

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0980676	(X3) Date Survey Completed 10/09/2018
Name of Provider or Supplier Storybook Pediatrics, Pc	Street Address, City, State 130 Enterprise Parkway, McDonough, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 09, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow a written policy and procedure for assessing employee and, if applicable, consultant competency. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a written policy and procedure for assessing employee competency. 2. An interview with Staff #1 (CMS 209) and the office manager in the lab on 10/09/18 at approximately 1:00 p.m. confirmed the laboratory SOP did not have the aforementioned policy and procedure.</p>
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.</p>

(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 the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow a written policy and procedure for reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a written policy and procedure for reporting imminently life threatening results, or panic, or alert value. 2. An interview with Staff #1 (CMS 209) and the office manager in the lab on 10/09/18 at approximately 1:00 p.m. confirmed the laboratory SOP did not have the aforementioned policy and procedure.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on document review and staff interview, the lab failed to verify the reportable range for patient test results on the ABX Micros 60 analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of maintenance, quality control, and calibration documents revealed the ABX Micros 60 was only tested for

the reportable range at installation (3-2-15). 2. Interview with testing personnel #1 (CMS 209 form) on 10/09/18 at approximately 1:00 PM in the lab, confirmed the reportable testing range was only tested at installation.

D5463

CONTROL PROCEDURES
CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on quality control (QC) document review and staff interviews, the lab failed to rotate control material testing among all operators who perform the test. Findings include: 1. Review of QC documents revealed that staff #1 (CMS 209) ran QC material daily in 2017-2018 to date. 2. Interview with testing personnel #1 (CMS 209 form) on 10/09/18 at approximately 1:00 PM in the lab, confirmed she had performed the QC daily.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of the facility testing reports and staff interview, the lab failed to include reference range and appropriate units of measurement on patient reports. Findings include: 1. Review of the facility testing reports (#1012016 & #322012) revealed the lab failed to include reference range and appropriate units of measurement on patient reports. 2. An interview with Staff #1 (CMS 209) and the office manager in the lab on 10/09/18 at approximately 1:00 p.m., confirmed the lack of the aforementioned information on the patient reports.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on personnel document review and staff interview, the lab director (LD) failed

to ensure that all personnel have the appropriate training documented. Findings include: 1. Review of testing personnel records revealed the lack of documented training for testing personnel. 2. An interview with Staff #1 (CMS 209) and the office manager in the lab on 10/09/18 at approximately 12:55 p.m. confirmed training documents were not available.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of testing personnel(TP) documents and staff interview, the technical consultant (lab director) failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of the TP records revealed the lack of documented 6 month competencies for testing personnel. 2. An interview with Staff #1 (CMS 209) and the office manager in the lab on 10/09/18 at approximately 12:55 p.m. confirmed 6 month competency documents were not available.

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(TP) documents and staff interview, the technical consultant (lab director) failed to perform annual competency on all testing personnel. Findings include: 1. Review of the TP records revealed the lack of documented annual competencies for testing personnel. 2. An interview with Staff #1 (CMS 209) and the office manager in the lab on 10/09/18 at approximately 12:55 p.m. confirmed annual competency documents were not available.