Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0508693	01/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Permian Cardiology Inc	400 Rosalind Redfern Grover Parkway Ste 240, Midland, 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	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
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 proficiency testing records and interview of facility personnel, the laboratory failed to document the review for six of six proficiency testing events in Chemistry and Hematology in 2017 and 2018. The findings included: 1. Review of the American Association of Bioanalysts (AAB) proficiency testing records for 2017 and 2018 (three testing events per year) found that the laboratory failed to document the review for six of six (6 of 6) proficiency testing events for Chemistry (3) and Non-Chemistry (3) in 2018. 2. Interview the laboratory director conducted on January 29,2019 at 09:40 AM confirmed that he did not document the review of all Chemistry and Mon-Chemistry testing events in 2018.
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 surveyor observations, control instructions for use, review of quality control records, calibration verification records, patient records, quality, and interview with facility personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. The findings included: Based on surveyor observations, review of laboratory procedures, and interview with facility personnel, the laboratory failed to follow established procedure for spinning urine specimens for urine microscopic analysis at 1800 revolutions per minute (RPM) for 3 of 3 randomly reviewed patient specimens. Refer to D5403. Based on a review of manufacturer's instructions, quality control records, patient test records, and interview of facility personnel, the laboratory failed to ensure that expired quality control material was not used to verify the quality of patient PSA results tested on the Vitros ECI. See D 5415. Based on a review of laboratory procedures, calibration verification records, and interview with facility personnel, the laboratory failed to perform calibration verification procedures at least every 6 months for 3 of 3 analytes (Sodium, Potassium, and Chloride) in 2018. Refer to D5439. Based on review of quality control instructions for use, quality control records, and interview with facility personnel, the laboratory failed to accurately define the acceptability of 2 of 2 lots of control material used to assess test performance on the Vitros 350 chemistry analyzer. Refer to D5469.
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 surveyor observations, review of laboratory procedures, and interview with facility personnel, the laboratory failed to follow established procedure for spinning urine specimens for urine microscopic analysis at 1800 revolutions per minute (RPM) for 3 of 3 randomly reviewed patient specimens. The findings included: 1. At 09:18

	hours on 1/29/2019 in the laboratory, the surveyor observed the Power Spin MX Centrifuge set to the following setting: Relative centrifugal force (RCF) - 1744 Revolutions per Minute (RPM) - 3400 In an interview at 09:18 hours on 1/29/2019 in the laboratory, the laboratory director stated that urine specimens for urine microscopic analysis were spun in the Power Spin MX Centrifuge in its current configuration. 2. Based on review of the laboratory's procedure "Clinitex Status Plus Analyzer - Urine Macroscopic - Urine Microscopic", under PROCEDURE MICROSCOPIC ANALYSIS, the document stated the following: "1. Transfer the urine (12 mL if possible) to the UriSystem Tube. If less than 2 ccs of specimen is available, perform microscopic exam on the urine and put the comment 'less than 2 cc specimen received - microscopic performed on unspun urine; in the comments. 2. Centrifuge the sample for 5 minutes at a minimum of 1800 rpm." 3. Based on random review of patient records, the following specimens were spun at 1800 RCF/3400RPM and not 1800 RPM, as indicated in the procedure: Patient: 34618 Date: 1/25/2019 Patient: 41240 Date: 1/24/2019 Patient: 25358 Date: 1/21/2019 4. In an interview at 09:18 hours on 1/29/2019 in the laboratory, the laboratory director stated the laboratory had thought the centrifuge had been set to the appropriate speed, but saw that is was currently set to 1800 RCF/3400RPM and not 1800 RPM, as indicated in the procedure.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Observations, review of manufacturer's instructions for use, review of patient test records and interview of facility personnel found that the laboratory failed to ensure that the BIO RAD quality control materials were not used beyond the expiration for monitoring the quality of Prostate Specific Antigen (PSA) tested on the Vitros ECI. The findings included: 1. Observations made during the tour of the facility found that the laboratory used the BIO RAD Immunoassay Plus Controls levels 1, 2 and 3 to verify the quality of results for analytes tested on the Vitros ECI. The laboratory tested patient specimens for : Vitamin B12 Thyroid Stimulating Hormone (TSH) Prostate Specific Antigen (PSA) Free Thyroxine (FT4) Ferritin Testosterone 2. Review of the manufacturer's instructions for use of the BIO RAD Immunoassay Plus Controls levels 1, 2 and 3 found under the heading STORAGE AND STABILITY: "This product is stable until the expiration date stored unopened at 2-8 degrees C. Reconstituted and refrigerated - After reconstituting and storing tightly capped at 2-8 degrees C, this product will be stable as follows: All analytes 7 days except Folate and PSA (Total) 3 days at 2-8 degrees C." 3. Review of patient test records for January 2019 found that the laboratory tested 15 patient specimens for PSA using expired quality control materials: January 3, 2019 - 3 patient specimens were tested: patients 95903, 88877 and 96068 January 4, 2019 - 2 patient specimens were tested: patients 96180 and 95811 January 10, 2019 - 3 patient specimens tested: patients 96718, 96639, 96711 January 17, 2019 - patient 97325 January 18, 2019 - 2 patient specimens were tested: patients 97391 and 97399 January 24, 2019 - 3 patient specimens were tested: patients 97981, 97889 and 97909 January 25, 2019 - patient 98010 4. Interview of the laboratory director conducted on January 29, 2019 at 10:14 AM confirmed that the laboratory used the BIO RAD Immunoassay Plus Controls

	levels 1, 2 and 3 to verify the quality of results for PSA after its expiration. He went on to say that he reconstituted the quality control materials each Monday and would use it for 7 days before reconstituting a new bottle
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, calibration verification records, and interview with facility personnel, the laboratory failed to perform calibration verification procedures at least every 6 months for 3 of 3 analytes (Sodium, Potassium, and Chloride) in 2018. The findings included: 1. Based on review of the laboratory's procedure "Calibration Verification Analytical Measurement Range Validation", the procedures stated the following: "INTERVAL: Calibration, calibration verification and/or AMR validation shall be performed at least every six months for all assays on the following instruments: Vitros 350 Vitros ECIQ" 2. Laboratories must perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided or specified, and at a frequency that meets or exceeds that recommended by the manufacturer. Where the manufacturer does not provide such instruction, the laboratory may calibrate using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months. Based on review of calibrations and instructions for use, the 3 of 3 analytes Sodium, Potassium, and Chloride used two levels of calibration material and are subject to calibration verification requirement at least every six months. 3. Based on a review of calibration verification records, the laboratory last performed calibration verification procedures on October 11, 2017. The elapsed time between October 11, 2017 and the date of the survey, January 29, 2019, is 1 year, 3 months, 18 days excluding the end date. 4. In an interview at 10:05 hours on 1/29/2019 in the laboratory, the Laboratory Director stated the calibration verification procedures had not been performed due to the high cost of the materials.
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. Review of quality control instructions for use, the laboratory's own quality control policy, quality control records, and interview of facility personnel, the laboratory failed to follow their own policy for establishing the mean and acceptability criteria for six of six analytes tested on the Vitros ECI. THIS IS A REPEAT DEFICIENCY FROM THE 08/2015 AND 08/16/2017 INSPECTIONS. The findings included: 1. Based on review of the BIO RAD Lyphochek Immunoassay Plus Controls found under the heading ASSIGNMENT OF VALUES - "The mean values and corresponding + 3 SD ranges in the Assignment of Values Data Charts (available Separately) wee derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control." 2. Review of the laboratory's own policy titled Quality Control Policy found on page 1 under the heading Assayed QC Material - "QC material can be provided with previously established means and SD ranges for determined assays. These means and SD ranges were established by the manufacturer on similar instruments or methods prior to the release of QC material. The information provided is a guideline and can be useful in determining the laboratory's mean and SD range. Documentation is provided with QC material. Laboratory is responsible for verifying stated mean and range. Evaluate assayed material using the following guidelines: For a minimum of 5 consecutive days run both the new and old lot numbers together. This is to establish that the new lot number is working. If this is not possible due to unavailability of products, then running control material using the stated means can be done. However, multiple runs should be used to accumulate data more quickly. also, utilizing peer group data when available can help verify ranges. Continue running the new lot number for an additional 25 days. Take the total 30 points and calculate the mean and a two standard deviation where 2 SD is no larger than 5% CV. Use this as the new lot number control range. If the old lot number of control is not available to run after the first five days use the manufacturers control ranges until the new lot number ranges can be established. A post 30 day, 60 day, and 90 day evaluation of new control lot number may require slight adjustments to the mean or standard deviation of both. The technical supervisor or designee will monitor and adjust control values as needed." 3. Review of quality control records found that that the laboratory tested each level of

BIO RAD Lyphochek Immunoassay Plus Controls quality control material levels 1, 2 and 3 10 times each and established ranges for the following analytes: Vitamin B12 Level 1 Mean =345.4 ng/ml Laboratory established + 1 SD =11.95 Manufacturer's Mean = 346 ng/ml Range of means + 3 SD range 222 - 470 ng/ml Level 2 Mean = 593.1 ng/ml Laboratory established + 1 SD =30.14 Manufacturer's Mean = 613 ng/ml Range of means + 3 SD range 476 - 751 ng/ml Level 3 Mean = 810.8 ng/ml Laboratory established + 1 SD =42.79 Manufacturer's Mean = 899 ng/ml Range of means + 3 SD range 733 - 1000 ng/ml TSH Level 1 Mean =0.303 uIU/ml Laboratory established + 1 SD =0.009 Manufacturer's Mean = 0.27 uIU/ml Range of means + 3 SD range 0.191 - 0.339 uIU/ml Level 2 Mean = 4.8 uIU/ml Laboratory established + 1 SD =0.245 Manufacturer's Mean = 4.74 uIU/ml Range of means + 3 SD range 476 - 751 uIU/ml Level 3 Mean = 28.11 uIU/ml Laboratory established + 1 SD = 0.994 Manufacturer's Mean = 29.7 uIU/ml Range of means + 3 SD range 25.0 - 34.3 uIU/ml PSA Level 1 Mean =0.821 ng/ml Laboratory established + 1 SD =0.037 Manufacturer's Mean = 0.807 ng/ml Range of means + 3 SD range 0.70 - 0.98 ng/ml Level 2 Mean = 2.494 ng/ml Laboratory established + 1 SD =0.067 Manufacturer's Mean = 2.38 ng/ml Range of means + 3 SD range 1.99 - 2.78 ng/ml Level 3 Mean = 13.1 ng/ml Laboratory established + 1 SD = 0.316 Manufacturer's Mean = 12.5 ng/ml Range of means + 3 SD range 10.6 - 14.8 ng/ml FT4 Level 1 Mean = 1.535 ng/ml Laboratory established + 1 SD =0.137 Manufacturer's Mean = 1.68 ng/ml Range of means + 3 SD range 1.21 - 2.15 ng/ml Level 2 Mean = 5.18 ng/ml Laboratory established + 1 SD = 0.187 Manufacturer's Mean = 5.33 ng/ml Range of means + 3 SD range 4.86 - 5.80ng/ml Ferritin Level 1 Mean =39.4 ng/ml Laboratory established + 1 SD = 0.843 Manufacturer's Mean =42.2 ng/ml Range of means + 3 SD range 28.2 - 56.1 ng/ml Level 2 Mean = 100.42 ng/ml Laboratory established + 1 SD =3.146 Manufacturer's Mean = 108 ng/ml Range of means + 3 SD range 79.6 - 136 ng/ml Level 3 Mean = 261.9 ng/ml Laboratory established + 1 SD = 9.758 Manufacturer's Mean = 285 ng/ml Range of means + 3 SD range 733 - >1000 ng/ml Testosterone Level 1 Mean =180.3 ng/ml Laboratory established + 1 SD = 6.183 Manufacturer's Mean = 150 ng/ml Range of means + 3 SD range 95.1 - 205 ng/ml Level 2 Mean = 900.3 ng/ml Laboratory established + 1 SD =26.58 Manufacturer's Mean = 801 ng/ml Range of means + 3 SD range 573 - 1029 ng/ml Level 3 Mean = 1714 ng/ml Laboratory established + 1 SD =38.06 Manufacturer's Mean = 1585 ng/ml Range of means + 3 SD range 1156 - 2014 ng/ml Review of Monthly Levy Jennings printouts for January 2019 found that the laboratory was using the manufacturer's means and range of means as their own limits of acceptability. 4. Interview of the laboratory director conducted on January 29, 2019 at 10:28 AM confirmed that the laboratory did not use their own established mean and acceptable ranges for the quality control products used. He went on to say that the laboratory used their established mean and the manufacturer's range of means (+ 3SD) as their own range of acceptability. 36342 B. Based on review of quality control instructions for use, quality control records, and interview with facility personnel, the laboratory failed to accurately define the acceptability of 2 of 2 lots of control material used to assess test performance on the Vitros 350 chemistry analyzer. The findings included: 1. Based on review of the Ortho-Clinical Diagnostics document "Performance Verifiers: Training Module", (Part. No. J04498), under How the Range of Means (ROM) is Used, the document states: "When using Performance Verifiers for routinely monitoring a properly operating system, all calculated means should be within the range of means. Each estimate of the mean should be statistically the same as all other estimated of the mean. the assessment of any two means will be discussed later on in this module. It is not expected that all individual daily QC values will fall within the range of means even if the system is showing acceptable performance However, the mean of a distribution of daily QC values for properly operating systems should always fall

	within the range of means." Based on review of the Ortho-Clinical Diagnostics document "Performance Verifiers: Training Module", (Part. No. J04498), under How the Within-Lab Standard Deviation is Used, the document states: "The baseline SD that is used to calculate control limits in the VITROS Chemistry System software may be a fixed criterion, such as within-lab SD from the Performance Verifier assay sheets, a calculated SD determined from the laboratory's experience with the VITROS Chemistry Systems, or your laboratory's medically useful limits. We recommend that you use the within-lab SD from the PV assay sheets for your baseline SD and your daily quality control decisions." 2. Based on a review of quality control records, the laboratory had used the range of means as an acceptability range and was not using the within-lab standard deviation. Example: Lot: D6497 Albumin Lab expected Mean: 2.44 Lab expected SD: 0.15 Vitros Performance Verifier Within-Lab SD: 0.090 Lot: B6272 ALT Lab expected Mean: 36.0 Lab expected SD: 5.0 Vitros Performance Verifier Within-Lab SD: 2.7 Lot: B6272 AST Lab expected Mean: 36.0 Lab expected SD: 3.0 Vitros Performance Verifier Within-Lab SD: 1.5 3. In an interview at 11:31 hours on 1/29/2019 in the laboratory, the Laboratory Director stated the lab had used the range of means as acceptability criteria and had not used the Within-lab SD as provided by the manufacturer.
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: Review of proficiency testing records and interview of facility personnel found that the laboratory director failed to ensure that proficiency testing reports were reviewed to evaluate the laboratory's overall performance. (see D 5211)
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 laboratory policies and procedures, quality control records, patient test records, and interview with laboratory staff, the Technical Consultant failed to provide technical oversight to the laboratory. Refer to D6042.
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 laboratory policies and procedures, quality control instructions for use, quality control records, and interview with facility personnel, the Technical Consultant failed to establish quality control parameters for acceptable levels of analytic performance and ensuring that these levels are maintained October 2018 and January 2019. The findings included: Based on review of quality control instructions for use, quality control records, and interview with facility personnel, the laboratory failed to accurately define the acceptability of 2 of 2 lots of control material used to assess test performance on the Vitros 350 chemistry analyzer. Refer to D5469.