Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0508693	06/23/2021
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
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 proficiency testing records and interview, the laboratory failed to rotate proficiency testing among all testing personnel for the Complete Blood Count (CBC) in 4 of 4 events. Findings follow. 1. Review of the American Association of Bioanalysts (AAB) proficiency testing records from the 1st, 2nd, and 3rd events of 2020 and the 1st event of 2021, showed all CBC testing was performed by testing personnel #1 (also the Laboratory Director). 2. Interview with the Laboratory Director on June 15, 2021 at 1025 hours in the laboratory acknowledged testing personnel #2 began testing CBCs in March 2019. Interview with the Laboratory Director on June 15, 2021 at 1105 confirmed he does all the proficiency testing and testing personnel #2 has not performed any of the proficiency testing.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions and interview, the laboratory failed to ensure the Sysmex XP-300 used to test the Complete Blood Count

	(CBC) was not adversely affected by vibrations from the mechanical rocker. Findings follow. 1. On June 15, 2021 at 0935 hours in the laboratory the surveyor observed the mechanical rocker sitting on top of the Sysmex XP-300. Upon investigation on June 15, 2021 at 1200 hours could physically feel the instrument vibrating from the mechanical rocker, and the vibrations stopped when the mechanical rocker was moved to the counter next to the analyzer. 2. Review of the Sysmex XP-300 Instructions for Use, revision Feb 2013, under Safety Information, 2.2 Installation stated, "Avoid shock and vibrations." 3. Interview with the Laboratory Director on June 15, 2021 at 1200 hours in the laboratory confirmed he could also feel the vibrations on the analyzer coming from the mechanical rocker and rearranged the counter space to make room for the mechanical rocker next to the analyzer.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of accuracy assessments and interview, the laboratory failed to verify the accuracy of microscopic urinalysis for 2 of 2 years reviewed from 2019, 2020, and to date in 2021. Findings follow. 1. Accuracy assessments for microscopic urinalysis were requested on June 16, 2021 at 0930 hours but not provided. 2. Interview with the Laboratory Director on June 16, 2021 at 0930 hours in the laboratory confirmed accuracy assessments for microscopic urinalysis were not performed.
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, the laboratory's policies and procedures, Sysmex XP-300 specimen test runs, and interview, the laboratory failed to ensure 1 out of 10 Complete Blood Count (CBC) specimens flagged on the Sysmex XP-300 were repeated or sent out to a reference laboratory. Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, revision Feb 2013, under 8.3 Histogram Flags stated, "Various information can be obtained from the histograms. The XP-300 extracts the characteristics of the histogram and displays them as histogram flags... When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following: Flag Probable Sample cause WL Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction 1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. 2) Check smear, etc. B. Review of the laboratory's policy and procedure titled Abnormal Results stated, "The following are used to handle abnormal results or flags: ...1. WL relative frequency of WBC-LD has exceeded the range: repeat or send

	out 2. WU relative frequency of WBC-UD has exceeded the range: repeat or send out 3. T1 discriminator positive cannot be determined: order manual differential 4. T2 discriminator positive cannot be determined: order manual differential 5. F1 relative frequency of T1 has exceeded the range: smear review 6. F2 relative frequency of T1 /T2 has exceeded the range: smear review 7. F3 relative frequency of T2 has exceeded the range: Path review 8. RL relative frequency of RBC-LD has exceeded the range: Path review 9. RU relative frequency of RBC-UD has exceeded the range: Path review 10. DW distribution width cannot be calculated: repeat or send out..." C. Review of the last 10 flagged runs from June 15 & 16, 2021 on the Sysmex XP-300 screen showed one set of results, sample ID# 184159, with the WL flags for White Blood Cell (WBC) and the WBC differential requiring a repeat or send out. D. Interview with the Laboratory Director on June 16, 2021 at 1120 hours in the laboratory acknowledged the results were reported and the specimen was not repeated or sent to the reference laboratory.
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 quality control records and interview, the laboratory failed to document reagent generation and lot number changes on the Vitros 350 used for Chemistry testing and the Vitros ECiQ for Endocrinology and Toxicology testing. Findings follow. 1. Review of the monthly quality control records from March 2021 and May 2021 maintained by the Orchards LIS system revealed no documentation of the reagent generation or lot number changes typically found in the comments section on the day of testing where the change occurred. 2. Interview with the Laboratory Director on June 16, 2021 at 1015 confirmed he does not document the generations and added, "but now I will." KEY: LIS = Laboratory Information System
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of competency evaluations and interview, the technical consultant failed to document the performance of individuals performing Complete Blood Counts (CBC) at least semiannually during the first year the individual tested patient specimens for 1 of 2 testing personnel (the Laboratory Director was also testing personnel #1). Findings follow. 1. Competency evaluations were requested on June 15, 2021 at 1025 hours for testing personnel #2, but not provided. 2. Interview with the Laboratory Director on June 15, 2021 at 1025 hours in the laboratory acknowledged testing personnel #2 began testing CBCs in March 2019 and he had not performed semiannual competency evaluations in the first year she tested specimens.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of competency evaluations and interview, the technical consultant failed to document the performance of individuals performing Complete Blood Counts (CBC) at least annually after the first year the individual tested patient specimens for 1 of 2 testing personnel (the Laboratory Director was also testing personnel #1) for 1 of 1 years. Findings follow. 1. Competency evaluations were requested on June 15, 2021 at 1025 hours for testing personnel #2, but not provided. 2. Interview with the Laboratory Director on June 15, 2021 at 1025 hours in the laboratory acknowledged testing personnel #2 began testing CBCs in March 2019 and he had not performed annual competency evaluations.