

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0672192	(X3) Date Survey Completed 08/11/2021
Name of Provider or Supplier Brazosport Hematology/Oncology	Street Address, City, State 100-B Medical, Lake Jackson, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the laboratory's policies, a review of the laboratory's quality control records for the Medonic M- Series hematology analyzer for July 2021, and staff interview, it was revealed that the laboratory failed to verify 1 of 1 new lot number of external quality control for complete blood count (CBC) testing on the Medonic M- Series hematology analyzer before placing them into use. Findings include: 1. A review of the laboratory's policy titled 'Complete Blood Count using CDS Medonic M-Series Hematology Analyzer' revealed the following: "New lot numbers of QC materials should be overlapped with existing lot numbers at least once for proper reactivity: - Run the current lot number of QC materials - Run the new lot number of QC materials - Print out copies of all results and save with other QC documentation for a minimum of 2 years." 2. A review of the laboratory's quality control records for the Medonic M- Series hematology analyzer for July 2021 revealed there was no documentation of the laboratory performing lot to lot verifications for the following lot numbers of external quality control materials: Con-Diff Low Lot number: 22105-31 exp: 10/12/21 Con-Diff Norm Lot number: 22105-32 exp: 10/12/21 Con-Diff High Lot number: 22105-33 exp: 10/12/21 3. An interview with testing person #2 (as indicated on the CMS 209 form) on 8/10/21 at 11:30 a.m. in the conference room, after review of the records, confirmed the above findings. Key: QC = Quality Control

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:
 Based on a review of the laboratory's personnel records and staff interview, it was revealed that the technical consultant failed to ensure 5 of 5 competency assessments performed for Complete Blood Count (CBC) testing in 2020 evaluated direct observation of instrument maintenance and function checks on the Medonic M-Series hematology analyzer. Findings include: 1. A review of the laboratory's personnel records revealed 5 of 5 competency assessments performed by the technical consultant in 2020 for CBC testing failed to contain documentation of direct observation of instrument maintenance and function checks on the Medonic M-Series hematology analyzer. 2. An interview with technical consultant #1 (as indicated on the CMS 209 form) on 8/10/21 at 10:25 a.m. in the conference room, after review of the records, confirmed the above findings.

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 a review of the laboratory's policies, a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of the technical

consultant performing competency assessments, at least semiannually during the first year of testing, for 1 of 6 testing personnel. Findings include: 1. A review of the laboratory's policy titled 'New Hire and Returning Training and Re-Training' revealed the following: "All new hire laboratory personnel will be fully trained and familiar with the clinic laboratory within 6 months of hire. Each laboratory personnel will be evaluated and signed off by the charge nurse and laboratory director physician. Technical consultant or lab director will complete new hire checklist, which includes education and competency on the medonic equipment. Technical consultant will evaluate competency annually after 1st year and document on competency assessment sheet." 2. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 8/10/21) revealed the laboratory identified 6 testing personnel performing moderate complexity testing. 3. A review of the laboratory's personnel records revealed the following documentation for testing person #4: a) Testing person #4 Hired in 2/2020 Competency assessment: 5/29/20 and 7/1/21 Based on the hire date, testing person #4 should have had at least 2 competency assessments performed prior to 2/2021. 4. An interview with technical consultant #1 (as indicated on the CMS 209 form) on 8/10/21 at 11:55 a.m. in the conference room, after review of the records, confirmed the above findings.