Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2010342	01/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mid-South Transplant Foundation	8001 Centerview Pkwy Ste 300, Cordova, TN	

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
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 observation of the laboratory, review of manufacturer documents, lack of records, donor test records and staff interview, the laboratory failed to verify the calibration of the tests performed on the two i-STAT instruments used for performing chemistry testing using the CG8+ cartridge and blood gas testing using the CG4+ cartridge every six months in 2022, 2023 and 2024. The findings include: 1. Observation of the laboratory on 01/10/24 at 8:15 am revealed two i-STAT

	instruments used for performing testing on brain-dead organ donors. i-STAT instrument serial numbers observed were 337295 and 328956. During observations, the technical consultant stated the following: The CG4+ cartridge was used for performing donor testing for Lactic Acid, pH, pO2, and pCO2. The Chem 8+ cartridge was used for performing donor testing for Sodium, Potassium, Chloride, Total Carbon Dioxide (TCO2), Blood Urea Nitrogen (BUN), Creatinine, Glucose, and ionized Calcium. 2. Review of the Abbott i-STAT document titled "CALIBRATION VERIFICATION" (Art:714377-00V, Rev. Date: 17-Feb-2023) revealed the following: "The Electronic Simulator simulates two levels of electronic signals that stress the analyzer's signal detection function both below and above the reportable ranges." 3. There was no documentation that calibration verification was performed every six months in 2022, 2023 or 2024 using a low, mid, and high value to verify the laboratory's reportable range. 4. Review of donor number AJLX397 revealed reporting of both blood gas and chemistry results on 12/26/22; blood gas and chemistry results were reported for donor number AKJY177 on 10/26/23. 5. Interview with the point-of-care testing supervisor on 01/10/24 at 3:30 pm confirmed the laboratory failed to perform calibration verification every six months for the blood gas and chemistry tests performed using the CG4+ and Chem 8+ cartridges on the two i-STAT instruments in 2022, 2023, or 2024. Word Key: pO2= partial pressure of oxygen pCO2=partial pressure of carbon dioxide
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records, and staff interviews, the laboratory failed to compare results between the tests performed on the two i-STAT instruments in use for performing chemistry testing using the CG8+ cartridge and blood gas testing using the CG4+ cartridge twice a year in 2022, 2023 or 2024. The findings include: 1. Observation of the laboratory on 01/10/24 at 8:15 am revealed two i-STAT instruments used for performing testing on brain-dead organ donors. i-STAT instrument serial numbers observed were 337295 and 328956. During observations, the technical consultant stated the following: The CG4+ cartridge was used for performing donor testing for Lactic Acid, pH, pO2, and pCO2. The Chem 8+ cartridge was used for performing donor testing for Sodium, Potassium, Chloride, Total Carbon Dioxide (TCO2), Blood Urea Nitrogen (BUN), Creatinine, Glucose, and ionized Calcium. 2. There was no documentation that comparisons between the two instruments were performed twice a year in 2022, 2023, or 2024. 3. Interview with the point-of-care testing supervisor on 01/10/24 at 3:30 pm confirmed the laboratory failed to compare results between the two i-STAT instruments used for performing chemistry tests on organ donors in 2022, 2023, and 2024. Word Key: pO2= partial pressure of oxygen pCO2=partial pressure of carbon dioxide