Public Health England

Hospital waters – how to ensure high quality microbiological testing

About Public Health England

Public Health England's mission is to protect and improve the nation's health and to address inequalities through working with national and local government, the NHS, industry and the voluntary and community sector. PHE is an operationally autonomous executive agency of the Department of Health.

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Hospital waters

Hospitals must ensure that water used in their healthcare facilities, is safe to minimise the potential risk of infection to people receiving treatment within the hospital environment. However in recent years published evidence has revealed, an increase in outbreaks and incidents of infection where the microbial source can be traced to contamination of the water used in hospitals (1-3).

In late 2011 and early 2012 there were a number infections associated with *Pseudomonas aeruginosa* that caused the deaths of four neonates in Northern Ireland. This incident is one of many that highlight the importance of water quality in the hospital environment. Regular microbiological examination of tap waters in augmented care areas of the hospital is an essential part of ensuring adequate water quality (2). In response to the outbreak in Northern Ireland the Department of Health (England) produced the *Health Technical Memorandum (HTM) 04-01 Addendum '*Pseudomonas aeruginosa – *advice for augmented care units*' that provides hospitals with information on controlling and minimising the risk of morbidity and mortality due to *P. aeruginosa* associated with water outlets (4). The HTM 04-01 Addendum also provides guidance on protocols for sampling, testing and monitoring water for *P. aeruginosa* and the importance of having a water safety group with the appropriate expertise in healthcare facilities.

Public health

Public Health England (PHE), is an organisation committed to helping people to stay healthy, and protecting them from threats to their health. The government wants everyone to be able to make healthier choices, regardless of their circumstances, and to minimise the risk and impact of illness. Microbiology laboratories that examine water samples from the hospital environment play an important role in supporting the appropriate management of facilities and controlling infection, thereby contributing to the management of public health threats. It is therefore important that PHE supports microbiology laboratories so they are able to demonstrate that their test procedures and the interpretation and understanding of test results are reliable, accurate and unequivocal. For this reason PHE provides tools such as external quality assessment (EQA) schemes and reference materials.

PHE tools available to help ensure the quality of testing

Reference Materials

PHE's Culture Collections operates an internationally renowned biological resource that provides a wide range of microbial and cell cultures to the biomedical community. Those resources include authenticated reference bacterial strains from the National Collections of Type Cultures (NCTC), some of which are available as certified reference materials. The use of reference materials with known quantifiable counts and known characteristics plays an important role in underpinning the accuracy and validity of laboratory results. Incorporating biological control materials into the quality assurance process helps to confirm that the media, reagents and equipment are performing within the desired specifications.

External Quality Assessment

Public Health England's (PHE) Food and Environmental Proficiency Testing Unit (FEPTU), has been providing EQA schemes to food and water microbiology testing laboratories for more than 20 years, both nationally and internationally. PHE has designed specific EQA schemes for laboratories that examine water samples from a wide range of hospital environments. Participating in these schemes allows laboratories to demonstrate their own competence with the microbiological examination of these types of samples and improve their understanding of the interpretation of the results obtained.

The use of EQA schemes is an integral component of a laboratory's quality assurance system. The simulated samples provided by PHE are of 'known but undisclosed content' and are tested in the same manner as routine samples to help to demonstrate that the results obtained for real samples are correct. Ensuring that the right results are obtained from the right samples is an essential component of effectively managing public health incidents and outbreaks.

PHE provides four hospital water EQA schemes; Endoscope Rinse Water, Dialysis Water, Hospital Tap Water and Hydrotherapy Pool Water because we understand the importance of water quality in the hospital environment and the potential impact of using unsafe waters.

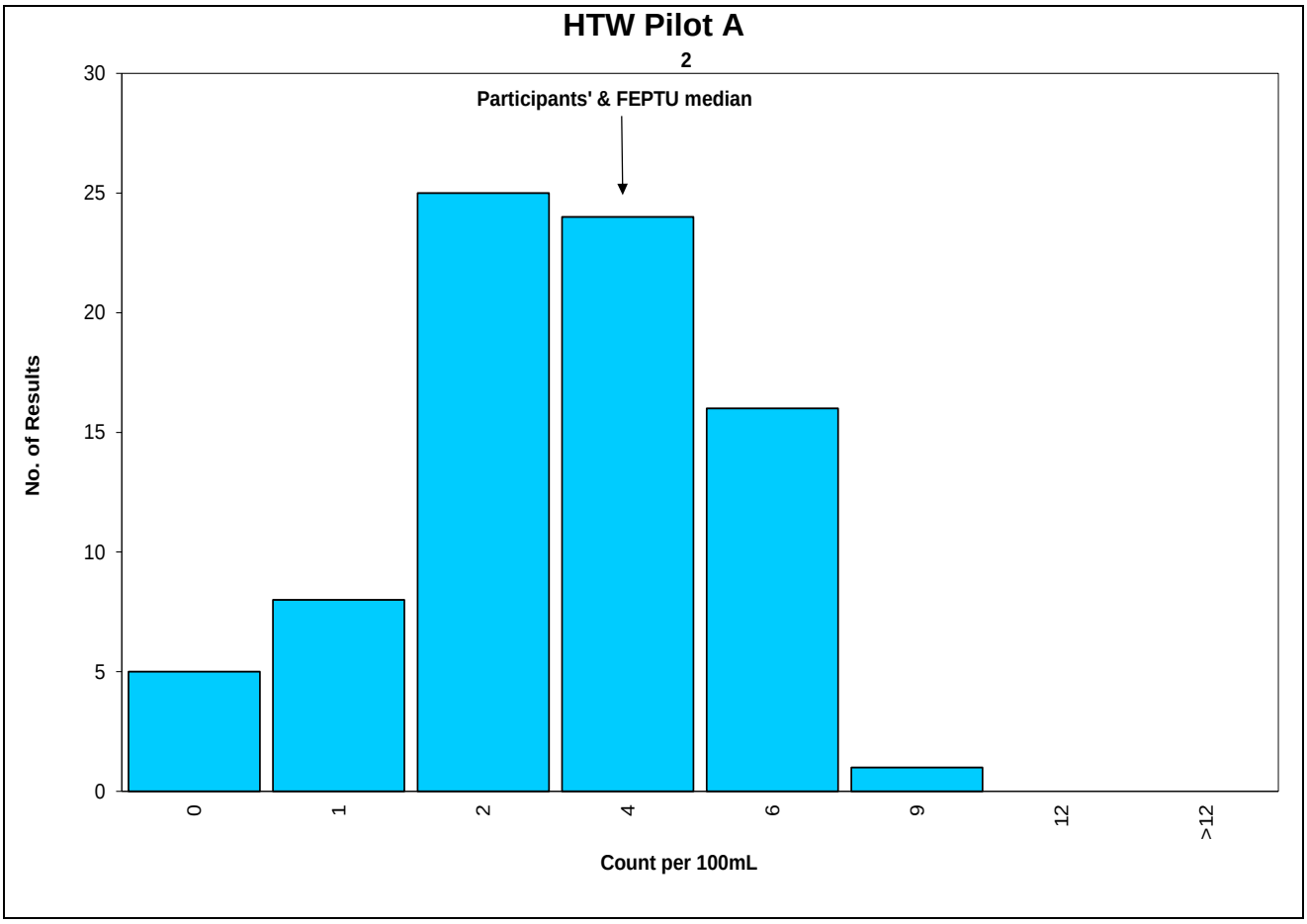
EQA for water from augmented care units

Contamination of hospital tap water can pose a serious threat to patient health, particularly for those patients who are immunocompromised. The PHE Hospital Tap Water Scheme has been designed for laboratories testing water samples from augmented care units.

A pilot EQA scheme was distributed in June 2013 to determine whether the proposed scheme was fit-for-purpose and engage testing laboratories in the scheme's design. 81 laboratories examined the samples and returned results. This pilot distribution showed that participants followed two main guidelines when they examined the samples; ISO 16266: 2006 – *Water quality: Detection and enumeration of* Pseudomonas aeruginosa – *Method by membrane filtration* and the *Health Technical Memorandum (HTM) 04-01 Addendum* Pseudomonas aeruginosa - *advice for augmented care units* (2013)(4). The procedures in those documents are very similar; HTM 04-01 Addendum states that 100 mL of water should be examined whereas ISO 16266 specifies that 'a measured volume' must be examined. Importantly the HTM 04-01 Addendum also provides additional information to hospitals on the management of water systems and the interpretation of results obtained on samples tested. There are also minor variations in the confirmatory testing procedures recommended within the two documents.

The results reported by participants for the pilot sample 'A' are presented in Graph 1 and shows the bacterial counts (expressed in colony forming units). This sample contained a strain of *Pseudomonas aeruginosa* and a *Bacillus licheniformis*; the median count reported by the participants was 4 cfu per 100mL (assigned value) on *Pseudomonas* agar containing cetrimide and sodium nalidixate (PCN)(image 1). The calculated expected range for this sample was 0 – 12 cfu per 100mL, two participants that reported a count of <1, their results were acceptable because those counts are in the expected range.

Graph 1: *P. aeruginosa* count reported per 100mL for sample A



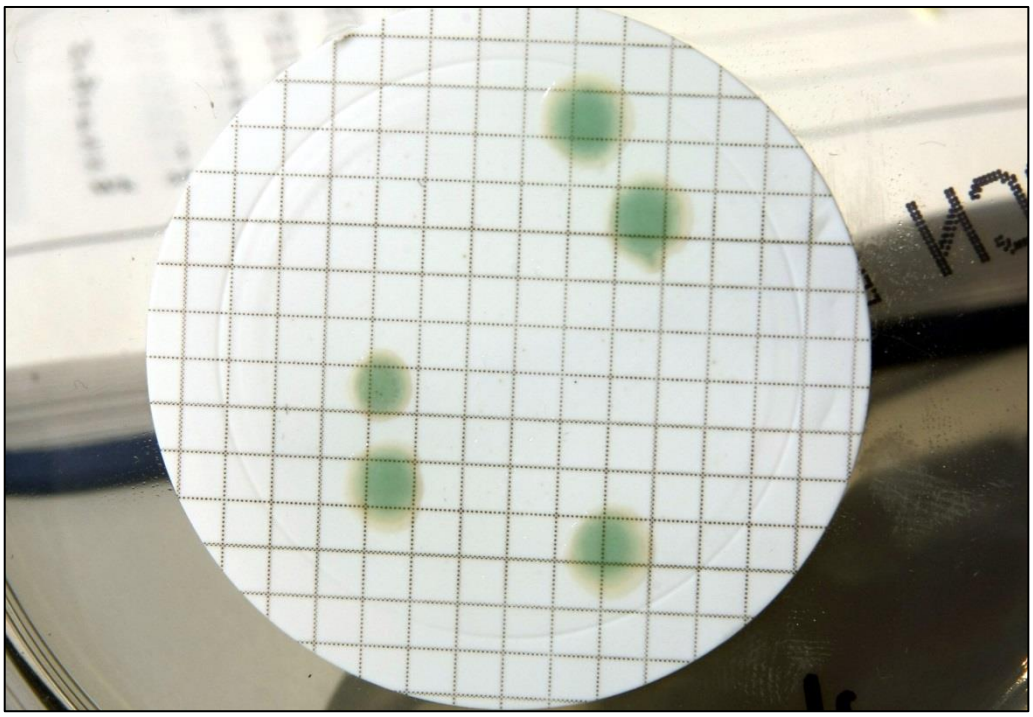


Image 1: *P.aeruginosa* on PCN agar incubated at 37°C for 48 hours

According to HTM 04-01 Addendum, the hospital's Water Safety Group (WSG) (or equivalent) should be informed if *P. aeruginosa* counts are 1–10 cfu per 100 mL. The WSG should risk-assess the use of water in the augmented care unit whilst asking for the water outlet to be retested. Two laboratories that reported the presence and a count for *P. aeruginosa*, had interpreted the sample as 'satisfactory'. Pilot sample 'B' contained *P. putida* only. This strain was included to help participating laboratories assess their ability to differentiate *P. aeruginosa* and other species of *Pseudomonas*. Four participants reported incorrectly the presence of *P. aeruginosa* and the range of counts reported was 1-3 cfu per 100mL. As has been demonstrated in Northern Ireland and elsewhere, contamination of hospital tap water can pose a serious threat to patient health, particularly for those patients in augmented care units who are immunocompromised (1-3). It is important for patient care that laboratories obtain and report accurate results and any interpretation given to their customer conforms to national guidance.

The full pilot report can be accessed from:
http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317139941788

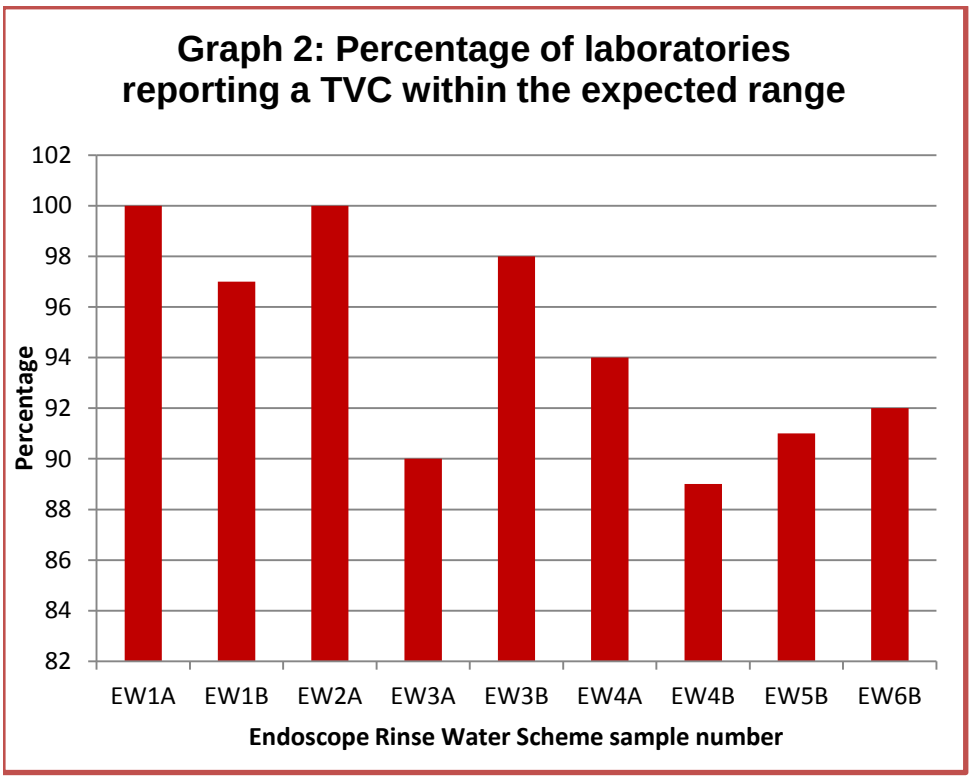
EQA for endoscope rinse water

Endoscopes are used for diagnostic and therapeutic purpose and require high level disinfection; endoscopes should be thoroughly cleaned and disinfected between patient procedures, and finally rinsed to remove any residual chemical toxicity. The final rinse-water should be free from extraneous material, both inorganic and organic including micro-organisms, which could compromise the patient. Total viable counts (TVCs) should be undertaken on the final rinse-water on a regular basis as indicated in the UK government's document *'Choice framework for local policy and procedures 01-06 – decontamination of flexible endoscope: testing methods'* (5).

This EQA scheme allows laboratories to demonstrate competence for enumeration of micro-organisms in the sample, detection and identification of *Pseudomonas aeruginosa* or other predominant organisms such as *Mycobacterium* spp., as well as the interpretation of the results obtained.

Graph 2 shows the overall results obtained by laboratories participating in this scheme over the last two years; performance over time in obtaining a total viable count within a statistically calculated expected range is shown. Overall, the performance of the laboratories ranges from 89 - 100% accuracy. This clearly shows that participating laboratories are consistently achieving accurate results with these EQA samples. If a laboratory is continuously obtaining EQA results below the expected range, they are advised to investigate the problem. Where laboratories wish to discuss with an expert

water microbiologist, performance improvements or understand the problem associated with the examination of this sample type, the organiser can be contacted.



EQA for water used to prepare dialysis fluid

Haemodialysis patients are particularly vulnerable to contaminants in the water used to prepare concentrates and dialysates. The Dialysis Water Scheme is designed for laboratories that examine the water used to prepare dialysis fluids in accordance with the testing recommendations stipulated in the European Renal Best Practice Guidelines (6).

Data (not shown) from the last two EQA distributions show that samples containing low levels of micro-organisms are more challenging for the participants, more outlying results are observed. However, we advise that participants who report unexpectedly high or low results for the enumerations on a single occasion should not be unduly concerned, although they should still assess the reason(s) for the outlying result. Regular participation in EQA schemes allows laboratories to monitor their performance over time which means they can conduct trend analyses to monitor and identify negative or positive bias with their results, which can be investigate further if they feel it is appropriate.

EQA for water from hydrotherapy pool water

Microbiological contamination of any type of pool water can result in pathogenic micro-organisms causing infections to bathers. Contaminants can be introduced into the pool by bathers (particularly from skin or due to faecal contamination), from pool filters or occasionally, from defects in the pool engineering. Hydrotherapy pools in hospitals require increased sampling frequencies compared to public swimming and spa pools because the people who use them are often immersed for long periods and may be more vulnerable to infection than the general public (7). The current Recreational and Surface Water Scheme (swimming pool sample type) has the same testing parameters as those that are required for the microbiological examination of hydrotherapy pool water. Table 1 shows the overall performance with this sample type over the last two distributions. Performance has been calculated on the participants' enumeration results, reported within the expected range.

Table 1: Summary of participants performance (in %) with swimming/hydroptherapy pool water EQA sample

	Sample number			
Testing parameter	**S57A**	**S57B**	**S53A**	**S53B**
Coagulase postive staphylococci	93%	NA	95%	NA
Coliform bacteria	96%	91%	NA	95%
Escherichia coli	94%	NA	NA	94%
Pseudomonas aeruginosa	NA	86%	92%	87%
Aerobic colony count 37°C / 24 hours	98%	97%	99%	88%

NA = Not applicable as sample did not contain the target organism

Table 1 shows the performance of the laboratories ranges from 87 - 99% accuracy. This clearly shows that participating laboratories are consistently achieving accurate results with these EQA samples, giving confidence to both your laboratory and the commissioner of the test, that testing is being carried out to a high standard.

Use of Certified Reference Materials (CRM)

The use of reference materials containing micro-organisms of known phenotypic properties is another important element of a quality assurance process. Julie Russell, Head of PHE's Culture Collections, wrote an article that was published in the IBMS gazette (Vol. 57 No.11) on 'Quality matters: an update from the culture collections' that discussed the importance of using controls in a laboratory. She provided data to illustrate why it is important that control strains should have proven authenticity which is achieved by extensive characterisation of the strains before they are provided to the testing laboratories such as the phenotypic, genomic and proteomic analysis. The use of CRMs in a testing laboratory helps to confirm that the methods and materials, including the culture media used in the examination of waters are performing properly. This is especially important for culture media with selective and differential properties, where CRMs can demonstrate that the target organism is detected at the required limit of detection.

PHE CRMs with known certified levels are also a valuable tool for ensuring that the water sample filtration processes have been performed correctly. This is particularly significant if laboratories regularly examine water samples containing low numbers of microorganisms, where the decisions about whether to take action regarding the continued use of water from a particular source are dependent on the microbiological results obtained.

Legislation on water quality

Currently no European legislation provides recommendations for minimum standards for the quality of water used for specific functions in hospitals. However, in the UK there are a number of documents providing guidance about the microbial quality of water to be used for endoscope washer/disinfectors, renal dialysis and hydrotherapy pools, as well as general guidelines relating to *Legionella* and *Pseudomonas aeruginosa* in hospital water. These documents also indicate the microbiological tests necessary to ensure that the quality of the waters used falls within safe microbiological parameters.

Hospitals need to have assurance that the quality of water used in patient treatment or in the general hospital environment is safe if public health risks are to be prevented or successfully managed. The use of EQA schemes, supported by validation of the different components of a test procedure by using reference materials are valuable tools for a microbiology laboratory in assuring the results obtained. These tools can be extremely valuable if they are used properly. Laboratories gain confidence in their ability

to produce accurate and reliable test results (provided that the EQA samples and reference materials are treated in the same way as routine samples). In addition the schemes also support laboratories in improving their understanding of how to interpret their microbiological results against the relevant guidelines.

For more detail on the schemes and how to gain the maximum benefits from participating in the schemes can be found on www.hpa.org.uk/eqa, or you can email us at foodeqa@phe.gov.uk.

To find out more information about the CRM controls visit PHE's Culture Collections website: http://www.phe-culturecollections.org.uk/products/lenticulediscs/index.aspx

All PHE EQA schemes are accredited by the United Kingdom Accreditation Service (UKAS) to the international standard ISO 17043:2010 *Conformity assessment – General requirement for proficiency testing*

All PHE CRMs are produced and quality controlled in accordance to ISO Guide 34:2009 *General requirements for the competence of reference material producers*

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