

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0321880	(X3) Date Survey Completed 09/17/2019
Name of Provider or Supplier Kaplan Barron Pediatrics	Street Address, City, State 4117 Browns Ln, Louisville, KY	
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 staff interview and record review of the policy and procedure manual on September 17, 2019, the laboratory failed to include, requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection, Microscopic examination, including the detection of inadequately prepared slides. Control procedures. Reference intervals (normal values). Imminently life-threatening test results, or panic or alert values prior to patient testing March 27, 2019. The findings include: 1. Policy review conducted on September 17, 2019, revealed the</p>

laboratory did not have all the necessary procedural requirements for the procedure "Unistat Bilirubinometer". 2. Interview with the laboratory staff on September 17, 2019, confirmed the laboratory did not have a system in place to ensure all the policies and procedures contained all the information needed to perform and report the test prior to patient testing.

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 staff interview and record review on September 17, 2019, the laboratory failed to monitor and document the humidity in the laboratory using the correct reference range where the testing was performed from September 23, 2017 through September 16, 2019. Findings include: 1. The Manufacturer's operations manual for the Madonic M analyzer listed an operating range for humidity for the analyzer between zero (0) percent to eighty (80) percent. 2. Review of the Maintenance log revealed the humidity was not monitored and documented from September 23, 2017 through September 16, 2019. 3. Testing personnel acknowledged in an interview, at 11:21 AM on September 17, 2019, the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily, using the manufacturer's recommended range.

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 record review and staff interview on September 17, 2019, the laboratory failed to ensure the laboratory director/technical consultant reviewed, approved, signed, and dated the performance specifications for the bilirubin analyzer prior to routine patient testing on March 27, 2019. Findings include: Record review revealed performance specifications (precision, accuracy, reportable range verification, reference range verification) were not established for the Unistat Bilirubinometer analyzer prior to patient testing on March 27, 2019. Interview with staff at 10:45 AM on September 17, 2019, revealed the laboratory failed to have a policy in place to ensure all performance specifications for each nonwaived unmodified test system was

reviewed, approved, signed, and dated by the laboratory director or technical consultant prior to reporting patient test results.