

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012509	(X3) Date Survey Completed 03/30/2023
Name of Provider or Supplier North Alabama Nephrology Center	Street Address, City, State 1311 North Memorial Parkway #200, Huntsville, 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)
V0228	<p>MIXING SYSTEMS-LABELING CFR(s): 494.40(a)</p> <p>5.4.4.1 Mixing systems: labeling Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine. Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied. Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents. Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of facility policy and interviews, it was determined the facility failed to ensure bicarbonate (bicarb) mixing systems were labeled for one of one observation as directed per the facility policy while patients were being dialyzed in the facility. This had the potential to negatively affect all patients being dialyzed by this facility. Findings include: Facility Policy: Concentrate Labeling Requirements Version 5 Published: 05/27/2021 Policy: Temporary Labeling When a mix tank contains a solution, a label identifying the solution must be conspicuously displayed on the tank and must remain until the mix tank is emptied. Mix tank labeling must include: Date and time of mixing. 1. During a tour of the water treatment room on 3/29/23 at 8:25 AM with Employee Identifier (EI) # 6, Certified Clinical Hemodialysis Technician (CCHT), an observation was conducted of the bicarb system mixing area which revealed the presence of one bicarb mix and distribution tank. The bicarb mix and distribution tank was filled with approximately 75 gallons of solution and two</p>

labels on the tank read, "Tank Empty, Date, Time, Initials". There was no label identifying the solution, date, time, and initials documented on the label of the mixing and distribution tank per the tank label and facility policy. The surveyor asked EI # 6, "Is this the bicarb solution the patients are currently dialyzing on?" EI # 6 replied, "Yes". The surveyor then asked EI # 6, "Is the tank labeled per the facility policy?" EI # 6, replied, "No". An interview was conducted on 3/29/23 at 8:40 AM with EI # 1, Facility Administrator, who verified the Bicarb mixing systems tank was not labeled as directed per the facility policy.