Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1073935	**(X3) Date Survey Completed** 06/02/2023
Name of Provider or Supplier Hca Houston Healthcare Er 24/7 Pearland	**Street Address, City, State** 2906 Broadway Street, Pearland, 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 was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 manufacturer's instruction for use, the laboratory's maintenance logs from January 2023 to March 2023, patient results, and confirmed in an interview, the laboratory failed to perform four of six bi-weekly maintenance following the manufacturer's instructions on one of one pocH-100i hematology analyzer. The findings were: 1. Review of the manufacturer's instruction for use (Code No. AJ021414 na. Date of Last Revision: 10/2017. Software Version: 00-23 and onwards.) under pg. 10 Maintenance revealed "Every two weeks (for 150 samples)-Clean Transducer." 2. Further review of the manufacturer's instruction for use under 4.1.4 Clean transducer revealed "Note: A message will appear when either the counter value exceeds 150 or 2 weeks have passed since the last cleaning of the transducer." 3. Review of the laboratory's maintenance logs from January 2023 to March 2023 revealed the laboratory failed to have documentation for four of six bi-weekly maintenance on pocH-100i hematology analyzer (SN: 66585). 1/22/2023-1/29/2023 2 /25/2023-3/4/2023 3/11/2023-3/18/2023 3/25/2023-3/31/2023 4. Review of the patient results for the above date revealed 119 patients had CBC test. Refer to CBC patient results alias. 5. An interview with the technical consultant #1 and the testing personnel #1 on 5/31/2023 at 2:30 pm in the break room confirmed the above findings. Key: CBC=Complete blood count

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, records, CMS 116 application, and confirmed in an interview, the laboratory failed to follow its own policy to have documentation for two of two calibration verification in 2022 on one of one pocH-100i hematology analyzer. The findings were: 1. Review of the laboratory's policy#13464378 on pg.3 under Calibration/calibration verification criteria revealed "At least every six months". 2. Review of the laboratory's records in 2022 revealed no documentation for two of two calibration verification on pocH-100i hematology analyzer (SN: G6585). 3. Review of the laboratory's CMS 116 application, signed by the laboratory director on 5/30/2023, revealed the annul hematology volume was 7000. 4. An interview with the technical consultant #1 on 5/31/2023 at 3:00 pm in the break room confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, QC records, patient results, and confirmed in an interview, the laboratory failed to perform two quantitative QC materials with different concentrations prior to patient testing for 57 of 59 days reviewed for PT/INR test on one of one Hemochron Signature Elite. The findings were: 1. Review of the laboratory's policy titled Laboratory Quality Management Plan CL-ML (PolicySTAT ID: 13402163) under Quality revealed the Hemochorn for PT /INR was not listed for IQCP. 2. Review of the laboratory's QC records from January 2023 to February 2023 revealed two level quantitative QC materials with different concentrations were not performed for 57 of 59 days reviewed. 1/1/2023-1/9/2023 1 /11/2023-2/6/2023 2/8/2023-2/28/2023 3. Review of the patient results from above revealed nine patients had PT/INR tests performed on Hemochron Signature Elite. 2/6 /23 Sample ID: G00128657369 2/9/23 Sample ID: WP4-01000000 2/9/23 Sample ID: WP4-02000000 2/9/23 Sample ID: WP4-03000000 2/9/23 Sample ID: WP4-

	04000000 2/9/23 Sample ID: WP4-05000000 2/15/23 Sample ID: G00128710921 2/19 /23 Sample ID: G00128732066 2/19/23 Sample ID: G00128731862 4. An interview with the technical consultant #2 on 5/31/2023 at 4:15pm in the break room confirmed the above findings. Key: QC=Quality Control IQCP=Individulized Quality Control Plsn
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies, QC Plan, QC records, CMS 116 application, and confirmed in an interview, the laboratory failed to have documentation of acceptable QC activities to support the frequencies stated in its own QC plan for two of two Quidel Triage Meter Pro of three of three moderate complexity tests: Troponin, D-Dimer, and urine drug screen. The findings were: 1. Review of the laboratory's policy titled Laboratory Quality Management Plan CL-ML (PolicySTAT ID: 13402163) under Quality revealed "The following test/equipment /device will have an Individualized Quality Control Plan (IQCP)....c. Triage (D-Dimer, UDS, Troponin)..." 2. Review of the laboratory's QC Plan for Quidel Triage Meter Pro, signed by LD in 2022, for three moderate complexity tests: Troponin, D-Dimer, and Tox drug screen revealed under monthly "Run two levels of controls on all instruments..." 3. Review of the laboratory's QC records revealed no documentation of acceptable QC activities to support the frequencies stated in its own QC plan. 4. Review of the laboratory's CMS 116 application, signed by the laboratory director on 5/30/2023, revealed the annul chemistry volume was 16000 and the annul hematology volume was 7000. 5. An interview with the technical consultant #2 on 5 /31/2023 at 4:15pm in the break room confirmed the above findings. Key: IQCP=Individualized Quality Control Plan QC=Quality Control CMS=Center for Medicare and Medicaid Services LD= Laboratory Director
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 review of the laboratory's QC plan and QC records, patient results, and confirmed in an interview, the Laboratory Director failed to ensure the laboratory provided quality services for all aspects of test performance. Refer to D5447 and D5481.