Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1072950	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Health Solutions Dba Urgent Doc-Lufkin	2132 S First St, Lufkin, TX	

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	Based on the survey conducted 01-22-2019, the laboratory was found to be out of compliance with the following conditions of 42 CFR: D2016 SUCCESSFUL PARTICIPATION 493.803 D6033 TECHNICAL CONSULTANT-MODERATE COMPLEXITY 493.1409 .
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of American Proficency Institute (API) proficiency testing (PT) documentation for testing in 2017 - 2018 and staff interview, the laboratory failed to participate successfully in testing for the following analytes in the specialty of Hematology: Findings: I. First event 2018 Review of API PT documentation for the

	first event 2018, confirmed by staff interview, showed the laboratory failed to achieve acceptable scores in Granulocytes and Lymphs + Monos, resulting in an unacceptable result for WBC Diff. Refer to D2121 (I). II. Second event 2018 Review of API PT documentation for the second event 2018, confirmed by staff interview, showed the laboratory failed to submit results within the time frame defined by the provider, resulting in 0% scores for all analytes. Refer to D2123. III. 3rd event 2018 Review of API PT documentation for the third event of 2018, confirmed by staff interview, showed the laboratory failed to achieve an acceptable score for White Cell Count. Refer to D2121 (III). .
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for the 1st, 2nd and 3rd testing events of 2018, confirmed by staff interview, the laboratory failed to attain satisfactory performance in hematology. Findings: I. First event 2018 1. Review of API PT documentation for the first event 2018 showed the laboratory failed to achieve acceptable scores in Granulocytes and Lymphs + Monos, resulting in an unacceptable result for WBC Diff. The person submitting the report to API (no longer employed at the site) had entered the results for Granulocytes and Lymphs + Monos incorrectly, substituting raw count numbers for percentages, reporting the following results displayed in the column marked "Reported." Actual instrument results for analyte percentages are shown in the column marked "Actual Result." Granulocytes (%) Sample Reported Expected Actual Result QBC-01 6 45-72 33 QBC-02 2 42-59 38* QBC-03 5 46-70 53 QBC-04 10 22-62 41 QBC-05 10 22-51 40 Lymphs + Monos (%) QBC-01 5 28-56 47 QBC-02 3 41-58 62* QBC-03 4 30-54 47 QBC-04 15 38-78 59 QBC-05 14 49-75 60 *indicates out of expected range 2. In an interview at the site on 01-22-2019, testing person 1, (CMS form 209) who also serves as the clinic manager, stated the error was discovered when test scores were reviewed and compared with instrument printouts following the test event. 4. The combination of unacceptable scores for samples QBC-02 and QBC-03 and an automatic passing score for the ungraded sample, QBC-04, resulted in an overall unacceptable score (60%) for Leukocyte Count. In an interview at the site on 01-22-2019, testing person 1 confirmed the documented scores. II. Second event 2018: Based on review of API PT documentation for the 2nd event of 2018 and staff interview, the laboratory failed to participate in testing for the specialty of hematology, resulting in a score of 0 for the testing event. Refer to D2123. III. Third event 2018: 1. Review of API PT documentation for the third event of 2018 showed the laboratory failed to achieve an acceptable score for White Cell Count as follows: White Cell Count (x10^9) Sample Reported Expected Score QBC-11 4.9 5.3-7.3 Unacceptable QBC-12 18.2 17.1-23.2 Acceptable QBC-13 8.6 9.6-13.0 Unacceptable QBC-14 16.2 15.9-21.6 Acceptable QBC-15 8.7 9.7-13.2 Unacceptable 2. In an interview at the site on 01-22-2019, testing person 1 confirmed the documented results. .
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a

	score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for the 2nd event of 2018 and staff interview, the laboratory failed to participate in testing for the specialty of hematology, resulting in a score of 0 for the testing event. Findings: 1. Review of API PT documentation for the second event 2018 showed the laboratory failed to submit results within the time frame defined by the provider, resulting in 0% scores for all analytes: Hematocrit 0% Failure to Participate Hemoglobin 0% Failure to Participate Leukocyte Count 0% Failure to Participate Platelet Count 0% Failure to Participate WBC Differential 0% Failure to Participate Granulocytes 0% Failure to Participate Lymphs + Monos 0% Failure to Participate 2. In an interview at the site on 01-22-2019, the area administrator stated that the employee normally responsible for submitting PT results had left the organization during the second event 2018 and no successor assigned. She further stated that when the lapse was discovered, testing was performed on the samples, yielding the following results: Granulocytes (%) Sample Reported Expected QBC-06 35 35-53 QBC-07 50 32-57 QBC-08 51 48-70 QBC-04 40 31-54 QBC-05 48 46-64 Hematocrit (%) QBC-06 31 31-36 QBC-07 35 33-39 QBC-08 22 21-24 QBC-04 33 31-36 QBC-05 27 26-30 Hemoglobin (g/dL) QBC-06 10.6 10.4-12.0 QBC-07 11.7 11.2-12.9 QBC-08 7.2 6.8-7.9 QBC-04 11.2 10.4-12.1 QBC-05 8.9 8.7-10.1 Lymphs+Monos (%) QBC-06 65 47-65 QBC-07 50 43-68 QBC-08 49 30-52 QBC-04 60 46-69 QBC-05 52 36-54 Platelet Count (x10^9) QBC-06 244* 123-207 QBC-07 233* 131-219 QBC-08 740 485-809 QBC-04 229* 125-210 QBC-05 499* 274-258 White Cell Count (x10^9) QBC-06 13.4* 13.8-18.8 QBC-07 19.7* 22.3-30.3 QBC-08 6.8 6.3-8.6 QBC-04 13.2* 14.2-19.3 QBC-05 8.6 6.9-9.5 *indicates out of expected range. .
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for the 1st, 2nd and 3rd events of 2018 and staff interview, the laboratory failed to achieve satisfactory performance for the analytes Leucocyte Count, WBC differential, Granulocytes and Lymphs + Monos in two out of three consecutive events. Refer to D 2121. .
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 laboratory quality control (QC) policy, QC documentation for 2017, 2018 and 2019 and staff interview, the laboratory failed to perform and document external QC for the QBC Star hematology analyzer according to requirements. Findings: 1. The laboratory procedure manual for hematology testing was reviewed. In the section for QC testing, the following was stated: "QBC controls are available for additional performance monitoring of the QBC STAR system. You must run liquid controls and document the results before you begin testing with a new lot or newly received shipment of QBC STAR Tubes. You must run liquid controls and document the results with each instance of instrument elocation or repair. Consult the package insert accompanying the controls for preparation instructions and expected results. You must follow any quality control requirements from your regulatory or accreditation agencies." (Laboratory Procedure Manual, page 20) 2. QC documentation was requested. Testing person 1 provided sheets showing daily QC results. On examination it was found that the target values listed were identical to the factory target values for electronic QC, run automatically by the instrument every 8 hours. All daily results listed were identical to the manufacturer's target values. 3. Results for daily external (liquid) QC results were requested. No documentation of daily external QC was available or could be provided during the survey. In an interview at the site on 01-22-2019, the area administrator stated that liquid QC was ordinarily performed according to laboratory policy, but had not been ordered or performed from mid-June 2018 to mid-October 2018 due to administrative staffing issues. In 2017, 365 patient tests were performed. In 2018, 235 patient tests were performed. From 01-01-2019 to 01-27-2019, 36 patient tests were performed. 4. Documentation of an Individual Quality Control Plan (IQCP) for hematology was requested. In an interview at the site, testing person 1 stated she had no knowledge of such a plan. No documentation indicating that an IQCP had been developed by the laboratory was found or could be provided during the survey. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of laboratory quality control (QC) policy, QC documentation for 2017, 2018 and 2019 and staff interview, the laboratory failed to perform and document external QC for the QBC Star hematology analyzer at least once per day patient specimens were analyzed. Refer to D5445. .

D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on surveyor observation, review of laboratory documentation and staff interview, the laboratory director failed to ensure that a technical consultant meeting the required qualifications was employed by the facility. Findings: 1. During the survey on 01-22-19, during review of the Laboratory Personnel Report (CMS form 209), the surveyor observed that there was no listing for the position of Technical Consultant. On inquiry, the area administrator stated she was not aware of the requirement for such a position. 2. Review of laboratory personnel documentation showed that the Laboratory Director did not meet the qualifications for Technical Consultant. 3. Further review of laboratory documentation revealed no personnel records identifying a laboratory employee meeting the educational, training or experience requirements of Technical Consultant, or documentation of reapportionment of duties by the Laboratory Director to another individual. .
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 review of laboratory quality control (QC) policy and testing results, confirmed by staff interview, the Laboratory Director failed to ensure that the QC program was established and maintained to assure the quality of hematology services provided. Refer to D5445. .
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 surveyor observation, review of survey documents and staff interview, the laboratory failed to employ a technical consultant to provide technical oversight of non-waived hematology testing performed at the site. Findings: 1. An entrance conference was conducted 01-22-2019 at 10:00 AM. Attending were the surveyor, the area administrator and the clinic manager. Survey documents were reviewed. Non-waived testing at the site consisted of hematology using a QBC Star centrifugal analyzer. 2. On review, the form CMS-209 was found to have no Technical Consultant listed on staff. Upon inquiry, it was stated by both the clinic manager and area administrator that the facility did not have anyone filling that position. Refer to D6004. .