Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0931677	10/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Perfusion Systems	1923 South Utica, Tulsa, OK	

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 recertification survey was performed on 10/16/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
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 a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to ensure the manufacturer's environmental specifications were met for quality control materials on 8 of 654 days. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor: (a) The laboratory used 4 Hemochron Signature Jr.+ analyzers to perform ACT (Activated Clotting Time) with the ACT+ test cassettes; (b) The QC materials were stored in the office refrigerator and the temperature was monitored each day. (2) The surveyor reviewed the manufacturer's environmental requirements for the QC (Quality Control) materials used with the ACT+ testing. The manufacturer required the QC vials be stored at a temperature between 2 and 8 degrees C (Centigrade): (3) The surveyor then reviewed the refrigerator temperature records from January 2018 through the date of the survey. The surveyor identified the refrigerator temperature was colder than 2 degrees C on 8 of 654 days reviewed. The specific findings follow: (a) January 2018: On 4 of 31 days, the temperature was 1 degree C: Days 20,21,25,26

	(b) February 2018: On 2 of 28 days: (i) The temperature was 1 degree C: Day 26 (ii) The temperature was 0 degree C: Day 14 (c) April 2018: On 1 of 30 days, the temperature was 1 degree C: Day 9 (d) May 2018: On 1 of 31 days, the temperature was 1 degree C: Day 14 (4) The surveyor reviewed the findings with the laboratory director. The laboratory director stated to the surveyor the laboratory failed to ensure the manufacturer's required storage temperature had been met as listed above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to follow the manufacturer's specifications for quality control materials for 4 of 4 lot numbers. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor: (a) The laboratory used 4 Hemochron Signature Jr.+ analyzers to perform ACT (Activated Clotting Time) with the ACT+ test cassettes; (b) The laboratory anaylzed two levels (Normal and Abnormal) of directCHECK Whole Blood Control every 30 days, and with a new cassette lot number. (2) The surveyor reviewed the manufacturer's instructions for the directCHECK Whole Blood Controls, which stated, "ITC recommends that each institution establish its own expected range or response based on the mean +/- 2 standard deviation of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a CV (Coefficient of Variation) of approximately 14%, or less for coagulation control tests"; (3) The surveyor then reviewed QC (Quality Control) records from 2018 through the date of the survey. For 4 of the 4 lot numbers of QC materials used during the review period, the laboratory failed to follow the manufacturer's instruction to ensure a CV of approximately 14% or less was obtained from the repeated test results used to establish the acceptable QC limits: (a) Normal Control, Lot #G7DNA010: Used from 3/17/18 through 11/28/18: (i) The laboratory tested the control 21 times but failed to determine the CV% from the repeats. (b) Abnormal Control, Lot #H7DCA020: Used from 12/15/18 through 4/28/19: (i) The laboratory tested the control 24 times but failed to determine the CV% from repeats. (c) Normal Control, Lot #G7DNA009: Used from 11/29/18 through the date of the survey (i) The laboratory tested the control 25 times but failed to determine the CV% from the repeats. (d) Abnormal Control, Lot J8DCA010: Used from 4/29/18 through the date of the survey (i) The laboratory tested the control 25 times but failed to determine the CV% from the repeats. (4) The surveyor reviewed the finding with the laboratory director, who stated to the surveyor, the laboratory did not ensure a CV% of approximately 14% or less was obtained for the QC materials listed above.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and

	specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions and interview with the laboratory director, the laboratory failed to take corrective action when the manufacturer's environmental specifications had not been met on 8 of 654 days. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor: (a) The laboratory used 4 Hemochron Signature Jr.+ analyzers to perform ACT (Activated Clotting Time) with the ACT+ test cassettes; (b) Two levels (Normal and Abnormal) of directCHECK Whole Blood Control materials were analyzed to monitor the testing acceptability as directed the in the laboratory's IQCP (Individualized Quality Control Plan); (c) The QC (Quality Control) materials were stored in the office refrigerator which was monitored daily. (2) The surveyor reviewed the manufacturer's environmental requirements for the QC materials. The manufacturer required the QC vials be stored at a temperature between 2 and 8 degrees C (Centigrade): (3) The surveyor then reviewed the refrigerator temperature records from January 2018 through the date of the survey. The surveyor identified the refrigerator temperature was colder than 2 degrees C on 8 of 654 days reviewed and there was no documentation the laboratory took corrective action (i.e., adjusted the temperature and rechecked temperature, observed the QC materials for degradation, tested the QC materials, etc.) for the unacceptable temperatures. The specific findings follow: (a) January 2018: On 4 of 31 days, the temperature was 1 degrees C: Days 20,21,25,26 (b) February 2018: On 2 of 28 days: (i) The temperature was 1 degree C: Day 26 (ii) The temperature was 0 degree C: Day 14 (c) April 2018: On 1 of 30 days, the temperature was 1 degree C: Day 9 (d) May 2018: On 1 of 31 days, the temperature was 1 degree C: Day 14 (4) The surveyor reviewed the findings with the laboratory director and asked if there was documentation that proved corrective action had been taken for the unacceptable refrigerator temperatures listed above. The laboratory director stated to the surveyor the laboratory did not have documentation that corrective action had been taken when the manufacturer's storage requirement for the QC materials had not been met.