Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2069134	04/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Assoc & Arash Tirandaz, Md	6124 W Parker Rd Suite 234, Plano, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 Southern Operations Branch-Dallas 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.
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: I. Based on review of laboratory policy, quality control (QC) records, corrective action logs, patient reports, 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 test run to ensure accurate and reliable test results for 434 of 434 patients in 2022 (04/2022) on the Beckman Coulter AU480 chemistry analyzer. Findings: 1. Review of the laboratory's policy titled "Quality Assurance Protocol" revealed: "VII. BASIC QULAITY CONTROL CRITERIA ... C. Quality Control Rules ... 3. General Policies ... c. Reevaluate all patient results analyzed before a failure in QC up to and including those, which were analyzed subsequent to the QC failure. Repeat testing will include all samples analyzed prior to an acceptable QC run and since the last acceptable QC run to determine whether the patient values are accurate and reliable. d. Appropriate corrective action is initiated to correct the problems that led to the unsatisfactory QC result; document corrective action and outcome. 2. Review of Beckman Coulter AU480 chemistry analyzer QC data and corrective action documentation revealed the troubleshooting the laboratory performed for the following sampling of QC test events in April 2022: QC Level 1: lot # 45891; expiration date 10/31/2023 QC Level 2: lot # 45892; expiration date 10/31 /2023 QC Level 3: lot # 45893; expiration date 10/31/2023 04/04/2022 Level 1 control 10:48 am QC ran and resulted in a failure for HDL 11:21 am QC repeated and resulted in a failure for HDL 11:58 am QC repeated and passed Level 2 control 10:48 am QC ran and resulted in a failure for HDL 11:21 am QC repeated and resulted in a failure for HDL 11:58 am QC repeated and passed Corrective action for the level 1 and 2 control was documented as: "Repeat QC, Level 2 came in lower while Level 1 stayed same" and "Calibrate & New QC". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/01/2022) Specimen IDs: 220401001, 20401002, 220401003, 220401004, 220401005, 220401006, 220401007, 220401008, 220401009, 220401010, 220401011, 220401012, 220401013, 220401014, 220401015, 220401016, 220401017, 220401018, 220401019, 220401020, 220401021, 220401022, 220401023, 220401024, 220401025, 220401026, 220401028, 220401029, 220401030, 220401031, 220401032, 220401033, 220401034, 220401035, 220401036, 220401037, 220401038, 220401039, 220401040, 220401041, 220401042, 220401043, 220401044, 220401045, 220401046, 220401047, 220401048, 220401049, 220401050, 220401051, 220401052, 220401053, 220401054, 220401055, 220401056, 220401058, 220401059 04/06/2022 Level 1 control 9:15 am QC ran and resulted in a failure for CO2 9:40 am QC repeated resulted in a failure for CO2 10:13 am QC repeated and passed Level 2 control 9:15 am QC ran and passed for CO2 9:40 am QC repeated resulted in a failure for CO2 10:13 am QC repeated and passed Level 3 control 9:15 am QC ran and passed for CO2 9:40 am QC repeated resulted in a failure for CO2 10:13 am QC repeated and passed Corrective actions for level 1, 2 and 3 controls were documented as: "Repeat QC all levels failed" and "Changed Reagent, performed W2, recalibrated, repeated patients". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/05/2022): Specimen IDs: 220405001, 20405002, 220405003, 220405004, 220405005, 220405006, 220405009, 220405010, 220405011, 220405012, 220405013, 220405014, 220405015, 220405016, 220405017, 220405018, 220405019, 220405020, 220405021, 220405022, 220405023, 220405024, 220405025, 220405026, 220405027, 220405028, 220405029, 220405030, 220405031, 220405032, 220405033, 220405034, 220405035, 220405036, 220405037, 220405038, 220405039, 220405040, 220405041, 220405042, 220405043, 220405044, 220405045, 220405046, 220405047, 220405048, 220405049, 220405050, 220405052, 220405053, 220405054, 220405055, 220405056, 220405057 04/07/2022 04/07/2022 Level 1 control 9:14 am QC ran and resulted in a failure for NA 9:28 am QC repeated resulted in a failure for NA 10:02 am QC repeated and passed Level 3 control 9:14 am QC ran and resulted in

a failure for NA 9:28 am QC repeated resulted in a failure for NA 10:02 am QC repeated and passed Corrective actions for Level 1 and 3 control were documented as: "Repeated QC, Lvl 1 & 3 failed" and "Recalibrate and fresh QC". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/06/2022): Specimen IDs: 220406001, 220406003, 220406004, 220406005, 220406006, 220406011, 220406012, 220406013, 220406014, 220406015, 220406016, 220406017, 220406018, 220406019, 220406021, 220406022, 220406023, 220406025, 220406026, 220406027, 220406028, 220406030, 220406031, 220406032, 220406033, 220406034, 220406036, 220406037, 220406038, 220406039, 220406040, 220406041, 220406042, 220406043, 220406044, 220406046, 220406047, 220406048, 220406049, 220406050, 220406051, 220406052, 220406053, 220406054, 220406055, 220406056, 220406057 04/08/2022 Level 1 control 9:40 am QC ran and resulted in a failure for CO2 9:56 am QC repeated and passed Corrective action for Level 1 was documented as "Calibrate & QC". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/07/2022): Specimen IDs: 220407001, 220407002, 220407003, 220407004, 220407006, 220407007, 220407009, 220407010, 220407012, 220407013, 220407014, 220407015, 220407016, 220407017, 220407018, 220407019, 220407020, 220407021, 220407022, 220407023, 220407024, 220407025, 220407026, 220407027, 22047028, 220407029, 220407030, 220407031, 220407032, 220407033, 220407034, 220407035, 220407036, 220407037, 220407038, 220407039, 220407040, 220407041, 220407042, 220407043, 220407044, 220407045, 220407046, 220407047, 220407048, 220407049, 220407050, 220407051, 220407052, 220407053, 220407054 04/11/2022 Level 2 control 10:52 am QC ran and resulted in a failure for NA 11:27 am QC repeated and passed Level 3 control 10:52 am QC ran and resulted in a failure for NA 11:27 am QC repeated and passed Corrective actions for Level 2 and 3 control were documented as: "Calibrated and Fresh QC". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/08/2022): Specimen IDs: 220408001, 220408002, 220408003, 220408004, 220408005, 220408006, 220408007, 220408008, 220408009, 220408011, 220408012, 220408013, 220408014, 220408015, 220408016, 220408017, 220408018, 220408019, 220408020, 220408021, 220408022, 220408023, 220408025, 220408026, 220408027, 220408028, 220408029, 220408030, 220408031, 220408032, 220408033, 220408034, 220408035, 220408036, 220408037, 220408038, 220408039, 220408041, 220408042, 220408044, 220408045, 220408046, 220408047, 220408048, 220408049, 220408050, 220408051, 220408052, 220408053, 220408054, 220408055, 220408056, 220408057, 220408058, 220408059, 220408060, 220408061, 220408062 04/12/2022 Level 1 control 9:11 am QC ran and failed for HDL 9:30 am QC repeated passed Corrective action for Level 1 control was documented as: "Calibrated & QC". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/11/2022): Specimen IDs: 220411001, 220411002, 220411003, 220411004, 220411006, 220411007, 220411008, 220411010, 220411011, 2204011012, 220411013, 220411014, 220411015, 220411016, 220411017, 220411018, 220411019, 220411020, 220411021, 220411022, 220412023, 220411024 220411025, 220411026, 220411031, 220411032, 220411034, 220411035, 220411036, 220411037, 220411038, 220411039, 220411041, 220411042, 220411043, 220411044, 220411045, 220411046, 220411047, 220411048, 220411049, 220411050, 220411051, 220411052, 220411053, 220411054, 220411055, 220411056,

220411057, 220411059, 220411060, 220401161, 220411062, 220411064 04/13/2022 Level 3 control 9:14 am QC ran and failed for HDL 9:31 am QC repeated passed Corrective action for Level 3 control was documented as: "calibrated". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/12/2022): Specimen IDs: 220412001, 220412002, 220412005, 220412006, 220412007, 220412009, 220412010, 220412011, 2204012012, 220412013, 220412015, 220412016, 220412017, 220412018, 220412019, 220412020, 220412021, 220412022, 220412023, 220412024 220412025, 220412026, 220412027, 220412028, 220412029, 220412030, 220412031, 220412032, 220412033, 220412034, 220412035, 220412036, 220412038, 220412039, 220412040, 220412041, 220412042, 220412043, 220412044, 220412045, 220412046, 220412047, 220412048, 220412049, 220412050, 220412051, 220412052, 220412053, 220412054 04/13/2022 Level 1 control 9:25 am QC ran and failed for UIBC 9:43 am QC repeated passed Corrective action for Level 1 control was documented as: "1st repeat failed, calibrated and QC'd". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/12/2022): Specimen IDs: 220412036, 220412050, 220412051, 220412053, 04/14 /2022 Level 3 control 9:13 am QC ran and failed for HDL 9:33 am QC repeated and failed for HDL 9:55 am QC was repeated and passed Corrective action for Level 3 control was documented as: "Repeated QC" and "calibrated". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/13/2022): Specimen IDs: 220413001, 220413003, 220413004, 220413006, 220413008, 220413010, 220413011, 2204013012, 220413014, 220413017, 220413018, 220413019, 220413020, 220413021, 220413022, 220413023, 220413024 220413025, 220413026, 220413027, 220413028, 220413029, 220413030, 220413032, 220413033, 220413034, 220413036, 220413037, 220413038 04/15/2022 Level 1 control 8:40 am QC ran and failed for CA 9:17 am QC repeated passed Corrective action for Level 1 control was documented as: "Calibrated". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/14/2022): Specimen IDs: 220414001, 220414002, 220414003, 220414004, 220414005, 220414007, 220414008, 220414009, 220414010, 220414011, 2204014012, 220414013, 220414015, 220414016, 220414017, 220414018, 220414020, 220414021, 220414024 220414025, 220414026, 220414027, 220414028, 22041409, 220414030, 220414031, 220441032, 220414034, 220414035, 220414036, 220414037, 220414038, 220414039, 220414041, 220414042, 220414043, 220414047, 220414049, 220414050, 220414051, 220414052, 220414053, 220414054, 220414055, 22014056, 220414057, 220414058, 220414059, 220414060 3. During an interview on 04/19/2020 at 11:25 am, the technical consultant and testing person confirmed the above findings. Word key: HDL- high-density lipoprotein CO2- carbon dioxide NA- sodium UIBC - total iron-binding capacity CA - calcium II. Based on review of laboratory policy, quality control (QC) records, corrective action logs, patient reports, 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 test run to ensure accurate and reliable test results for 44 of 44 patients in 2022 (04/2022) on the Siemens Centaur CP endocrinology analyzer. Findings: 1. Review of the laboratory's policy titled "Quality Assurance Protocol" revealed: "VII. BASIC QULAITY CONTROL CRITERIA ... C. Quality Control Rules ... 3. General Policies ... c. Reevaluate all patient results analyzed before a failure in QC up to and including those, which were analyzed subsequent to the QC failure. Repeat testing will include all samples analyzed prior to an acceptable QC run and since the last acceptable QC

	run to determine whether the patient values are accurate and reliable. d. Appropriate corrective action is initiated to correct the problems that led to the unsatisfactory QC result; document corrective action and outcome. 2. Review of Siemens Centaur CP endocrinology analyzer QC data and corrective action documentation revealed the troubleshooting the laboratory performed for the following sampling of QC test events in April 2022: QC Level 1: lot # 85281; expiration date 05/31/2023 QC Level 2: lot # 85282; expiration date 05/31/2023 QC Level 3: lot # 85283; expiration date 05/31 /2023 04/07/2022 Level 1 control 10:26 am QC ran and resulted in a failure for FT4 11:27 am QC repeated and resulted in a failure for FT4 1:01 pm QC repeated and passed Corrective action for the level 1 control was documented as: "QC Repeated failed, calibrated and passed". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/06/2022): Specimen IDs: 220406007, 220406008, 220406011, 220406013, 20406015, 220406017, 220406018, 220406019, 220406022, 220406023, 220406029, 220406031, 220406032, 220406033, 220406035, 220406040, 220406047, 220406051 04/08/2022 Level 1 control 10:38 am QC ran and resulted in a failure for FT4 1:22 pm QC repeated and passed Corrective action for the level 1 control was documented as: "Fresh QC used" and "changed low reagent". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/07/2022): Specimen IDs: 220407003, 220407004, 220407016, 220407021, 220407025, 220407034, 220407038, 220407039, 220407047, 220407053 04/15/2022 Level 3 control 9:20 am QC ran and resulted in a failure for PSA 10:25 am QC repeated and failed for PSA 11:00 am QC repeated and passed Corrective action for Level 3 control were documented as: "Repeat QC" "Calibrate". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/14/2022): Specimen IDs: 220414018, 220414021, 220414023, 220414028, 220414057, 220414060 04/18/2022 Level 1 control 10:09 am QC ran and resulted in a failure for FT4 10:47 am QC repeated and failed for FT4 11:52 am QC repeated and passed Corrective action for the level 1 control was documented as: "Repeat QC" and "calibrate". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (04/15/2022): Specimen IDs: 220415006, 220415010, 220415016, 220415020, 220415021, 220415023 220415025, 220415033, 220415039, 220415041 3. During an interview on 04/19/2020 at 11:25 am, the technical consultant and testing person confirmed the above findings. Word key: FT4- free thyroxine PSA- prostate-specific antigen