

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0672192	<b>(X3) Date Survey Completed</b> 12/07/2022
<b>Name of Provider or Supplier</b> Brazosport Hematology/Oncology	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on the review of MLE proficiency records from August 2021 to September 2022, the laboratory personnel CMS 209 report, CMS 116 application, and confirmed in an interview found the laboratory failed to test the proficiency samples by personnel who routinely perform the testing in the laboratory for four of four hematology testing events. The findings were: 1. Review of MLE proficiency records from August 2021 to September 2022 revealed for four of four hematology testing events were all performed by TP#1. 2021 MLE-M3 Hematology 3rd event 2022 MLE-M1 Hematology 1st event 2022 MLE-M2 Hematology 2nd event 2022 MLE-M3 Hematology 3rd event 3. Review of the laboratory Personnel CMS 209 Report signed by the LD on 12/07/2022 revealed the laboratory has 6 TP. 4. Review of the laboratory's CMS 116 application signed by the LD on 12/07/2022 revealed the annual volume was 3000. 5. An interview with the director of laboratory service, a POCT medical technologist, and a lead registered nurse on 12/07/2022 at 9:50 am in the conference room/breakroom confirmed the above findings. Key: MLE=Medical Laboratory Evaluation CMS=Center of Medicare and Medicaid Services LD=Laboratory Director TP=Testing personnel POCT=Point-of-care</p>

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy, the laboratory daily logs from 12/1/2021 to 11/30/2022, CMS 116 application, and confirmed in interview revealed the laboratory failed to document daily maintenance for 50 of 50 days reviewed following the laboratory's policy on one of one Boule Medonic M-Series hematology instrument. The findings were: 1. Review of the laboratory's policy titled COMPLETE BLOOD COUNT using CDS MEDONIC M-Series Hematology ANALYZER under page 9 Daily Maintenance revealed " 1. Wipe OT sample probe and Pre-dilute probe with alcohol wipe. 2. Remove possible trace of salt crystals or blood at the top of the Open Tube probe, Pre-dilute probe, probe rinse cup, and around the top of the Cap Pierce. 3. Clean outside of instrument with soft cloth or DI water if needed." 2. Further review of the laboratory's policy titled COMPLETE BLOOD COUNT using CDS MEDONIC M-Series Hematology ANALYZER under page 7 Maintenance revealed "Daily cleaning should be performed according to the Medonic M-Series User's Manual....All maintenance should be documented (a maintenance log is recommended)...." 3. Random review of the laboratory's daily logs from 12/1/2021 to 11/30/22 revealed no documentation of daily maintenance for 50 of 50 days reviewed for one of one Boule Medonic M-Series hematology instrument (SN: 18551). 4. Review of the laboratory's CMS 116 application signed by the LD on 12/07/2022 revealed the annual volume was 3000. 5. An interview with the director of laboratory service, a POCT medical technologist, and a lead registered nurse on 12/07/2022 at 11:40 am in the conference room/breakroom confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services LD=Laboratory Director POCT=Point-of-care