Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2030207	10/26/2021
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 entrance conference was held with the laboratory representative. 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 representative at the exit conference. The laboratory representative was 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 in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
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 review of laboratory policy, manufacturer's instructions, QC (quality control) records, and staff interview, the laboratory failed to follow their own written policy for ensuring quality control values met the manufacturer's expected results before putting the controls into use for 1 of 1 lot in 2021 (October). Findings included: 1. Review of the laboratory's policy "Quality Control and Assessment" revealed: "PROCEDURE FOR CHANGE IN LOT OF ASSAYED CONTROL MATERIAL

	(when performing daily quality control testing) "Assayed" controls have a 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 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." 2. Review of "COULTER 4C-ES CELL CONTROL" instructions for use revealed: "ASSIGNED VALUES AND EXPECTED RESULTS ... EXPECTED RANGES ... Before your current cell control lot(s) expire, perform the following on your new lot(s): Confirm that recovered values are within the TABLE OF EXPECTED RESULTS" 3. Review of QC records in October 2021 revealed the laboratory placed the following hematology control into use on 10/11/2021 without ensuring quality control values met the manufacturer's expected results: Low control lot #068600, expiration date: 12/20/2021 Normal control lot #078600, expiration date: 12/20/2021 High control lot #088600, expiration date: 12/20/2021 4. During an interview on 10/25/2021 at 2:50 pm, the Technical Consultant stated that the laboratory did not run QC five times before placing a new lot of QC material into use to ensure quality control values met the manufacturer's expected results, confirming the findings.
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 manufacturer's instructions, laboratory policy, review of laboratory records, and confirmed in interview the laboratory failed to perform calibration verification for the Beckman Coulter AcT Diff 2 hematology analyzer every 6 months as required in 2021. Findings included: 1. Review of the Beckman Coulter AcT Diff 2 operator's manual revealed: "5.1 OVERVIEW ... Beckman Coulter recommends that you calibrate your instrument according to the regulations required by your inspecting agency." 2. Review of the laboratory's policy "Linearity

	and Calibration Verification" revealed: "CALIBRATION VERIFICATION ... Calibration verification is performed every six months, as stated in current CLIA regulations." 3. Review of Beckman Coulter AcT Diff 2 hematology analyzer calibration records revealed the last calibration verification was performed 01/06/2021 There were no calibration verification records for 07/2021 (every 6 months). 4. During an interview on 10/25/2021 at 3:24 pm, the technical consultant confirmed that calibration verification for the Beckman Coulter AcT Diff 2 hematology analyzer had not been performed since 01/06/2021.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, manufacturer's package inserts, Abbott Architect ci4100 chemistry analyzer quality control (QC) records (June 2021-August 2021), and staff interview, the laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of the Architect performance with current and accurate statistical parameters for 4 of 10 randomly reviewed analytes. Findings included: 1. During a tour of the laboratory on 10/26/2021, an Abbott Architect ci4100 Chemistry Analyzer (Serial Number:910281900) was observed to be performing testing on patient samples for the following analytes: a. GGT (Gamma-glutamyl transferase) b. TRF (Transferrin) c. Apo A (Apolipoprotein A) d. AST (Aspartate Aminotransferase) 2. The laboratory policy titled, "Quality Control and Assessment" (Approved by the Laboratory Director on 06/21/2021) revealed the following: "Procedure for change in lot of assayed control material Assayed controls have stated means and standard deviations in their product literature; we have established means and adjust them to our facility as necessary ... Once the laboratory's mean and range is established range adjustments may be made under the supervisor or Technical Consultant. Any unexpected trends or shifts should be investigated as possible instrument, reagent, or control problems before any changes are implemented." 3. Review of laboratory "Establishment of QC" quality control reference ranges for the above analytes: a. GGT Level 1: 21.48-24.36 U /L Level 2: 54.62-59.94 U/L Level 3: 133.40-142.86 U/L b. TRF Level 1: 169.99-181.91 mg/dL Level 2: 240.59-257.01 mg/dL Level 3: 338.83-357.57 mg/dL c. Apo A Level 1: 104.66-114.16 mg/dL Level 2: 154.19-167.40 mg/dL Level 3: 238.73-261.84 mg/dL d. AST Level 1: 35.56-41.15 U/L Level 2: 101.98-107.25 U/L Level 3: 82.74-153.86 U/L 4. Review of Abbott Architect ci4100 chemistry analyzer quality control (QC) records (June 2021-July 2021) revealed the following quality control range adjustments for the above analytes: a. GGT Level 1: 21-23 U/L 06/10/2021 Control Instrument Comment: "Will rerun. Fresh, see note. Rerun good. Range adjusted." Level 2: 57-61 U/L 06/01/2021 Control Instrument Comment: "Will rerun. Fresh, see

	note. Rerun good. Range adjusted." b. TRF Level 1: 176-189 mg/dL 07/21/2021 Control Instrument Comment: "Will rerun. Fresh, see note. Rerun good. Range adjusted." Level 2: 250.269 mg/dL 07/21/2021 Control Instrument Comment: "Will rerun. Fresh, see note. Rerun good. Range adjusted." c. Apo A Level 1: 97-103 mg/dL 07/21/2021 Control Instrument Comment: "Will rerun. Fresh, see note. Rerun good. Range adjusted." Level 3: 217-227 mg/dL 07/22/2021 Control Instrument Comment: "Will rerun. Fresh, see note. Rerun good. Range adjusted." d. AST Level 2: 100-106 U /L 06/10/2021 Control Instrument Comment: "Will rerun. Fresh, see note. Rerun good. Range adjusted." The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of the Architect performance with current and accurate statistical parameters for 4 of 5 randomly reviewed analytes. 5. During an interview with the laboratory technical consultant at 10:15 AM on 10/26/2021, in the facility office, the technical consultant was asked to provide documentation of investigation for each range adjustment of the above analytes quality control. No documentation was provided. This confirmed the above findings. Word Key U/L : Units per litre mg/dL : milligrams per decilitre
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, AcT Diff 2 hematology quality control (QC) records, corrective action logs, patient test records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 47 of 47 patients in 2020 (December random review) and 140 of 140 patients in 2021 (August-October random review). Findings included: 1. Review of Quality Control and Assessment laboratory policy revealed: "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 the 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 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 no run patient samples. Send specimens to the appropriate reference laboratory, according to the patient's insurance carrier's stipulations. 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." The policy did not state how to evaluate patients when test systems adjustments were made for QC failures since the last acceptable QC run. 2. Review of AcT diff 2 hematology quality control (QC) records, corrective action logs and pateint test records revealed test system adjustments performed for the following sampling of QC test events in December 2020, August through October 2021: QC High level lot #088400 expiration date 12/08/2020 12/04/2020 QC High level 7:58 am QC failed for WBC, LY, MO, GR, LY#, MO#, GR# 8:00 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO#, GR# 8:08 am QC was repeated and passed Corrective action log stated: "High control out of range. Remixed and reran control level, level still out giving x's & --- as results will zap apertures & flush line and rerun control level, level in range." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (12/03/2020): Patient IDs: 68014, 72673, 69158, 66587, 71514, 72659, 65849, 60898, 66904, 66805, 58104 QC Low level lot #068800; expiration date 02/01 /2021 QC Normal level lot #078800; expiration date 02/01/2021 12/14/2021 QC Low level 8:35 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 8:40 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO#, GR# 8:45 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO#, GR# 8:53 am QC was repeated and passed Corrective action log stated: "Low control out of range, Apeture [sic] zapped and flushed, reran control, still out of range. Repeated flush twice, reran control. Control now in range" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (12/11/2020): Patient IDs: 65989, 60842, 60843, 66884, 75534, 72601, 70044, 67614, 72561, 67230, 60152, 70367, 71237 12/21/2020 QC Low level 8:01 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 8:07 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO#, GR# 8:14 am QC was repeated and passed Corrective action log stated: "Background count failed, reran, rerun ok, Low control blanked out, remixed, reran, rerun blanked out again, zapped apetutres [sic] flushed line, reran Low control, failed, flush line again, reran low control, 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 (12/18/2020): Patient IDs: 65358,71370, 70341, 72684, 58361, 68100, 58819, 62620, 72640, 70120, 67277, 70771 12/28/2020 QC Low level 8:04 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 8:10 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO#, GR# 8:15 am QC was repeated and passed QC Normal level 8:16 am QC failed for PLT 8: 20 am QC was repeated and failed for PLT 8:23 am QC was repeated and failed for RBC, HCT 8:26 am QC was repeated and failed for PLT 8:28 am QC was repeated and failed for PLT 8:33 am QC was repeated and failed for PLT 8:53 am QC was repeated and passed Corrective action log stated: "Low control out of range. Apeture [sic] zapped and flushed, reran control, still out of range. Repeated flush twice, reran control. Control now in range. Normal control PLt, high remixed, reran control, Normal was remix & reran for the second time PLt still high. Remixed & reran for the 3rd time RBC & Hct Low. Normal control reran after remixing for the 3rd time. Control Reran Normal control PLT still High. Two Levels in range, will put in new Lot of control and run patient today." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (12/23/2020): Patient IDs: 72267, 57859, 72703, 58941, 60881, 71814, 72096, 71561, 72677, 65181, 70687 QC Low level lot

#068000, expiration date 09/27/2021 08/02/2021 QC Low level 6:40 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 6:44 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO#, GR# 6:50 am QC was repeated and passed Corrective action log stated: "Background failed, reran Background passed, Low control failed, remixed, reran control level, Control level failed, zapped appetures [sic], flush Lines, remixed & reran control Level, level 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 (07/30/2021): Patient IDs: 73301, 71923, 72149, 72245, 61979, 72173, 71908, 73253, 57950 08/09/2021 QC Low level 7:28 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 8:07 am QC was repeated and failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 8:15 am QC was repeated and passed Corrective action log stated: "Low control failed, remixed & reran control failed. Shocked /flushed & remixed ran Low control again 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 (08/06/2021): Patient IDs: 72680, 62489, 72815, 73385, 57983, 63864, 60178, 71518, 61932, 63305, 59240, 70700, 72792, 73268 08/23/2021 QC Low level 6:38 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 6:43 am QC was repeated and failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 6:45 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO# 6:47 am QC was repeated and passed Corrective action log stated: "Low control failed, remixed & reran low control twice failed. Flushed /Shocked, remix & ran control 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 (08/20/2021): Patient IDs: 73241, 58467, 67656, 71089, 73122, 71119 QC Low level control lot #068400, expiration date: 11/22/2021 08/30/2021 QC Low level 7:17 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 7:21 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO#, GR# 7:23 am QC was repeated and passed Corrective action log stated: "Startup failed. Shutdown & restart passed. Low control failed. Shocked /Flushed reran twice 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 (08/27/2021): Patient IDs: 73334, 73333, 67054, 73443, 71317, 71258, 67939, 70886, 58377, 73140, 60715, 60716, 69771 09/02/2021 QC Low level 6:40 am QC failed for WBC, LY, MO, GR, LY#, MO#, GR# 6:47 am QC was repeated and failed WBC, LY, MO, GR, LY#, MO#, GR# 6:54 am QC was repeated and passed Corrective action log stated: "Low control failed ... zapped apetures [sic] remixed & reran control level, Rerun Good." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (09/01/2021): Patient IDs: 67222, 61986, 66644, 73139, 66819, 71970, 73129, 61533, 70923, 65457, 71821, 70799, 73365, 70683, 67296, 71120, 67320, 71759, 72705, 58048, 73476, 65419, 58156, 58154, 70656, 64258 09/07/2021 QC Low level 6:54 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 6:57 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO# 7:03 am QC was repeated and passed Corrective action log stated: "Low control failed, remixed & reran low control twice failed. Flushed /Shocked, remix & ran control 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 (09/02/2021): Patient IDs: 72096, 60067, 57970, 72221, 73249, 65166, 57859, 71268, 59569, 66131, 58734, 73264, 71049, 73462, 71048, 73501, 67465, 72925, 60055, 72771, 73504, 70412, 73511, 66987 09/13/2021 QC Low level 6:52 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 6:58 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO# 7:00 am QC was repeated and passed Corrective action log stated: "Low control failed. Remixed/reran. Failed twice. Shocke [sic] /flushed. Low control 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 (09/10/2021): Patient IDs: 72340, 73358, 71065, 73347, 69666, 72139, 58597, 71282, 70987, 71037, 60355, 60791 09/20/2021 QC Low level 7:05 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 7:11 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO# 7:16 am QC was repeated and passed Corrective action log stated: "Start up failed shout [sic] down & restart passed. Low control failed. Shocked/flushed reran Low control failed twice 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 (09/17/2021): Patient IDs: 70262, 72198, 71391, 67193, 71617, 72099, 70589, 73331, 70660, 73332, 73387, 68077 QC Low level lot #068600, expiration date: 12/20/2021 10/18/2021 QC Low level 6:56 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 7:01 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO# 7:03 am QC was repeated and passed Corrective action log stated: "Low control failed. Shocked, zapp [sic] low control. Failed again. Remixed/reran low control 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 (10/15/2021): Patient IDs: 71861, 69132, 73626, 71832, 62698, 72392, 68054, 61847, 61845, 58165 10/25/2021 QC Low level 6:22 am QC failed for all parameters WBC, LY, MO, GR, LY#, MO#, GR#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV 6:26 am QC was repeated and failed for WBC, LY, MO, GR, LY#, MO# 6:39 am QC was repeated and passed Corrective action log stated: "Background check failed, rerunning background check. Background passed. Low control failed, remixed & reran control level, low control fail again. Zapped Apetures [sic], Flush lines, remixed & reran controls, control level in range." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (10/22/2021): Patient IDs: 71861, 72385, 58361, 598433, 70132, 61702, 72514, 70673, 58512, 73442, 62347, 69285, 65941, 66345 3. During the exit interview on 10 /26/2021 at 10:26 am, the technical consultant stated that patients were not evaluated since the last acceptable QC run when test system adjustments were performed, confirming the above findings. Word Key: WBC - white blood cell LY - lymphocyte MO - monocyte GR - granulocyte RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW - red cell distribution width PLT - platelet MPV - mean platelet volume 44278 II. Based on review of laboratory policy, Abbott Architect ci4100 chemistry analyzer quality control (QC) records (June 2021), patient reports and staff interview, the laboratory failed to evaluate and document all patient test results obtained in the unacceptable QC run and since the last acceptable QC run to ensure accurate and reliable test results for 30 of 30 patients. Findings included: 1. Review of laboratory policy titled, "Quality Control and Assessment" (Approved by the Laboratory Director on 06/21/2021) revealed the following: "Chemistry Abbott Architect ci4100 1. Run 3 levels of Technopath liquid controls (Level 1,2,3) daily to monitor the performance of the analyzer reagent.

	Quality control should be run in the morning after performance of daily maintenance and before any patient testing is initiated. 2. It is also important to check the quality control in the following situations: a. following analyzer calibration b. after loading a new lot of reagent c. after major service has been performed d. selected maintenance procedures e. service call or component replacement f. when there are unusual shifts or trends in patient results or when results do not match the patient's clinical picture." 2. Review of laboratory "Establishment of QC" quality control reference ranges for the above analytes: a. Potassium Quality Control Level 1: 2.54-2.67 mmol/L Level 2: 3.84-3.97 mmol/L Level 3: 6.50-6.81 mmol/L b. Sodium Level 1: 115.71-122.24 mmol/L Level 2: 142.86-149.09 mmol/L Level 3: 162.49-166.59 mmol/L c. Chloride Level 1: 73.79-94.56 mmol/L Level 2: 92.34-96.27 mmol/L Level 3: 103.76-106.75 mmol/L d. AST (Aspartate Aminotransferase) Level 1: 35.56-41.15 U/L Level 2: 101.98-107.25 U/L Level 3: 82.74-153.86 U/L e. TSH (Thyroid stimulating hormone) Level 1: 0.05-0.06 ulU/mL Level 2: 3.24-4.28 ulU/mL Level 3: 16.38-20.59 ulU/mL 3. Review of Abbott Architect ci4100 chemistry analyzer (Serial Number: 910281900) quality control (QC) records (June 2021-August 2021) revealed the following days quality control values were outside the reference range for the above analytes and test system adjustments were performed: a. 06/02/2021 Potassium- Level 1: 2.3 mmol/L Corrective Actions: "Will rerun. Fresh QC. Reagent Change. Rerun good." Level 2: 3.6 mmol/L Corrective Actions: "Will rerun. Fresh QC. Reagent Change. Rerun good." Sodium- Level 1: 102 mmol/L Corrective Actions: "Will rerun. Fresh QC. Reagent Change. Rerun good." Chloride- Level 1: 88 mmol/L Corrective Actions: "Will rerun. Fresh QC. Reagent Change. Rerun good." b. 06/03/2021 TSH- Level 1: 0.0512 ulU/mL Corrective Actions: "Will rerun. Fresh QC. Reagent Change. Rerun good." c. 06/09/2021 AST Level 2: 101 U/L Corrective Actions: "Will rerun. Fresh QC. Reagent Change. Rerun good." The laboratory failed to evaluate and document all patient test results obtained in the unacceptable QC run and since the last acceptable QC run to ensure accurate and reliable test results. 4. Review of patient records, revealed the following patients not evaluated since the last acceptable quality control in June 2021: Potassium; Sodium; Chloride: I. 06/01/2021 a. Patient Identification: 71893; 73155; 71893; 62537 58199; 58198; 59230; 66653 II. TSH 06 /02/2021 b. Patient Identification: 71521; 66987; 66131; 57664; 65716;71951;70285; 57891;70394 III. AST 06/09/2021 c. Patient Identification: 67820;58852;72759 ; 62477 ;69239;71223;69864;57759;60539;72021;70610;72339; 60206 5. During an interview with the laboratory technical consultant at 10:15 AM on 10/26/2021, in the facility office, the technical consultant was asked to provide documentation of evaluation of patient test results obtained in the unacceptable QC run and since the last acceptable QC run to ensure accurate and reliable test results for 30 of 30 in June 2021. No documentation was provided. This confirmed the above findings. Word Key U/L: Units per litre mmol/L: millimoles per litre ulU/L: Micro-international units per milliliter