Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0941055	(X3) Date Survey Completed 09/22/2021
Name of Provider or Supplier Heart Institute Of Brownsville,Llp	Street Address, City, State 213 Heart Drive, Brownsville, 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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 the manufacturer's user manual for the Medonic M-series hematology analyzer, review of the laboratory's policies, random review of patient test results for December of 2019 and September of 2021 and interview with the staff it was determined the laboratory failed to establish and follow protocols for flagged Complete Blood Count (CBC) results. The findings were: 1. Review of the manufacturer's user manual for the Medonic M-series hematology analyzer (published May 2009) revealed: "Abnormalities: Follow your laboratory's protocol for verification on all samples with anomalies and/or abnormal distributions signaled by the instrument." And, "BD - WBC DIFF: high interference between populations. Action: Blood sample too old or pathological sample. 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." 2. A review of the laboratory's "Policy for Handling Flagged CBC Differentials" (signed into effect by laboratory director on June 30, 2016) revealed: "It will be the policy of this laboratory to return (sic) flagged CBC results. If the second run still shows flags, then lab will evaluate the flagged differentials according to the procedures in the unit's operator manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure is correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature for 15 to 20 minutes, or by re-drawing the patient. If the flags disappear, then report that result. If the flags persist, follow the manufacturer's instructions." 3. Further review of the "Policy for Handling Flagged CBC Differentials" revealed there were no protocols established on how to address the flags with a slide review, or other verification of results' protocols as per manufacturer's instructions. 4. Random review of patient test results for December of 2019 and September of 2021 identified the following patients with flagged CBC results that were reported to provider: ID: 060373 Tested: 12/02/2019 Sequence: 6647 Flag: OM ID: 081328 Tested: 09/16/2021 Sequence: 2337 Flag: BD 5. In an interview on 09/22/2021 at 1045 hours in the conference room the Technical Consultant (as stated in the Form 209 signed by the laboratory director on 09/22/2021) stated that repeat flagged results are not to be reported and the sample is to be sent for review to a reference laboratory. This confirmed the findings. Key: WBC-White Blood Cells
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's January to August 2021 Quality Control records for the ALERE Triage MeterPRO (# 00078103) instrument (used in testing for cardiac enzymes), review of laboratory's policies and interview with the staff it was determined the laboratory failed to document over time review of daily quality control records for 8 of the 8 months reviewed. The findings were: 1. Review of the laboratory's January to August 2021 Quality Control records for the ALERE Triage MeterPRO # 00078103 revealed there was no documentation of over time review of the daily quality control records. 2. Review of the laboratory's policies revealed there was no policy in place to address review of daily quality control over time for the ALERE Triage MeterPRO instrument. 3. In an interview on 09/22/2021 at 1030 hours in the conference room the Technical Consultant (as stated in the Form 209 signed by the laboratory director on 09/22/2021)stated that the laboratory does not have documentation of over time review of the daily quality control records for the ALERE Triage MeterPRO instrument. This confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan records, review of the laboratory's quality control records for the ALERE Triage MeterPRO instrument (used in testing for cardiac enzymes) and interview with the staff, it was determined the laboratory failed to verify acceptability of controls with concurrent testing for 3 of 3 control lots reviewed. The findings were: 1. Review of the laboratory's Individualized Quality Control Plan (IQCP) records for cardiac enzymes revealed the laboratory modified the frequency of quality control testing on the ALERE Triage MeterPRO instrument from each day of testing to every 30 days. 2. Review of the laboratory's quality control records for the ALERE Triage MeterPRO instrument revealed there was no documentation of running control concurrent with established control testing as follows: Control Lot C3673AN, Exp. 2021-11-07 Opened: 04/21/2021 Tested:04/21/2021 and 05/19/2021 Control Lot C3660AN, Exp. 2021-09-11 Opened: 6/29/2021 Tested: 06/29/2021 and 07/27/2021 Control Lot C3674AN, Exp.2021-11-25 Opened:08/24/2021 Tested 08/24/2021 and 09/21/2021 3. In an interview on 09/22/2021 at 1030 hours in the conference room the Technical Consultant (as stated in the Form 209 signed by the laboratory director on 09/22/2021) stated that the laboratory does not verify acceptability of controls with concurrent control testing for the ALERE Triage MeterPRO instrument. This confirmed the findings.