

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012500	(X3) Date Survey Completed 09/16/2021
Name of Provider or Supplier Fmc Capitol City	Street Address, City, State 255 South Jackson Street, Montgomery, 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)
V0250	<p>DIALYS PROPOR-T-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 observations, facility policy, Digital Dialysate Meter Operation Manual, and interview, it was determined the staff failed to: 1. Follow Instructions for Use (IFU) Myron L D6 Meter, facility policy and procedures for monitoring dialysate conductivity prior to treatment initiation. 2. Follow the facility policy and test the dialysate pH (the acidity or alkalinity of a substance) when a bath acid concentration was changed which affected Patient Identifier (PI) # 18, an unsampled patient. This affected 3 of 3 observations made and had the potential to negatively affect all patients who dialyze at this facility. Findings include: Facility Policy: Checking Conductivity and pH of Final Dialysate Published: 08/03/2020 Version: 7 Purpose: The purpose of this policy is to provide guidelines to verify final dialysate conductivity and pH prior to initiating hemodialysis treatments ... Test Verification Prior to Treatment Incenter setting: 2 staff members will verify the conductivity and pH parameters prior to treatment ... Policy ...Dialysate pH must be tested when changing acid concentrate formulations (example 1 K (Potassium) to 2 K during the treatment.... Facility Procedure: Myron L D6 Measuring Procedures Version: 1 Published: 06/14/2017 Measuring Dialysate Conductivity and pH 7. Return sample to cart or sampling area and perform measurements according to the D6 meter's IFU (Instructions for use). Digital Dialysate Meter Operation Manual Myron L D-6 Meter 02/16/2018 VII. Specific Recommended Measuring Procedures Page 12 CAUTION: For Cond/Res/TDS (Conductivity/Resistively/Total Dissolved Solids) Measurements:</p>

- The pH/ORP (Oxidation Reduction Potential) sensor well cap MUST be sealed. - Any crystals or other residue around the cap MUST be rinsed away to prevent contamination of the conductivity sample. - The conductivity cell MUST be rinsed and filled at least 3 times with sample before each measurement is taken. For pH/ORP measurements: - Both the pH/ORP sensor well and the conductivity cell must be rinsed and filled at least 3 times with sample before each measurement is taken ... A. Measuring Conductivity & Total Dissolved Solids ... 1. Rinse cell cup 3 times with sample to be measured. 2. Refill cell cup with sample. 3. Press COND or TDS button. 4. Take reading ... C. Measuring pH (D-6) 1. Remove protective cap ... 2. Rinse pH/ORP sensor well and conductivity cell 3 times with sample to be measured. Shake out each sample to remove any residual liquid. 3. Refill pH/ORP sensor well and conductivity cell with sample. 4. Press pH button. 5. Note value displayed. 6. Important: After use, fill pH/ORP sensor well with Myron L pH Sensor Storage Solution and replace protective cap ... Never use distilled water or plain tap water ... 1. During observations of care on 9/14/21 at 9:45 AM, the surveyor observed EI (Employee Identifier) # 5, PCT, (Patient Care Technician) perform dialysate conductivity and pH testing using a Myron L D-6 meter. EI # 5 filled a cup with dialysate and proceeded to the test station "dirty sink" area. EI # 5 filled the D-6 meter conductivity cell and sensor well with a dialysate sample 1 time, then obtained the conductivity and pH reading confirmed by EI # 4, Registered Nurse, who was present during conductivity and pH test. EI # 5 discarded the dialysate solution in the dirty sink, placed the D 6-meter on the sink counter then exited the test station. EI # 5 failed to rinse the residue from the meter. EI # 5 failed to follow the manufacturer's instructions for use for dialysate testing, rinse and fill the conductivity cell at least 3 times with sample before each measurement was taken, then refill cell cup with the dialysate sample and obtain the reading. 2. On 9/14/21 at 10:00 AM at station 19, EI # 5, PCT initiated dialysis treatment for a 2 K 2.5 Ca (calcium) bath. At 10:37 AM, EI # 5 placed a jug bath labeled 3 K 2.5 Ca at the base of the HD (hemodialysis) machine at station 19 for PI # 18. The surveyor asked EI # 5 why the dialysis bath was changed? EI # 5 stated, "I just looked at the orders and this is the bath ordered". EI # 5 failed to test the dialysate pH when the dialysis bath acid concentrate was changed from 2 K to 3 K. In an interview on 9/16/21 at 8:45 AM, EI # 1, Clinic Manager confirmed staff failed to follow facility policy and check conductivity and pH of final dialysate when the acid concentrate was changed. 3. At 11:17 AM the surveyor observed EI # 5, perform dialysate conductivity and pH testing using a Myron L D6 meter at the "dirty sink" area. EI # 5 filled the conductivity cell and sensor well of the D6 meter with a dialysate sample 1 time and obtained the readings for conductivity and pH. EI # 5 then emptied the solution in the dirty sink placed the D6 meter on the sink without rinsing the D6 meter Reverse Osmosis (RO) water. EI # 5 failed to follow the manufacturer's instructions for use for dialysate testing, rinse and fill the conductivity cell at least 3 times with sample before each measurement was taken, then refill cell cup with the dialysate sample and obtain the reading. 4. At 11:18 AM the surveyor observed EI # 8, CCHT (Certified Clinical Hemodialysis Technician), perform dialysate conductivity and pH testing using a Myron L D6 meter at the dirty sink area. EI # 8 filled the conductivity cell and sensor well of the D6 meter with a dialysate sample 1 time and obtained the readings for conductivity and pH. EI # 8 then emptied the solution in the dirty sink placed the D6 meter on the sink without rinsing the D6 meter RO water. EI # 8 failed to follow the manufacturer's instructions for use for dialysate testing, rinse and fill the conductivity cell at least 3 times with sample before each measurement was taken, then refill cell cup with the dialysate sample and obtain the reading. A telephone interview was conducted on 9/17/21 at 10:55 AM with EI # 1, Clinic Manager who verified the staff failed to follow the IFU Myron L D6 Meter. 30952