

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 852587	(X3) Date Survey Completed 02/07/2025
Name of Provider or Supplier Fresenius Kidney Care Richmond County	Street Address, City, State 2556 Tobacco Road Suite A, Hephzibah, GA	
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)
V0250	<p>DIALYS PROPOROT-MONITOR PH/CONDUCTIVITY CFR(s): 494.40(a)</p> <p>5.6 Dialysate proportioning: monitor pH/conductivity It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.</p> <p>This STANDARD is not met as evidenced by: Based on observation, staff interviews, a review of the facility's Policy and Procedures (P&P), a review of the manufacturer's Directions for Use (DFU), and a review of the Association for the Advancement of Medical Instrumentation (AAMI) for "Dialysate for hemodialysis" (ANSI/AAMI RD52: 2004), it was determined that the facility failed to ensure that there was a safe environment for all patients, as evidenced by the failure of two of two Patient Care Technicians, (PCT AA and PCT BB) observed, to independently verify the hemodialysis machine's dialysate pH (potential of Hydrogen- a measurement that can determine the acidity or alkalinity of a solution), at Station (S), (S7), during preparation and initiation of hemodialysis treatments of two of two patients, (P), (P#8 and P#2), on 2/5/25 and 2/6/25, respectively. This deficient practice had the potential to negatively affect the health and safety of P#2, P#8 and the other 17 patients, (P#1, P#3, P#9, P#10, P#11, P#12, P#13, P#14, P#15, P#16, P#17, P#18, P#19, P#20, P#21, P#22, and P#23), whose dialysate or dialysis bath (the fluid that the hemodialysis machine proportions from bicarbonate concentrate, acid concentrate and treated water used to exchange solutes with the blood in a dialysis filter), concentration prescriptions were different from the facility's standard dialysate, which was 2 Potassium / 2.5 Calcium. Complications as minor as nausea and fatigue or as severe as metabolic acidosis (a decrease in pH that could cause rapid breathing, confusion, dizziness, shortness of breath, and chest pain) could result if dialysate composition is incorrect. The facility census was 37. Findings include: During</p>

observation in the Patient Treatment Room on 2/5/25 between 10:50 a.m. and 11:00 a.m., the following was revealed: - At 10:50 a.m., PCT AA was observed (after P#8 had started hemodialysis treatment at Station [S] 7), pulling out the red wand (used to pull the acid concentrate) from the acid concentrate jug, then PCT AA plugged the red wand to the wall box. The dialysate concentration in the jug was 3 Potassium/2.5 Calcium, whereas, the dialysate concentration from the wall box was 2 Potassium and 2.5 Calcium. P#8's prescription was 2 Potassium/2.5 Calcium bath. The machine's dialysate conductivity dropped to 12 (acceptable range is 13.0 - 14.2 +/- 0.3 mS/cm - milliSiemen per centimeter), which caused the machine to alarm, then it stabilized to 13.8 at 10:54 a.m. PCT AA did not independently or manually re-test the machine dialysate's pH. The facility used Myron L D6 to manually test for pH and Conductivity. - At 10:55 a.m., PCT AA was asked by this surveyor why she did not manually verify the dialysate pH after she changed the dialysate concentration (from jug to wall box). PCT AA stated that the dialysis machine did the testing of pH and conductivity and she added that no one ever told her that she needed to re-check the pH if the dialysate or bath was changed. - At 11:00 a.m., the Biomedical Technician (BMT) was notified of the above finding and the BMT stated that even though the dialysis machines were the new 2008T BlueStar Premium Dialysis Machines (with software 2.71 or higher will have the ability to have "Independent Conductivity/pH" selected as an option), the PCTs were made aware that the pH must be manually verified after a dialysate or bath was changed and when the conductivity dropped during dialysis treatment. During observation in the Patient Treatment Room on 2/6/25 between 10:45 a.m. and 11:00 a.m., the following was revealed: - At 10:45 a.m., P#2 was seated at S7 and his prescribed bath was 2 Potassium / 2 Calcium from a jug. The jug was almost empty which set the machine to alarm showing the conductivity dropped. PCT BB replaced the jug with the same bath concentration of 2 Potassium/2 Calcium). PCT BB did not manually/independently verify the machine's dialysate pH. - At 10:55 a.m., PCT BB was asked by this surveyor why she did not manually verify the machine's dialysate pH after replacing the jug. PCT BB stated that because she did not change the bath composition, there was no need to manually verify the machine's dialysate pH. PCT BB also stated that the Bluestar machines check the pH and Conductivity automatically. - On 2/6/25 at 11:00 a.m., the Facility Administrator was notified of the above findings. - A review of patients' dialysate prescriptions that were different from the facility's standard dialysate (2 Potassium/2.5 Calcium), revealed the following: - P#9, P#10, P#11, P#15, P#20, and P#22, had 2.0 Potassium/3.0 Calcium dialysate prescriptions. - P#1, P#12, P#13, P#14, P#16, P#17, P#18, P#19, P#21, and P#23, had 3.0 Potassium/2.5 Calcium dialysate prescriptions. - P#2 and P#3, had 2.0 Potassium/2.0 Calcium dialysate prescriptions. - A review of facility Policy, with reference number: 25912, titled, "Checking Conductivity and pH of Final Dialysate", version 12, and published: 02/03/2025, stated: BlueStar Machine - Fresenius 2008T machines with software 2.71 or higher will have the ability to have "Independent Conductivity/pH" selected as an option. If this feature is activated, the machine performs the Independent Conductivity measurement... The machine will perform the independent pH calculation only if it is equipped with BiBag (a single-use bag of dry sodium bicarbonate powder that is used in bicarbonate hemodialysis [sic]) and BiBag is actively in use. When replacing the concentrate to same or new formula or replacing bicarbonate (except is using BiBag), pH must be checked. BlueStar Requirements for Changing Concentrates: * Concentrate Changes During BlueStar Treatments: - Replace current acid concentrate with same catalog number (ex. 2251 to 2251). - Verify Concentrate Matches Selected in the Dialysate Screen. - Check pH with Meter or Strip after 10 minutes. - Replace current acid concentrate with the different catalog number (ex. 2251 to 3251). - Verify Concentrate Matches Selected in the Dialysate Screen. - Check pH with Meter or Strip after 10 minutes. - A review of

Fresenius 2008T Hemodialysis BiBag System Operator's Instruction (English) 508213
Revision K -January 12, 2024 stated: Page 4. Warning! When changing concentration during treatments always verify the conductivity and approximate pH of the dialysate through independent means. Independent means could be by using an external conductivity meter, pH meter, pH paper or by using the machine independent conductivity test. The wrong concentrate composition, conductivity, or pH may cause serious injury or death. - According to AAMI RD52:2004, Section 5.6, "Dialysate Proportioning", it is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method.