

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1058162	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Rankin Children's Group	Street Address, City, State 281 Belle Meade Pointe, Flowood, MS	
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 the Abbott Cell-Dyn Emerald Operator's Manual, the Laboratory Procedure Manual, and 106 patient complete blood count (CBC) reports from 12/2/20 through 12/31/20, the laboratory failed to establish a written procedure for performing CBC testing and interpreting CBC results when patient results are flagged by the Abbott Cell-Dyn Emerald hematology analyzer, which was put in use for patient CBC testing on 5/2/19. Findings include: Review of the Abbott Cell-Dyn Emerald Operator's Manual revealed for WBC Measurand Flags - L1, L2, L3, L5 - the action required is "Follow your laboratory's review criteria or review a stained smear to</p>

confirm the differential results and verify the WBC (white blood cell count)." For Platelet Measurand Flags - P1, P2, P3 - the action required is "Review a stained smear to determine the cause and confirm the platelet count." Review of the Laboratory Procedure Manual revealed no procedure for addressing these WBC and Platelet Measurand Flags. Review of patient CBC reports from the Abbott Cell-Dyn Emerald from 12/2/20 through 12/31/20 revealed complete blood counts with flagged results for 51 patients reported on the following 19 days: 12/2/20 - 1 CBC with L3 flag. 12/3/20 - 4 CBCs with L3 flag, 1 CBC with L2L3 flag. 12/4/20 - 1 CBC with L3 flag, 1 CBC with L2L3 flag. 12/7/20 - 2 CBCs with L3 flag, 1 CBC with L2L3 flag. 12/8/20 - 2 CBCs with L3 flag, 1 CBC with L2L3 flag. 12/9/20 - 1 CBC with L3 flag, 3 CBCs with L2L3 flag. 12/10/20 - 1 CBC with L2L3 flag. 12/11/20 - 5 CBCs with L3 flag, 1 CBC with L2L3 flag. 12/14/20 - 4 CBCs with L3 flag, 2 CBCs with L2L3 flag. 12/15/20 - 1 CBC with L3 flag, 2 CBCs with L2L3 flag. 12/16/20 - 2 CBCs with L3 flag, 1 CBC with L2L3 flag. 12/17/20 - 1 CBC with L2L3 flag. 12/18/20 - 3 CBCs with L2L3 flag. 12/21/20 - 1 CBC with L2L3 flag. 12/22/20 - 1 CBC with L2L3 flag. 12/23/20 - 2 CBCs with L3 flag. 12/29/20 - 1 CBC with L3 flag, 1 CBC with L2L3 flag. 12/30/20 - 1 CBC with L2 flag, 2 CBCs with L2L3 flag. 12/31/20 - 1 CBC with L3 flag.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the Abbott Cell-Dyn Emerald Operator's Manual, used as the procedure for performing complete blood counts (CBC), and lack of documentation of review by the laboratory director, the laboratory director failed to approve, sign, and date the Operator's Manual before the Abbott Cell-Dyn Emerald hematology analyzer was put in use for patient testing on 5/2/19. Findings include: Review of the Abbott Cell-Dyn Emerald Operator's Manual, used as the procedure for performing complete blood counts since 5/2/19, revealed no documentation of the laboratory director's approval and signature.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on review of the verification of performance specifications for the Abbott Cell-Dyn Emerald hematology analyzer performed at installation and lack of documentation of review of these records, the laboratory director failed to ensure that the verification procedures used were adequate to determine the accuracy, precision, and linearity of the Abbott Cell-Dyn Emerald hematology analyzer, which was put in

use for patient complete blood count (CBC) testing on 5-2-19. Findings include: Review of the verification of performance specifications for the Abbott Cell-Dyn Emerald hematology analyzer revealed a linearity study, precision, and method comparison with the Beckman Coulter AcT diff 2 hematology analyzer were performed. However, there was no documentation of review of these records by the laboratory director to ensure these verification procedures were adequate to determine the accuracy, precision, and linearity of the Abbott Cell-Dyn Emerald hematology analyzer before the system was put in use for patient CBC testing on 5-2-19.

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 review of the Abbott Cell-Dyn Emerald Operator's Manual, the Laboratory Procedure Manual, and 106 patient complete blood count (CBC) reports from 12/2/20 through 12/31/20, the laboratory director failed to ensure a written procedure was available to testing personnel for performing CBC testing and interpreting CBC results when patient results are flagged by the Abbott Cell-Dyn Emerald hematology analyzer, which was put in use for patient CBC testing on 5/2/19. Findings include: Review of the Abbott Cell-Dyn Emerald Operator's Manual revealed for WBC Measurand Flags - L1, L2, L3, L5 - the action required is "Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC (white blood cell count)." For Platelet Measurand Flags - P1, P2, P3 - the action required is "Review a stained smear to determine the cause and confirm the platelet count." Review of the Laboratory Procedure Manual revealed no procedure for addressing these WBC and Platelet Measurand Flags. Review of 106 patient CBC reports from the Abbott Cell-Dyn Emerald from 12/2/20 through 12/31/20 revealed complete blood counts with flagged results for 51 patients were reported during this time frame. Refer to D5403 (Failure to establish a written procedure for flagged CBC results).