

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0481909	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Hunt Regional Pediatric Clinic Greenville	Street Address, City, State 5101 Wellington St Suite C, Greenville, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory policies and procedures, confirmed by staff interview, the laboratory procedure manual did not include required elements for hematology testing on the Horiba Micros 60, urine sediment examination or uricult colony counts. Findings: 1. Laboratory procedure manuals were reviewed. The manual for the Horiba Micros 60 hematology analyzer consisted of printouts from the manufacturer's online user manual. Not included in this manual were: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. b. The</p>

reportable range for test results as established in initial validation studies for the instrument. c. A listing of normal ranges for patient tests. d. Laboratory procedures for actions taken in the event of critical or alert values, including result entry and reporting protocol. 2. No laboratory procedures for examination of urine sediment or urine colony counts were found or could be provided during the survey. It should be noted that while reference materials for these types of testing were present in the facility, they were not available as an assembled manual reviewed and approved by the laboratory director. 3. In an interview at the site on 11-06-2019, the laboratory director and testing person 1 (CMS form 209) confirmed that no such manuals were available at that time.