Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0972490	07/28/2026
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	The laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an recertification survey completed on July 27, 2026 and recertification is recommended. Standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of calibration instructions for use, calibration records, and interview, the laboratory failed to ensure the retention of manufacturers' assay information sheets for the Tosoh Bioscience G8 Hemoglobin A1c calibrators for records requested 7/27 /2026. The findings included: 1. Review of the laboratory instructions for the "Hemoglobin A1c Calibrator Set" included the following assigned values for calibrator assigned values and acceptability criteria: "Lot No ZS4001, Exp 9/2/2026 Calibrator 1: 5.94% Calibrator 2: 10.71% ... Calibrator (1) will be automatically measured three times and Calibrator (2) will be automatically measured two times to calculate calibration coefficients "a" and "b". This will, in turn, calibrate subsequent samples using those calibration coefficients. Note that Calibration will have to be performed again if the following results are produced. - Difference between the 2nd and 3rd s-A1c (%) values exceeds 0.3%. - Difference between the 4th and 5th s-A1c (%) values exceeds 0.3%. - Any of the four calibrator results differ from its assigned value by 30 % or more." 2. Review of laboratory calibration records for hemoglobin A1C for the Tosoh Bioscience G8 analyzer failed to include the lot number and expiration date of the calibrator set being utilized on the analytical printout records

	from the analyzer. Surveyor asked for the mechanisms that the laboratory used to track the calibration lot acceptability, when they weren't on the analytical data, and none could be provided Surveyor asked for the Hemoglobin A1C Calibration assay sheets for previous lots, and none could be provided. 3. In an interview on 7/27/2026 at 15:53 hours, in the conference room, technical consultant 1 confirmed the laboratory did not retain the Hemoglobin A1C Calibration assay sheets, that included the calibration acceptability, for the Tosho Bioscience G8 Hemoglobin A1C analyzer.
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: I. Based on review of laboratory policy, Bio-Rad instructions for use for chemistry quality control (QC), laboratory quality control records, and interview, the laboratory failed to have a mechanism in place to ensure the detection of immediate errors as they occur in QC for NT-ProBNP testing during one of one lot rollover reviewed in July 2026. The findings included: 1. Review of the laboratory policy titled "New Lot Quality Control - Chemistry", section II "Procedure" included the following instructions: ".. 2. Enter the mean and standard deviation (SD) for the associated assays for that lot of QC from the manufacturer's insert." 2. Based on review the "Bio-Rad Liquichek Cardiac Markers Plus Control LT" instructions for use, section "Assignment of Values" stated the following: "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Chart were derived from replicate analyses and are specific for this lot of product." 3. Review of NT-proBNP QC lot rollover, started 6/29/2026, included the following QC acceptable ranges from the assayed QC sheets, and the laboratory acceptable ranges used for daily acceptability: Lot 10030150, EXP 12/31/2028 QC Level, mean, [2SD] Level 1, 45.6 pg/mL, [36.6 - 54.6 pg/mL] Level 3, 2270 pg/mL, [1936.6 - 2603.3 pg/mL] Verses in laboratory acceptability: QC level, mean [2SD] Level 1, 45.6 pg/mL, [32.1 - 59.1 pg/mL] Level 2, 2270 pg/mL, [1770.0 - 2770.0 pg/mL] Surveyor asked for an explanation of how the 2SD laboratory acceptability was larger than the 3SD acceptability from the assayed control sheet, and the TC stated they didn't realize the acceptable range listed in the manufacturer's instructions were 3SD ranges and not 2SD ranges. 4. Review of laboratory daily NT-ProBNP QC from 6/29/2026 through 7/28/2026 included the following 5 days where QC was outside of the assayed 2 SD acceptability and not detected: 7/17/2026 Level 3, 1932.0 pg/mL 7/20/2026 Level 1, 31.8 pg/mL Level 3, 1823.0 pg/mL 7/21/2026 Level 1, 34.9 pg/mL Level 3, 1927.0 pg/mL 7/22/2026 Level 1, 32.9 pg/mL Level 3, 1873.0 pg/mL 7/23/2026 Level 1, 32.1 pg/mL Level 3, 1864.0 pg/mL 5. In an interview on 7/28/2026 at 10:12 hours in the conference room, after the review of records, the technical consultant (TC) confirmed the laboratory acceptability range exceeded the assayed 2SD acceptability range, and was unable to detect errors as they occurred. Key: pg/mL: picograms per milliliter NT-ProBNP: N

terminal Pro Brain Natriuretic Peptide II. Based on review of laboratory policy, laboratory quality control instructions for use, laboratory QC records, and confirmed in interview, the laboratory failed to ensure a mechanism was in place for the detection of errors as they occur in daily QC for eight of eight chemistry analytes reviewed in October 2025 and April 2026. The findings included: 1. Review of the laboratory policy titled "New Lot Quality Control - Chemistry", section II "Procedure" included the following instructions: ".. 2. Enter the mean and standard deviation (SD) for the associated assays for that lot of QC from the manufacturer's insert." 2. Review the "Bio-Rad Liquid Assayed Multiqual" and "Lyphochek Immunoassay Plus Control" instructions for use, section "Assignment of Values" stated the following: "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Chart were derived from replicate analyses and are specific for this lot of product." 3. Review of laboratory quality control acceptability for use in daily testing, and assay acceptability ranges included the following eight analytes with a laboratory 2SD acceptability the same, or wider, than the manufacturer's 3SD acceptability range, for records reviewed in October 2025 and April 2026: Bio-Rad Multiqual, Lot 46023, EXP 5/31/2027, put into use March 2025 Calcium: Laboratory 2SD acceptability, [IFU Assayed 3SD acceptability] Level 1: 5.18 - 6.19 mg/dL, [5.18 - 6.19 mg/dL] Level 3: 12 - 13.7 mg/dL, [12.0 - 13.7 mg/dL] CK: Laboratory 2SD acceptability, [IFU Assayed 3SD acceptability] Level 1: 55 - 87 U/L, [54.6 - 86.9 U/L] Level 3: 355 - 496 U/L, [355 - 496 U/L] Chloride: Laboratory 2SD acceptability, [IFU Assayed 3SD acceptability] Level 1: 73 - 84 mEq/L, [72.8 - 83.7 mEq/L] Level 3: 114 - 136 mEq/L, [114 - 136 mEq/L] CO2: Laboratory 2SD acceptability, [IFU Assayed 3SD acceptability] Level 1: 9 - 18 mEq/L, [9.22 - 18.3 mEq/L] Level 3: 18 - 30 mEq/L, [17.6 - 29.8 mEq/L] Lyphocheck Immunoassay Plus Control, Lot 40460, EXP 5/31/2027, put into use July 2025. Ferritin: Laboratory 2SD acceptability, [IFU Assayed 3SD acceptability] Level 1: 42.7-68.2 ng/mL, [42.7 - 68.2 ng/mL] Level 3: 271.0 - 412.0 ng/mL, [271 - 412 ng/mL] PSA: Laboratory 2SD acceptability, [IFU Assayed 3SD acceptability] Level 1: 0.66 - .098 ng/mL, [0.656 - 0.982 ng/mL] Level 3: 9.35 - 13.7 ng/mL, [9.35 - 13.7 ng/mL] TSH: Laboratory 2SD acceptability, IFU [Assayed 3SD acceptability] Level 1: 0.142 - 0.362 mIU/mL, [0.142 - 0.362 mIU/mL] Level 3: 24.5 - 34.10 mIU/mL, [24.5 - 34.1 mIU/mL] Estradiol: Laboratory 2SD acceptability, [IFU Assayed 3SD acceptability] Level 1: 33.8 - 142.0 pg/mL, [33.8 - 142 pg/mL] Level 3: 483.0 - 959.0 pg/mL, [483 - 959 pg /mL] Surveyor asked why the 2SD laboratory acceptability was the same as, or larger than, the 3SD acceptability from the assayed control sheet. The TC stated they didn't realize the acceptable range listed in the manufacturer's instructions were 3SD ranges and not 2SD ranges. 4. In an interview on 7/28/2026 at 10:12 hours in the conference room, after the review of records, the technical consultant (TC) confirmed the laboratory acceptable 2SD range was equal to, or exceeded the manufacturers assayed 3SD acceptability range, and was unable to detect errors as they occurred. Key: CO2 - carbon dioxide CK - creatine kinase PSA - prostate specific antigen TSH - thyroid stimulating hormone mEq/L - milliequivalents per liter mg/dL - milligrams per deciliter mIU/mL - micro International Units per milliliter ng/mL - nanograms per milliliter pg/mL - picograms per milliliter U/L - units per liter