Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0661011	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Laboratory Services, Inc	12011 Lee Jackson Memorial Hwy Suite 200, Fairfax, VA	

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 CLIA recertification survey was conducted at Tristar Medical Labs, Inc on March 25-26 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) and Testing Personnel (TP) failed to sign nine (9) of forty-eight (48) attestation statements reviewed from May 2017 until March 2019. Findings include: 1. Review of the laboratory's PT for twenty (20) events in 2017 and twenty-eight (28) events in 2018 revealed the LD and TP did not sign the following attestation statements: 2017 College of American Pathologists (CAP) B-B Bacteriology Event B; 2017 CAP C-C General Chemistry and Therapeutic Drug Survey Event C; 2017 CAP K-B Ligand Assay, General Event B; 2017 CAP CGL-A Coagulation, Limited Event A; 2018 CAP C-A General Chemistry and Therapeutic Drug Survey Event A; 2018 CAP C-C General Chemistry and Therapeutic Drug Survey Event C; 2018 CAP K-B Ligand Assay, General Event B; 2018 CAP FH-B Hematology Event B; and 2018 CAP CGL-B Coagulation, Limited Event B. A total of 9 events. 2. In an exit interview on 3/26 /19 at approximately 12:30 PM, the TC confirmed the findings.
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. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, and an interview with Testing Personnel (TP) C, the laboratory failed to retain the "Liquichek Immunoassay Plus Control Levels 1, 2, and 3" manufacturer's assay information inserts documenting Prostatic Specific Antigen (PSA), Lutenizing Hormone (LH), Vitamin B12, T-uptake, Free T3, Free T4, Total T3, Total T4, Thyroid Stimulating Hormone (TSH), Folate, Testosterone, Follicle Stimulating Hormone (FSH), and Human Chorionic Gonadotropin (HCG) QC acceptable ranges for one (1) of two (2) lot numbers utilized from April 19, 2018 up to the date of survey on March 25, 2019. Findings include: 1. Review of the laboratory's QC records from April 19, 2018 up to the date of survey on March 25, 2019 revealed the laboratory received and utilized 2 lot numbers of the "Liquichek Immunoassay Plus Control Levels 1, 2, and 3". One lot number QC, lot number 40920, had no documentation of acceptable ranges or manufacturer's package inserts retained. The surveyor requested the manufacturer's assay information insert for lot 40920. The laboratory provided no documentation to review. In an interview on 3/26/19 at approximately 10:30 AM, TP C stated she/he did not save the package insert. 2. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: ***REPEAT DEFICIENCY*** Based on review of the laboratory's policy and procedure manual, manufacturer package inserts, quality control (QC) records, calibration records, patient records, quality assessment (QA) checklists, and interviews with the Laboratory Director (LD), Technical Consultant (TC), and Testing Personnel (TP), the laboratory failed to: 1. establish the "Mean of the PT Normal Range with each new lot" of "HemosIL RecombiPlasTin 2G" (Cross Reference D 5411); 2. ensure the Rapid Plasma Reagin (RPR) kit was within the manufacturer's stated expiration date (Cross Reference D 5417); 3. perform and document the Access 2 weekly maintenance (Cross Reference D 5429); 4. follow the established policy performing calibration for the GEN S and LH 750 Hematology analyzers every three months (Cross Reference D 5437-**REPEAT DEFICIENCY**); 5. establish QC ranges for the "Liquichek Immunoassay Plus Controls" and the "TOSOH Hemoglobin A1c Controls" (Cross Reference D 5469 A & B); 6. perform the twice annual

	comparison of the Hematology and Chemistry instruments (Cross Reference D 5775); and 7. establish and follow a corrective action policy for the Access 2 when " flags" were observed for the QC materials (Cross Reference D 5779).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's reagent information inserts, ACL Elite Pro ProThrombin (PT) records, patient test records and interview with the Technical Consultant (TC) and Testing Personnel (TP) C, the laboratory failed to follow the manufacturer's instructions to establish the "Mean of the PT Normal Range with each new lot" of HemosIL RecombiPlasTin 2G reagent for three (3) of three (3) new lots while reporting four-hundred ninety-four (494) patients. Findings include: 1. Review of the manufacturer's reagent information insert for the HemosIL RecombiPlasTin 2G reagent revealed a statement, "Enter the ISI value from the insert and establish the Mean of the PT Normal Range with each new lot." 2. Review of the ACL Elite Pro instrument records revealed the following 3 lot numbers of HemosIL RecombiPlasTin 2G reagent used from 9/20/17 until the date of the survey 3/25/19: 078441 exp 4/30 /19 in use 9/20/17 to 5/7/18; 184979 exp 1/31/20 in use 5/8/18 to 10/15/18; and 1174066 exp 11/30/19 in use 10/16/18 to date of survey, 3/26/19. 3. Review of the Elite Pro PT records revealed no documentation of the "Mean of the PT Normal Range" being established for each new lot number from 9/20/17 until 3/25/19. The surveyor requested documentation of the "Mean of the PT Normal Range" for each of the above listed lot numbers of reagents. The laboratory provided no documentation to review. 4. Review of the Elite Pro PT patient test records revealed 494 patients were tested from 9/20/17 to 3/25/19. 5. In an interview on 3/25/19 at approximately 5:00 PM, the TC and TP C confirmed the 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 a review of the manufacturer's package insert for the "ASI RPR Card Test for Syphilis", Rapid Plasma Reagin (RPR) Quality Control records (QC), RPR patient test logs, and interview with the Laboratory Director (LD) and Technical Consultant (TC), the laboratory failed to follow manufacturer's instructions and ensure the RPR test kit was within the manufacturer's stated expiration date for one (1) of one (1) lot numbers of reagents while reporting two-hundred thirteen (213) patients. Findings include: 1. Review of the manufacturer's package insert for the ASI RPR Card Test for Syphilis revealed the "Handling and Procedural Notes", which stated "5. Do not use past the expiration date indicated on the kit.". 2. Review of the RPR QC records

	revealed the laboratory used the ASI RPR Card Test for Syphilis (lot number CGK12RS, expiration date 9/2018) past the expiration indicated on the kit from 10/1 /18 until 2/28/19. 3. Review of the RPR patient test logs revealed 213 patients were tested from 10/1/18 until 2/28/19. 4. In an interview on 3/25/19 at approximately 2:00 PM, the LD and TC confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter Access 2 instrument maintenance logs, user manual instructions, and interview with the Technical Consultant (TC) and Testing Personnel (TP) C, the laboratory failed to perform and document the Access 2 weekly maintenance for thirteen (13) of (16) months reviewed from December 2017 to March 2019. Findings include: 1. Review of the laboratory's Beckman Coulter Access 2 user manual instructions revealed the following weekly maintenance procedures: "Clean instrument exterior; Inspect liquid water bottle; Check waste filter bottle; Inspect/clean primary probe; Replace/clean aspirate probes; Run system check." 2. Review of the Access 2's maintenance log revealed no documentation of the weekly maintenance for the following months: 2018-March, April, May, June, July, August, September, October, November, and December; 2019-January, February, March. A total of 13 months with no documented weekly maintenance. The surveyor requested documentation of the Access 2 weekly maintenance for the above listed months. The laboratory provided no documentation to review. 3. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC and TP C confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on review of the laboratory's Hematology manual, Hematology calibration records, and interview with the Laboratory Director (LD) and Technical Consultant (TC), the laboratory failed to follow their established calibration procedure for the calibration of the GEN S and LH750 Hematology analyzers every three (3) months from April 2017 until March 2019. Findings include:

	1. Review of the laboratory's Hematology manual revealed a policy for the Beckman Coulter instruments GEN S and LH750 which stated, "Calibration and Calibration Verification: 1. Instrument calibration is performed every three months per year (manufacturer recommendations) and when indicated by quality control records, instrument maintenance, or parts replacement." 2. Review of the calibration records for the Hematology analyzers revealed calibration was performed on the following dates: 4/26/17 GEN S 10/10/17 GEN S 5/29/18 GEN S 3/19/19 GEN S 11/7/17 LH 750 3/19/19 LH 750 The surveyor requested calibration documentation for the four (4) missing GEN S calibrations and the six (6) missing LH 750 calibrations. The laboratory provided no documentation to review. 3. In an interview on 3/25/19 at approximately 2:30 PM, the LD and TC confirmed the findings.
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: A. Based on a review of the manufacturer's Quality Control (QC) assay information inserts, Beckman Coulter Access 2 QC records, and interview with the Technical Consultant (TC), the laboratory failed to follow manufacturer's instructions to establish QC ranges for two (2) of two (2) lot numbers of "Liquichek Immunoassay Plus Control Levels 1, 2, and 3" QC materials used for monitoring accuracy of patient testing performed on the Access 2 from April 2018 to March 2019. Findings include: 1. Review of the manufacturer's quality control (QC) assay information inserts for the "Liquichek Immunoassay Plus Control Levels 1, 2, and 3" QC materials revealed the statement: "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 2. Review of the laboratory's Access 2 QC records from April 2018 to the date of the survey on 3/25/19 revealed the following two (2) Bio-Rad Lyphochek Immunoassay Plus Control lot numbers were utilized to monitor patient Prostatic Specific Antigen (PSA), Lutenizing Hormone (LH), Vitamin B12, Vitamin D, Thyroid-uptake (T-uptake), Free T3 (FT3), Free T4 (FT4), Total T3, Total T4, Thyroid Stimulating Hormone (TSH), Folate, Testosterone, Follicle Stimulating Hormone (FSH), Ferritin and Human Chorionic Gonadotropin (HCG) test results analyzed on the laboratory's Access 2 instrument: 40920 and 40941. The surveyor requested to review documentation that the laboratory established ranges for each of the 2 new lot numbers of QC. The laboratory provided no documentation to review. 3. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings. B. Based on a review of the manufacturer's quality control (QC) assay information inserts, TOSOH G8 records, and interview with the Technical Consultant (TC), the laboratory failed to follow manufacturer's instructions and

	establish QC ranges for one (1) of one (1) lot numbers of "TOSOH Hemoglobin A1c Control" materials used for monitoring the accuracy of patient Hemoglobin (Hgb) A1c testing from April 2017 to March 2019. Findings include: 1. Review of the manufacturer's quality control (QC) assay information inserts for the "TOSOH Hemoglobin A1c Controls" revealed the statement: "It is recommended that each laboratory establish its own control limits from day-to-day use of the test." 2. Review of the laboratory's TOSOH G8 QC records from April 2017 to the date of the survey on March 25, 2018 revealed TOSOH Hemoglobin A1c Control lot number 7065 (included Level 1 and 2) was utilized to monitor patient Hgb A1c test results analyzed on the TOSOH G8. The surveyor requested to review documentation that the laboratory established the ranges for lot number 7065. The laboratory provided no documentation to review. 3. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's policy and procedure manual, Chemistry instrument records and interview with the Technical Consultant (TC), the laboratory failed to perform the twice a year instrument comparison of test results for the two (2) Beckman Coulter LX-20 Chemistry analyzers in calendar years 2017 and 2018. Findings include: 1. Review of the laboratory's policy and procedure manual revealed no policy for the twice a year comparison of the LX-20 Chemistry instruments. 2. Review of the Chemistry instrument records revealed no documentation of the twice a year instrument comparison of the LX-20 Chemistry instruments, serial numbers 1689 and 1691, for calendar years 2017 and 2018. The surveyor requested to review the LX-20 instrument comparisons for calendar years 2017 and 2018. The laboratory provided no documentation to review. 3. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings. B. Based on a review of the laboratory's policy and procedure manual, Hematology instrument records and interview with the Technical Consultant (TC), the laboratory failed to perform the twice a year instrument comparison of test results for the two (2) Hematology analyzers in calendar years 2017 and 2018. Findings include: 1. Review of the laboratory's policy and procedure manual revealed no policy for the twice a year comparison of the Hematology instruments. 2. Review of the Hematology instrument records revealed no documentation of the twice a year instrument comparison of the Beckman Coulter GEN S and Beckman Coulter LH-750 Hematology instruments for calendar years 2017 and 2018. The surveyor requested to review the GEN S and LH-750 instrument comparisons for calendar years 2017 and 2018. The laboratory provided no documentation to review. 3. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:
Based on review of the Beckman Coulter Access 2 Quality Control (QC) records, calibration records, policy and procedure manual, "Beckman Coulter Access 2 Instructions for Use", the laboratory's corrective action logs, Access 2 patient records and interviews with the Technical Consultant (TC) and Testing Personnel (TP) C, the laboratory failed to establish and follow a corrective action policy for the Access 2 when " flags" were observed from April 19. 2018 to March 11, 2019 while reporting one thousand six-hundred fifty-nine (1659) patients. Findings include: 1. Review of the Access 2 QC and calibration records revealed the following "flags" for the Access 2 QC BioRad Liquichek Immunoassay Controls 1 and 2: 04/19/18 Digoxin (DIG)-CEX 04/20/18 Folate (FOL)-PEX Vitamin B12 (B12)-PEX 04/25/18 DIG-PEX 04/27 /18 B12-CEX 05/09/18 Prostatic Specific Antigen (PSA)-CEX, LEX, PEX 05/21/18 DIG-PEX Ferritin (FER)-CEX 06/25/18 FOL-PEX Thyroid Stimulating Hormone (TSH)-CEX 07/14/18 FOL-CEX, PEX, EXS Prolactin (PRL)-CEX, PEX, EXS PSA-CEX, PEX, EXS B12-EXS PSA-EXS Testosterone (TEST)-PEX, EXS 07/16/18 Human Chorionic Gonadotropin (HCG)-CEX, PEX 08/08/18 DIG-CEX, PEX 08/10 /18 TEST-CEX, LEX, PEX 08/31/18 TSH-CEX 09/05/18 TEST-CEX, LEX, PEX HCG-CEX, PEX B12-CEX 09/18/18 DIG-PEX PSA-CEX, PEX B12-CEX, PEX TSH-LEX Free T3 (FRT3)-PEX 09/20/18 TSH-CEX 09/21/18 T4-CEX, PEX Total T4 (TotT4)-CEX, PEX Total T3 (TotT3)-CEX, PEX TEST-CEX, LEX, PEX 09/26 /18 PSA-CEX 10/04/18 Follicle Stimulating Hormone (FSH)-PEX 10/05/18 PSA-CEX 10/08/18 TEST-LEX, PEX 11/02/18 PRL-LEX, PEX 11/19/18 DIG-CEX, EXS B12-EXS 12/04/18 TSH-CEX, EXS TotT4-CEX, EXS, PEX TotT3-CEX, EXS, PEX B12-EXS, PEX Vitamin D (VitaD)-EXS 12/10/18 DIG-CEX, PEX, EXS T-uptake (TU)-PEX, EXS B12-PEX, EXS FOL-PEX, EXS TotT3-CEX TotT4-PEX, EXS TSH-CEX, EXS 12/14/18 PSA-CEX, EXS, PEX B12-CES, EXS Free T4 (FRT4)-EXS TSH-CEX, EXS 12/17/18 B12-CEX, EXS TotT4-CEX, EXS FRT4-EXS TSH-CEX, EXS PSA-CEX, EXS VitD-EXS 12/31/18 FSH-CEX, PEX Lutenizing Hormone (LH) -CEX PEX DIG-CEX, PEX FER-CEX, PEX TotT4-CEX, PEX FOL-CEX, PEX TotT3-CEX, PEX PSA-LEX Vita B12-CEX, PEX FRT4-CEX, PEX HCG-CEX, LEX, PEX 02/11/19 FRT3-CEX, PEX FRT4-CEX, PEX FER-CEX, PEX DIG-CEX, PEX 02/18/19 DIG-CEX, PEX FOL-CEX, PEX TEST-CEX, PEX, LEX 02/27/19 DIG-CEX, PEX 03/01/19 TotT3-CEX 03/06/19 TotT4-CEX 03/11/19 TotT4-CEX TotT3-CEX B12-CEX 2. Review of the laboratory's policy and procedure manual revealed a lack of a corrective action policy for the Access 2 Chemistry analyzer. The surveyor asked the laboratory for a copy of their Access 2 corrective action policy. The TC stated they follow the corrective action instructions from the "Beckman Coulter Access 2 Instructions for Use". 3. Review of the "Beckman Coulter Access 2 Instructions for Use" revealed a section, "7: Troubleshooting, Non-Fatal Flags", which listed the following "Non-Fatal Flags" and "Corrective Actions": CEX-The calibration curve or cut-off value is expired. Corrective Actions-1. Recalibrate the assay. 2. Repeat the test (s). EXS-The substrate is expired. Corrective Actions-1. Change the substrate bottle from the Supplies screen. 2. Repeat the test (s). LEX-The reagent pack lot is expired. Corrective Actions-1. Unload the expired reagent pack and load a new one. If the lot number of the new reagent pack is different then the expired pack, recalibrate the assay. 2. Repeat the test (s). PEX-The open pack stability time has elapsed for the reagent pack. The system measures this from the time it first punctures the pack. Corrective Actions-1. Unload the expired reagent pack and load a new one.

	If the lot number of the new reagent pack is different then the expired pack, recalibrate the assay. 2. Repeat the test (s). 4. Review of the laboratory's corrective action logs revealed a lack of documentation of corrective actions taken for the "flags" listed above in number 1. The surveyor requested documentation of the corrective actions taken for the "flags" listed. The laboratory provided no documentation to review. 5. In a conservation with TP C on 3/26/29 at approximately 9:30 AM, TP C stated she/he was instructed by the laboratory owner to use the expired reagents. She /he was told by the laboratory owner that if the calibration curve passed then the results were OK. 6. Review of the Access 2 patient records revealed 1659 patients were reported between 4/19/18 and 3/11/19. 7. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the laboratory policy and procedure manual, "Quality Assurance Plan", manufacturer's package inserts and instrument manuals, quality control (QC) records, calibration records, instrument maintenance records and interviews, the laboratory's current quality assurance policy failed to identify and address failures in the analytic system for the specialties of Chemistry and Hematology from January 1, 2017 until the dates of the survey, March 25-26, 2019. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the following policy, "Quality Assurance Plan Hematology Section, Routine Chemistry Section, Special Chemistry and Microbiology Section" (signed by the Laboratory Director (LD) on March 22, 2017), stated: "The Quality Assurance Plan consists of three major components: 1. Assessment of workload and productivity through monitoring of specific Volume Indicators. 2. Review of quality of work through the use of Primary Function Indicators. 3. Action taken to correct the problems identified by the Volume and Primary Function Indicators, and identification of "system" problems which affect operations noted in the Comments Section. Comment Section: identification and/or corrective action of anything affecting Hematology, Routine Chemistry, Special Chemistry and Microbiology Section's Operation." 2. Review of the laboratory's "Monthly Quality Assurance Meeting Forms for Hematology, Routine Chemistry, Special Chemistry and Microbiology Sections" revealed completed forms from January 2017 until the dates of the survey, March 25-26, 2019, signed and dated as reviewed by the LD. 3. Review of the manufacturer's package inserts and manuals, QC records, calibration records, and instrument maintenance records revealed the quality assurance plan failed to identify and address issues when the laboratory: -failed to follow manufacturer's instrument package inserts and establish QC ranges for Liquichek Immunoassay Controls and Hemoglobin A1c controls (Cross Reference D 5411 A & B); -failed to follow manufacturer's instructions and establish "Mean of the PT Normal Range" with each new lot number of HemosIL RecombiPlasTin reagent (Cross Reference D 5411); -failed to follow manufacturer instructions and ensure the Rapid Plasmin Reagin (RPR) test kit was within the manufacturer stated expiration date (Cross Reference D 5417); -failed to perform and document the Access 2 weekly maintenance (Cross

	Reference D 5429); -failed to follow their established policy and perform calibration the GEN S and LH 750 every three (3) months (Cross Reference 5437-REPEAT DEFICIENCY); -failed to take and document corrective actions for "flags" observed for QC on the Access 2 (Cross Reference D 5779. 4. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116, policy and procedure manual, and interviews with the Laboratory Director (LD) and Technical Consultant (TC), the laboratory failed to implement a mechanism to ensure the accuracy of manually transcribed patient results from manual worksheets and instrument printouts into the ProLIS laboratory information system from May 2017 until the date of the survey on March 25-26, 2019. Findings include: 1. Review of the laboratory's CMS-116 revealed the following tests were performed by the laboratory: HCG using the Sure Vue Serum Urine hCG/STAT kit; H. pylori using the Alfa Scientific Instant View H. Pylori kit; RPR using ASI RPR Card Test for Syphilis kit; PT/INR and APTT analyzed on the ACL Elite Pro; and Prostatic Specific Antigen (PSA), Lutenizing Hormone (LH), Vitamin B12 (B12), Vitamin D, Thyroid-uptake (T-uptake), Free T3 (FT3), Free T4 (FT4), Total T3, Total T4, Thyroid Stimulating Hormone (TSH), Folate, Testosterone, Follicle Stimulating Hormone (FSH), Ferritin and Human Chorionic Gonadotropin (HCG) analyzed on the Access 2. In a conversation with the LD and TC on 3/25/19 at approximately 4:00 PM, it was revealed patient results from the above listed tests were entered manually into the laboratory's information system, ProLIS. 2. Review of the laboratory's policy and procedure manual revealed no procedure or mechanism to detect clerical errors for manually entered test results. The surveyor requested the laboratory's procedure or mechanism to detect clerical errors for manually entered test results. The laboratory provided not procedure or mechanism to review. 3. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the 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 the review of policy and procedure manuals, validation records, Quality

	Control (QC) records, Quality Assessment (QA) records, calibration records, the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel records, patient test records, and interviews with the Laboratory Director (LD), Technical Consultant (TC), and Testing Personnel (TP), the LD failed to: 1. approve the MicroScan AutoScan 4's validation (Cross Reference D 6013); 2. ensure the laboratory's QC program was established and maintained (Cross Reference D 6020); and 3. ensure the current QA plan could identify and address Hematology and Chemistry failures in the analytic system (D 6021)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a tour, review of the Beckman Coulter Microscan AutoScan 4 validation records, patient test logs and interview with Testing Personnel F and Technical Consultant (TC), the Laboratory Director (LD) failed to sign as reviewed and approved the AutoScan 4's validation documentation prior to testing sixty-one (61) patients from September 9, 2018 to the date of the survey, March 25, 2019. Findings include: 1. During a tour of the laboratory, the surveyor observed a Beckman Coulter Microscan AutoScan 4. The surveyor asked if the instrument was new since the last survey. TP F stated the AutoScan 4 was installed in June 2018 and patient testing began on 9/10/18. 2. Review of the Beckman Coulter Microscan AutoScan 4 validation records revealed the AutoScan 4 (Serial number 300326) was installed and validated in June 2018 by a Beckman Coulter technical specialist. The surveyor noted the validation documents lacked evidence of review and approval by the Laboratory Director. The surveyor requested to review documentation of the LD's review and approval of the AutoScan 4's validation. The laboratory provided no documentation to review. 3. Review of the AutoScan 4's patient test log revealed 61 patients were tested on the instrument from 9/10/18 to the date of the survey, 3/25/19. 4. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the Quality Control (QC) records, manufacturer's operating

	guides, package inserts, instrument records, and interviews, the laboratory director failed to ensure the laboratory's QC plan was established and maintained (Cross Reference D5469 and D 5479).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the Quality Assurance (QA) plan, manufacturer's operating guides, package inserts, Quality Control (QC) records, calibration records, patient records, personnel records and interviews, the laboratory director failed to ensure the laboratory's QA plan was established and maintained (Cross Reference D5791, D6020, and D6029).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), Testing Personnel (TP) records, and interviews, the Laboratory Director (LD) failed to ensure that one (1) of one (1) new TP had documented training and competency assessments prior to performing patient testing procedures for Microbiology in March 2018. Findings include: 1. Review of CLIA CMS-209 form and Testing Personnel records revealed that TP F was a new TP hired in March 2018 (See attached Personnel Code Sheet). 2. Review of TP records and an interview with the LD and TP F on 3/25 /19 at approximately 1:00 PM revealed that there was no documentation of training and competency assessment for TP F. TP F stated he/she began testing in March 2018. The surveyor requested documentation of TP F's initial training and competency. The laboratory provided no documentation to review. 3 In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the

	performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of CMS-209 Laboratory Personnel Report Form (CLIA), Testing Personnel (TP) records, and interview, the Technical Consultant (TC) failed to perform and document semi-annual competency assessment for one (1) of one (1) new testing personnel in 2018. Findings include: 1. Review of the CMS-209 and TP records revealed no documentation of the semi-annual competency assessment by the TC for TP F- hired in March 2018. The surveyor requested documentation of TP F's semi-annual competency. The laboratory provided no documentation to review. 2. In an exit interview on 3/26.19 at approximately 12:30 PM, the TC confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), Testing Personnel (TP) records, and interview with the Laboratory Director (LD) and Technical Consultant (TC), the TC failed to perform and document annual competency assessments for two (2) of two (2) TP in 2018. Findings include: 1. Review of the CMS-209 form revealed there were 2 TP, TP B and TP C, performing patient testing in 2018. (See attached personnel code list.) 2. Review of the TP B and TP C's records revealed no documentation of annual competency assessments performed by the TC in 2018. The surveyor requested the 2018 competency assessments for TP B and TP C. The laboratory provided no documentation for review. 3. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a tour, review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS-209), analyzer validation records, Testing Personnel (TP) records, and an interview with the Technical Consultant (TC) and the Laboratory Director (LD), the TC failed to document training and competency evaluations for two (2) of two (2) TP after the Beckman Access 2 was installed on November 16, 2017. Findings include: 1. During a laboratory tour, at approximately 9:30 AM, the

	surveyor noted a Beckman Access 2 analyzer in use for Endocrinology testing. The Laboratory Director stated: "The Access 2 was installed in November 2017." 2. Review of the laboratory's CMS-209 and TP records revealed 2 TP, TP B and TP C, who were employed in 2017 and performed Chemistry testing on the Access 2 (See the Personnel Code Sheet). 3. Review of the laboratory's instrument validation records revealed the Beckman Access 2 analyzer installation (Serial Number 570266) was performed by a Beckman Coulter field service technical specialist on 11/16/17. 4. Review of the Beckman Coulter Access 2 Instructions for Use revealed a statement, "Competency Checklist is to be completed prior to patient testing for operators". 5. Review of the laboratory's TP records revealed a lack of Access 2 operator competency checklists for TP B and TP C. The surveyor requested the Access 2 competency checklist for TP B and TP C. The laboratory provided no documentation to review. 6. In an exit interview on 3/26/19 at approximately 12:30 PM, the TC confirmed the findings.