Rapid analysis of critical electrolytes and impurities in dialysis solutions

Dialysis, including hemodialysis and peritoneal dialysis, is a treatment for patients that suffer from kidney failure. In hemodialysis, blood is pumped from the patient's body through an extracorporeal artificial kidney circuit, where blood-borne toxins and excess water are filtered out of the blood through a semipermeable dialyzer membrane into an electrolyte and plasma-resembling medium (i.e., dialysate). Hemodialysis and continuous renal replacement therapies require blood access.

Citrate phosphate dextrose adenine (CPDA) nutrition anticoagulant solution is used to prevent blood clots.

Peritoneal dialysis is prescribed for patients with acute or chronic renal failure when non-dialytic medical therapy is decided to be inadequate. In peritoneal dialysis, the patient infuses a quantity of dialysate into the peritoneal cavity, and the peritoneal membrane acts as the semipermeable membrane. After a rest period, the dialysate fluid is drained, and a fresh supply of peritoneal dialysate is added to the peritoneal cavity.

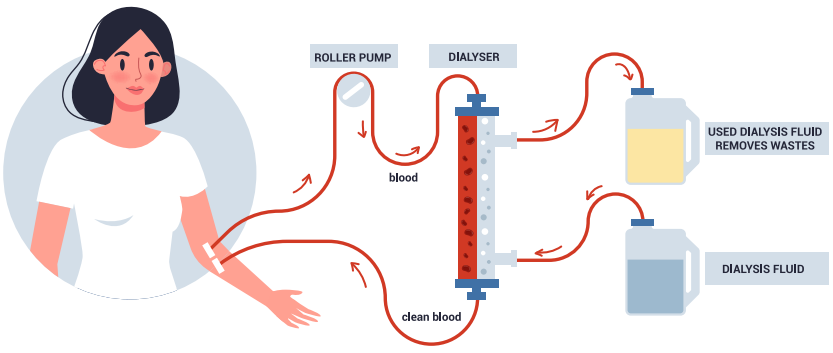

Figure 1. Hemodialysis.

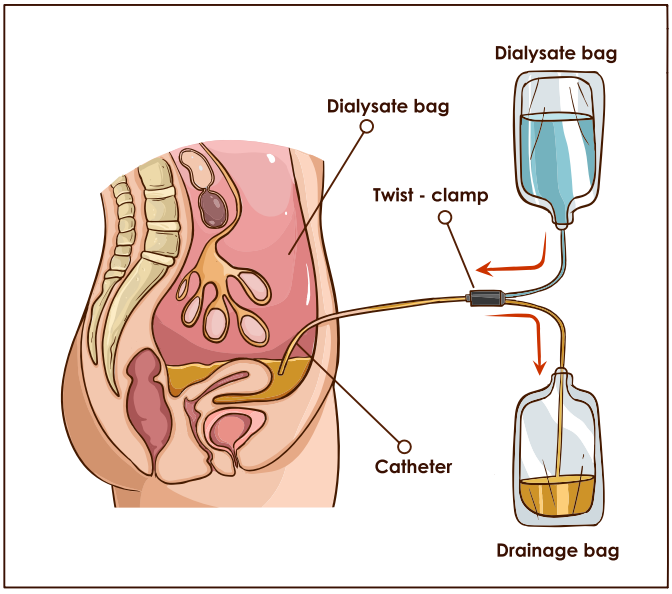

Figure 2. Peritoneal dialysis.

What is dialysis fluid's composition?

Dialysis fluid can be considered a drug to be adjusted to the individual patient's needs. In modern machines, dialysate is made by mixing two concentrate components, which may be provided as liquid or dry (powder) concentrates.

Dialysis solution, also known as, Dialysate, dialysis fluid, or bath, is a solution of pure water, glucose, electrolytes and salts. Citrate, lactate, acetate in acidic form and/or the corresponding salts of acetic acid (acetate), citric acid (citrate) or lactic acid (lactate) are used in HD and PD dialysis solutions. Dialysis solution composition containing chloride salts may contain a mixture of physiologically-acceptable cations, such as sodium, potassium calcium, magnesium or ammonium.

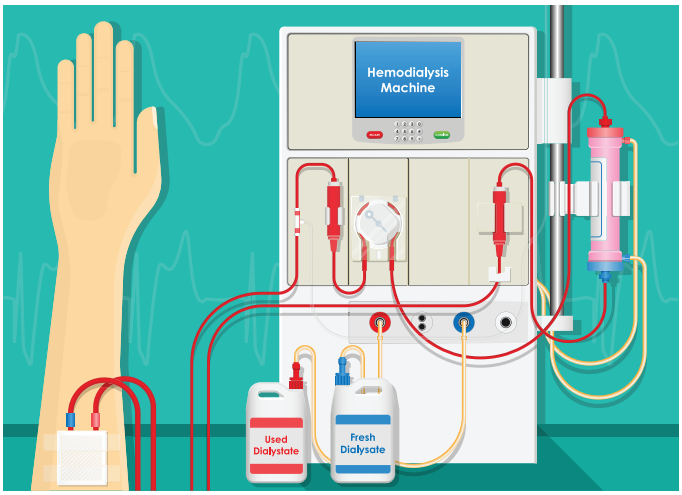

Figure 3. Hemodialysis equipment setup.

Dialysis solutions are tested for their compositions and process impurities to meet the patient's safety and regulatory regulations.

Dialysis solutions analytics

Analytical testing for dialysis products starts with sterilized water for injection as per USP/EP guidelines, electrolytes and impurities. Common tests for sterilized water include the pH and conductivity, nutrients like nitrate, total oxidizable nitrogen (TON) and total phosphorous. Electrolytes are important for the dialysate concentrate production, as well as, ready to use finished dialysis solution. Tests for dialysis solution includes determination of glucose, chloride, and acids such as: acetic acid; lactic acid; citric acid; or their respective salt form. Other process critical parameters include chloride, sulfate, phosphate, calcium and magnesium.

Anticoagulant citrate phosphate dextrose adenine (CPDA) solution is a sterile solution of citric acid, sodium citrate, monobasic sodium phosphate, dextrose, and adenine in water for injection. Determination of citrate, phosphate, dextrose and adenine concentration are important for regular production and release of the finished CPDA nutrition anticoagulant solution. Citrate and phosphate are quantified by ion chromatography as per the USP General Chapter <345>. Dextrose in CPDA is determined by tedious gravimetric method, and adenine using high performance liquid chromatography (HPLC) with ultraviolet (UV) detector.

The glucose degradation products (GDPs) such as acetaldehyde, formaldehyde, or hydroxy methyl furfural (HMF) give rise to bioincompatible reactions in peritoneal dialysis patients. These glucose degradation products are determined by pre-column derivatization followed by HPLC or UV spectrophotometric methods.

Multiple wet chemical and chromatographic techniques are needed for the complete dialysis solution analysis.

Consolidated — high throughput solution

Why operate multiple analyzers when you can do all your essential testing with one? With the liberating technology of the Thermo Scientific™ Gallery™ discrete analyzer you can deliver reliable analyses for multiple parameters—like citrate, phosphate and sugar content—all from a single sample. This system's automated workflow and fast analysis work together to ensure high throughput and low cost-per-test. More testing, from fewer instruments and with fewer techs. Now that's smart.

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Thermo Scientific™ Gallery™ and Thermo Scientific™ Gallery™ Plus discrete analyzers automate manual wet chemistry methods, colorimetric/photometric, enzymatic and electrochemical (pH and conductivity) analysis, mimicking the operation of lab chemists, to provide fast, reproducible results in a compact, benchtop design. The discrete cell technology also allows laboratories to measure multiple analytes simultaneously while reducing total analysis and operator time. The Gallery discrete analyzer, with miniaturized components and unique low-volume cuvette design, accommodates small reagent volumes, minimizes reagent waste. The key to improved productivity is processing many parameters simultaneously with high-throughput analysis and walkaway operation.

Figure 4. Rapid multiparameter analysis — walkaway solution for peritoneal dialysis solutions, hemodialysis solutions, or hemofiltration solutions analyses.

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