| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D2141868 | 08/08/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Urgent Family Clinic Llc | 301 North John Young Parkway, Kissimmee, 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 |
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| **D0000** | An Initial Certification survey was conducted on August 8, 2019. Urgent Family Clinic LLC was not in compliance with 42 CFR 493, requirements for clinical laboratories. |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to enroll in proficiency testing with an approved proficiency testing program from 4/01/19 to 8/08/19.<br>Findings: An attempt to review the laboratory's proficiency testing revealed that no documentation of proficiency testing was available for inspection. The laboratory performs testing on the following analytes: Albumin, Alkaline Phosphatase, Alanine Transaminase (ALT), Amylase, Aspartate Aminotransferase (AST), Bilirubin, Calcium, Chloride, Cholesterol, Creatinine, Carbon Dioxide (CO2), Erythrocytes Count (RBC), Gamma-Glutamyl Transferase (GGT), Glucose, Hematocrit, Hemoglobin, High Density Lipoprotein (HDL), Leukocyte Count (WBC), Iron, Platelet Count, Potassium, Protein Total, Rheumatoid Factor, Sodium, Thyroid Stimulating Hormone, Thyroxine (T4), Triglycerides, Triiodothyronine (T3), Urea |

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| | Nitrogen, and White Blood Cell (WBC) Differential. During an interview on 8/08/19 at 11:51 AM, Testing Personnel B stated they were not enrolled in proficiency testing with an approved proficiency testing company. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and staff interview, the laboratory failed to establish a policy on training and competency assessment, and failed to document the training and competency assessment on 3 out of 3 Testing Personnel from 4/01/19 to 8/08/19 (A, B & C). Findings: An inspection of the laboratory showed that there was no policy on training and competency assessment or documentation of training and competency assessment on 3 out of 3 Testing Personnel A, B and C from 4/01/19 to 8/08/19. During an interview on 8/06/19 at 3:30 PM, Testing Personnel B stated there was no documentation of training and competency. At 3:39 PM, Testing Personnel B stated there were no policy on training and competency. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5401. Based on observation and interview, the laboratory failed to have a procedure manual from 4/01 /19 to 8/08/19. Cross Reference D5413. Based on observation, record review and interview, the laboratory failed to record the refrigerator temperature, the freezer temperature, and the temperature and humidity of the room where testing was performed from 4/01/19 to 8/08/19. Cross Reference D5433. Based on record review and interview, the laboratory failed to maintain documents for maintenance for the GeneXpert bacteriology analyzer and the Beckman Coulter Act Diff 2 hematology analyzer. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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 |

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| | examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview, the laboratory failed to have a procedure manual from 4/01/19 to 8/08/19. Findings: Observation from the survey conducted on 8/08/19 revealed that the laboratory failed to have a procedure manual. During an interview on 8/08/19 at 3:39 PM, Testing Personnel B acknowledged that they didn't have a procedure manual. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview, the laboratory failed to record the refrigerator temperature, the freezer temperature, and the temperature and humidity of the room where testing was performed from 4/01/19 to 8/08/19. Findings: The laboratory stores laboratory testing supplies (calibrators, controls, reagents & standards) in the refrigerator and freezer. Observation revealed that there were no thermometers in the refrigerator and freezer. Observation of the laboratory supplies contained in the refrigerator showed the temperature of the refrigerator should be between 2 and 8 degrees Celsius. Observation of the laboratory supplies contained in the freezer showed the temperature of the freezer should be between minus 20 and minus 70 degrees Celsius. The laboratory performs laboratory testing on a Beckman Coulter AU 480 chemistry analyzer, a Beckman Coulter Access 2 immunoassay analyzer, a Beckman Coulter Act Diff 2 hematology and a GeneXpert bacteriology analyzer. The manuals for the instruments noted that the room temperature of the laboratory should be between 18-32 degrees Celsius and humidity of 20% to 80%. Review of the laboratory's logs showed that there were no logs for the refrigerator temperature, freezer temperature, room temperature, and humidity of the room. During an interview on 8/08/19 at 3:20 AM, Testing Personnel B stated that they did not record the refrigerator and freezer temperature. At 4:01 AM, Testing Personnel B stated that they did not record the room temperature or the humidity of the laboratory. |
| **D5433** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(1)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to maintain documents for maintenance for the GeneXpert bacteriology analyzer and the Beckman Coulter Act Diff 2 hematology analyzer. Findings: The laboratory started testing on 4/01/19. Review of the maintenance log recorded on the GeneXpert showed that the laboratory had started recording the maintenance for the last 2 weeks only. Review of the laboratory's log showed that there was no maintenance log available for review for the Beckman Coulter Act Diff 2 analyzer from 4/01/19 to 8/08/19. During an interview on 8/08/19 at 2:21 PM, Testing Personnel B acknowledged that the maintenance logs for the GeneXpert was not filled out prior to the last 2 weeks. At 2:40 PM, Testing Personnel B acknowledged there was no maintenance log for the Beckman Coulter Act Diff 2 analyzer. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interview, the Laboratory Director failed to provide overall management and direction. Findings: Cross Reference D6007. Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for the analytical phase of testing performance. Cross Reference D6015. Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enroll in proficiency testing with an approved proficiency testing program from 4/01/19 to 8/08 /19. Cross Reference D6030. Based on observation and staff interview, the Laboratory Director failed to ensure a policy was established for training and competency assessment. The Laboratory Director failed to document the training and competency on 3 out of 3 Testing Personnel from 4/01/19 to 8/08/19 (A, B & C). |
| **D6007** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(1)<br><br>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for the analytical phase of testing performance, failed to ensure that the refrigerator |

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| | temperature, the freezer temperature, and the temperature and humidity of the room where testing was performed from 4/01/19 to 8/08/19 was documented, and failed to ensure that for maintenance for the GeneXpert bacteriology analyzer and the Beckman Coulter Act Diff 2 hematology analyzer was documented. Findings: Observation from the survey conducted on 8/08/19 revealed that the laboratory failed to have a procedure manual. During an interview on 8/08/19 at 3:39 PM, Testing Personnel B acknowledged that they didn't have a procedure manual. The laboratory stores laboratory testing supplies (calibrators, controls, reagents & standards) in the refrigerator and freezer. Observation revealed that there was no thermometers in the refrigerator and freezer. Observation of the laboratory supplies contained in the refrigerator showed the temperature of the refrigerator should be between 2 and 8 degrees Celsius. Observation of the laboratory supplies contained in the freezer showed the temperature of the freezer should be between minus 20 and minus 70 degrees Celsius. The laboratory performs laboratory testing on a Beckman Coulter AU 480 chemistry analyzer, a Beckman Coulter Access 2 immunoassay analyzer, a Beckman Coulter Act Diff 2 hematology and a GeneXpert bacteriology analyzer. The manuals for the instruments noted that the room temperature of the laboratory should be between 18-32 degrees Celsius and humidity of 20% to 80%. Review of the laboratory's logs showed that there were no logs for the refrigerator temperature, freezer temperature, room temperature, and humidity of the room. During an interview on 8/01/19 at 3:20 AM, Testing Personnel B stated that they did not record the refrigerator and freezer temperature. At 4:01 AM, Testing Personnel B stated that they did not record the room temperature or the humidity of the laboratory. The laboratory started testing on 4/01/19. Review of the maintenance log recorded on the GeneXpert showed that the laboratory had started recording the maintenance for the last 2 weeks only. Review of the laboratory's log showed that there was no maintenance log available for review for the Beckman Coulter Act Diff 2 analyzer from 4/01/19 to 8/08/19. During an interview on 8/08/19 at 2:21 PM, Testing Personnel B acknowledged that the maintenance logs for the GeneXpert was not filled out prior to the last 2 weeks. At 2:40 PM, Testing Personnel B acknowledged there was no maintenance log for the Beckman Coulter Act Diff 2 analyzer. |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing with an approved proficiency testing program from 4/01/19 to 8/08/19. Findings: An attempt to review the laboratory's proficiency testing revealed that no documentation of proficiency testing was available for inspection. The laboratory performs testing on the following analytes: Albumin, Alkaline Phosphatase, Alanine Transaminase (ALT), Amylase, Aspartate Aminotransferase (AST), Bilirubin, Calcium, Chloride, Cholesterol, Creatinine, Carbon Dioxide (CO2), Erythrocytes Count (RBC), Gamma-Glutamyl Transferase (GGT), Glucose, Hematocrit, Hemoglobin, High Density Lipoprotein (HDL), |

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| | Leukocyte Count (WBC), Iron, Platelet Count, Potassium, Protein Total, Rheumatoid Factor, Sodium, Thyroid Stimulating Hormone, Thyroxine (T4), Triglycerides, Triiodothyronine (T3), Urea Nitrogen, and White Blood Cell (WBC) Differential. During an interview on 8/08/19 at 11:51 AM, Testing Personnel B stated they were not enrolled in proficiency testing with an approved proficiency testing company. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and staff interview, the Laboratory Director failed to ensure a policy was established for training and competency assessment. The Laboratory Director failed to document the training and competency on 3 out of 3 (A, B, and C) Testing Personnel from 4/1/19 to 8/8/19. Findings: An inspection of the laboratory showed that there was no policy or documentation on training and competency assessment on 3 out of 3 (A, B, and C) Testing Personnel from 4/1/19 to 8/8/19. During an interview on 8/6/19 at 3:30 PM, the Testing Personnel B stated there were no documentation of training and competency. During an interview on 8/6/19 at 3:39 PM, the Testing Personnel B stated there were no policy on training and competency. |