at approximately 4 p. m. confirmed there were no attestation statements for the aforementioned PT events at the time of survey.
D3011	FACILITIES CFR(s): 493.1101(d)

	Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory did not ensure protection from physical and electrical hazards as required. Findings include: 1. Observation during the laboratory tour at approximately 5:00 p.m. on 5/21/18 revealed there was no fire extinguisher in the facility. 2. An interview with the technical consultant at the nurses station at approximately 6:15 p.m. on 5/21/18 confirmed there was not a fire extinguisher in the facility.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on document review, the laboratory failed to provide a laboratory director (LD) - approved policy and procedure manual (SOP), failed to perform quality control (QC) before evaluating chemistry patient samples, and failed to evaluate an unregulated chemistry analyte at least twice annually for accuracy and precision. This condition level contributed to the Immediate Jeopardy.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and a laboratory specialist consultant interview, the laboratory failed to twice annually verify the accuracy of any test it performs that is not included in subpart I for regulated analytes which contributed to the Immediate Jeopardy. Findings include: 1. PT document review revealed the laboratory failed to twice annually verify the unregulated analyte, troponin, for 2017 and 2018 thus far. 2. An interview with the laboratory specialist consultant on 5/21/18 in a conference room at approximately 4 p.m. confirmed the laboratory failed to twice annually verify the accuracy of the unregulated analyte, troponin, for 2017 and 2018 thus far.
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 quality control (QC) document review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems. This condition-level deficiency contributed to the Immediate Jeopardy. Refer to D5421, D5445
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and a laboratory specialist consultant interview, the laboratory failed to follow written procedures for testing as specified in the SOP. Findings include: 1. SOP review revealed the laboratory failed to keep Emerald Cell-DYN Levy-Jennings charts for a minimum of two years as specified in the laboratory SOP. 2. An interview with the laboratory specialist consultant in a conference room on 5-21-18 at approximately 4: 00 p.m. confirmed the laboratory failed to keep the Emerald Cell-DYN Levy-Jennings charts for a minimum of two years.
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 review of analytical verification documents and a laboratory specialist consultant interview, the laboratory failed to demonstrate the accuracy, precision, and reportable range of each chemistry analyte before initiating patient testing which contributed to the Immediate Jeopardy. Findings include: 1. Chemistry verification document review revealed the laboratory failed to demonstrate the accuracy, precision, and reportable range for troponin before initiating patient testing in 2017. 2. An interview with a laboratory specialist consultant on 5/21/18 in a conference room at approximately 3:30 p.m. confirmed the accuracy, precision, and reportable range for troponin was not determined before initiating patient testing in 2017.
D5437	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration document review and a laboratory specialist consultant interview, the laboratory failed to perform calibrations with the frequency specified by the manufacturer. Findings include: 1. Cell-Dyn Emerald calibration document review revealed calibration was performed on the following dates: 9/22/16, 8/1/17, and 4/2/18. This calibration frequency was not consistent with manufacturer's specifications of every 6 months. 2. An interview with the laboratory specialist consultant on 5/21/18 at approximately 4:30 p.m. in a conference room confirmed the Cell-Dyn was not calibrated in 2017 and 2018 with the manufacturer's specified frequency.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and a laboratory specialist consultant interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. Cell-Dyn Emerald QC document review revealed the laboratory failed to produce Levy-Jennings QC reports at the time of survey for January, 2017. 2. An interview with the laboratory specialist consultant on 5/21/18 in a conference room at approximately 4 p.m. confirmed no Levy-Jennings QC reports were available at the time of survey.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) document review and a laboratory specialist consultant interview revealed the laboratory failed to perform and document control procedures as required which contributed to the Immediate Jeopardy. Findings include: 1. This STANDARD is not met as evidenced by a record review of i -STAT Chemistry QC reports revealed the laboratory failed to perform troponin QC on the i-STAT Chemistry Analyzer for the following dates that troponin patient samples were run: 8/21/17,4/7/18, and 5/3/18. 2. An interview with a laboratory specialist consultant on 5/21/18 in a conference room at approximately 3:30 p.m. confirmed troponin QC was not performed on the i-STAT for the aforementioned dates troponin patient test samples were performed.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on hematology quality control (QC) document review and a laboratory specialist consultant interview, the laboratory failed to perform corrective action for controls that failed to meet the laboratory's established criteria for acceptability. Findings include: 1. Cell-Dyn Emerald QC document review revealed the following controls were out of acceptable reference range with no corrective action: 2016 - Low Control (L6298): 12/4/16 -- White Blood Count (WBC) = 3.1 (1.9 - 2.7) acceptable reference range; 12/22/16 -- WBC = 2.8 (1.9 - 2.7) acceptable reference range; 2018 -- Low Control (L7352): 1/12/18 -- WBC = 2.5 (2.2 - 2.4); Normal Control (N7352) -- WBC = 15.8 (7.7-8.1), Lymphocytes = 3.8 (2.0 - 2.2), Granulocytes = 11.2 (5.1 - 5.3), Red Blood Count (RBC) = 5.77 (4.08 - 4.18), Hemoglobin (Hgb) = 16.4 (11.3 - 11.7), Hematocrit = 47.5 (34.1 - 35.1), Platelets = 168 (196 - 220); 1/21/18 -- N7352: WBC = 9.2 (7.7 - 8.1), RBC = 4.59 (4.08 - 4.18), Hgb = 12.8 (11.3 - 11.7); High Control (H7352) -- 1/13/18: WBC = 20.2 (17.5 - 18.5). 2. An interview with the laboratory specialist consultant on 5/21/18 in a conference room at approximately 4:00 p.m. confirmed no corrective action was documented for the Cell-Dyn Emerald QC for the aforementioned dates.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of testing records, proficiency test (PT) documents, quality control (QC) documents, the laboratory policy and procedure manual (SOP), calibration and verification documents, and testing personnel (TP) documents, the laboratory director (LD) failed to provide overall management and direction of the lab in the speciality of Chemistry. This condition-level deficiency contributed to the Immediate Jeopardy. Findings include: For details refer to Condition: D 5016, D5400 Standard: D5217, D5421, D5441, D5445, D5783, D6011, D6015, D6031, D6065
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory director (LD) failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. Findings include: 1. Observation during the laboratory tour at approximately 5:00 p.m. on 5/21/18 revealed there was not a fire extinguisher in the building. 2. An interview with the technical consultant at the nurses station at approximately 6:15 p.m. on 5/21/18 confirmed there was not a fire extinguisher in the building.
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 test (PT) reports and interview with the laboratory specialist consultant (LSC), the laboratory director (LD) failed to enroll in an approved PT program for the laboratory testing performed. Findings include: 1. PT report review revealed the LD failed to enroll in PT for the chemistry analyte, troponin for 2017 and 2018 thus far. 2. An interview with the LSC on 5/21/18 at approximately 4:00 p.m. confirmed the LD failed to enroll in PT

D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual (SOP) and laboratory director (LD) interview, the LD failed to ensure that an approved SOP is available to all personnel responsible for any phase of the laboratory testing process. Findings include: 1. SOP review revealed the LD failed to read, review, and approve the laboratory SOP for 2016, 2017, and 2018 thus far. 2. An interview with the LD in a conference room on 5/21/18 at approximately 6:30 p.m. confirmed the LD did not read, review, and approve the SOP for 2016, 2017, and 2018 thus far.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and an interview with the laboratory specialist consultant, the laboratory failed to employ qualified individuals to perform moderate-complexity testing due to lack of education documentation. Findings include: 1. TP document review revealed TP #4 (CMS 209) was unqualified to perform moderate-complexity laboratory tests due to lack of education documentation. 2. An interview with the laboratory specialist consultant on 5/21/18 in a conference room at approximately 4:00 p.m. confirmed there was no education documentation available at the time of survey for TP #4 (CMS 209).