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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 19D0676751 | (X3) Date Survey Completed 04/05/2018 |
| Name of Provider or Supplier Children's Pediatric Mandeville | Street Address, City, State 3020 Gause Blvd East, Slidell, 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 on April 5, 2018 at Mandeville Pediatric Clinic-CLIA ID # 19D0676751. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited. |
| D5411 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC). Findings: 1. Observation by surveyor during the laboratory tour on April 5, 2018 revealed the laboratory utilizes the Medonic for CBC testing. 2. Review of the laboratory's policy for CBC's revealed "If parameter of System information messages are generated, refer to User Manual Section 9." 3. Review of the Medonic Operator's Manual revealed the following messages and actions for flags: a) Hemoglobin (HGB) Indicators: Indicator: HL, Action: "Run a 'prime cycle,' before re-analyzing the sample 4. Review of the laboratory's CBC Quality Control records for March 2018 revealed the following eight (8) dates were reported without addressing flags: a) March 1, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control: HGB: 5.5 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 11.6 HL; HL-HGB measuring problem-run prime cycle High Control: HGB: 15.3 HL; HL-HGB measuring problem-run prime cycle b) March 19, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control: 5.4 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 12.0 HL; HL-HGB measuring problem-run prime</p> |

cycle High Control: HGB: 15.5 HL; HL-HGB measuring problem-run prime cycle c) March 20, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control: HGB: 5.5 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 11.8 HL; HL-HGB measuring problem-run prime cycle High Control: HGB: 15.4 HL; HL-HGB measuring problem-run prime cycle d) March 26, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control: HGB: 5.4 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 11.4 HL; HL-HGB measuring problem-run prime cycle High Control: HGB: 15.0 HL; HL-HGB measuring problem-run prime cycle e) March 27, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control: HGB: 5.4 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 11.7 HL; HL-HGB measuring problem-run prime cycle High Control: HGB: 15.2 HL; HL-HGB measuring problem-run prime cycle f) March 28, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control: HGB: 5.4 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 11.5 HL; HL-HGB measuring problem-run prime cycle High Control: HGB: 15.1 HL; HL-HGB measuring problem-run prime cycle g) March 29, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control : HGB: 5.4 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 11.6 HL; HL-HGB measuring problem-run prime cycle High Control: HGB: 15.0 HL; HL-HGB measuring problem-run prime cycle h) March 30, 2018: Autobackground: HGB: 0.0 HL; HL-HGB measuring problem-run prime cycle Low Control: HGB: 5.4 HL; HL-HGB measuring problem-run prime cycle Normal Control: HGB: 11.6 HL; HL-HGB measuring problem-run prime cycle High Control: HGB: 15.2 HL; HL-HGB measuring problem-run prime cycle 5. In interview on April 5, 2018 at 11:00 am, Personnel 2 stated she contacted the service representative for Medonics about the HGB flag. Personnel 2 stated she was told to calibrate the instrument. Personnel 2 further stated she calibrated the instrument which corrected the issue temporarily. Personnel 2 stated she recontacted the service representative and was told as long as the control values were within acceptable range the runs were ok to accept. 6. Review of the laboratory's "Instrument Action Log" form revealed the laboratory contacted Medonics on February 6, 2018 with the following problem noted: " HGB discrepancy." Further review revealed the laboratory contacted Medonics on March 16, 2018 with the following problem noted "HGB discrepancy still after calibration." The log revealed no further actions were documented since March 16, 2018. 7. Review of CBC patient test records from March 2018 revealed the following forty three (43) patients were reported without addressing HGB HL flags: March 1, 2018: Patients 1 -3 March 19, 2018: Patients 4-14 March 20, 2018: Patients 15-20 March 26, 2018: Patients 21-28 March 27, 2018: Patients 29-36 March 28, 2018: Patients 37-42 March 30, 2018: Patient 43 8. In interview on April 5, 2018 at 11:00 am, Personnel 2 stated the identified patients with HL flags for HGB were not repeated. Personnel 2 confirmed a the prime cycle was not re-run and patients re-analyzed per manufacturer's instructions. 9. In further interview, Personnel 2 contacted Medonics representative on April 5, 2018, while surveyor was on site and stated the representative told her for HGB HL flags to follow manufacturer's instructions.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5411.