Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0672192	09/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Brazosport Hematology/Oncology	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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory Medical Laboratory Evaluation (MLE) proficiency test records from 2018 and 2019, laboratory records, and confirmed in interview, the laboratory failed to verify the accuracy of their hematology testing after receiving a score of 0% for failure to participate in 1 of 4 PT events. Findings were: 1. Review of the MLE testing events from 2018 and 2019 revealed 1 of 4 events (MLE event 2) when the laboratory received a grade of 0% for failure to participate. The laboratory missed the cutoff to submit test results. 2. Review of the laboratory MLE event 2 proficiency test records revealed no documentation of the self-evaluation for 5 of 5 specimens analyzed. MLE event 2 HD 06 HD 07 HD 08 HD 09 HD 10 2. An interview with the testing person #2 on 9/24/19 at 1435 hours in the conference room confirmed the above findings. She was unaware the laboratory was required to perform a self-evaluation of the MLE results.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5401, D5421, 5783
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review manufacturer's instructions, laboratory policy, patient results, and confirmed in interview, the laboratory failed to follow the laboratory policy to resolve CBC flags prior to their release to the healthcare provider on the Medonic M-series hematology analyzer. The findings were: 1. Review of the manufacturer's instructions for the Medonic M-series hematology analyzer under section 9: Parameter and System Information Messages, under "Introduction" stated, "The Medonic M-Series has several parameter and system information messages related to the measured parameters and the instrument. These messages alert the operator of possible pathologic samples and parameter value and instrument errors." 2. Further review of the operator's manual under, "System Information Messages" stated: "HF Message: HGB Measuring Problem - run prime cycle Action: Run a "Prime cycle," before re-analyzing the sample." "OM Message: WBC DIFF: Only one WBC population found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." "BD Message: WBC DIFF: High interference between populations. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." "TM Message: WBC DIFF: Too many WBC population found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 3. Review of the laboratory's policy for Complete Blood Counts Using CDS Medonic M-Series Hematology Analyzer revealed "results with these flags: BD, NM, OM, TM indicate that the blood sample is too old or there is a pathological issue. These specimens should be sent to CHI St. Luke's lab to be verified." 4. Random review of patient test records from February, July, August 2019 and December 2018 revealed 11 of 20 patient test records with the following flags and no documentation of the verification of the results per the laboratory policy. Date Patient ID Flag 08/01 /19 3835 OM 08/05/19 3862 OM 08/07/19 3925 BD 08/20/19 4131 BD 08/28/19 4263 OM 07/02/19 3352 OM 07/11/19 3498 OM 02/04/19 7928 TM 02/25/19 8234

	OM 12/03/18 7027 BD 12/17/18 7244 OM 5. An interview with testing person #2 on 9 /24/19 at 1440 hours in the conference room confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to document the verification studies for the new Medonic M-series hematology analyzer: Findings were: 1. Review of the manufacturer's instructions (P/N 203050D R 03.17.09) revealed "CLIA regulations require that all new analyzers have testing performed to validate: the analytical measurement range (AMR or linearity) of the instrument; the accuracy and precision of the instrument." 2. Review of the laboratory records revealed the laboratory received a new Medonic M-series hematology analyzer in 05/2019 (SN18551). 3. Review of the laboratory records revealed no documentation of the linearity, accuracy and precision studies of the new instrument. 4. An interview with the laboratory director on 9/24/19 at 1530 hours in the conference room confirmed the above findings. She stated that the laboratory performed controls but no linearity, accuracy and precision prior to patient testing. She was unaware the laboratory was required to perform verification studies on the new instrument.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records, patient test records, and confirmed in interview, the laboratory failed to document corrective actions when quality control was outside of the acceptable limits for the Medonic M-series hematology analyzer. Findings were: 1. Review of the laboratory policy Laboratory Quality Control Program revealed "upon detection of QC failure, appropriate actions will be taken in accordance with manufacturer's guidelines for the system in question. Corrective actions will be documented on the troubleshooting log for systemic instrument problems identified...corrective actions for random errors, reagent problems, or calibrator/control problems will be documented directly on the QC log

	for the run involved." 2. Random review of the quality control records from December 2018, February, July, and August 2019 revealed the following days with quality control outside of the acceptable limits and no documentation of the corrective action. Lot 2180831 12/26/18 lot 2180832 12/3/18 lot 2180833 12/3/18 12/4/18 12/13/18 lot 2190521 07/01/19 07/15/19 lot 2190522 07/10/19 lot 2190523 07/15/19 3. Random review of the patient test records of the above dates revealed the laboratory performed CBC testing on the following dates. Date Patient ID 12/03/18 7016 7020 7025 12/04 /18 7040 7043 7048 12/13/18 7215 7219 7222 12/26/18 7332 7333 7340 07/01/19 3303 3310 3319 07/10/19 3451 3454 3457 07/15/19 3524 3529 3533 4. An interview with the testing person #2 on 9/24/19 at 1435 hours in the conference room confirmed the above findings. She acknowledged that the testing person should document their corrective actions.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007, D6013, and D6020)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology. Refer to D5401.
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 laboratory verification records and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete verification studies for the Medonic M-series hematology analyzer prior to start of patient testing. Refer to D5421
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and confirmed in interview, the laboratory director failed to ensure the laboratory established and maintained a quality control program. Refer to D5783
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education to qualify them for moderately complex testing for 2 of 4 testing personnel. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a

	high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education to qualify 2 of 4 testing personnel for moderately complex testing for CBC (complete blood count) on the Medonic M-Series hematology analyzer. Findings were: 1. A review of personnel records available revealed no documentation of education for 2 of 4 testing personnel (TP#3, TP#4). TP#3 (date of hire 9/8/15) TP#4 (date of hire 8/7/19) 2. An interview with the testing person #2 on 9/24/19 at 1430 hours in the conference room confirmed the above findings. CMS - Centers of Medicare and Medicaid Services This is a repeat deficiency from the 4/25/17 survey.