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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 19D1079564 | (X3) Date Survey Completed 08/30/2019 |
| Name of Provider or Supplier Red Stick Pediatrics | Street Address, City, State 888 Tara Blvd, Baton Rouge, LA | |
| 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 certification survey was conducted at Red Stick Pediatrics - CLIA ID # 19D107956 on August 30, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited. |
| D2128 | <p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document remedial action for unacceptable Hematology scores. Findings: 1. Review of the laboratory's 2018 and 2019 Proficiency Testing (PT) results revealed the laboratory received the following unacceptable results: a) 2019 Event 2: Sample FH6 for Red Blood Cell (RBC) - 80% b) 2019 Event 2: Sample FH6 for Hematocrit (HCT) - 80% 2. Further review revealed no documentation of corrective action, investigation or remedial action of these unacceptable scores. 3. In interview on August 30, 2019 at 10:06 am, Personnel 2 confirmed the laboratory did not investigate proficiency testing unless the event or analyte was less than 80%.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p> |

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 record review and interview with personnel, the laboratory failed to establish a written procedures for all aspects of testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written instruction for Proficiency Testing, to include how to test proficiency samples, who is responsible for proficiency testing reviews, assessment of unacceptable results 2. In interview on August 30, 2019, Personnel 2 confirmed the laboratory's policy and procedure manual did not include the identified policies.

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 record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the manual did not include detailed instructions for Corrective Action to include but not limited to: when corrective action should be taken, who is responsible for corrective action, at what point patient assessment is required and the documentation process for corrective action. 2. Interview with Personnel 2 on August 30, 2019 confirmed the policy did not specifically address corrective action.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing. Findings: 1. Review of the laboratory's policy revealed the laboratory performs the following three (3) levels of QC each day of CBC testing which must be acceptable prior to patient testing. 2. Review of the laboratory's QC records revealed quality control was unacceptable prior to patient testing on the following four (4) days: a) August 24, 2018: Level (L) Low QC run in High file showing out of range - 8 patients with CBC testing b) October 26, 2018: Level (H) High Platelets - Patient 000172452 c) May 4, 2018: Level (L) Low Platelets - Patient 00012253, 000171833, 000172708 d) May 8, 2018: Level (L) Low Platelets - Patients 171850, 171851, 171852, 171848, 171626, 170495 3. Further review of Quality Control and laboratory records revealed no corrective action log or documentation. 4. In interview on August 30, 2019 Personnel 2 and 3 confirmed no corrective action was documented for the above QC runs.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to monitor, assess, and correct quality issues in the Analytic Systems. Refer to D5783

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2128.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services in the Analytic System and to identify failures as they occur. Refer to D5791.

D6025

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure patient test results were reported only when system functioning properly. Refer to D5783

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401 & D5403.