METHOD STATEMENT

Determinand:
Total Viable Count (TVC)

Matrix:
Sample Type: Process and Purified Waters (suitable pure for example endoscope rinse waters / deionised waters and dialysate fluid waters).

Principle of Method:
A viable count is used to determine the number of cells in the sample capable of forming colonies on a suitable agar medium, with the assumption that each viable cell can yield one colony. For this reason, the viable count is often called the colony count or plate count.
There are two ways of performing a colony count: the pour plate method and membrane filtration. Pour plates are prepared by pipetting a known volume of sample water into a sterile Petri dish and then adding molten agar and mixing gently by swirling the plate.
For membrane filtration typically 100ml of sample is filtered, and the membrane filter placed on pre-poured plates of set agar. Customers may request that a sample is tested in duplicate for the filtration method, particularly samples from endoscope rinse waters.
Following incubation under the relevant conditions, the numbers of colony forming units are counted.

Sampling and Sample Preparation:
Once taken, microbiological samples should be transferred immediately to dark storage conditions and kept at a temperature between 5 ± 3°C for transport to the laboratory. If samples are not analysed immediately on receipt in the laboratory, they should be kept at a temperature between 5 ± 3°C, in dark conditions until analysis commences.
Samples should be analysed as soon as practicable on the day of collection. In exceptional circumstances, if there is a delay, storage under the above conditions should not exceed 24 hours before the commencement of analysis.
Where an exceedance has occurred, a statement reflecting this is included with the report.

Interferences
Large numbers of organisms may produce confluent growth. Samples known to contain large numbers of organisms should be diluted before testing.

Performance of Method:

Limit of Detection:
The Limit of Detection for this method is calculated as detailed in internal Procedure GOP7.2B.

Uncertainty of measurement:
The Uncertainty of Measurement for this method is calculated as detailed in internal Procedure GOP7.6C and the results are recorded on GQF7.6.3.

References:
Environment Agency – The Microbiology of Drinking Water (2012) – Part 7 – Methods for the Enumeration of Heterotrophic Bacteria
Standing Committee of Analysts – The Microbiology of Water and Associated Materials (2017) - Practices and Procedures for Laboratories
The European Pharmacopoeia 2008.
The United States Pharmacopeia 2008
NHS estates – washer-disinfectors validation and verification – Health Technical Memorandum 2030.

Health Technical Memorandum 01-06: Decontamination of flexible endoscopes. March 2016.
BS EN ISO11663:2015 - Quality of dialysis fluid for haemodialysis and related therapies
BS EN ISO 15883-1:2009 +A1:2014 - Washer-disinfectors Part 1: General requirements, terms and definitions and tests
BS EN ISO 15883-4:2009 - Washer-disinfectors Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes