

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0317377	(X3) Date Survey Completed 06/06/2019
Name of Provider or Supplier Rankin Children's Group	Street Address, City, State 1405 Crossgates Drive West, Brandon, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) and verification of accuracy records since the last survey on 6-8-17 and confirmation by Testing Personnel #1, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to verify the accuracy of mycoplasma testing performed on the moderate complexity Meridian Bioscience ImmunoCard Mycoplasma test kit, at least twice annually, since 6-8-17. Findings include: Review of proficiency testing records revealed PT is not performed for mycoplasma testing. Review of verification of accuracy records since 6-8-17 revealed the accuracy of mycoplasma was verified by sending a split sample to the laboratory's reference lab on 8-17-17, 6-22-18, and 4-5-19. Testing Personnel #1 confirmed verification of accuracy for mycoplasma testing was not performed twice annually for 2018.</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. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)</p>

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 Procedure Manual and quality control records for mycoplasma testing with the moderate complexity Meridian Bioscience ImmunoCard Mycoplasma test from 2-8-17 through 6-3-19, the laboratory failed to establish quality control procedures for mycoplasma testing to include the number, type, and frequency of testing control materials. Findings include: Review of the Laboratory Procedure Manual revealed no quality control procedure for mycoplasma testing to include the number, type, and frequency of testing control materials. Review of the quality control records for mycoplasma testing with the moderate complexity Meridian Bioscience ImmunoCard Mycoplasma test from 2-8-17 through 6-3-19 revealed no documentation of the performance of controls for thirty-two days of patient testing during this time frame. Refer to 5449 (Failure to include a positive and negative control each day of patient testing).

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records for mycoplasma testing with the moderate complexity Meridian Bioscience ImmunoCard Mycoplasma test from 2-8-17 through 6-3-19, lack of documentation of an Individualized Quality Control Plan (IQCP), and confirmation by Testing Personnel #1, the laboratory failed to include a positive and negative control for thirty-two days of testing, during this time frame, when a total of thirty-nine mycoplasma tests were performed and reported. Findings include: Review of quality control records for mycoplasma testing from 2-8-17 through 6-3-19 revealed a positive and negative control were not documented, as performed, for the following days when patient testing was performed and results reported: 10-6-17-- Mycoplasma results reported for Patients #19271 and #6742. 10-30-17--Mycoplasma results reported for Patient #5035. 11-6-17--Mycoplasma results reported for Patient #36471. 11-10-17--Mycoplasma results reported for Patient #18869. 11-17-17-- Mycoplasma results reported for Patient #23020. 11-20-17--Mycoplasma results reported for Patient #20673. 12-11-17--Mycoplasma results reported for Patient #18683. 12-12-17--Mycoplasma results reported for Patients #19678 and #15286. 12-18-17--Mycoplasma results reported for Patient #11607. 12-19-17--Mycoplasma results reported for Patients #20261 and #24510. 1-24-18--Mycoplasma results

reported for Patient #94501. 1-25-18--Mycoplasma results reported for Patient #1475. 2-3-18--Mycoplasma results reported for Patient #20383. 2-26-18--Mycoplasma results reported for Patient #23921. 6-20-18--Mycoplasma results reported for Patient #14524. 11-29-18--Mycoplasma results reported for Patient #1304. 1-7-19--Mycoplasma results reported for Patients #24333 and #13398. 1-9-19--Mycoplasma results reported for Patient #12966. 1-10-19--Mycoplasma results reported for Patient #23222. 1-14-19--Mycoplasma results reported for Patient #23211. 1-28-19--Mycoplasma results reported for Patient #10987. 2-4-19--Mycoplasma results reported for Patients #14400, #20122, #18779. 2-12-19--Mycoplasma results reported for Patient #15395. 2-15-19--Mycoplasma results reported for Patient #13704. 2-19-19--Mycoplasma results reported for Patient #93317. 2-20-19--Mycoplasma results reported for Patient #93653. 3-12-19--Mycoplasma results reported for Patient #96267. 3-26-19--Mycoplasma results reported for Patient #22601. 4-3-19--Mycoplasma results reported for Patient #13918. 4-15-19--Mycoplasma results reported for Patient #96228 and #19985. 4-24-19--Mycoplasma results reported for Patient #24272. 6-3-19--Mycoplasma results reported for Patient #13845. Testing Personnel #1, listed on the CMS 209 personnel form, confirmed an IQCP was not established for mycoplasma testing with the Meridian ImmunoCard Mycoplasma test.

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.

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 review of personnel records, the CMS 209 personnel form, patient complete blood count (CBC) test reports, and lack of documentation of training, the laboratory director failed to ensure Testing Personnel #1, #2, #3, #4, #5, #6, and #7, listed on the CMS 209 personnel form, received appropriate training for performing CBC testing with the Abbott Cell-Dyn Emerald hematology analyzer, prior to testing patient specimens. Findings include: Review of personnel records for the testing personnel listed on the CMS 209 personnel form revealed no documentation of training on the Abbott Cell-Dyn Emerald hematology analyzer for Testing Personnel #1 through #7. Review of patient CBC test reports since 5-2-19 revealed all seven of these personnel have performed patient CBC testing with the Abbott Cell-Dyn Emerald hematology analyzer, since it was put into use for patient testing on 5-2-19.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of quality control records for mycoplasma testing with the moderate complexity Meridian Bioscience ImmunoCard Mycoplasma test from 2-8-17 through 6-3-19 and the technical consultant monthly review forms, the technical consultant documented monthly review of these quality control records, but failed to detect lack of performance of a positive and negative mycoplasma control for thirty-two days during this time frame, when a total of thirty-nine patient results were reported. Refer to D5449 (Failure to include a positive and negative control each day of patient testing).