Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0995592	04/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Paris Cardiology Center	1775 Fm 195, Paris, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the laboratory's verification records, a review of the laboratory's reference ranges for analytes tested on the Sysmex pocH-100i hematology analyzer, and staff interview, it was revealed the laboratory failed to have documentation of verifying its patient normal ranges for 17 of 17 analytes tested on the Sysmex pocH-100i hematology analyzer. Findings include: 1. A review of the laboratory's

	verification records for the Sysmex pocH-100i hematology analyzer (Serial number G5445) revealed verification studies were performed on October 8, 2018. 2. The laboratory was asked to provide documentation of verifying the following patient normal ranges for the 17 analytes tested on the Sysmex pocH-100i hematology analyzer. No documentation was provided. WBC: 4.5 - 10.5 RBC: 4.00 - 8.00 HGB: 11.0 - 18.0 HCT: 35.0 - 60.0 MCV: 80.0 - 99.9 MCH: 27.0 - 31.0 MCHC: 33.0 - 37.0 PLT: 150 - 450 LYM%: 20.5 - 51.5 MXD%: 1.7 - 9.3 NEUT%: 42.2 - 75.2 LYM#: 1.2 - 3.4 MXD#: 0.1 - 0.6 NEUT#: 1.4 - 6.5 RDW-SD: 37.0 - 54.0 RDW-CV: 11.6 - 13.7 MPV: 7.8 - 11.0 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 4/15/21 at 10:40 a.m. in the conference room, after review of the records, confirmed the above findings. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW- red cell distribution width PLT - platelet LYM - lymphocytes MXD - mixed cells (monocytes, basophils, eosinophils) NEUT - neutrophils
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 the laboratory's quality control records for the Alere Triage meters from 2019 and 2020 and staff interview, it was revealed that the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for 2 of 2 analytes tested on the Alere Triage meters. Findings include: 1. A review of the laboratory's quality control records for the Alere Triage meters (serial numbers 66514 and 65768) from 2019 and 2020 revealed the laboratory runs the Alere Total Control levels 1 and 2 with each new lot or shipment of test materials or every 30 days. 2. Further review of the quality control records from 2019 and 2020 revealed the laboratory failed to have a method in place for monitoring and evaluating quality control results over time for the following 2 analytes tested on the Alere Triage meters: CK-MB (creatine kinase myocardial band) TNI (troponin) 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 4/15/21 at 10: 33 a.m. in the conference room revealed the laboratory only assessed quality control values each day and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings.
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: Based on a review of the Sysmex pocH-100i Implementation Manual, a review of the laboratory's quality control records for the Sysmex pocH-100i from May 2019 to April 2020, and staff interview, it was revealed that the laboratory failed to verify new lot numbers of external quality control for complete blood count (CBC) testing on the Sysmex pocH-100i hematology analyzer before placing them into use. Findings include: 1. A review of the Sysmex pocH-100i Implementation Manual (MKT-30-1003, Rev. 9, 12/2011) revealed the following: "Upon receipt of a new lot of control material, it is recommended that controls of the new lot be run in parallel with the current lot for ten replicates over multiple days to demonstrate instrument specific control ranges. It is important to note that the controls for the current lot are the controls of record and that he parallel process must be completed before the current lot expires. Thus, Sysmex recommends that you begin parallel testing immediately after receipt of a new lot." 2. A review of the laboratory's quality control records for the Sysmex pocH-100i from May 2019 to April 2020 revealed there was no documentation of the laboratory performing lot to lot verifications for the following lot numbers of external quality control materials: Sysmex Eightcheck-3WP X-TRA Hematology Controls: Low Abnormal lot: 90300710 expired: 5/8/19 Normal lot: 90300711 expired: 5/8/19 High Abnormal lot: 90300712 expired: 5/8/19 Low Abnormal lot: 91140710 expired: 7/31/19 Normal lot: 91140711 expired: 7/31/19 High Abnormal lot: 91140712 expired: 7/31/19 Low Abnormal lot: 91980710 expired: 10/23/19 Normal lot: 91980711 expired: 10/23/19 High Abnormal lot: 91980712 expired: 10/23/19 Low Abnormal lot: 0010710 expired: 4/8/20 Normal lot: 00010711 expired: 4/8/20 High Abnormal lot: 00010712 expired: 4/8/20 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 4/15/21 at 11: 19 a.m. in the conference room, after review of the records, confirmed the above findings.