Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2132802	06/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Children's Clinic Of Rusk, Pllc	1375 Dickinson Drive, Rusk, 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
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 review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2018 and 2019, confirmed y staff interview, laboratory testing personnel failed to attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods. Findings: 1. API PT documentation for 2018 and 2019 was reviewed. Attestation statements for microbiology, 2nd event 2018 and hematology, 3rd event 2018, though signed by the laboratory director, lacked the signature of the individual performing the test. 2. In an interview at the site on 06-19-2019, testing person 1 (CMS form 209) stated that he had performed the testing in both events but failed to sign the attestation forms. .
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 laboratory procedures, confirmed by staff interview, the laboratory failed to provide a written procedure for operation of the Horiba Micro 60

	hematology analyzer. Findings: 1. Review of the laboratory procedure manual showed no approved procedure for operation of the Horiba Micro 60 hematology analyzer. On request, the manufacturer's user manual was offered. Review of the user manual revealed no indication of director review or approval. 2. In an interview at the site on 06-19-2019, the clinic manager confirmed that no approved laboratory procedure for operation of the Micro 60 analyzer was available. .
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 surveyor observation and review of laboratory procedure, the manufacturer's user manual failed to include the elements required for its use as a laboratory procedure. Refer to D 5401. .
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 surveyor observation, review of laboratory documentation associated with the installation of the Horiba Micro 60 hematology analyzer and staff interview, the laboratory failed to document verification of accuracy, precision or reportable range or to verify appropriateness of the laboratory's reference intervals for the patient population served. Findings: 1. In the course of the survey, a copy of the verification study for the Horiba Micro 60 analyzer, put in use 01-04-2018, was requested. On

	review it was found that the materials provided by the manufacturer included instructions for conducting verification studies, but no evidence that these studies had been performed was present. 2. In an interview at the site on 06-19-2019, testing person 1 stated that he had participated in the initial installation testing of the instrument, but was unclear on specifics regarding the extent and purpose of that testing, conducted principally by a field service representative. 3. No documentation showing validation testing data or evidence of analysis was found or could be made available at the time of the survey.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: . Based on review of initial verification documentation for the Horiba Micro 60 hematology analyzer, the laboratory technical consultant (who also serves as laboratory director) failed to verify testing procedure or ensure the establishment of performance characteristics for that system. Refer to D 5421.