Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1043419	08/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Worldwide Clinical Trials	2455 Ne Loop 410 Suite 150, San Antonio, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification 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.
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 review of the laboratory's package insert for Siemens Dade Innovin Prothrombin Time (PT) reagent, review of New Lot Establishment Studies for Innovin for 2019, 2020, and 2021 and interview with the staff it was determined the laboratory failed to retain Mean Normal PT (mean value of the normal range) evaluation records for 1 of 3 records reviewed. The findings were: 1. Review of the laboratory's package insert for Siemens Dade Innovin Prothrombin Time (PT) reagent revealed "The mean normal PT (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot". 2. Review of the laboratory's New Lot Establishment Studies for Prothrombin Time (PT) Siemens Dade Innovin

	hematology coagulation reagent for 2019, 2020, and 2021 revealed the laboratory did not retain Mean Normal PT evaluation records for Innovin lot number 549708 used in 2019. 3. In an interview on 08/12/2021 at 1000 hours in the conference room the Technical Consultant number 2 (as defined on CMS Form 209 signed by laboratory director on 08/10/2021) stated that she was unable to find records of establishment of the new Mean Normal PT for Innovin Lot number 549708. This confirmed the findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to follow its policy for assessing the competencies of technical consultants. The findings include: 1. A review of the laboratory's policy titled "Personal Competency" (revision date: 04/16/2019) revealed: "The Laboratory Director will evaluate the competency of the technical consultant." The policy did not specify the frequency at which of evaluations would be performed. 2. A review of the laboratory's submitted Form CMS 209 revealed the facility identified 2 technical consultants. 3. A review of the laboratory's personnel records revealed competency assessments were performed by (as listed on Form CMS 209): a) Technical consultant number 1 performed by technical consultant number 2 performed in April 2020 b) Technical consultant number 2 performed by technical consultant number 1 performed in April 2020 4. The laboratory was asked to provide documentation of the laboratory director performing the competency assessments as stated in its policy. No documentation was provided. 5. An interview with the laboratory manager on 08/10 /2021 at 1600 hours in the conference room revealed the facility did not have the laboratory director perform the competency assessments on the technical consultants. This confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in

	the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, and staff interview, it was revealed the laboratory failed to have documentation of including all the required elements in 8 of 20 procedures reviewed. The findings include: 1. A review of 20 laboratory's procedures revealed the laboratory failed to have all of the required elements in 8 of 20 procedures. The procedures and missing elements were: a) Total BhCG Missing: Supplies/materials Safety precautions Sample requirements b) FSH Missing: Supplies /materials Safety precautions Sample requirements c) HAVAB-M Missing: Supplies /materials Safety precautions Sample requirements d) HBsAg Missing: Supplies /materials Safety precautions Sample requirements e) Anti-HCV Missing: Supplies /materials Safety precautions Sample requirements f) HIV AG/AB Combo Missing: Supplies/materials Safety precautions Sample requirements g) Prolactin Missing: Supplies/materials Safety precautions Sample requirements h) Free T3 Missing: Supplies/materials Safety precautions Sample requirements 2. The laboratory was asked to provide documentation of procedures which contained the missing elements. No documentation was provided. 3. An interview with the laboratory manager on 08 /12/2021 at 1035 hours in the conference room - after her review of the records- confirmed the findings. 44698 Based on review of the laboratory's Sysmex XN Hematology analyzer's operator's manual, review of the laboratory's Hematology policies and procedures, review of random hematology analyzer patient result reports for September 2020 and August 2021 and interview with the staff it was determined the laboratory failed to have protocols in place for addressing and reporting of test alert values for 3 of 3 instances reviewed. The findings were: 1. Review of the laboratory's Sysmex XN Hematology analyzer's operator's manual section 10.1.4 Numerical Data of the Analysis Results under Notations revealed: Notation Meaning Description [*] Low reliability Indicates that the reliability of the data is low 2. Review of the laboratory's policies and procedures revealed the operation of the Sysmex XN-Series Hematology Analyzer policy, effective date 05/15/2020 under section VIII REPORTING ABNORMAL RESULTS TO PHYSICIAN revealed "Complete this section with your laboratory's procedure for reporting abnormal results. This may include criteria for specimen repeats, recollection, specimen rejection, pathology review, results to be called and footnoting of reports, etc." Note: No mention of how to address low reliability results was found in the laboratory's policies. 3. Review of a random sampling of laboratory's hematology analyzer patient result reports for September of 2020 and August of 2021 revealed the following samples had low reliability notation of [*] and comments to review results: Sample 122249 tested on 09/08/2020 Sample 173332 tested on 08/05/2021 Sample 173383 tested on 08/06/2021 4. Review of the facility's patient reports for the above samples revealed the flagged results were reported to physician. 5. In an interview on 08/10 /2021 at 1430 in the conference room the Technical Consultant number 2 (as defined on CMS Form 209 signed by laboratory director on 08/10/2021) stated that results flagged with the notation of [*] are repeated to verify results prior to reporting. She could not find those instructions in the laboratory's policies. This confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the manufacturer package inserts for coagulation Dade Ci-Trol #1, and Ci-Trol #3 controls and interview with the staff it was determined the laboratory failed to document open dates (required to determine control's stability interval), or revised expiration dates on 2 of 2 control vials in use. The findings were: 1. Surveyor observations on 08/10/2021 at 1020 hours in the laboratory revealed the following opened coagulation controls stored in the refrigerator: Ci-Trol #1 Lot number 564804E with expiration date of 2022-05-19 Ci-Trol #3 Lot number 556523A with expiration date of 2022-07-02 Note: Neither control vial had documented open date, or revised expiration date. 2. Review of the Ci-Trol Coagulation Controls Level 1 and Level 3 manufacturer's package insert under section Storage and Stability revealed: "Store unopened vials at 2 to 8 C and use by the expiry date given on the label. Stability after reconstitution: at 2 to 8 C (closed vial) 16 hours at 5 to 25 C (closed vial) 8 hours." 3. An interview on 08/10/2021 at 1030 hours in the laboratory Technical Consultant number 2 (as defined on CMS Form 209 signed by laboratory director on 08/10/2021) stated that there should have been open dates documented on the coagulation control vials to establish the acceptable interval of stability. This confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies for the Abbott Architect Buphrenorphrine assay, and staff interview, it was revealed the facility failed to have complete studies. The findings include: 1. A review of the laboratory's verifications studies for the Abbott Architect Buphrenorphrine assay (qualitative) performed in June 2019 revealed the facility failed to have documentation of evaluating the precision of the assay. 2. The laboratory was asked to provide documentation of evaluating precision. No documentation was provided. 3. An interview with the laboratory manager on 08/11/2021 at 1530 hours in the conference room - after her review of the records- 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 review of the laboratory's maintenance records for the CLINITEK NOVUS instrument (used in urine analysis) for January, February and March of 2021, review of the manufacturer's Operator's Manual, and interview with the staff it was determined the laboratory failed to document the required End of Day maintenance for 3 of 90 instances reviewed. The findings were: 1. Review of the manufacturer's Operator's Manual for the CLINITEK NOVUS instrument revealed: "Daily maintenance includes the following tasks: " Cleaning the rack handler " Cleaning the SG well " Emptying the waste bottle" 2. Review of the laboratory's maintenance records for the CLINITEK NOVUS instrument for January, February and March of 2021 revealed the following dates had no documentation of End of Day maintenance: 01/12/2021 03/12/2021 03/16/2021 Note: The End of Day maintenance was defined on the laboratory's Clinitek/PRO System Maintenance Log as: Clean track and racks UF1000i Empty waste container 3. In an interview on 08/11/2021 at 1430 hours in the conference room the Technical Consultant number 2 (as defined on CMS Form 209 signed by laboratory director on 08/10/2021) confirmed that End of Day maintenance was not documented for the above dates. This confirmed the findings.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on random review of the laboratory's Quality Control (QC) records for Coagulation Prothrombin Time (PT) for February of 2020, review of the package insert for Siemens Dade Innovin PT reagent, review of patient records and interview with the staff it was determined the laboratory failed to run quality controls every 8 hours as required for 4 of 29 days reviewed. The Findings were: 1. Review of the package insert for Siemens Dade Innovin PT reagent under section of Internal Quality Control revealed "Two levels of quality control material (normal and pathological range) must be measured at start of the test run, with each calibration, upon reagent vial change and at least every eight hours on each day of testing." 2. Review of the laboratory's QC records for Coagulation PT for February of 2020 revealed the laboratory failed to run quality controls every 8 hours for the following dates: 02/03 /2020 Control 1 performed at 7:15am Control 3 performed at 7:20am Next QC performed on 02/04/2020 02/07/2020 Control 1 performed at 6:54am Control 3 performed at 6:54am Next QC performed on 02/08/2020 02/17/2020 Control 1 performed at 8:11am Control 3 performed at 8:11am Next QC performed on 02/18 /2020 02/28/2020 Control 1 performed at 6:49am Control 3 performed at 6:48am Next QC performed on 03/01/2020 3. Random review of the laboratory's patient records revealed patient testing was performed past the required 8 hours QC interval as follows: Specimen 305751 Tested 02/03/2020 at 4:42pm Last QC ran 02/03/2020 at 7: 20am Elapsed time from QC: 9hrs 22min Specimen 312293 Tested 02/03/2020 at 4: 43pm Last QC ran 02/03/2020 at 7:20am Elapsed time from QC: 9hrs 23min

	Specimen 309635 Tested 02/07/2020 at 4:09pm Last QC ran 02/07/2020 at 6:54am Elapsed time from QC: 9hrs 15min Specimen 310224 Tested 02/07/2020 at 4:11pm Last QC ran 02/07/2020 at 6:54am Elapsed time from QC: 9hrs 17min Specimen 312582 Tested 02/07/2020 at 4:10pm Last QC ran 02/07/2020 at 6:54am Elapsed time from QC: 9hrs 16min Specimen 312607 Tested 02/07/2020 at 4:14pm Last QC ran 02 /07/2020 at 6:54am Elapsed time from QC: 9hrs 20min Specimen 298117 Tested 02 /17/2020 at 4:22pm Last QC ran 02/17/2020 at 8:11am Elapsed time from QC: 8hrs 11min Specimen 300895 Tested 02/17/2020 at 4:21pm Last QC ran 02/17/2020 at 8: 11am Elapsed time from QC: 8hrs 10min Specimen 302942 Tested 02/28/2020 at 4: 26pm Last QC ran 02/28/2020 at 7:11am Elapsed time from QC: 9hrs 15min Specimen 309640 Tested 02/28/2020 at 4:25pm Last QC ran 02/28/2020 at 7:11am Elapsed time from QC: 9hrs 14min Specimen 312723 Tested 02/28/2020 at 3:35pm Last QC ran 02/28/2020 at 7:11am Elapsed time from QC: 8hrs 24min 4. In an interview on 08/11/2021 at 11:40 hours in the conference room the Technical Consultant number 2 (as defined on CMS Form 209 signed by laboratory director on 08/10/2021) stated that the laboratory runs PT controls every 8 hours, and was not aware of patient sample testing beyond the required 8 hours QC interval. This confirmed the findings.
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: Based on review of the laboratory's quality control records, review of patient test records, and staff interview, it was revealed the facility failed to have documentation of evaluating patient's whose samples were tested prior to a quality control failure. The findings include: 1. A review of the laboratory's quality control records from August 2021 revealed the following failures which required calibration to resolve: a) Architect 8200 (1) date: 07/21/2021 analyte: Magnesium Failed levels: 2 and 3 b) Architect 8200 (2) date: 08/06/2021 analyte: Amphetamines Failed level: 2 date: 08/03 /2021 analyte: Glucose Failed levels: 1, 2, and 3 date: 08/03/2021 analyte: Total Protein Failed levels: 1, 2, and 3 2. A review of patient test records from August 2021 identified the following patients which were tested on each instrument the testing day previous to the failure and thus, required corrective actions: a) Architect 8200 (1) date: 07/20/2021 analyte: Magnesium 35 patients Specimen ID 170762 170771 170768 170753 170752 170741 170709 170706 170714 170681 170684 170674 170683 170685 170678 170663 170659 170665 170629 170634 170641 170635 170640 170669 170666 170649 170651 170655 170656 170590 170587 170588 170589 170593 170594 b) Architect 8200 (2) date: 08/06/2021 analyte: Amphetamines 25 patients Specimen ID 173166 173178 173179 173181 173184 173224 173227 173239 173240 173242 173244 173246 173248 173294 173296 173297 173300 173303 173305 173306 173308 173310 173311 173322 173324 date: 08/02/2021 analyte: Glucose 9 patients Specimen ID 172695 172699 172703 172704 172708 172711 172729 172740 172743 date: 08/02/2021 analyte: Total Protein Failed

	levels: 1, 2, and 3 10 patients Specimen ID 172743 172740 172699 172693 172695 172696 172711 172704 172703 172708 date: 08/03/2021 analyte: Cholesterol Failed levels: 1, 2, and 3 3. The laboratory was asked to provide documentation of performing corrective actions on the identified patient results. No documentation was provided. 4. An interview with Technical Consultant number 1 (as listed on Form CMS 209) on 08/12/2021 at 1025 hours in the conference room - after her review of the records- 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 review of the laboratory's Sysmex XN Hematology analyzer's operator's manual, review of the laboratory's Hematology policies and procedures, review by comparison of patient complete blood counts (CBC) laboratory vs instrument reports for September 2020 and August 2021 and interview with the staff it was determined the laboratory's Quality Assurance (QA) assessment failed to identify that flagged results were reported to provider for 3 of 3 instances reviewed. The findings were: 1. Review of the laboratory's Sysmex XN Hematology analyzer's operator's manual section 10.1.4 Numerical Data of the Analysis Results under Notations revealed: Notation Meaning Description [*] Low reliability Indicates that the reliability of the data is low 2. Review of the laboratory's policies and procedures revealed no policy to address alert values and ensure appropriate results were reported for samples run in duplicate or repeated. 3. Review by comparison of patient complete blood counts (CBC) laboratory vs instrument reports revealed the laboratory did obtain reliable results upon repeat/duplicate testing but reported results of low reliability (containing the low reliability flag [*]) as follows: Sample 122249 Tested 09/08/2020 at 12:33pm; repeated/duplicated at 12:34pm Instrument results: NEUT 2.85* [10?3/ul] 69.5* [%] EO 0.16* [10?3/ul] 3.9* [%] Repeat/duplicate instrument results: NEUT 2.94 [10?3 /ul] 71.6 [%] EO 0.12 [10?3/ul] 2.9 [%] Reported results: WBC 5.65 Eosinophils % 3.90 Eosinophils (abs) 0.16 Neutrophils % 69.50 Neutrophils (abs) 2.85 Sample 173332 Tested 08/05/2021 at 3:14pm; repeated/duplicated at 3:16pm Instrument results: WBC 5.65* [10?3/ul] NEUT 3.52* [10?3/ul] 62.4* [%] LYMPH 1.50* [10?3 /ul] 26.5* [%] MONO 0.50* [10?3/ul] 8.8* [%] EO 0.08* [10?3/ul] 1.4* [%] BASO 0.04* [10?3/ul] 0.7* [%] Repeat/duplicate instrument results: WBC 5.45 [10?3/ul] NEUT 3.49 [10?3/ul] 63.9 [%] LYMPH 1.42 [10?3/ul] 26.1 [%] MONO 0.41 [10?3 /ul] 7.5 [%] EO 0.08 [10?3/ul] 1.5 [%] BASO 0.03 [10?3/ul] 0.6 [%] Reported results: WBC 5.65 Basophils % 0.7 Basophils (abs) 0.04 Eosinophils % 1.4 Eosinophils (abs) 0.08 Lymphocytes % 26.5 Lymphocytes (abs) 1.50 Monocytes % 8.8 Monocytes (abs) 0.50 Neutrophils % 62.4 Neutrophils (abs) 3.52 Sample 173129 Tested 08/06 /2021 at 7:57am; repeated/duplicated at 7:59am Instrument results: NEUT 3.59* [10?3 /ul] 58.3* [%] EO 0.12* [10?3/ul] 2.0* [%] Repeat/duplicate instrument results: NEUT 3.77 [10?3/ul] 60.2 [%] EO 0.00 [10?3/ul] 0.0 [%] Reported results: Eosinophils % 2.0 Eosinophils (abs) 0.12 Neutrophils % 58.30 Neutrophils (abs) 3.59 4. In an interview on 08/10/2021 at 1430 in the conference room the Technical Consultant number 2 (as defined on CMS Form 209 signed by laboratory director on 08/10/2021) stated that she was unaware the low reliability results are being reported.

	This confirmed the findings. Legend: WBC White blood cells NEUT Neutrophils LYMPH Lymphocytes MONO Monocytes EO Eosinophils BASO Basophils (abs) Absolute counts [10?3/ul]
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2021, and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were reviewed by the appropriate staff. The findings include: 1. A review of the laboratory's policy titled "Proficiency Testing and Assessment" (revision date: 06 /13/2018) under section "5. Evaluation of Reports" revealed: "Upon the return of the proficiency test results, the Clinical Laboratory Manager will review the scores of the survey(s) to check for any unacceptable test results, trends or biases." 2. A review of the laboratory's College of American Pathologist's (CAP) proficiency testing results from 2021 identified 4 of 18 results which were signed as reviewed by someone other than the clinical laboratory manager. They were: 2021 CGL-A event 1 2021 FH9-A event 1 2021 RT-A event 1 2021 VM-A event 1 3. The laboratory was asked to provide documentation of the clinical laboratory manager reviewing the results. No documentation was provided. 4. An interview with the laboratory manager on 08/10 /2021 at 1520 hours in the conference room - after her review of the records- 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 review of the laboratory's records, review of the laboratory's policies, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to have documentation of performing competency assessments on testing personnel prior to testing patient samples. The findings include: 1. A review of the laboratory's records revealed the laboratory placed a Sysmex CS-2500 coagulation analyzer into use on February 8, 2021. 2. A review of the laboratory's policy titled "Personal Competency Evaluation" (revision date: 04/16/2019) revealed: "... evaluations must be performed at least semiannually unless test methodology or

	instrumentation changes, in which case, prior to reporting patient test results the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation." 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on testing personnel prior to them performing patient testing. a) Testing personnel #2 competency assessment performed: 08/09 /2021 b) Testing personnel #4 competency assessment performed: 04/20/2021 c) Testing personnel #5 competency assessment performed: 04/20/2021 d) Testing personnel #6 competency assessment performed: 05/14/2021 e) Testing personnel #9 competency assessment performed: 05/14/2021 4. The laboratory was asked to provide documentation of competency assessments being performed prior to personnel performing patient testing. No documentation was provided. 5. An interview with the laboratory manager on 08/10/2021 at 1600 hours in the conference room - after her review of the records- confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 2 of 10 testing personnel on the Sysmex CS-2500 analyzer. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 10 testing personnel who performed testing on the Sysmex CS 2500 analyzer. 2. A review of the laboratory's personnel records revealed 2 testing personnel did not have documentation of training on the Sysmex CS-2500 analyzer. They were (as listed on Form CMS 209): Testing personnel number 4 Testing personnel number 6 3. The laboratory was asked to provide documentation of the missing training. No documentation was provided. 4. An interview with the laboratory manager on 08/10/2021 at 1600 hours in the conference room - after her review of the records - confirmed the findings.