**Specification of Services for Microbiological Testing of Dialysis Water**

**1. Introduction**

This document outlines the specifications for the microbiological testing of dialysis water. These services are essential for ensuring the safety and quality of water used in dialysis treatments, protecting patients from potential harm.

**2. Scope of Services**

* **Sampling:** Provision of the following services:
	+ Microbiological analysis of water samples collected from the Renal department of St. Georges Hospital site. The analysis included endotoxin testing and Total Viable Cell (TVC) count following incubation at 37 degrees C for 72 hours.
	+ Collection of water samples Weekly from Renal Unit Courtyard Clinic, Ring road, ST Georges Hospital, Blackshaw Road, Tooting, SW17 0QT.
	+ The analysis of all water samples for Copper, Fluoride, Magnesium, Nitrates, Potassium, Sodium, Aluminium, Calcium, Arsenic, Cadmium, Chromium, Lead, Sulphate, Barium, Silver, Thallium, Zinc, Chlorine, Mercury and Beryllium.
* **Testing:** Microbiological analysis of dialysis water samples for the following parameters:
	+ Total Viable Count (TVC) of bacteria (specify method, e.g., membrane filtration, spread plate)
	+ Endotoxin levels (specify method, e.g., Limulus Amebocyte Lysate (LAL) assay)
* **Reporting:** Provision of test results to the Renal Unit, including:
	+ Date and time of sampling
	+ Date and time of testing
	+ Test results for each parameter, clearly indicating units of measurement
	+ Interpretation of results with reference to relevant guidelines (e.g., ISO 23500-4:2024, Renal Association recommendations)
	+ Notification of any results exceeding pre-defined action levels (see Section 4)
* **Quality Control:** Implementation of a robust quality control program, including:
	+ Use of certified reference materials
	+ Regular calibration of equipment
	+ Participation in external quality assessment schemes (e.g., proficiency testing)
	+ Documentation of all quality control procedures

**3. Testing Frequency and Sample Locations**

* **Frequency:** Samples will be collected and tested weekly.
* **Sample Locations:** Samples will be collected form Renal Unit Courtyard Clinic, Ring Road, ST Georges Hospital, Blackshaw Road, Tooting, SW17 0QT.

**4. Action Levels and Reporting Procedures**

* **Action Levels:**
	+ TVC: Action Level 1: > 50 CFU/mL; Action Level 2: > 100 CFU/mL
	+ Endotoxin: Action Level 1: > 0.12 EU/mL; Action Level 2: > 0.25 EU/mL
* **Reporting Procedures:** Results will be sent to the Renal technical manager or his team in a format that is or can be manipulated into trend analysis for internal reporting. A two week turn around for results or sooner dependant on type of test:
	+ Endotoxin results within two days in special circumstances
	+ TVC’s results within a week
	+ Chems results up to two weeks

**5. Responsibilities**

* Suppliers responsibilities include performing the tests, reporting results, maintaining quality control, and adhering to this specification.

**6. Standards and Guidelines**

All testing and reporting shall be conducted in accordance with the latest versions of the following standards and guidelines:

* ISO 23500-4:2024 Preparation and quality management of fluids for haemodialysis and related therapies
* Any other current relevant national or international guidelines, e.g., local water quality regulations, Renal Association recommendations.

**7. Review and Amendment**

This Specification of Services shall be reviewed Yearly and may be amended by mutual written agreement of both parties.