Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0485154	04/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ne Tarrant Internal Medicine Assoc, Llp	469 Westpark Way, Euless, 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 entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives 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 to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1240 Pre-Analytic Systems 493.1403 Laboratory Director, (moderate complexity). 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: I. Based on American Proficiency Institute (API) Proficiency Testing (PT) 2021 records, and staff interview, the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 2 of 3 Hematology proficiency testing events in 2021. Findings Included: 1. Review of API instructions stated the following: "ATTESTATION STATEMENT SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation

	statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of the laboratory's API proficiency testing 2021 records (Hematology 1st, 2nd and 3rd Events), revealed the laboratory director or designee failed to sign the attestation statement for the following: 2021 API Hematology 2nd Event The Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 2021 API Hematology 3rd Event The Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 3. During an interview on 04/21/2022 at 02:46 p.m. in the patient room, the laboratory consultant, after review of the proficiency testing records, confirmed the above findings. II. Based on American Proficiency Institute (API) Proficiency Testing (PT) 2021 records, and staff interview, the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 Chemistry proficiency testing events in 2021. Findings Included: 1. Review of API instructions stated the following: "ATTESTATION STATEMENT SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of the laboratory's API proficiency testing 2021 records (Chems 1st, 2nd and 3rd Events), revealed the laboratory director or designee failed to sign the attestation statement for the following: 2021 API Chemistry 3rd Event The Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 3. During an interview on 04/21/2022 at 02:46 p.m. in the patient room, the laboratory consultant, after review of the proficiency testing records, confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) 2022 records, and staff interview, it was revealed the laboratory director failed to review 1 of 1 Chemistry proficiency testing events in 2022. Findings Included: 1. Review of the laboratory's API proficiency testing 2022 records (Chemistry 1st Event) revealed the laboratory failed to obtain a score of 100% in the 1st event of 2022. Further review revealed the laboratory director failed to document review and corrective action taken for proficiency testing failure, for the following proficiency testing events: 2022 API Chemistry 1st Event- Endocrinology; CH-05 Thyroid Stimulating Hormone 2. During an interview on 04/21/2022 at 02:46 p.m. in the patient room, the laboratory consultant, after review of the proficiency testing records, confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, and staff interview, the laboratory failed to meet the requirements for preanalytic systems, as evidenced by: 1. The laboratory failed to ensure patient hematology specimens were monitored for temperature prior to transport. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, patient test records, and staff interview, the laboratory failed to ensure patient hematology specimens were monitored for temperature prior to transport for 10 of 10 patients processed on 04/18/2022 and 12 of 12 patients on 04/19/2022. Findings Included: 1. During a tour of the facility, the laboratory consultant informed the surveyor of an onsite patient collection area. No refrigerator was observed in the collection area. 2. Review of "Horiba ABX Micros ES 60" (Version BP7290) hematology analyzer operator's manual revealed the following: "Sample Stability: 48 hours post-draw stability (at refrigerated temperature)" 3. Review of final patient reports revealed the following hematology samples collected and not stored in the refrigerator, when testing was delayed, prior to patient analysis: 04/18/2022 a. Patient ID: 102679CLA; 429603795; 461847878; 032032PAY; 644; 122145EMB; 12171930; 270544; 38041; 062647TIC 04/19/2022 b. Patient ID: 463844024; 06231941; 101902HAG; 463844024; 05231941; 101902HAG; 628349487; 032057NEU; 04271975; 02263MIN; 110855BAR; 266026 The laboratory failed to ensure patient hematology specimens were monitored for temperature prior to transport for 10 of 10 patients processed on 04/18/2022 and 12 of 12 patients on 04/19/2022. 4. During an interview on 04/21/2022 at 01:35 p.m. in the patient room, the laboratory consultant stated storage temperatures of hematology specimens were not monitored prior to patient analysis. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
I. Based on direct observation, review of manufacturer's instructions, laboratory environmental records (1/2022 - 03/2022) and confirmed in staff interview, the laboratory failed to ensure relative humidity and temperature acceptable ranges were within manufacturer's specifications for the Roche Cobas c 311 chemistry analyzer for 3 of 3 months in 2022. Findings Included: 1. During a tour of the facility, one Roche Cobas c 311 chemistry analyzer was observed processing patient samples. 2. Manufacturer's instructions for the Roche Cobas c 311 chemistry analyzer revealed the following acceptable operating temperature range: "Ambient Temperature: 15 to 32 C Ambient Humidity: 30 to 85 %" 3. Review of laboratory environmental records (01/2022-03/2022) revealed the following room temperature and humidity ranges: "Room Temp.: 15 to 30 C Humidity: 15-80%" The laboratory failed to ensure relative humidity and temperature acceptable ranges were within manufacturer's specifications for the Roche Cobas c 311 chemistry analyzer for 3 of 3 months in 2022. 4. During an interview on 04/21/2022 at 02:46 p.m. in the patient room, the laboratory consultant, after review of manufacturer specifications, confirmed the above findings. II. Based on direct observation, review of manufacturer's instructions, laboratory environmental records (1/2022 - 03/2022) and confirmed in staff interview, the laboratory failed to ensure room temperature range was within manufacturer's specifications for the Roche Cobas c 411 chemistry analyzer for 3 of 3 months in 2022. Findings Included: 1. During a tour of the facility, one Roche Cobas c 411 chemistry analyzer was observed processing patient samples. 2. Manufacturer's instructions for the Roche Cobas c 411 chemistry analyzer revealed the following acceptable operating temperature range: "Ambient Temperature: 18 to 32 C" 3. Review of laboratory environmental records (01/2022-03/2022) revealed the following room temperature range: "Room Temp.: 15 to 30 C" The laboratory failed to ensure room temperature range was within manufacturer's specifications for the Roche Cobas c 411 chemistry analyzer for 3 of 3 months in 2022. 3. During an interview on 04/21/2022 at 02:46 p.m. in the patient room, the laboratory consultant, after review of manufacturer specifications, confirmed the above findings. III. Based on direct observation, review of manufacturer's instructions, laboratory environmental records (1/2022 - 03/2022) and confirmed in staff interview, the laboratory failed to ensure room temperature range was within manufacturer's specifications for Roche Cobas chemistry reagents for 3 of 3 months in 2022. Findings Included: 1. During a tour of the facility, one Roche Cobas c 311 and c 411 chemistry analyzers were observed processing patient samples. Further observations revealed the following reagents stored at room temperature: a. ISE Standard: Low; Lot Number:53323901; Expiration:2/29/2024 b. ISE Standard: High; Lot Number:53323301; Expiration:2/29/2024 c. ISE Dil. Gen 2: Lot Number: 571314015; Expiration:5/31/2023 d. Procell: Lot Number:56745401; Expiration:5/31 /2023 e. Cleancell: Lot Number:56745401; Expiration:5/31/2023 f. Cell Wash: Lot Number: 57592401; Expiration:6/30/2023 2. Manufacturer's instructions for the Roche Cobas reagents revealed the following acceptable storage temperature range: "15 to 25 C" 2. Review of laboratory environmental records (01/2022-03/2022) revealed the following room temperature range: "Room Temp.: 15 to 30 C" The laboratory failed to ensure room temperature range was within manufacturer's specifications for Roche Cobas chemistry reagents for 3 of 3 months in 2022 3. During an interview on 04/21/2022 at 02:46 p.m. in the patient room, the laboratory consultant, after review of manufacturer specifications, confirmed the above findings.

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 review of Roche Cobas operator's manual, laboratory maintenance logs, and confirmed in interview, the laboratory failed to perform monthly maintenance for 12 of 12 months (March 2021-March 2022) as required by the manufacturer for the Roche Cobas c311 Chemistry analyzer. Findings Included: 1. Review of Roche Cobas c311 operator's manual (Version 2.0) revealed the following: "Monthly Maintenance: M8: Replacing reaction cells and cleaning incubator bath and drain filter Replace reaction cells once a month because they gradually deteriorate over a prolonged period of time." 2. Review of laboratory maintenance logs, "Cobas c 311 analyzer Maintenance Log" revealed the laboratory failed to document reaction cell replacement monthly maintenance on the Roche Cobas c311 chemistry analyzer for 12 of 12 months (March 2021-March 2022). 3. During an interview on 04/21/2022 at 02:46 p.m. in the patient room, the laboratory consultant, after review of the maintenance records, 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 review of laboratory policy, chemistry quality control (QC) logs, QC corrective action documentation, patient records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable QC run to ensure accurate and reliable test results for 38 of 38 patients tested on 10/05/2021, 26 of 26 tested on 11/02/2021, 24 of 24 tested on 11/03/2021 and 14 of 14 tested on 12/03/2021. Findings Included: 1. Review of laboratory policy titled, "Quality Control" (Approved by the laboratory director on 02/28/2022) revealed the following: "A minimum of two levels of control will also be run after changed in reagent lot, after reconstitution of reagent and/or calibration, major preventative maintenance, or change in parts." The laboratory policy failed to state how to evaluate patients when test systems adjustments were made for QC failures since the last acceptable QC run. 2. Review of QC logs revealed the following days of QC failure and test system adjustments performed: a. Glucose QC Failure Date: 10/06/2021; Level: 1; Recalibration b. Albumin QC Failure Date: 11/03/2021; Level: 1; Recalibration c. Albumin QC Failure Date: 11/04/2021; Level: 1; Recalibration d. Calcium QC Failure Date: 12/04 /2021; Level: 1; Recalibration 3. The following randomly reviewed patients were not

	evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed: a. 10/05/2021 Patient ID: 110862; 268053; 121747; 052449; 61162; 121284; 071742; 022164; 042148; 467765914 b. 11 /02/2021 Patient ID: 264873; 267474; 071256; 010851; 267095 c. 11/03/2021 Patient ID: 270236; 266620; 11530; 271456; 052388; 263542; 070655 d. 12/03/2021 Patient ID: 081154; 270153; 090466SAI; 558400970; 121862WEB 4. During an interview on 04/21/2022 at 01:35 p.m. in the patient room, the laboratory consultant confirmed patients were not evaluated since the last acceptable QC run when test system adjustments were performed on the chemistry analyzer for the above listed dates in 2021.
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's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, and staff interview, the Laboratory Director failed to provide overall management as evidenced by: 1. The Laboratory Director failed to ensure all requirements were met for preanalytic systems. Refer to D6007.
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 direct observation, review of manufacturer's instructions, laboratory policies, client services policy, daily specimen log, patient test requisitions and final reports, and confirmed in interview, the Laboratory Director failed to ensure requirements were met for preanalytic systems as evidence by: 1. The laboratory failed to ensure patient hematology specimens were monitored for temperature prior to transport. Refer to D5311.