

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2010342	(X3) Date Survey Completed 01/03/2019
Name of Provider or Supplier Mid-South Transplant Foundation	Street Address, City, State 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
D5537	<p>ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d)</p> <p>For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, quality control records for the i-STAT instrument, patient/donor records, and interview with the technical consultant, the laboratory failed to perform one level of quality control (QC) each 8 hours of patient/donor arterial blood gas testing in 2017 and 2018. The findings include: 1. Review of the laboratory's procedure manual for the i-STAT instrument revealed: "will perform 2 levels of external controls every 24 hours of testing on authorized brain dead donors." 2. Review of quality control records and patient/donor records for the i-STAT arterial blood gas instrument revealed the following: Patient/donor #1 12.10.18--QC performed at 17:56. Patient testing performed beginning at 18:38 with the last patient test performed on 12.11.18 at 04:45. No QC was performed after the first 8 hour period. Patient/donor #2 06.22.18--QC performed at 09:52. Patient testing performed beginning at 15:46 with the last patient test performed on 6.23.18 at 04:59. No QC was performed after the first 8 hour period. 6.23.18--QC performed at 08:35. Patient testing performed after QC performance beginning at 10:10 with the last patient test performed at 18:22. No QC was performed after the first 8 hour period. Patient/donor #3 12.7.17--QC performed at 21:35. Patient testing performed beginning 12.08.17 at 06:11 with the last patient test performed 12.08.17 at 13:41. No QC was performed after first 8 hour period. Patient/donor #4 05.19.17 QC performed at 21:23. Patient testing performed beginning 05.20.17 at 02:25 with the last patient test performed on 05.20.17 at 18:15. No QC was performed after the first 8 hour period. 5.20.17 QC performed at 22:55. Patient testing was performed beginning at 23:</p>

27 with the last patient test performed on 5.21.17 at 12:31. No QC was performed after the first 8 hour period. 3. Interview with technical consultant number two on 01.03.2019 at 12:30 confirmed the laboratory did not perform at least one level of QC each 8 hours of patient/donor arterial blood gas testing in 2017 and 2018. The laboratory does not have an Individualized Quality Control Plan in place for the reduced QC frequency.