Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0497096	06/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Brazosport Clinical Laboratory Inc	54 Flag Lake Plaza, 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 to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for storage of test kits. The findings were: 1. Direct observation on June 19, 2018 at 0925 in the testing person's office revealed the following items stored in an overhead cabinet: a. Hemocue Hb 201 Microcuvettes (4 unopened boxes): lot 1709238 b. Consult 10SG Urine Reagent Strips (1 unopened box): lot URS7100115 2. Further observation revealed no means to monitor and document the room temperature of the office where the items were stored. 3. Review of the manufacturer's instructions for the Hemocue Hb 201 Microcuvettes (PN 151712 160127) under,

	"Storage and handling" stated, "Storage for individually packaged cuvettes: The microcuvettes are to be stored at room temperature (15-30 degrees Celsius, 59-86 degrees Fahrenheit) and in a dry place." 4. Review of the manufacturer's instructions for the Consult 10SG Urine Reagent Strips under, "Storage and Stability" stated, "Store as packaged in the closed canister or the sealed pouch either at room temperature or refrigerated (2-30 degrees Celsius or 36-86 degrees Fahrenheit." 5. The findings were confirmed in interview with the testing person on 06/19/2018 at 0930 hours in her office.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on a review of proficiency testing records from 2016 (event 3), 2017 (events 1, 2, 3), and 2018 (event 1) and confirmed in interview of facility personnel, it was revealed that the facility failed to test all proficiency samples in the same manner as it tests patient specimens. The findings were: 1. A review of five proficiency testing events (there are three events per year) from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (event 1) revealed that the testing person repeated each proficiency test sample three times. 2. An interview with the testing person on June 19, 2018 at 1015 in her office confirmed the findings. When asked if each patient sample was ran three times and if that was how the laboratory performed patient testing, she stated, "No."
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records from 2016 (event 3), 2017 (events 1, 2, and 3) and 2018 (event 1), and confirmed in interview of facility personnel, the laboratory failed to retain attestation statements for 1 of 5 testing events. The findings were: 1. A review of five proficiency testing events (there are three events per year) from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (event 1) revealed that the laboratory failed to provide documentation of retaining the attestation statement for the 3rd testing event in 2016. 2. An interview with the testing person on June 19, 2018 at 1015 in her office confirmed the findings.

D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, review of quality assurance reports, and confirmed in interview of facility personnel, the laboratory's quality assurance plan failed to identify that the laboratory was not handling proficiency testing samples the same way as patient samples. The findings were: 1. Review of proficiency testing records from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (event 3) revealed that the laboratory tested each proficiency testing sample three times. 2. Review of the laboratory's quality assurance reports from 3rd quarter 2016, 1st quarter 2017, 2nd quarter 2017, 3rd quarter 2017, and 1st quarter 2018 revealed the reports stated, "Tests were ran 3 times. The additional two proficiency tests are attached to this form." 3. An interview with the testing person on June 19, 2018 at 1015 in her office confirmed the findings. When asked if each patient sample was ran three times and if that was how the laboratory performed patient testing, she stated, "No."
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of patient reports, and confirmed in interview of facility personnel revealed the laboratory's policy failed to resolve flags on CBC (complete blood count) results. The findings were: 1. Review of the laboratory's policy "Protocol for Medonic M-Series WBC Differential Abnormalities" approved by the laboratory director on 09/15/2016 stated under "Brazosport Lab Protocol" for "BD, NM, OM, and TM" flags: "The

	testing personnel will use a white piece of paper and cover up these readings as they are not considered to be accurate. If these reading are needed, the ordering provider will order a CBC with differentials at an outside lab." 2. Review of the manufacturer's instructions for the Medonic M-Series hematology system analyzer (Article no: 1504248, May 2009) stated, ""Abnormalities: Follow your laboratory's protocol for verification on all samples with anomalies and/or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability toward lysing of their ctyoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments." And, BD - WBC DIFF: high interference between populations: Blood sample too old or pathological sample. Action: Follow laboratory's protocol for verification of results. OM - 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. TM - WBC DIFF: too many WBC populations found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 3. Random review of patient final reports from April 2018 and May 2018 revealed the following patient results that were resulted with flags: Patient ID: 20452JA Date: 04/10/2018 Patient ID: 25584RO Date: 04/17/2018 Patient ID: 23503AM Date: 04/23/2018 Patient ID: 26623CO Date: 05/04/2018 Patient ID: 26161AL Date: 05/15/2018 4. The findings were confirmed in interview of the testing person on 06/19/2018 at 1230 hours in the office. She revealed that the provider is notified verbally of the flags and then the decision for follow-up is made. Key: WBC - white blood count DIFF - differential
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 review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competencies twice within the first year for testing for 1 of 1 testing persons. The findings were: 1. A review of the laboratory's personnel records revealed testing personnel number 1 (as listed on Form CMS 209) started employment with the laboratory on February 22, 2017. 2. Further review of the personnel file for testing personnel 1 revealed documentation of only 1 competency assessment being performed within the first year of employment. The competency assessment was performed on February 23, 2017. 3. On June 19, 2018 at 0940 hours in the testing person's office, the laboratory was asked to provide documentation of the technical consultant performing a second competency assessment on testing personnel 1 within her first year of patient testing. No documentation was provided. 4. An interview with the testing person on 06/19/2018 at 0940 hours in her office confirmed the findings. When asked if she received a 2nd competency assessment within her first year of patient testing, she stated, "No."
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 staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 testing personnel (refer to D6065). Key: CMS - Centers for Medicare and Medicaid Services
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 files, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 06/15/2018) revealed the laboratory identified 1 testing personnel. 2. A review of the laboratory's personnel records revealed 1 of 1 testing personnel did not have documentation of education to qualify them to perform moderate complexity testing. Testing personnel #1 had a start date of 02/22/2017 and was currently performing patient testing as of the survey on 06 /19/2018. 3. An interview with the office manager on 06/19/2018 at 1245 hours in the testing person's office revealed the laboratory did not have documentation of education for testing personnel #1. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services