Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0487422	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
North Texas Medical Center	1900 Hospital Blvd, Gainesville, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing and interview with the Technical Supervisor the laboratory failed to have correction action on results for the analytes Direct Bilirubin and Neonatal Bilirubin for the testing events 2017 3 event 2018 1 event 2018 2 events. Findings Included: Review of API proficiency revealed 20% for Direct Bilirubin in the 3rd testing event of 2017, 40% for Direct Bilirubin in the 1st testing event in 2018, 40% for Direct Bilirubin in the 2 2nd testing event of 2018, 0% for Neonatal Bilirubin the 3rd testing event in 2017, and 50% for Neonatal Bilirubin in the 1st testing event of 2018 correction action failed to correct the problem. During an interview on 05/14/2019 at 11:00 AM the Technical Supervisor confirmed that there was no corrective action failed to correct the problem for the aforementioned testing events.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: A review of the laboratory's policies and procedures and staff interview, it was revealed the laboratory failed to have documentation of quality assessment policies

	and procedures to identify, monitor and assess problems in the general laboratory systems . The findings were as follows: a. A review of the laboratory's policies and procedures revealed the laboratory failed to have documentation of a quality assessment program to identify, monitor, and assess problems in the general laboratory's systems. b. The laboratory was asked to provide documentation of a quality assessment plan (Proficiency Testing). c. An interview with Technical Supervisor as listed on Form CMS 209 on 05/14/2019 at 11:27 hours in the office revealed the laboratory failed to have quality assessment documentation. This confirmed the findings. refer to D5227
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A review of the laboratory's Individualized Quality Control Plans,(IQCP) and staff interview, revealed the laboratory failed to have documentation of establishing new Individualized Quality Control Plans frequency . The findings were: a. A review of the laboratory's IQCP Serum HCG 30 days I-STAT 30 days Leuko EZ 30 days Triage Cardiac Panel 30 Days Mono Immumio Stat 30 days . The laboratory failed to provide documentation for the frequency performing Quality Control .b An interview with the technical supervisor on 05/14/2019 at 1438 hours in the office - 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: A. Based on review of the laboratory's procedure manual, manufacturer's instructions, Quality Control (QC) data, and interview with staff, the laboratory failed to ensure

	availability of statistical parameters (mean and standard deviation - SD) for day-to-day acceptability of chemistry control material (Lot #Q5358) Performance Verifier. Findings included: a. Review of the laboratory's Quality Control (Vitro's Performance Verifier) stated a range of means ; The laboratory failed to establish a Monitor for shifts in mean." for the analytes HDL Cholesterol and Total Bilirubin for October 2017. Review of "STANDARD DEVIATION CALCULATIONS" stated, "SD=auto calculated in LIS. Meditech." b. Review of QC data from 10/2017 and 03/2017, included Lot #Q5358 (Level 1), . The laboratory was unable to provide the statistical parameters (mean and SD) established for the ranges used for acceptability. The following analytes included parameters used for acceptability: 10/2017 - for 10/2017 Level 1 HDL Cholesterol : Mean 44.5 SD 1.57 Laboratory Mean 49.39 10/2017 - for Total Bilirubin Level 1: Mean 1.35, SD 0.10 Laboratory mean 1.538 c. During an interview on 05/15/2019 at 9:50 am, Technical Supervisor was asked how ranges of new lot numbers of control material were established, she stated, "With a new lot number, there are 20 runs over 2 weeks for 10 days. Expected is what is currently programmed from the Performance Verifier package insert, those values are inserted. Calculated is the lab's values. We never change the values." The laboratory was unable to provide the statistical parameters established when the Lot #'s were put into use. d. During an interview on 05/15/2019 at 1:00 PM, the technical supervisor confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of quality control records for the corrective action policy and confirmed in interview, the laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Findings were as follows: a .At the time of the survey the laboratory failed to provide a Quality Control policy to include patients prior to quality control failures back to the last successful quality control run were evaluated to ensure the accuracy of the patient results reported. b. An interview of the Technical Supervisor on 05/15/2019 at 09:00 hours in the laboratory confirmed the above 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. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of quality assessment reports and interview, the laboratory failed to establish a written policy for ongoing mechanism to monitor, assess and correct problems identified in analytical systems. Findings were: a. At the time of the survey the laboratory failed to provide a Quality assessment policy that Quality Control and problems in the analytical systems (manual Calculations of INR Bun/Creat A/G Anion Gap and Indices) . b An interview with the technical supervisor on 05/142019 at 15:00 hrs in the office confirmed the above findings
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. 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 director failed to specify, in writing, the duties and responsibilities for all supervisors, consultants and testing personnel. The findings included: a. At the time of the survey the laboratory failed to provide a document designates what duties the Technical Supervisor was to perform. b. The above statement was confirmed by the Technical Supervisor on 05/14/2019 at 10:00 hrs.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on the laboratory's policies, the quality control log, and interview, the technical supervisor failed to establish a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

	This STANDARD is not met as evidenced by: Based on review of testing personnel documentation, verified by staff interview, the laboratory technical supervisor (CMS form 209) failed to evaluate and sign of Quality Control and Proficiency Testing. Findings were as follows: 2. In an interview at the site on 05-15-2019, at 11;00 hrs technical Supervisor (CMS form 209) confirmed the above statement.