Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0492871	02/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
North Houston - Trmc, Llc Dba Hca Houston Er 24 /7	10655 Steepletop, Houston, 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	An announced validation survey was performed from February 6, 2024 to Feburary 7, 2024. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D2077	GENERAL IMMUNOLOGY CFR(s): 493.837(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of API proficiency testing Policy, API proficiency testing records in 2023, and confirmed in an interview, the laboratory failed to have documentation of self-evaluation for not participating for one of one regulated analyte, Infectious mononucleosis, in 2023 Immunology/Immunohematology - 2nd Event. The findings were: 1. Review of API Proficiency Testing Performance Evaluation page revealed "Laboratories are responsible for documenting and performing corrective actions for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of the laboratory's API PT records in 2023 revealed two of two samples for infectious mononucleosis was "Failure to participate" in 2023 Immunology/Immunohematology - 2nd Event

	2023 Immunology/Immunohematology - 2nd Event Analyte: Infectious mononucleosis, Sample: IM-06 Sample: IM-07 3. Review of the API Participant Data Summary revealed the peer results for IM-06 as Positive and IM-07 as Negative. 4. Review of the laboratory's API 2023 Immunology/Immunohematology - 2nd Event revealed no documentation of self-evaluation comparing to the participant data summary of infectious mononucleosis. 5. In an interview on 02/01/2024 at 12:00 pm in the office, the laboratory manager confirmed the findings. Key: API= American Proficiency Institute PT=Proficiency Testing TP=Testing personnel
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, maintenance logs in 2023, patient results, and confirmed in an interview, the laboratory failed to document two of four quarterly maintenance for Sysmex XP-300 hematology Analyzer. The findings were: 1. Review of the laboratory's policy titled FSED Sysmex XP-300 Maintenance & QC Policy under Quarterly (or every 4500 samples) Maintenance revealed "Clean SRV once every 3 months or when "Clean SRV" appears every 4500 cycles." 2. Review of the laboratory's maintenance logs in 2023 revealed the laboratory had no documentation of cycles. 3. Further review of the laboratory's maintenance logs in 2023 revealed the laboratory failed to document two of four quarterly maintenance for Sysmex XP-300 hematology Analyzer (SN: A7341). Quarterly maintenance performed and documented on 04/04/2023 Next quartly maintenance due: 07/04/2023 Quarterly maintenance performed and documented on 09/05/2023 and 09/18/2023 Next quartly maintenance due: 12/18/2023 4. Review of the patient results revealed the laboratory performed 589 patient CBC testing from 07/04/2023 to 09/04/2023 and 656 patient CBC testing from 12/18/2023 to 01/04/2024. 5. In an interview on 02/06 /2024 at 1:47 pm in the office, the laboratory manager confirmed the findings. Key: CBC=Complete Blood Count
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 the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have U.S. equivalency documentation to qualify 4 of 17 testing personnel (TP) who performed moderate complexity testing. (Refer to 6065).
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 the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have U.S. equivalency documentation to qualify 4 of 17 TP who performed moderate complexity testing. The findings were: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report, signed by the LD on 01/29/2024, revealed the laboratory identified 17 TP who performed moderate complexity testing. 2. Review of the laboratory's TP educational credential records revealed the laboratory failed to have U.S. equivalency documentation to qualify 4 of 17 TP who performed moderate complexity testing. According to CMS form 209, signed by the laboratory director on 01/29/2024, TP# 2 TP# 3 TP# 4 TP# 17 3. In an interview on 02/06/2024 at 10:00 am in the office, the laboratory manager confirmed the findings. Key: CMS=Center of Medicare and Medicaid Services U.S.=United States TP=Testing personnel LD=Laboratory Director