Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2030207	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Andrew Chung Md, Pllc	3600 Gaston Ave #755, Dallas, 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 announced recertification survey was conducted 05/24/2023 to 05/25/2023. The laboratory was found out of compliance with the following conditions: 493.1240 Preanalytic systems 493.1403 Laboratories performing moderate complexitytesting; laboratory director
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 laboratory policy, manufacturer's instructions, patient test records, and confirmed in interview, the laboratory failed to meet the requirements of the preanalytical phase of testing as evidenced by: 1. The laboratory failed to ensure patient complete blood count (CBC) specimens were not analyzed beyond the manufacturer's stability requirements prior to testing on the Sysmex XN- 330 hematology analyzer for 6 of 20 specimens in May 2023 (random sampling). 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 review of laboratory policy, manufacturer's instructions, patient test records, and confirmed in interview, the laboratory failed to ensure patient complete blood count (CBC) specimens were not analyzed beyond the manufacturers stability requirements prior to testing on the Sysmex XN- 330 hematology analyzer for 6 of 20 specimens in May 2023 (random sampling). The findings include: 1. Review of the laboratory policy titled "Hematology Analyzer XN-330" revealed: "E. Stored Specimen Stability 1. EDTA blood samples should be analyzed with [sic] 24 hours when stored at room temperature (18-26C). 2. If samples cannot be analyzed within 24 hours, store in a refrigerator at 2-8C." 2. Review of the Sysmex Basic Operation guide revealed: "Chapter 4 Analyzing Samples ... 4.3 Preparing Samples ... Handling whole blood Mix the venous blood with an anticoagulant (EDTA-2K or EDTA-3K). Draw the amount of venous blood that is specified for the amount of EDTA anticoagulant. The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2 to 8C until it can be analyzed ..." 3. Review of the Sysmex Method Verification Manual revealed: "Section 3 Method Verification Protocols ... It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Correlation Studies (CAS assists with data reduction) Sensitivity Studies (See Application Manual) Reference Range Verification (See Application Manual) Stability Study (See Application Manual) Mixing Study (See Application Manual) Typically, integration studies are performed on new analyzers to verify and document satisfactory analyzer performance according to the manufacturer's specifications. It is up to the laboratory to perform more extensive studies if they deem it necessary to satisfy requirements over and above what is contained in these protocols." 4. Review of the "Stability Study" section from the Sysmex Application Manual revealed: "Stability Study (for Customer Reference Only) Stability studies may be performed to determine the readiness of a sample for CBC, differential and reticulocyte count analysis. Short term stability may be performed with fresh samples drawn and analyzed at intervals within one (1) hour. Long term stability is conducted under storage conditions and over a period of time defined by the laboratory as acceptable for specimen analysis. Typical long term studies include analysis of room temperature (18-26C) and refrigerated (4C) samples at intervals from zero to 48, 56 or 72 hours." 5. A random review of patient test records from May 2023 revealed the following 6 patients whose CBCs were performed beyond the manufacturer's 4-hour stability requirement: Sample Number: 99061960 Collection date/time: 05/22/2023 at 07:42 hours Analysis date/time: 05/22 /2023 at 15:36 hours Elapsed time from collection to analysis: 7 hours 54 minutes Sample Number: 99061980 Collection date/time: 05/23/2023 at 07:37 hours Analysis date/time: 05/23/2023 at 13:38 hours Elapsed time from collection to analysis: 6 hours 1 minutes Sample Number: 99061971 Collection date/time: 05/23/2023 at 07:28 hours Analysis date/time: 05/23/2023 at 11:56 hours Elapsed time from collection to analysis: 4 hours 28 minutes Sample Number: 99061977 Collection date/time: 05/23 /2023 at 07:31 hours Analysis date/time: 05/23/2023 at 11:58 hours Elapsed time from collection to analysis: 4 hours 27 minutes Sample Number: 99061972 Collection date /time: 05/23/2023 at 07:28 hours Analysis date/time: 05/23/2023 at 12:34 hours Elapsed time from collection to analysis: 5 hours 6 minutes Sample Number: 99061978 Collection date/time: 05/23/2023 at 07:34 hours Analysis date/time: 05/23

	/2023 at 12:40 hours Elapsed time from collection to analysis: 5 hours 6 minutes The laboratory did not ensure their written preanalytical requirements were consistent with manufacturer's preanalytical requirements. The laboratory extended the specimen stability beyond manufacturer's instructions for the above CBC specimens and could not provide studies to support the extended stability. 6. During an interview on 05/24 /2023 at 11:44 a.m., the surveyor asked the Technical Consultant if the laboratory performed specimen stability studies to support the laboratory's established specimen stability parameters. The Technical Consultant stated that the laboratory did not perform any specimen stability studies. This confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure Abbott Architect ci4100 calibration materials did not exceed their expiration dates. The findings include: 1. During a tour of the laboratory storage areas on 05/25 /2023 at 02:03 p.m., the surveyor observed the following expired calibration materials in the K2 Scientific refrigerator behind a clinical workstation: 1 box of CoV-2 IgG Calibrators; Lot# 46098FN00; Expiration: 2023-04-28 1 box of Ferritin Calibrators; Lot# 34005UD00; Expiration: 2023-03-18 1 box of Total PSA Calibrators; Lot# 39035FN00; Expiration: 2023-03-11 1 box of Vitamin B12 Calibrators; Lot# 40665UD00; Expiration: 2023-02-24 1 box of Total PSA Calibrators; Lot# 39035FN00; Expiration: 2023-03-11 1 box of CoV-2 IgG II Calibrators; Lot# 44088FN00; Expiration: 2023-04-06 1 box of iPTH Calibrators; Lot# 02422E000; Expiration: 2023-02-16 1 box of FSH Calibrators; Lot# 36297UD00; Expiration: 2023-05-22 1 box of BNP Calibrators; Lot# 44K24022; Expiration: 2023-05-02 During a tour of the laboratory storage areas on 05/25/2023 at 02:08 p.m., the surveyor observed the following expired calibration materials in the Danby freezer next door to the draw station: 1 box of CoV-2 IgG II Calibrators; Lot# 41477FN00; Expiration: 2023-01-27 1 box of LH Calibrators; Lot# 381202UD00; Expiration: 2023-02-14 2. During the exit interview on 05/25/2023 at 02:11 p.m., the Technical Consultant confirmed the above findings. Key: CoV-covid IgG- immunoglobulin G PSA- prostate specific antigen iPTH- intact parathyroid hormone FSH- follicle stimulating hormone BNP- B-type natriuretic peptide LH- luteinizing hormone
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to perform calibration verification for the Abbott Architect ci4100 chemistry analyzer every 6 months in 2022 and 2023. The findings include: 1. Review of the laboratory policy titled "Linearity and Calibration Verification" revealed: "CALIBRATION VERIFICATION... Calibration verification is performed every six months, as stated in current CLIA regulations." 2. Review of the laboratory's "Linearity Calibration Log Book" for the Abbott Architect ci4100 chemistry analyzer revealed calibration verification was performed 01/2022 and 07/2022. The following analytes (random sampling) did not have documented calibration verification in 01 /2022: Follicle stimulating hormone (FSH) Free thyroxine (FT4) Further review of the "Linearity Calibration Log Book" revealed no calibration verification was performed for any analytes at the next scheduled time on 01/2023. The laboratory failed to perform calibration verification for the Abbott Architect ci4100 chemistry analyzer every 6 months. 3. During an interview on 05/25/2023 at 12:21 p.m., the Technical Consultant confirmed the above findings. This is a repeat citation from the previous survey conducted on 10/26/2021.
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 review of laboratory policy, quality control (QC) package inserts, QC records, and confirmed in interview, the laboratory failed to perform QC material overlap studies for 3 of 3 levels of Technopath liquid controls (Multichem S Plus and MultiChem IA Plus) for the Abbott Architect ci4100 chemistry analyzer in 2022. The findings include: 1. A review of the laboratory policy titled "Quality Control and

	Assessment" revealed: "PROCEDURE FOR CHANGE IN LOT OF ASSAYED CONTROL MATERIAL (when performing daily quality control testing) "Assayed" controls have stated means and standard deviations in their product literature, we have established means and adjust them to our facility as necessary: The laboratory should run each level of new control material 5 times, with alternating personnel and on multiple days when possible, to verify that control samples fall within manufacturer stated ranges. Results may be compared to against those found within the package insert and placed in the quality control binder, or results may be placed on the chart template following, to show acceptability of new lot control material. Additionally, the laboratory may begin the new [sic] of control material using the manufacturers stated means and ranges, but should verify and adjust according to the following procedure: 1. You may begin patient testing with the stated means and ranges, but you should gather at least 20 control points for each level in use. 2. The sum of these points divided by the number of samples run is your "actual mean" for that control." 2. Review of the package inserts for the Technopath liquid controls (Multichem S Plus and MultiChem IA Plus) revealed the following: "ASSIGNMENT OF VALUES The values provided in the data sheet were derived from replicate analyses and are specific for a particular lot of product. These values have been generated using third party manufacturers' instrument systems and are specific to one measurement procedure. Technopath makes no accuracy claims regarding these values. Tests were performed by the control manufacturer and/or by independent laboratories, for various methods and instrument systems. As a tool to assist in establishing their own mean, laboratories can import the values into their ARCHITECT system ... Values are provided only as guidelines, each laboratory should establish its own statistical limits. Laboratory means may vary from the values listed during the shelf life of the control ..." 3. Review of quality control records from 2022 and 2023 revealed the following quality control lot numbers that were placed into service and the laboratory failed to perform QC material overlap studies: Multichem S Plus Level 1- Lot# 10907211; Expiration: 2023-12-31 Level 2- Lot# 10907212; Expiration: 2023-12-31 Level 3- Lot# 10907213; Expiration: 2023-12-31 Multichem IA Plus Level 1- Lot# 35006211; Expiration: 2023-09-30 Level 2- Lot# 35006212; Expiration: 2023-09-30 Level 3- Lot# 35006213; Expiration: 2023-09-30 The laboratory was asked to provide documentation of QC material overlap studies for the Technopath liquid controls (Multichem S Plus and Multichem IA Plus) levels 1,2, and 3. None was provided. 4. During an interview on 05/24/2023 at 03:10 p.m., the Technical Consultant confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Abbott Architect ci4100 quality control (QC)

records, and confirmed in interview, the laboratory failed to document corrective actions for 6 of 161 QC runs that included failures for Sodium (Na), 1 of 19 QC runs that included failures for Albumin, 20 of 145 QC runs that included failures for carbon dioxide (CO2), 7 of 80 runs that included failures for free thyroxine (FT4), and 10 of 105 runs that included failures for follicle stimulating hormone (FSH) in 2022 (November and December) and 2023 (March through May). The findings include: 1. Review of laboratory policy titled "Quality Control and Assessment" revealed: "PURPOSE To identify control materials used throughout the laboratory and to formulate a comprehensive plan to perform, monitor, evaluate, and take corrective action with control values obtained ... THREE CONTROL PROTOCOL 1. Accept the run if: a. All levels are within 2 SD of the established mean b. One level is between 2 SD and 3 SD and the other two levels are within 2 SD of the established mean, for that run only (1-2S) 2. Reject the run if: a. All levels are outside of 2 SD of the established mean b. Two of three levels are outside of 2 SD (2 of 3-2S) c. The same level is out of 2 SD and within 3 SD on two consecutive runs (2-2S) 3. If the run is rejected: a. Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient results. 4. If the run is rejected: a. Rerun the controls. If they are still outside acceptable limits, open fresh controls and rerun. If the controls are within limits, run and report patient results. b. If after rerun, the controls are out of acceptable limits, check the following variables: expiration date of reagents, change in lot numbers of controls or reagents, date of last calibration, and maintenance procedures. c. If control values are still unacceptable, troubleshoot according to the manufacturer's guidelines. d. If the situation persists, do not run patient samples. Send specimens to the appropriate reference laboratory, according to the patient's insurance policy. e. When the situation is corrected and controls are again acceptable, patient testing may resume and results may be reported. Always document any corrective actions taken on the Corrective Action Log for follow-up review ..." 2. Review of Abbott Architect ci4100 QC records revealed the laboratory failed to document corrective actions for QC failures in 2022 and 2023 on the following dates and times: A. Sodium Multichem S Plus Level 1- Lot# 10907211; Expiration: 2023-12-31 Level 2- Lot# 10907212; Expiration: 2023-12-31 Level 3- Lot# 10907213; Expiration: 2023-12-31 12/01/2022 Multichem S Plus Level 1 08:31:33 hours- QC failed 08:47:53 hours- QC was repeated and failed 09:13:58 hours- QC was repeated and passed 03/02/2023 Multichem S Plus Level 2 08:28:18 hours- QC failed 09:54:38 hours-QC was repeated and passed 04/24/2023 Multichem S Plus Level 1 08:45:42 hours- QC failed 09:32:29 hours- QC was repeated and passed Multichem S Plus Level 2 08:48:59 hours- QC failed 09:36:14 hours- QC was repeated and passed Multichem S Plus Level 3 08:52: 35 hours- QC failed 09:39:50 hours- QC was repeated and passed B. Albumin Multichem S Plus Level 1- Lot# 10907211; Expiration: 2023-12-31 Level 2- Lot# 10907212; Expiration: 2023-12-31 Level 3- Lot# 10907213; Expiration: 2023-12-31 03/02/2023 Multichem S Plus Level 2 08:29:03 hours- QC failed 09:55:23 hours- QC was repeated and passed C. CO2 Multichem S Plus Level 1- Lot# 10907211; Expiration: 2023-12-31 Level 2- Lot# 10907212; Expiration: 2023-12-31 Level 3- Lot# 10907213; Expiration: 2023-12-31 11/03/2022 Multichem S Plus Level 2 10:08: 08 hours- QC failed 12:15:33 hours- QC was repeated and failed 11/07/2022 Multichem S Plus Level 2 09:55:30 hours- QC failed and was not repeated 11/08 /2022 Multichem S Plus Level 2 08:46:25 hours- QC failed 09:34:27 hours- QC was repeated and failed 11/09/2022 Multichem S Plus Level 2 08:45:20 hours- QC failed and was not repeated 11/10/2022 Multichem S Plus Level 2 07:55:23 hours- QC failed and was not repeated 11/14/2022 Multichem S Plus Level 2 08:52:51 hours-QC failed and was not repeated 11/15/2022 Multichem S Plus Level 2 08:58:47 hours- QC failed. Corrective action was documented for this QC point. 09:52:58 hours- QC

	failed and was not repeated 12/06/2022 Multichem S Plus Level 2 09:46:42 hours- QC failed 11:00:23 hours- QC failed and was not repeated. 12/07/2022 Multichem S Plus Level 2 08:44:31 hours- QC failed 10:16:24 hours- QC was repeated and failed 11:23:16 hours- QC was repeated and passed 12/13/2022 Multichem S Plus Level 2 08:57:52 hours- QC failed 10:23:56 hours- QC was repeated and passed 12/20/2022 Multichem S Plus Level 2 08:57:22 hours- QC failed 10:22:19 hours- QC was repeated and failed 11:12:30 hours- QC was repeated and passed 03/02/2023 Multichem S Plus Level 2 08:32:21 hours- QC failed 09:58:41 hours- QC was repeated and passed 04/24/2023 Multichems S Plus Level 1 08:49:44 hours- QC failed 09:36:41 hours- QC was repeated and passed Multichem S Plus Level 2 08:53:02 hours- QC failed 09:40:17 hours- QC was repeated and passed Multichem S Plus Level 3 08:56:38 hours- QC failed 09:43:53 hours- QC was repeated and passed D. FT4 Multichem IA Plus Level 1- Lot# 35006211; Expiration: 2023-09-30 Level 2- Lot# 35006212; Expiration: 2023-09-30 Level 3- Lot# 35006213; Expiration: 2023-09-30 11/17/2022 Multichem IA Plus Level 3 10:09:08 hours- QC failed and was not repeated 11/28/2022 Multichem IA Plus Level 1 09:39:24 hours- QC failed 11:49:35 hours- QC was repeated and passed Multichem IA Plus Level 2 09:50:30 hours- QC failed 11:58:36 hours- QC was repeated and passed Multichem IA Plus Level 3 10:11: 49 hours- QC failed 12:07:00 hours- QC was repeated and passed 12/08/2022 Multichem IA Plus Level 3 09:56:44 hours- QC failed 10:51:40 hours- QC was repeated and passed 12/20/2022 Multichem IA Plus Level 3 09:59:26 hours- QC failed 10:45:03 hours- QC was repeated and passed 05/15/2023 Multichem IA Plus Level 2 09:53:04 hours- QC failed 11:38:43 hours- QC was repeated and passed E. FSH Multichem IA Plus Level 1- Lot# 35006211; Expiration: 2023-09-30 Level 2- Lot# 35006212; Expiration: 2023-09-30 Level 3- Lot# 35006213; Expiration: 2023-09-30 11/28/2022 Multichem IA Plus Level 1 09:38:12 hours- QC failed 11:48:05 hours- QC was repeated and failed 12:58:00 hours- QC was repeated and passed 11/30 /2022 Multichem IA Plus Level 1 09:25:06 hours- QC failed 10:59:20 hours- QC was repeated and passed 12/01/2022 Multichem IA Plus Level 1 09:34:57 hours- QC failed 10:15:10 hours- QC was repeated and passed 12/07/2022 Multichem IA Plus Level 3 09:42:56 hours- QC failed and was not repeated 12/28/2022 Multichem IA Plus Level 1 10:51:56 hours- QC failed 13:11:25 hours- QC was repeated and passed 05/15/2023 Multichem IA Plus Level 1 09:35:39 hours- QC failed 11:29:43 hours- QC was repeated and passed Multichem IA Plus Level 2 09:51:52 hours- QC failed 11:37:31 hours- QC was repeated and passed Multichem IA Plus Level 3 10:03:16 hours- QC failed 11:43:13 hours- QC was repeated and passed 05/18/2023 10:36:13 hours- QC failed and was not repeated 3. During an interview on 05/25/2023 at 11:52 a.m., the Technical Consultant confirmed the above findings.
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 laboratory policy, manufacturer's instructions, patient test records, and confirmed in interview, the laboratory director failed to provide overall management and direction for moderate complexity testing as evidenced by: 1. The laboratory director failed to meet the requirements for the preanalytical 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 review of laboratory policy, manufacturer's instructions, patient test records, and confirmed in interview, the laboratory failed to meet the requirements for the preanalytical systems as evidenced by: 1. The laboratory failed to ensure patient complete blood count (CBC) specimens were not analyzed beyond the manufacturer's stability requirements prior to testing on the Sysmex XN- 330 hematology analyzer for 6 of 20 specimens in May 2023 (random sampling). Refer to D5311.