Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2007040	05/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Townsen Memorial Hospital	1475 Fm 1960 Bypass East, Humble, 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 of the laboratory was conducted on 05/12/2026. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). 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
D5309	TEST REQUEST CFR(s): 493.1241(e) (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of laboratory's test menu, manufacturer instructions, laboratory's test records and staff interviews, the laboratory failed to ensure the laboratory's information system (LIS) transcribed lactate specimen type correctly from the order to the final report for four of eight final reports reviewed from February and March 2026. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory offers blood gases (PO2, PCO2), pH and lactate testing by using the i-STAT CG4+ cartridge with the i-STAT 1 System. 2. Review of manufacturer instructions "i-STAT CG4+ CARTRIGE" (document 767935-00 Rev. B, Rev. Date: 07-Sep-2020) revealed: "The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of pH, PO2, PCO2, and lactate in arterial and venous whole blood in point of care or clinical laboratory settings." 3. In an interview on 05/12/2026 at 1130 hours in the conference room the laboratory's testing person number one (as indicated on submitted CMS Form 209) stated that the laboratory performed CG4+ cartridge testing on both arterial and venous blood, each having a separate order in the LIS. He also stated that the collector designated whether the sample is venous or arterial blood. 4. Review of laboratory's test orders, records

	and final reports for arterial blood samples from February and March 2026 revealed the following final reports had the correct arterial blood designation (ABG) on the report for the blood gasses and pH results, but the lactate had the designation of venous blood (Ven) erroneously transcribed by LIS from the order: Sample: MR#: Tested: 0205:BG00002S MR00143894 02/05/2026 0213:BG00002S MR00145933 02 /13/2026 0304:BG00001S MR00147974 03/04/2026 0304:BG00002R MR00147974 03/04/2026 Key: MR# - Medical record number 5. In an interview on 05/12/2026 at 1200 hours in the conference room the laboratory's technical supervisor (as indicated on submitted CMS Form 209) confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory's quality assurance records and staff interview, the laboratory's quality assurance failed to identify and correct issues with arterial blood specimen type transcription for one of four analytes tested using the i-STAT CG4+ CARTRIGE. Refer to D5309.
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 manufacturer instructions, laboratory's IQCP (Individualized Quality Control Plan), policies/procedures, patient test records and staff interview, the laboratory failed to ensure overall quality of analytic processes was maintained for one of three test platforms used by the laboratory from 2024 through 2026, the i-STAT 1 System. Refer to D5411.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's IQCP (Individualized

	Quality Control Plan), policies/procedures, patient test records and staff interview, the laboratory failed to ensure requirements for i-STAT CG4+ CARTRIGE testing on the i-STAT 1 System were followed for two of eight patient test records reviewed from February and March 2026. Findings included: 1. Review of manufacturer instructions "i-STAT CG4+ CARTRIGE" (document 767935-00 Rev. B, Rev. Date:07-Sep-2020) revealed: "Blood Collection Options and Test Timing (time from collection to cartridge fill) Analyte Test Timing pH 10 minutes PCO2 10 minutes PO2 10 minutes Lactate Immediately" 2. Review of laboratory's "IQCP PLAN: I_STAT CG4+ (pH, PCO2, PO2, Lactate.) 2025" revealed: "All CG4+ samples will be run within 10 minutes of collection. 2025 data met criteria." 3. Review of laboratory's policies /procedures revealed the laboratory did not have protocols in place addressing rejection criteria for samples not tested within 10 minutes of collection. 4. Review of Laboratory's patient test records February and March 2026 revealed the following test timing: Patient Medical Record: MR00145933 Collected: 02/13/2026 at 1349 hours Received: 02/13/2026 at 1407 hours Results finalized: 02/13/2026 at 1409 hours Time tested (Instrument Printout): 02/13/2026 at 1405 hours Elapsed time from collection to instrument testing: 16 minutes Patient Medical Record: MR00148815 Collected: 03 /07/2026 at 2038 hours Received: 03/07/2026 at 2055 hours Results finalized: 03/07 /2026 at 2105 hours Time tested (Instrument Printout): 03/07/2026 at 2101 hours Elapsed time from collection to instrument testing: 27 minutes 5. In an interview on 05 /12/2026 at 1120 hours in the conference room the laboratory's technical supervisor (as indicated on submitted CMS Form 209) stated that sometimes collection/receipt times entered in the system are incorrect, but after review of the data presented, confirmed the findings.
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. This STANDARD is not met as evidenced by: Based on review of laboratory's policies procedures, quality control (QC) records and staff interview, the laboratory failed to define and document evaluation of QC over time for two of two chemistry test platforms used by the laboratory in 2024 and 2025, the Triage Meter Pro and the i-STAT 1 System. Findings included: 1. Review of laboratory's policies/procedures revealed the laboratory's documents did not define requirements for evaluation of QC over time for two of its test platforms, the Triage Meter Pro and the i-STAT 1 System. 2. Review of laboratory's QC records revealed there was no documentation of QC evaluation over time for either the Triage Meter Pro or the i-STAT 1 System analyzers. 3. In an interview on 05/12/2026 at 1050 hours in the conference room the laboratory's technical supervisor (as indicated on submitted CMS Form 209) confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory's quality assurance records and staff interview the laboratory's quality assurance failed to identify and correct issues in following testing requirements for one of two moderate complexity i-STAT 1 System cartridges, the i-STAT CG4+ CARTRIGE. Refer to D5411.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient's Complete Blood Count (CBC) test reports from November 2025 to January 2026 and staff interview, the laboratory failed to document the correct abbreviation for Mid Cell Population cells (MID), that matched the analyzer printout, on six of six patient test reports reviewed. Findings include: 1. A random review of analyzer printouts from the Medonic M-Series hematology analyzer revealed the laboratory provided a three part differential as part of the CBC that included: - Granulocytes # and Granulocytes % - Lymphocytes # and Lymphocytes % - Mid Cell Population # and Mid Cell Population % 2. A random review of patient test reports from November 2025 to January 2026 revealed the laboratory failed to include the correct abbreviation for Mid Cell Population cells- MID# (absolute) and MID% (percentage), that matched the analyzer printout, on the following 6 patient's test reports: Patient ID: 022597 Resulted: 11/7/25 Patient ID: 023346 Resulted: 11/26/25 Patient ID: 024229 Resulted: 12/16/25 Patient ID: 024383 Resulted: 12/18/25 Patient ID: 024385 Resulted: 12/18/25 Patient ID: 025317 Resulted: 1/11/26 *The above listed patient reports documented Monocytes- MONO# and MONO% instead of Mid Cell Population cells- MID# and MID%. 3. In an interview on 5/12/26 at 10:18 a.m. in the conference room, after review of the records, the laboratory director confirmed the above findings.
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 manufacturer instructions, laboratory's IQCP (Individualized Quality Control Plan), policies/procedures, patient test records, quality assurance records and staff interviews, the laboratory director failed to ensure overall laboratory management and oversight was maintained for one of three test platforms used by the laboratory from 2024 through 2026, the i-STAT 1 System. Findings included: 1. The laboratory director failed to ensure testing is performed as required for one of two moderate complexity i-STAT 1 System cartridges, the i-STAT CG4+ CARTRIGE. Refer to 6014. 2. The laboratory director failed to ensure laboratory's quality assurance identified and corrected issues in analytic systems. Refer to 6020.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's IQCP (Individualized Quality Control Plan), policies/procedures, patient test records and staff interview, the laboratory director failed to ensure testing is performed as required for one of two moderate complexity i-STAT 1 System cartridges, the i-STAT CG4+ CARTRIGE. Refer to D5411.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory's quality assurance records and staff interview, the laboratory director failed to ensure laboratory's quality assurance identified and corrected issues in analytic systems. Refer to D5791.