

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012508	(X3) Date Survey Completed 12/12/2019
Name of Provider or Supplier Birmingham East Dialysis	Street Address, City, State 1105 East Park Drive, Birmingham, AL	
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 (Each deficiency should be preceded by full regulatory or LSC identifying information)
V0199	<p>RO-MEETS AAMI/MONITORED, RECORDED ON LOG CFR(s): 494.40(a)</p> <p>5.2.7 Reverse osmosis: meets AAMI/monitored/recorded on log Refer to RD62:2001, 4.3.7 Reverse osmosis: When used to prepare water for hemodialysis applications, either alone or as the last stage in a purification cascade, reverse osmosis systems shall be shown to be capable, at installation, of meeting the requirements of Table 1, when tested with the typical feed water of the user, in accordance with the methods of [AAMI] 5.2.2. 5.2.7 Reverse osmosis Users should carefully follow the manufacturer's instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters. 6.2.7 Reverse osmosis All results of measurements of RO performance should be recorded daily in an operating log that permits trending and historical review.</p> <p>This STANDARD is not met as evidenced by: Based on review of facility Daily Water Treatment Log, DaVita Daily Water Treatment Log Explanation and staff interviews, it was determined the staff failed to check and document the product water quality values daily. Findings include: DaVita Daily Water Treatment Log Explanation Copyrighted 2017 ...RO (Reverse Osmosis) Product Water Quality... Enter the Product Water Quality values displayed on the RO Monitor. If the observed Quality value is outside the acceptable limits or if the RO monitor is not operational, immediately contact the Biomedical Team for direction and assistance. Review of the November 2019 Daily Water Treatment Log(s) revealed no documentation of the RO Product Water Quality from 11/18/19 to 11/24/19. An interview was conducted on 12/12/19 at 10:01 AM with Employee Identifier # 1, Facility Administrator, who confirmed the above findings.</p>