Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2105383	10/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Terrell Urgent Care	104 Lee Street, Terrell, 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
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 American Proficiency Institute (API) proficiency testing (PT) documentation, confirmed by staff interview, the laboratory failed to participate in the third hematology testing event of 2018. Findings: 1. API PT results were reviewed, revealing scores of zero for all parameters in hematology for the 3rd event of 2018. The scores were accompanied with a notation "failure to participate." 2. In an interview at the site on 10-09-2019, testing person 1 (TP 1, CMS form 209) stated that she was generally responsible for ensuring PT was completed and submitted on time, but during the 3rd event testing of 2018 she had been on extended medical leave. 3. In the same interview TP 1 confirmed that patient testing had not been suspended during the event. Review of API PT documentation showed that the laboratory had participated successfully in the previous two PT events. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure for hematology testing using the Sysmex PocH-100i analyzer, the laboratory failed to utilize a written procedure for the reporting of critical values or protocol for disposition of specimens returning such values. Findings: 1. Laboratory procedures were reviewed. The procedure for hematology testing did not include information to direct the operator in the event of patient results showing alert or panic values. 2. In an interview at the site, TP1 stated that it was known by testing personnel that all alert or panic values were to be brought to the attention of the ordering provider immediately and that the decision to refer the specimen for further testing was left to the provider. TP1 further confirmed that the procedure provided did not include these instructions. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on review of laboratory patient hematology reports, confirmed by staff interview, the laboratory report did not include positive patient identification or the name and address of the laboratory location. Findings: 1. Review of patient report examples showed patients identified by first and last name only. 2. Information on laboratory test reports did not include the laboratory name or physical address. 3. In an interview at the site on 10-09-2019, TP 1 confirmed that the reports reviewed were true examples of patient results issued by the laboratory. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: . Based on review of API PT documentation and staff interview, the laboratory director (LD-CMS form 209) failed to ensure that proficiency testing results for hematology were returned within the timeframes established by API. Refer to D 2123. .
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 review of testing personnel competency verification documentation, confirmed by staff interview, the laboratory technical consultant failed to annually document evaluation of the performance of staff responsible for moderate complexity hematology testing. Findings: 1. Review of the competency evaluation documents in laboratory personnel files showed competency verification forms completed as follows: Testing person Date completed TP 1 01-20-2017 TP 2 06-19-2017 TP 3 02-18-2018 No competency verification was documented for TP 1 or TP 2 in 2018 or 2019. No competency verification was documented for TP 3 in 2019. 2. In an interview at the site on 10-09-2019, TP 1 stated she was not aware competency verification was required annually for laboratory testing personnel. The laboratory technical consultant was not on site at the time of the survey. .