Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2095721	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr Karelys Rivera And Associates Pa	3126 Centerpoint Drive, Edinburg, 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. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Lab Director, moderate complexity D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant; moderate complexity D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing records from 2016, 2017, and 2018, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to ensure that proficiency testing was performed by all personnel who routinely performed testing. The findings were: 1. A review of the laboratory's AAFP proficiency testing records from 2016 (events 1, 2, and 3), 2017 (events 1, 2, and 3), and 2018 (events 1

	and 2) revealed testing personnel number one (as listed on Form CMS-209) performed the analysis of proficiency testing samples for 8 of 8 testing events. 2. An interview with testing personnel one (as listed on Form CMS-209) on 08/28/2018 at 13:50 hours in the break room confirmed the findings. She revealed the laboratory did not have a proficiency testing policy. CMS - Centers for Medicare and Medicaid Services
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 proficiency testing records, and confirmed in interview of facility personnel, the laboratory director failed to sign 8 of 8 attestation statements. The findings were: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing records under, "Attestation Statement" stated, " ...By signature below, the lab is authorizing results to be submitted to the regulatory/accrediting agencies." 2. Review of the laboratory's proficiency testing records for 2016 (events 1, 2, and 3), 2017 (events 1, 2, and 3), and 2018 (events 1 and 2) revealed the laboratory director's name was printed in the area designated for the director instead of signed. 3. An interview with testing personnel number one (as listed on CMS Form-209) on 08/28/2018 at 14:00 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 Academy of Family Physicians (AAFP) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of reviewing and evaluating proficiency testing results. The findings were: 1. Review of the laboratory's proficiency testing records for 2016 (events 1, 2, and 3), 2017 (events 1, 2, and 3), and 2018 (events 1 and 2) revealed the laboratory had printed out final scores, but there was no documentation that the laboratory's performance had been evaluated. 2. An interview with testing personnel one (as listed on Form CMS-209) on 08/28/2018 at 13:50 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 direct observations, review of manufacturer's instructions, review of quality control records, review of environmental records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to monitor evaluate overall quality of the analytic system as evidenced by: 1. The laboratory failed to resolve flags on CBC (complete blood count) results prior to their release to the healthcare provider. (refer to D5405) 2. The laboratory failed to define an acceptable room temperature and humidity range according to the manufacturer's instructions for the Abbott Cell-Dyn Emerald. (refer to D5413) 3. The laboratory failed to perform a patient normal range verification study when the Abbott Cell-Dyn Emerald was implemented in May 2015. (refer to D5421) 4. The laboratory failed to provide documentation of performing semi-annual maintenance at the required intervals on the Abbott Cell-Dyn Emerald. (refer to D5429) 5. The laboratory failed to have a policy to detect immediate errors and errors over time for the Abbott Cell-Dyn Emerald. (refer to D5441) 6. The laboratory failed to perform lot to lot quality control verifications prior to implementing a new lot of quality control for the Abbot Cell-Dyn 18 Plus controls. (refer to D5469-A) 7. The laboratory failed to establish its own means and ranges for quality control on the Abbott Cell-Dyn Emerald. (refer to D5469-B).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to resolve CBC (complete blood count) results with flags prior to their release to the healthcare provider. The findings were: 1. According to testing personnel one (as listed on Form CMS-209 at 16:00 hours in the laboratory, if a patient's CBC results with a flag, the CBC is repeated. If the flag persists she stated, the laboratory "would send it out for confirmation." 2. Review of the manufacturer's instructions for the Abbot Cell-Dyn Emerald (9140847G-November 2013) under, "WBC Measurand Flags" stated, "An asterisk (*) for count invalidation of (s) suspect measurand flags are displayed with the corresponding results. The flags are generated after the instrument evaluates the measurand data for a particular measurand or group of measurands. The results may be suspect due to interfering substances or the inability of the instrument to measure a particular measurand due to a sample abnormality. The name of each flag, how it is displayed, the cause of the flag, and the action to be taken are given in the following explanations." Measurand: WBC and Differential Result Flag: * Text in Flags Box: L1 (white text) Cause: May be due to platelet aggregates, NRBC, giant platelets, cryoglobulins, incomplete lysis of RBC, small lymphocytes, fibrin clots, shift in WBC cell distribution due to EDTA anticoagulant equilibration. Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review

	a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required. Measurand: Differential Result Flag: s Text in Flags Box: L2 (white text) Cause: May indicate the presence of myelocytes, lymphoblasts, or basophils Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. Measurand: Differential Result Flag: s Text in Flags Box: L3 (white text) Cause: May indicate the presence of eosinophils or myelocytes Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. Measurand: Differential Result Flag: * Text in Flags Box: L5 (white text) Cause: Large-size cells present Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required. 3. Random review of patient final reports from August 2018 revealed the following 7 of 15 patient results were resulted with flags when the CBC was not sent out for confirmation: Patient ID: 04 27 2010 CBC was repeated, but flag persisted Flag: L2 Patient ID: 08 13 2011 CBC not repeated Flag: L3 Patient ID: 01 19 2006 CBC not repeated Flag: L3 Patient ID: 07 07 2012 CBC not repeated Flag: L3 Patient ID: 08 03 2010 CBC not repeated Flag: L3 Patient ID: 06 27 2011 CBC not repeated Flag: L3 Patient ID: 05 22 2010 CBC not repeated Flag: L3 4. An interview with testing personnel one (as listed on Form CMS-209) on 08/28/2018 in the laboratory at 16:10 hours in the laboratory confirmed the findings. When asked in the 7 of 15 results were sent out for confirmation to resolve the flags, she stated, "No." Key: WBC - white blood cell NRBC - nucleated red blood cell RBC - red blood cell EDTA - ethylenediaminetetraacetic acid CMS - Centers for Medicare and Medicaid Services
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory maintenance records, and confirmed in interview of facility personnel, the laboratory failed to define an acceptable room temperature and humidity range according to the manufacturer's instructions. The findings were: 1. Review of the manufacturer's instructions for the Abbott Cell Dyn hematology analyzer (9140846G-November 2013) under, "Site Requirements" stated, "To ensure the instrument and reagents function properly, it is important to maintain the temperature between 64 degrees to 90 degrees Fahrenheit (18-32 degrees Celsius)." And; "Maximum relative humidity of 80% for temperatures up to 90 degrees Fahrenheit." 2. Review of the laboratory's environmental records for January 2016 to July 2018 revealed the laboratory had a defined room temperature range of 16-35 degrees Celsius and relative humidity of up

	to 85%. 3. An interview with testing personnel number one (as listed on Form CMS-209) on 08/28/2018 at 16:45 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 direct observation, review of verification records for the Abbott Cell Dyn Emerald hematology analyzer, and confirmed in interview of facility personnel, the laboratory failed to verify its patient normal ranges. The findings were: 1. Direct observation made on 08/28/2018 in the laboratory revealed the patient reference ranges matched the manufacturer's reference ranges entered during the instrument installation. 2. Review of the laboratory's instrument verification records for the Abbott Cell Dyn Emerald (serial number 035013-804487) revealed the laboratory implemented the analyzer in May 2015. 3. Further review of the laboratory's instrument verification records revealed the laboratory failed to have documentation of verifying its patient normal ranges for CBC (complete blood count). 4. An interview with testing personnel one (as listed on Form CMS-209) on 08/28/2018 at 16:45 hours in the break room confirmed the findings. She revealed the laboratory used the manufacturer's normal ranges but did not perform any type of verification. Key: CMS - Centers for Medicare and Medicaid Services
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 instrument manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing semi-annual instrument maintenance on the Abbott Cell-Dyn Emerald. The findings included: 1. Review of the manufacturer's instructions for the maintenance on the Abbott Cell-Dyn Emerald (9410861E-August 2012) under the Maintenance section it stated, "Semi-Annually: Lubricate the pistons." 2. Review of the laboratory's maintenance logs for the Abbott Cell-Dyn Emerald hematology analyzer revealed there was a section to document semi-annual maintenance. The laboratory documented performing semi-annual maintenance as follows: November 2015 May 2016 (6 months later) June 2017 (13 months later) 3. June 2017 was the last documented semi-annual maintenance. The date of the survey was August 28, 2018 (15 months later than the last documented

	semi-annual maintenance). 4. An interview with testing personnel one (as listed on Form CMS-209) on 08/28/2018 at 16:45 hours in the break room confirmed the findings. She revealed that the maintenance was performed by the service engineer but was unable to locate the preventative maintenance records that would document the performance of the procedure. Key: CMS - Centers for Medicare and Medicaid Services
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records from January 2016 to July 2018, and confirmed in interview, the laboratory failed to have a policy to detect immediate quality control (QC) errors and errors over time. The findings were: 1. The laboratory failed to have a policy to monitor immediate quality control (QC) errors and errors over time. 2. Review of quality control records from January 2017 to July 2018 revealed the laboratory performed three levels of quality control each day of patient testing, and printed Levy-Jennings reports at the end of each month. The records revealed no documentation of the laboratory monitoring QC statistics at intervals to assess the analytical process. 3. In an interview of testing personnel one (as listed on Form CMS-209) at 08/28/2018 at 15:00 hours in the break room, the above finding were confirmed. She confirmed the laboratory did not have any policies, only the operator's manual. Key: CMS - Centers for Medicare and Medicaid Services
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 review of the laboratory's quality control records from January 2016 to July 2018 and staff interview, it was revealed the laboratory failed to have documentation of verifying control values prior to placing the control into use. The findings were: 1. The laboratory failed to have a policy for verifying new lots of Cell-Dyn 18 Plus Controls prior to placing them into use. 2. The current lot number in use by the laboratory at the time of the survey on August 28, 2018 was 8183 (expiration date: 10-19-2018). There was no documentation available for review to determine that the laboratory had validated the lot number prior to putting it into use on 07-10-2018. 3. An interview with testing personnel one (as listed on Form CMS-209) on 08/28 /2018 at 15:45 hours in the break room confirmed the findings. She confirmed the laboratory did not verify the controls prior to placing them into use. She stated when a current expired, the laboratory would, "Start the new lot the next day." B. Based on direct observation, review of manufacturer's instructions for Cell-Dyn 18 Plus Controls, and confirmed in staff interview, the laboratory failed to have documentation of establishing its own means and ranges prior to placing new controls into use. The findings were: 1. A review of the manufacturer's instructions for the Abbott CELL-DYN 18 Plus Control (9231581a 350005-4), under the section titled "Performance Characteristics", revealed: "The assigned values are presented as a mean and recovery range. The mean assay values are derived from repetitive testing on several instruments operated and maintained according to the manufacturer's instructions; they do not necessarily apply to a single instrument. The recovery ranges are intended to reflect inter-laboratory variability; thus, they are wider than the +\- 2 SD QC range for one instrument. Always perform quality control according to good laboratory practice, laboratory director's requirements, and any regulatory or accreditation requirements." 2. Direct observation made on 08/28/2018 at 14:45 hours in the laboratory revealed the manufacturer's means and ranges were those entered into the hematology analyzer for the current lot number of controls. Lot Number 8183 Paramater Assay Value Mean WBC 2.1 0.4 RBC 2.13 0.20 HGB 5.2 0.5 HCT 16.8 2.0 PLT 61 25 3. The laboratory was asked to provide documentation of establishing its own means and ranges. No documentation was provided. 4. An interview with testing personnel one (as listed on Form CMS-209) at 14:45 hours in the laboratory confirmed the findings. She confirmed the values in the analyzer were the manufacturer's means and ranges and they did not establish their own. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet CMS - Centers for Medicare and Medicaid Services
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 direct observations, review of manufacturer's instructions, review of quality control records, review of enviromental records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing quality assessment program that would identify and correct problems indentified in its analytic systems as follows: 1. The laboratory failed to resolve flags on CBC results prior to their release to the

	healthcare provider. (refer to D5405) 2. The laboratory failed to define an acceptable room temperature and humidity range according to the manufacturer's instructions for the Abbott Cell-Dyn Emerald. (refer to D5413) 3. The laboratory failed to perform a patient normal range verification study when the Abbott Cell-Dyn Emerald was implemented in May 2015. (refer to D5421) 4. The laboratory failed to provide documentation of performing semi-annual maintenance at the required intervals on the Abbott Cell-Dyn Emerald. (refer to D5429) 5. The laboratory failed to have a policy to detect immediate errors and errors over time for the Abbott Cell-Dyn Emerald. (refer to D5441) 6. The laboratory failed to perform lot to lot quality control verifications prior to implementing a new lot of quality control for the Abbot Cell-Dyn 18 Plus controls. (refer to D5469-A) 7. The laboratory failed to establish its own means and ranges for quality control on the Abbott Cell-Dyn Emerald. (refer to D5469-B).
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 personnel records, review of manufacturer's instructions, review of proficiency testing records, review of quality control records, review of patient testing records, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6013, D6014, D6016, D6018, D6020, D6021, D6029, D6030, D6031, and D6032)
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 review of the laboratory's Abbott Cell-Dyn Emerald hematology analyzer verification records, and confirmed in interview of facility personnel, the laboratory director failed to ensure verification records were complete prior to patient testing. (refer to D5421)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to ensure that CBC (complete blood count) results with flags were verified prior to their release to the healthcare provider. (refer to D5405)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of proficiency testing results, review of attestation sheets, and confirmed in interview of facility personnel, the laboratory director failed to ensure proficiency testing was rotated among all testing persons. (refer to D2007)
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 proficiency testing results and confirmed in interview of facility personnel, the laboratory director failed to ensure proficiency testing results were reviewed. (refer to D5211)
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 quality control records, and interview of facility personnel, the laboratory director failed to establish a quality control plan. (refer to D5441 and D5469)
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 direct observation, review of manufacturer's instructions, review of quality control records, review of environmental records, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to establish a quality assurance plan. (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 personnel records, and confirmed in interview of facility personnel, the laboratory director failed to ensure each testing person had the appropriate education and training prior to testing patients. The findings were: 1. Review of the laboratory's personnel records revealed testing personnel three (as listed on Form CMS-209) did not have the appropriate education records on file to qualify her to perform moderate complexity testing in Hematology. The education records provided for review was a medical assisting certificate. 2. Review of the laboratory's personnel records revealed to training records were available for review for testing personnel three (as listed on Form CMS-209). 3. An interview with testing personnel one (as listed on Form CMS-209) on 08/28/2018 at 13:25 hours in the patient exam room confirmed the findings. She confirmed that testing personnel three (as listed on Form CMS-209) was having trouble getting a copy of her high school diploma. Key: CMS - Centers for Medicare and Medicaid Certificate
D6030	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of personnel records, and confirmed in interview of facility personnel, the laboratory director failed to establish policies and procedures for competency testing. The findings were: 1. Based on review of the laboratory's personnel records revealed no competency assessments were available for review for each of its testing persons. 2. An interview with testing personnel one (as listed on Form CMS-209) on 08/28/2018 at 13:50 hours in the break room confirmed the findings. She revealed the laboratory did not have a policy and procedure manual and there were competency assessments available for review. Key: CMS - Centers for Medicare and Medicaid Services
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of laboratory records, and interview of facility personnel, the laboratory director failed to ensure that an approved procedure manual was available to testing persons. The findings were: 1. A review of records revealed there was not a laboratory procedure manual approved, signed and dated by the laboratory director. 2. In an interview with testing personnel one (as listed on Form CMS-209) on 08/28 /2018 at 13:50 hours in the break room confirmed the findings. She stated the laboratory did not have a policy and procedure manual.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each

	consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records, and confirmed in interview with facility personnel, the laboratory director failed to specify in writing, the responsibilities and duties of each consultant and each testing person. The findings were: 1. Review of personnel records for testing person one, testing person two, and testing person three (as listed on Form CMS-209) revealed no job descriptions were available for review that specified in writing their responsibilities. 2. Further review of personnel records revealed no job descriptions were available for review for the laboratory director, clinical consultant, or the technical consultant. 3. The above findings were confirmed in interview with testing personnel one (as listed on Form CMS-209) at 14:30 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services
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 a review of the CMS Form- 209, interviews and laboratory test logs revealed the laboratory had no technical consultant available to provide the required technical oversight for the laboratory. (Refer to D6034) Key: CMS - Centers for Medicare and Medicaid Services
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on a review of personnel documents and interview of facility personnel it was revealed that the facility failed to designate a technical consultant for its moderate complexity testing in the specialty of Hematology. The findings were: 1. Review of the CMS Form-209, approved by the laboratory director on August 27, 2018 revealed the laboratory did not designate a technical consultant. 2. An interview with the office manager on 08/28/2018 at 16:30 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

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 personnel records and interview of facility personnel, it was revealed that the facility failed to ensure that prior to testing patients' specimens, all personnel had the appropriate education required to perform moderate complexity testing. (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 personnel records and interview of facility personnel, it was revealed that the facility failed to ensure that prior to testing patient specimens, all personnel had the appropriate education required to perform moderate complexity testing. The findings were: 1. A review of personnel records revealed that one of three personnel performing moderate complexity testing on the Abbott Cell-Dyn Emerald hematology analyzer did not have documentation available, at the time of the survey, for proof of at minimum a high school diploma or equivalent. 2. An interview with testing person one (as listed on Form CMS-209) on 08/28/2018 at 14:00 hours in the break room confirmed the findings. She revealed testing person three (as listed on Form CMS-209) had only been able to provide her MA (medical assistant) certificate, as she was having difficulty obtaining her high school diploma. Key: CMS - Centers for Medicare and Medicaid Services