Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0255180	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urban Family Practice Associates, Pc	2520 Windy Hill Rd Suite 301, Marietta, 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 August 15, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on document review, observations,and staff interviews the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems. Significant deficiencies noted in specimen identification and integrity, personnel competency policy, evaluation of proficiency testing (PT) results, corrective action of PT, and quality assurance (QA) policy. Findings include: For details refer to : D5203, D5209, D5211, D5221, D5291
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to ensure positive specimen identification. Findings include: 1. SOP review revealed the policy and procedure for specimen labeling required only one unique specimen identifier. 2. An interview with Staff #2 (CMS 209)in the conference room on 8/15/18 at approximately 6:00 p.m. confirmed the policy and procedure for specimen labeling in the SOP required only one unique specimen identifier.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess laboratory personnel competency. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a six-procedure policy and procedure for assessing laboratory personnel competency. 2. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed the SOP did not contain a six-procedure competency policy and procedure.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review, the laboratory director (LD) failed to review the PT results when received. Findings include: 1. Review of the American Academy of Family Practice (AAFP) PT results for 2017 testing event #3 and 2018 testing events #1 and #2 revealed the lab director failed to review the results upon receipt. 2. Interview with staff # 2 (CMS 209 form) on 8/15/18 in the basement conference room at approximately 5:30 PM confirmed the PT results were not reviewed. *Repeat deficiency
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to document corrective actions for PT results less than 100%. Findings include:

	1. Review of the American Academy of Family Practice (AAFP) PT results for 2017 testing events #1 and #3 revealed the lab did not document corrective actions for bacteriology results of 80%. 2. Interview with staff # 2 (CMS 209 form) on 8/15/18 in the basement conference room at approximately 5:30 PM confirmed the PT results did not have corrective actions documented.
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 review of the laboratory policy and procedure manual (SOP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems (Quality Assurance) identified in the general laboratory systems requirements. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a QA policy. 2. An interview with Staff #2 (CMS 209) in a basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed the laboratory SOP did not contain a QA policy.
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 review of the laboratory policy and procedure manual (SOP), review of quality control (QC) documents, and observation during the laboratory tour, the laboratory failed to meet the applicable analytic systems requirements: the laboratory failed to establish and provide a policy and procedure for all tests, assays, and examinations performed by the laboratory; the laboratory failed to monitor laboratory humidity, the laboratory failed to verify accuracy, precision, and reportable range of hematology quality control (QC); the laboratory failed to perform required equipment calibrations; the laboratory failed to monitor over time the accuracy and precision of test performance;the laboratory failed to establish reference ranges for all control materials. Refer to D5401, D5413 (repeat), D5421, D5429 (repeat), D5441, D5469
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 staff interview, the laboratory failed to establish and follow a written policy and procedure for all tests, assays, and examinations performed by the laboratory. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a written policy and procedure for performed Streptococcus (Strep) cultures. 2. An interview with Staff #2 (CMS 209) in a basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed the laboratory SOP did not contain a Strep culture policy and procedure. This is a REPEAT DEFICIENCY.
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 review of the laboratory policy and procedure manual (SOP), the hematology instrument operator's manual, and staff interview, the laboratory failed to monitor laboratory humidity and temperature as specified by the manufacturer. Findings include: 1. SOP review and Horiba Micros 60 operations manual review revealed the laboratory failed to establish a policy and procedure for monitoring laboratory humidity and failed to follow the Horiba Micros 60 operations manual specifications for monitoring laboratory humidity. 2. SOP review revealed the laboratory failed to monitor room temperature as required. 3. Review of 2017 Daily Humidity logs revealed : January 2017-no records available, February 2017- 0 days missed of 20 days, March 2017- 4 days missed of 23 days, April 2017- 3days missed of 20 days, May 2017- 4 days missed of 22 days, June 2017- 3 days missed of 23 days. March 2017- 1 day logged when practice was closed and April 2017- 1 day logged when practice was closed. 4. Review of 2018 Daily Humidity logs revealed : January 2018-6 days missed of 22 days, February 2018-6 days missed of 20 days, March 2018- 7 days missed of 22 days, April 2018- 3 days missed of 21 days, May 2018- 6 days missed of 22 days, June 2018- 6 days missed of 22 days. 5. Review of daily temperature charts of January 2017 to June 2017 revealed 7 of 128 opened days were missed (no temperature recorded); 1 day logged was a holiday; 3 days logged were Saturday. (11 of 128 days were logged improperly.) 6. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 6:00 p. m. confirmed the laboratory was not monitoring laboratory humidity or temperatures each day of patient testing or establish a written procedure.
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 hematology quality control (QC) and staff interview, the laboratory failed to verify the accuracy, precision, and reportable range of test results for the test system. Findings include: 1. Micros 60 Hematology analyzer QC document review revealed the laboratory failed to perform linearities to verify the accuracy, precision, and reportable range of test results for 2016, 1017, and 2018 thus far. 2. An interview with Staff #2 (CMS 209) in a basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed no Hematology linearitites were performed for the Micros 60 Hematology analyzer for 2016, 2017, and 2018 thus far.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to perform and document equipment maintenance as required. Findings include: 1. Observation during the laboratory tour on 8/15/18 at approximately 5:30 p.m. revealed the Labcorp urinalysis centrifuge calibrations were not performed in 2016, 2017, and 2018 thus far. 2. Observation during the laboratory tour on 8/15/18 at approximately 5:30 p.m. revealed the AMSCOPE SN#1567596 microscope was not calibrated since purchase in early 2017. No maintenence records were available on the previous used microscope for 2016-2017. 2. An interview with Staff #2 (CMS 209) at approximately 5:30 p.m. in the laboratory confirmed the aforementioned calibrations were not performed. This is a REPEAT DEFICIENCY.
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 review of Hematology quality control (QC) and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance. Findings include: 1. Hematology QC review revealed the laboratory failed to provide Levey-Jennings charts for Hematology for 2016, 2017, and 2018 thus far. 2. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed the laboratory did not monitor Hematology QC over time with the implementation of Levey-Jennings charts for 2016, 2017, and 2018 thus far.
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 quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on urine microscopics and potassium hydroxide (KOH) slides. Findings include: 1. No documents were available to review on urine microscopic exams or KOH slides at the time of survey. 2. An interview with Staff #2 (CMS 209) in the lab on 8/15/18 at approximately 5:20 p.m. confirmed controls were not performed on the aforementioned tests.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control (QC) document review and staff interview, the laboratory failed to establish or verify the criteria for acceptability of all control materials. Findings include: 1. Micros 60 hematology analyzer QC document review revealed the laboratory failed to establish reference ranges for all control materials. 2. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed no reference ranges were established for low, normal, or high controls for 2016, 2017, and 2018 thus far.

D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on bacteriology quality control (QC) document review and staff interview, the laboratory failed to test negative control material on the Strep Select media. Findings include: 1. Review of QC documents on the Strep Select media revealed only positive growth was tested. 2. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 5:30 p.m. confirmed no negative controls were tested for 2016, 2017, and 2018 thus far.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on bacteriology quality control (QC) document review and staff interview, the laboratory failed to perform sterility checks on the Strep Select media. Findings include: 1. Review of the QC documentation revealed the factory sterility checks were recorded. No in-lab sterility checks were performed for 2016, 2017, and 2018 thus far. 2. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 5:30 p.m. confirmed in-lab sterility checks were not performed for the aforementioned dates.
D5523	PARASITOLOGY CFR(s): 493.1264(a)(d) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documents and staff interview, the laboratory

	failed to perform or document controls on saline wet mounts as required. Findings include: 1. Review of QC documents revealed no QC records available on wet mounts at the time of the survey for 2016, 2017, and 2018 thus far.. 2. Interview with staff #2 (CMS 209 form) on 8/15/18 at approximately 5:20 PM in the lab, confirmed QC wass not performed on wet mounts 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 document reviews, observations, interviews, and procedure manual review, the laboratory director failed to provide overall management and direction for multiple facets of the laboratory including: Quality Assurance (QA), Quality Control (QC), maintenance, testing personnel requirements, Proficiency Testing (PT), Technical Consultant (TC), and policy & procedures. Findings include: For details refer to D5203, D5209, D5211, D5221, D5291, D5401, D5413, D5421, D5429, D5441, D5449, D5469, D5471, D5477, D5523, D6017, D6020, D6021, D6032, D6054
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Quality Control (QC) document review and staff interview, the laboratory director failed to ensure QC was established and performed as required. Findings include: 1. Review of QC documents revealed the lab did not perform QC on potassium hydroxide (KOH) slides, wet prep slides, or urine microscopic exams in 2016, 2017, and 2018 thus far. 2. Hematology QC review revealed the laboratory failed to provide Levey-Jennings charts for Hematology for 2016, 2017, and 2018 thus far. No long term QC monitoring was performed for the aforementioned dates.. 3. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed the laboratory did not monitor the aforementioned QC.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on quarterly Quality Assurance (QA) document review and staff interview, the laboratory director failed to ensure a QA program was established in writing and the check list followed. Findings include: 1. Review of the 2017 first and third quarter and 2018 first, second, & third quarter QA checklists revealed that the forms were prefilled answers, signatures, and copies made. Only the dates were added as indicated. 2. All answers were marked as "Y" (yes) to all monitors but all monitors were not indicated for the dates provided. 3. SOP review revealed the laboratory failed to establish and follow a written QA policy. 4. An interview with Staff #2 (CMS 209) in the basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed the lack of written QA policy and adherence to a QA policy for the aforementioned dates.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with Staff #2 (CMS 209) in a basement conference room on 8/15/18 at approximately 6:00 p.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by:

	Based on document review, observations, interviews, and procedure manual review, the Technical Consultant (TC) (laboratory director) failed to provide technical oversight or fulfill the TC duties for multiple facets of the laboratory including: quality assurance (QA), quality control (QC), maintenance, testing personnel competency, proficiency testing (PT), and proper usage of policy & procedures. Findings include: For details refer to : D5291, D5413, D5421, D5429, D5441, D5449, D5469, D5471, D5477, D5523, D6054
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on staff competency document review and staff interview, the technical consultant (TC)(lab director) failed to perform annual competency evaluations on the staff. Findings include: 1. Review of the staff competency documents revealed the TC has not performed competency on staff#2 (CMS 209 form) since 12/19/14. 2. Review of the staff competency documents revealed the TC did not perform competency on staff#3 (CMS 209 form); an unqualified staff #2 (CMS 209 form) performed the competency on staff#3 (Last documented competency on staff #3 was 10/20/16.) 2. An interview on 8/15/18 at 3:25 PM in the basement conference room with Staff #2 (CMS 209 form) confirmed the TC did not perform the aforementioned competencies.