Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2099494	08/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Allison H Henderson Md Pa	1112 N Floyd Road, Suite 8, Richardson, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D5400 - 42 C.F.R. 493.1421 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1421 Condition: Laboratory Manager D6033 - 42 C.F.R. 493.1421 Condition: Technical Consultant D6063 - 42 C.F.R. 493.1421 Condition: Testing Personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
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 review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director and testing personnel signing 3 of 3 attestation statements. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2021 Hematology with Diff D (Q3) and Hematology with Diff D 2022 (Q1 and Q2) revealed the laboratory failed to have documentation of the signatures of the

	laboratory director and testing personnel on 3 of 3 attestation statements. They were: 2021 Hematology with Diff D Q3 2022 Hematology with Diff D Q1 2022 Hematology with Diff D Q2 2. The laboratory was asked to provide documentation of the laboratory director and testing personnel signing the identified attestation statements. No documentation was provided. 3. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1106 hours in the 'avengers room' - after her review of the records- confirmed the findings.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' hematology proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to score at least 80% for White Blood Cell Differential for 1 of 3 events reviewed. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2021 Hematology with Diff D (Q3) and Hematology with Diff D 2022 (Q1 and Q2) revealed the laboratory failed attain a score of at least 80% for White Blood Cell Differential on 1 of 3 events. 2021 Hematology with Diff D Q3 White Blood Cell Differential: Score 67% 2. The laboratory was asked to provide documentation of corrective actions being performed. No documentation was provided. 3. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1106 hours in the 'avengers room' - after her review of the records- confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' proficiency testing results from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of the review of 3 of 3 events. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2021 Hematology with Diff D (Q3) and Hematology with Diff D 2022 (Q1 and Q2) revealed the laboratory failed to have documentation of the review of the results for 3 of 3 events. They were: 2021 Hematology with Diff D Q3 2022 Hematology with Diff D Q1 2022 Hematology with Diff D Q2 2. The laboratory was asked to provide documentation of the review of identified results. No documentation was provided. 3. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1106 hours in the 'avengers room' - after her review of the records- 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: Based on review of the laboratory's records and staff interview, it was revealed the facility failed to meet analytic system requirements. The findings include: 1. The laboratory failed to have documention of following the manufacturer's instructions for resolving flags on Complete Blood Count results (refer to D5411). 2. The laboratory failed to document cleaning the transducer every two weeks (refer to D5429). 3. The laboratory failed to have documentation of performing quality control testing for 36 of 51 testing days (refer to D5447). 4. The laboratory failed to have documentation of monitoring and assessing cumulative quality control data indicated potential problems with accuracy bias and QC Data Parameter SDI Ranges (refer to D5791).
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 review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer, review of patient test records and staff interview, it was revealed the laboratory failed to have documention of following the manufacturer's instructions for resolving flags on Complete Blood Count results. The findings were: 1. A review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer (Code no. AJ921414 na, Revision date: April 2015) under the section titled "2.1.8. Histogram flags" revealed the following flags, probable causes, and corrective actions to perform to resolve: a) Flag "WL" Probable Cause: Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase in large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids. Correction: Check smear Warm sample and repeat analysis b) Flag "T2" Probable Cause: Aged sample, incomplete lysing of red blood cells, etc., causing the first two WBC populations in the WBC-Histogram not to be separated, presence of CMS or other immature granulocytes. Correction: Check smear Warm sample and repeat analysis c) Flag "AG" Probable Cause: Presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids, etc. Correction: Check smear Warm sample and repeat analysis Wash blood cells 2. A sampling of patient samples from July 2021 to July 2022 identified 7 of 8 patient results with one or more of the identified flags which were reported to the provider without documentation of corrective actions being performed: a) July 7, 2021 Specimen ID: 135464 Flag: WL b) August 4, 2021 Specimen ID: 3942022 Flags: WL and AG c) May 25, 2022 Specimen ID: 4974589 Flag: T2 d) June 24, 2022 Specimen ID: 4986761 Flag: T2 e) July 1, 2022 Specimen ID: 4804523 Flag: T2 f) July 14, 2022 Specimen ID: 4996616 Flag: T2 g) July 18,

	2022 Specimen ID: 4995300 Flag: T2 3. The laboratory was asked to provide documentation of performing corrective actions prior to reporting the results to the provider. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1138 hours in the 'avengers' room revealed the facility reported out complete blood counts with flags. She stated corrective actions were not performed. This confirmed the findings. Key WBC- white blood cell
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 manufacturer's instructions for the Sysmex pocH-100i hematology analyzer, review of the laboratory's maintenance records from January 2022 to July 2022, and staff interview, it was revealed the laboratory failed to document cleaning the transducer every two weeks. The findings include: 1. A review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer (Code no. AJ921414 na, Revision date: April 2015) under the section titled "Section 6 Maintenance" revealed: "Every Two weeks - clean the transducer" 2. A review of the laboratory's Sysmex pocH-100i hematology analyzer maintenance records from January 2022 to July 2022 revealed the laboratory documented performing the 'every two week" maintenance on the following days" January 5 January 26 (3 weeks later) February 9 February 25 March 23 (4 weeks later) April 8 April 29 (3 weeks later) May 12 Mary 26 June 1 June 22 (3 weeks later) July 6 July 29 (3 weeks later) 3. The laboratory was asked to provide documentation of performing the "two week" maintenance as required. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1115 hours in the 'avengers' room - after her review of the records - confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records for the Sysmex poocH-100i hematology analyzer from January 2022 to July 2022, review of patient test records from January 2022 to July 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing for 36 of 51 (71%) testing days. The findings include: 1. A review of the laboratory's quality control records for the Sysmex poocH-100i hematology analyzer from January 2022 to July 2022 identified the laboratory performed quality control testing on the following 15 days:January 14 February 10 February 15 February 18 March 18 March

	16 April 19 April 29 May 2 May 11 May 20 May 23 May 25 June 15 July 29 2. A review of patient test records from January 2022 to July 2022 identified the following days when patient testing was performed and results reported without documentation of quality control testing being performed: January 7 Patient: 4308228 Patient: 4992678 January 10 Patient: 3523927 January 19 Patient: 4035049 January 24 Patient: 4730415 January 27 Patient: 3106366 January 28 Patient: 3916571 Patient: 4876095 February 2 Patient: 4722260 March 1 Patient: 3989794 March 2 Patient: 4952840 March 15 Patient: 4930495 March 22 Patient: 4928897 March 29 Patient: 4925550 March 30 Patient: 4933972 April 4 Patient: 3406337 April 5 Patient: 4947583 April 6 Patient: 3938116 May 5 Patient: 4568439 May 10 Patient: 4961733 Patient: 4697632 June 1 Patient: 4970565 June 3 Patient: 3942022 Patient: 3941182 June 8 Patient: 4975805 June 9 Patient: 4996617 June 10 Patient: 4980096 June 17 Patient: 4976412 June 23 Patient: 4884410 June 24 Patient: 4986761 June 30 Patient: 4986600 July 1 Patient: 4804523 July 7 Patient: 4990769 July 8 Patient: 4993683 July 14 Patient: 4995918 Patient: 4996616 July 18 Patient: 4995300 July 22 Patient: 5001255 July 25 Patient: 4265127 Patient: 3409486 July 26 Patient: 4996566 3. The laboratory was asked to provide documentation of performing quality control testing on the days identified. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1030 hours by the front desk revealed the laboratory did not perform quality control testing on the listed days. She stated she did not find any record of control material being tested on the instrument. This 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 Insight quality control reviews for the EIGHTCHECK-3WP X-TRA hematology controls, and staff interview, it was revealed the laboratory failed to have documentation of monitoring and assessing cumulative quality control data indicated potential problems with accuracy bias and QC Data Parameter SDI Ranges. The findings include: 1. A review of the laboratory's Sysmex Insight quality control records for the EIGHTCHECK-3WP X-TRA hematology controls from May 2021 to July 2022 revealed the manufacturer identified the following codes for potential problems with the laboratory's quality control results over time: a) Accuracy Bias Code "W" "Your mean on this level is approaching a statistical bias in accuracy. Please follow your SOP for troubleshooting" b) QC Data Parameter SDI Ranges "If you CV is 1.5 times greater than the Group CV, your result is presented in bold type and an investigation is warranted." 2. Further review of the laboratory's Sysmex Insight records identified the following results which were indicated by the manufacturer as requiring investigation: a) Lot: 1139 In Use: 5/19/2021 to 8/25/2021 HCT Level 2 code: W MXD# Level 3 Lab SDI in bold type b) Lot: 1223 In Use: 08/11/2021 to 11/17/2021 RBC Level 3 code: W HCT Level 2 code: W HCT Level 3 code: W LYM% Level 1 Lab SDI in bold type c) Lot: 1307 In Use: 11/03/2021 to 02/09/2022 HCT: Level 2 code: W MCH: Level 2 code: W MCH: Level 2 Lab SDI in bold type d) Lot: 2026 In Use: 01 /26/2022 to 05/04/2022 WBC: Level 1 Lab SDI in bold type RBC: Level 1 Lab SDI in

	bold type RBC: Level 2 Lab SDI in bold type HGB: Level 1 Lab SDI in bold type HGB: Level 2 Lab SDI in bold type e) Lot: 2110 In Use: 04/20/2022 to 07/27/2022 RBC: Level 3 Code: W 3. The laboratory was asked to provide documentation of assessing and correcting the problems identified by the quality control manufacturer. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1400 hours in the 'avengers' room revealed the quality control reports where in her email and had not been reviewed by the anyone. This confirmed the findings. Key WBC -white blood cell RBC - red blood cell HCT - hematocrit HGB - hemoglobin MCH - mean corpuscular hemoglobin LYM% - percent lymphocytes QC - quality control
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and staff interview, it was revealed the facility failed to have a procedure which defined the laboratory's panic values and the steps to document for the notification of the provider. The finding include: 1. A review of the laboratory's procedure manual revealed the facility failed to have documentation of a procedure which defined the laboratory's panic values and the steps to document for the notification of the provider. 2. The laboratory was asked to provide documentation of panic value procedure. No documentation was provided. 3. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08 /11/2022 at 1300 hours in the laboratory revealed the laboratory did not have defined panic values nor did it have a procedure for the notification of panic values. This 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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The findings include: 1. The laboratory failed to have documentation of the review of 3 of 3 events (refer to D6018). 2. The laboratory director failed to ensure corrective actions were performed for proficiency testing (refer to D6019). 3. The laboratory director failed to ensure quality control testing was performed each day of patient testing (refer to D6020). 4. The laboratory director failed to ensure the monitoring and assessing of cumulative quality control data (refer to D6021). 5. The laboratory director failed to ensure testing personnel had documentation of education and training to perform testing (refer to D6029).
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 American Association of Bioanalysts' proficiency testing results from 2021 and 2022, and staff interview, it was revealed the laboratory director failed to have documentation of the review of 3 of 3 events (refer to D5211).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' hematology proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory director failed to ensure corrective actions were performed when the laboratory failed to score at least 80% for White Blood Cell Differential (refer to D2121).
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 review of the laboratory's quality control records, patient test records and staff interview, it was revealed the laboratory director failed to ensure quality control testing was performed each day of patient testing (refer to D5447).
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 review of the laboratory's Sysmex Insight quality control reviews for the EIGHTCHECK-3WP X-TRA hematology controls, and staff interview, it was revealed the laboratory director failed to ensure the monitoring and assessing of cumulative quality control data (refer to D5791).
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's personnel records and staff interview, it was revealed the laboratory director failed to ensure testing personnel had documentation of education and training to perform testing (refer to D6065 and D6066).
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the technical consultant failed to provide technical oversight for the laboratory. The findings include: 1. The technical consultant failed to provide technical oversight for the laboratory (refer to D6036). 2. The technical consultant failed to ensure quality control testing was performed each day of patient testing (refer to D6042). 3. The technical consultant failed to ensure corrective actions were performed prior to reporting patient results (refer to D6044). 4. The technical consultant failed to ensure testing personnel had documentation of training (refer to D6066).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413

	The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the technical consultant failed to provide technical oversight for the laboratory. The findings include: 1. The technical consultant failed to ensure corrective actions were performed on flagged Complete Blood Count results (refer to D5411). 2. The technical consultant failed to ensure required maintenance was performed as required (refer to D5429). 3. The technical consultant failed to ensure quality control testing was performed each day of patient testing (refer to D5447). 4. The technical consultant failed to ensure the laboratory defined its panic values and how these values were to be reported (refer to D5813).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, patient test records and staff interview, it was revealed the technical consultant failed to ensure quality control testing was performed each day of patient testing (refer to D5447).
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the manufacturer's instruction for the Sysmex pocH-100i hematology analyzer, review of patient test records, and staff interview, it was revealed the technical consultant failed to ensure corrective actions were performed prior to reporting patient results (refer to D5411).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the technical consultant failed to ensure testing personnel had documentation of training (refer to D6066).
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION 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 education to qualify 3 of 3 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and 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 education to qualify 3 of 3 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 3 of 3 testing personnel. The personnel files contained the following items: Testing personnel number 1 Course in Medical Assisting Testing personnel number 2 Diploma in Medical Assisting Testing personnel number 3 Emergency Medical Technician certification 3. The laboratory was asked to provide documentation of education to qualify the testing personnel. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11 /2022 at 1015 hours in the 'avengers' 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 on the Sysmex poocH-100i hematology analyzer. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 3 of 3 testing personnel on the Sysmex poocH-100i hematology analyzer. 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. An interview with testing personnel number 3 (as listed on Form CMS 209) on 08/11/2022 at 1015 hours in the 'avengers' room - after her review of the records- confirmed the findings.