Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0972490	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Tyler Internal Medicine Associates Pa	1910 Roseland Blvd, Tyler, 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 onsite survey conducted from 08/24/2022 to 8/25/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, reagent instructions for use, laboratory documents, and confirmed in interview, the laboratory failed to perform calibration verification, as described by the laboratory policy, for one out of six reagents, Vitamin D, reviewed meeting the designated criteria in 2021. The findings include: 1. Review of the laboratory policy titled "Laboratory Procedure Quality Control Program", section D. Calibration Verification stated: "Calibration verification is required for most tests that do not use at least (3) levels of calibration materials that challenge the limits of linearity for the test or test system." 2. Review of the Vitamin D instructions for use, section "Calibrator Contents" listed the following 2 calibrators: "1 Set of VITROS 25-OH Vitamin D Total calibrators 1 and 2". Surveyor queried on 8/24/2022 at 1435 hours for the calibration verification records for 2021 for Vitamin D and none was provided. 3. Review of the laboratory monthly usage total report from 8/1/2021 to 8/1/2022 listed the total volume of Vitamin D tests performed at 9,121. 4. In an interview on 8/24/2022 at 14:45 hours, in the conference room, the technical consultant confirmed that Vitamin-D calibration only had two levels and that calibration verification had not been performed on Vitamin-D as per the laboratory policy for 2021.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documents, and confirmed in interview, the laboratory failed to have a step-by-step policy for the processing, handling, and reporting of urine microscopic testing. The findings include: 1. In a tour of the laboratory on 8/24/2022 at 09:05 surveyor observed a fixed-speed Horizon 642 E Centrifuge next to the urinalysis station. Surveyor queried testing person (TP) 2 for the centrifuge used for the centrifugation of urinalysis for microscopic analysis and they indicated to the Horizon 642 E Centrifuge stating they spin it for 2 minutes, and that the laboratory performs urine microscopic testing on all urines. Surveyor reviewed the most "Centrifuge Performance Test" verification taped to the side of the analyzer that stated the centrifuge had a max setting at 3,546 rotations per minute (RPM) performed on 3/1/2021. 2. Surveyor queried for the laboratory procedure for performing urine microscopic testing and TP 2 stated there was no laboratory policy for the handling, processing, and reporting of urine microscopic testing. 3. Review of the laboratory monthly usage total report from 8/1/2021 to 8/1/2022 listed the total volume for "Urinalysis, complete" performed at 11,900. 4. In an interview on 8/24 /2022 at 10:40 hours, in the conference room, the technical consultant confirmed that the laboratory did not have a step-by-step policy for urine microscopic testing.
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:
Based on a review of quality control (QC) documents, QC package inserts, and confirmed in an interview the laboratory failed to establish statistical parameters for a two standard deviation (SD) range to detect immediate errors in the quality control analytical process from January 2022 to July 2022 for five of five analytes reviewed on the Vitros 5600. The findings include: 1. In a review of the laboratory Levey-Jennings (LJ) records from the laboratory information system (LIS) for January to July 2022 for the Vitros 5600 chemistry analyzer had the following QC ranges set as 2 standard deviation (SD) for five of five reagents in use. CRP Level 1: Lot Number 68971, Exp 10/31/2022 Put in use: 11/9/2021 Base line (Mean): 1.01 Range: 0.45 - 1.57 CRP Level 3: Lot Number 68973, Exp 10/31/2022 Put in use: 11/9/2021 Base line (mean): 3.03 Range: 2.28 - 3.78 E2 (Estradiol) Level 1: 50381, Exp 8/31/2022 Put in use: 11/18/2019 Mean: 91.80 Range: 56.38 - 123.98 E2 Level 3: Lot 40383, Exp 8/31/2022 Put in use: 11/18/2019 Mean: 837.96 Range: 668.5-1007 Potassium Level 1: Lot 45911, Exp 3/31/2024 Put in use: 11/15/2021 Mean 2.66 Range: 2.53 - 2.79 Potassium Level 3: Lot 45913, Exp 3/31/2024 Put in use: 11/15/2021 Mean: 8.02 Range: 7.66 - 8.39 PTH Level 1: Lot 88711, Exp: 7/31/2024 Put in use: 1/3/2022 Mean: 51.05 Range: 38.95 - 63.15 PTH2 Level 2: Lot 88712, Exp 7/31/2024 Put in use: 1/3/2022 Mean 685.73 Range: 503.73 - 867.73 T Vitamin D Level 1: Lot 5602882, Exp 7/31/2024 Put in use: 1/3/2022 Mean: 40.00 Range: 18.3 - 61.7 T Vitamin D Level 3: Lot 88713, Exp 7/31/2024 Put in use: 1/3/2022 Mean: 106.0 Range: 76.85 - 135.15 Surveyor queried on 8/24/2022 at 13:10, how the ranges for the above analytes were established. Testing person (TP) 3 stated they utilized the ranges provided on the bio rad package insert. 2. Review of the Bio-rad package insert for the above QC had the following statement regarding the provided QC ranges: "The assigned values were determined using the reagent and/or instrument manufacturer's protocol and may not represent +/- 3SD ranges." After discussion with the technical consultant on 8/24/2022 at 13:00 hours, it was discovered that the 3SD ranges provided on the Bio-rad package insert had been set as a 2SD range in the LIS. 3. In an interview with the technical consultant on 8/24/2022 at 13:30, the technical consultant agreed that the ranges in use for the above QC ranges in use were too wide to detect immediate error.