

Protecting and improving the nation's health

# **Summary of Results**

# External Quality Assessment of Water Microbic ogy Dialysis Water Scheme

Distribution Number: DW17 Sample Numbers DW17 Sample Numbers

Distribution Date:	November 2013
Results Due:	30 Novem er 20 8
Report Date:	0" Dec mbe. 18
Samples prepared and	Ang (`a Appea
quality control tested by:	Richaru Borrill
	Thomas Harper
\ \	Nargaret Njenga
	Zak Prior
	Judith Spellar
	Lili Tsegaye
Data analys id by.	Joanna Donn
	Manchari Rajkumar
Report compiled by:	Joanna Donn
	Manchari Rajkumar
	_
Authorised by:	Nita Patel

This report must not be reproduced without permission of the organisers.

Public Health England
Food and Environmental Proficiency Testing Unit (FEPTU)

61 Colindale Avenue

London NW9 5EQ

Tel: +44 (0)20 8327 7119 Fax: +44 (0)20 8200 8264 Email: foodeqa@phe.gov.uk For further information about the scheme please refer to:

Scheme Guide: https://www.gov.uk/government/publications/food-and-water-proficiency-testing-schemes-scheme-guide

#### **Guide to Scoring and Statistics:**

https://www.gov.uk/government/publications/food-and-water-proficiency-testing-schemes-scoring-systems-and-statistics

#### General guidance for z-scores:

Participants' enumeration results are converted into z-scores using the following formula:

*xi* = participants' result (expressed as a log<sub>10</sub> value)

 $Z = (X_i - X_{pt})$   $X_{pt}$  = assigned value (participants' consensus median (expressed as a log 10 value))

 $\sigma_{pt}$  = the fixed standard deviation for the examination (calculated by FEPTU)

The  $\sigma_{pt}$ -value expresses the acceptable difference between the individual participant's result and the participants' consensus median. The  $\sigma_{pt}$ -value used for calculating z-scores in the Dialysis Water Scheme is 0.35. A guide to interpreting z-scores follows, although laboratories must interpret their scores in the context of their own laboratory situation:

z = -1.99 to +1.99 satisfactory z = -2 to -2.99 or +2 to +2.99 questionable z = < -3.00 or > +3.00 unsatisfactory

It is usually recommended that z-scores exceeding ± 2.0 are investigated to establish the possible cau >. As a general rule, PHE recommends that all questionable and unsatisfactory results are investigated.

**FEPTU Quality Control:** To demonstrate homogeneity of the sample, a minimum of 10 L FNTIC JLE® discs, selected randomly from a batch, are tested in duplicate for the enumeration test.

To demonstrate stability of the sample, a minimum of six LENTICULE c'scs, elected ray domly from a batch, are examined throughout the distribution period for the enumeration test

The FEPTU results are determined using a method based on ISO 13955 `1014 - Water for haemodialysis and related therapies.

The FEPTU results are used for guidance in the prelining of the results notification, letters are posted on the website immediately after every distribution; electronic notification, heir availability is sent to all participants.

Refer to section 17.0 of the Scheme Guide if you it re experienced difficulties with any of the examinations . https://www.gov.uk/government/publications.od-a.d-ws\_er-proficiency-testing-schemes-scheme-guide

Participants are reminded that reporting irrect o. false regative results for water samples could have serious public health implications.

Please contact FEPTU staff i r adv = .nd information:

Repeat sample Carmen Gomes or Kermin Daruwalla Tel: +44 (0)20 8327 7119

Data Analysis Manchari Rajkumar or Nita Patel Fax: +44 (0)20 8200 8264

Email: foodega@phe.gov.uk

Microbiological adv Nita Patel or Zak Prior FEPTU's website

General comments and complaints Nita Patel or Zak Prior

Scheme consultants Caroline Willis or Julie E. Russell

Scheme Co-ordinator Nita Patel

**Accreditation:** PHE Water EQA Scheme for Dialysis Water is accredited by the United Kingdom Accreditation Service (UKAS) to ISO/IEC 17043:2010.



Sample: DW17A

Contents: No micro-organisms

### **Expected Results:**

All counts are expressed as colony forming units (cfu) per mL.

The fixed standard deviation value (  $\sigma_{Pl}$  value) used for calculation of the z-score is **0.35** for this parameter

Results	
FEPTU median (MF) <sup>1</sup>	0
No. results returned	68
Assigned value (Participants' median all results)	0
Interpretation based on assigned value**	Satisfactory/Acceptable
Uncertainty of assigned value	N/A
Participants' mean (all results)	N/A
Expected Range	N/A
Standard deviation**	N/A
No of outlying counts	WA
False positives	11
False negatives	
Your result	
Your interpretation	
Score for perform ince assessment	
Z-score	

<sup>&</sup>lt;sup>1</sup> Membrane filtration

<sup>\*\*</sup> Robust  $S^*$  based on median absolute deviation about the participants' median (MADe)

Total sent samples	74
Not examined	2
Non returns	4

<sup>\*</sup> Reference: https://academic.oup.com/ndt/search-results?f TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity

Sample: DW17B

Contents: Enterobacter cloacae 79 (wild strain), Enterococcus faecalis 98 (wild strain)

#### **Expected Results:**

All counts are expressed as colony forming units (cfu) per mL.

The fixed standard deviation value ( $\sigma_{pt}$  value) used for calculation of the z-score is **0.35** for this parameter

Results	
FEPTU median (MF) <sup>1</sup>	125
No. results returned	68
Assigned value (Participants' median all results)	152
Interpretation based on assigned value**	Unsatisfactory/Unacceptable
Uncertainty of assigned value	5
Participants' mean (all results)	149
Expected Range	87 - 217
Standard deviation**	33
No of outlying counts	7,
False positives	
False negatives	2
Your result	
Your interpretation	
Score for perform lice assessmen	
Z-score	

<sup>&</sup>lt;sup>1</sup> Membrane filtration

 $<sup>^{\</sup>star\star}$  Robust  $S^{\star}$  based on median absolute deviation about the participants' median (MADe)

Total sent samples	74
Not examined	2
Non returns	4

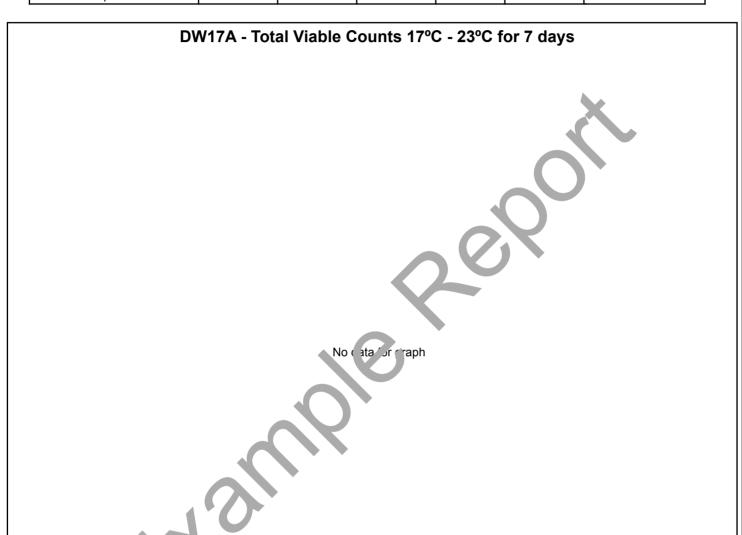
<sup>\*</sup> Reference: https://academic.oup.com/ndt/search-results?f TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity

# **Method based presentation**

DW17A: Total Viable Counts 17°C - 23°C for 7 days

# FEPTU Method: Membrane Filtration

Method	Number of	Excluded	Percentage	Median	Robust S*	Range Re	ported
	Results	Results	of the total				
Membrane Filtration	21	6	36	0	0	0 -	1
Not Stated	0	1	0				
Other	2	0	3				
Pour	28	1	49	0	0	0 -	555
Spread	6	4	10				



# Sample: DW17A

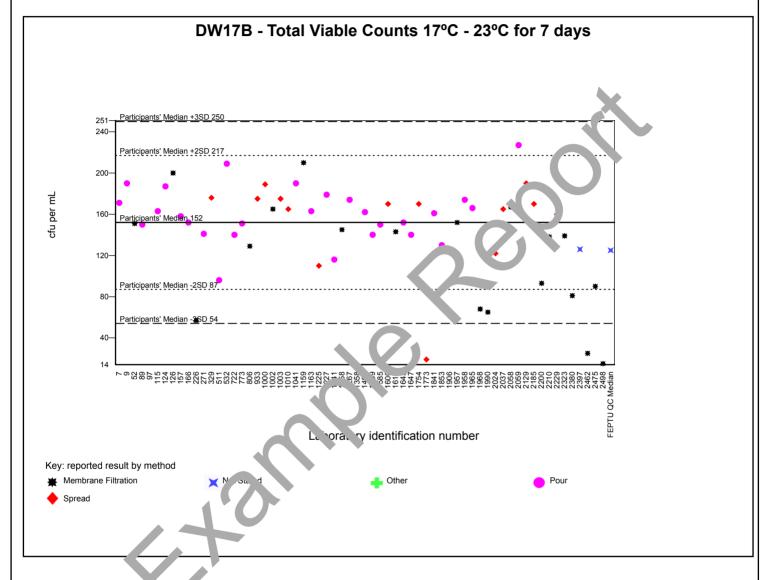
Total Viable Counts 17°C - 23°C for 7 days Method	Total Viable Counts 17°C - 23°C for 7 days Media	Total Viable Counts 17°C - 23°C for 7 days Standard Method	Count
Membrane Filtration	R2A	European pharmacopoeia 5.0	1
Membrane Filtration	R2A	ISO 11663:2014	1
Membrane Filtration	R2A	ISO 13959:2014	5
Membrane Filtration	R2A	ISO 23500:2014	3
Membrane Filtration	R2A	Other; please state	3
Membrane Filtration	R2A	PHE guidelines	1
Membrane Filtration	R2A	UK Renal Association Guidelines	1
Membrane Filtration	TGEA	European Renal Best Practice Guidelines	1
Membrane Filtration	TGEA	ISO 13959:2014	2
Membrane Filtration	TGEA	Other; please state	4
Membrane Filtration	TGEA	UK Renal Association Guideling	2
Membrane Filtration	TSA	ISO 13959:2014	1
Membrane Filtration	TSA	Other; please s'	1
Other	R2A	European pharma poeia 5.	1
Other	YEA	ISO 2000-19.	1
Pour	None	!Cr 13959:₂ 14	1
Pour	Other	ISC 222:1 99	1
Pour	R2A	SO 116c 2014	3
Pour	R2A	ISC 13959:2014	4
Pour	R2A	Other; please state	1
Pour	R2A	PHE guidelines	1
Pour	R2A	UK Renal Association Guidelines	1
Pour	TGEA	ISO 13959:2014	3
Pour	TGEA	PHE guidelines	1
Pour	TGEA	UK Renal Association Guidelines	1
Pour	YEA	ISO 13959:2014	1
Pour	Υ-	ISO 23500:2014	1
Pour	YEA	ISO 6222:1999	5
Pour	YL	UK Renal Association Guidelines	4
Spread	R2A	ISO 11663:2014	1
Spread	r{2A	ISO 13959:2014	2
Spread	R2A	Other; please state	2
Spread	TGEA	European pharmacopoeia 5.0	1
Spread	TGEA	ISO 11663:2014	1
Sprear'	TSA	Other; please state	1
Sp nd	TSA	UK Renal Association Guidelines	1
Spreau	YEA	European pharmacopoeia 5.0	1
Spread	YEA	ISO 11663:2014	1

# **Method based presentation**

DW17B: Total Viable Counts 17°C - 23°C for 7 days

### **FEPTU Method: Membrane Filtration**

Method	Number of	Excluded	Percentage	Median	Robust S*	Range	Rep	orted
	Results	Results	of the total					
Membrane Filtration	19	4	30	138	0	15	-	210
Not Stated	1	1	1					
Other	1	0	1					
Pour	28	0	44	160	0	0	-	227
Spread	14	0	22	170	0	19	-	190



# Sample: DW17B

otal Viable Counts 17°C Total Viable Counts 17°C - 23°C for 7  - 23°C for 7 days  Method Media		Total Viable Counts 17°C - 23°C for 7 days Standard Method	Count
	R2A	ISO 23500:2014	1
Membrane Filtration	R2A	European pharmacopoeia 5.0	1
Membrane Filtration	R2A	ISO 11663:2014	1
Membrane Filtration	R2A	ISO 13959:2014	5
Membrane Filtration	R2A	ISO 23500:2014	1
Membrane Filtration	R2A	Other; please state	3
Membrane Filtration	R2A	PHE guidelines	1
Membrane Filtration	TGEA	European Renal Best Practice Guidelines	1
Membrane Filtration	TGEA	ISO 13959:2014	1
Membrane Filtration	TGEA	Other; please state	4
Membrane Filtration	TGEA	UK Renal Association Guideling	2
Membrane Filtration	TSA	ISO 13959:2014	1
Membrane Filtration	TSA	Other; please s'	1
Other	YEA	ISO 6222: 99	1
Pour	Other	ISO 0000:19.	1
Pour	R2A	IC' 11663:≥ 14	3
Pour	R2A	ISO '959.7 14	4
Pour	R2A	mer plean state	1
Pour	R2A	PF _ guidelines	1
Pour	R2A	UK Renal Association Guidelines	1
Pour	TGEA	ISO 13959:2014	3
Pour	TGEA	PHE guidelines	1
Pour	TGEA	UK Renal Association Guidelines	1
Pour	YEA	ISO 13959:2014	1
Pour	YEA	ISO 23500:2014	1
Pour	YEA	ISO 6222:1999	5
Pour	Υ-	UK Renal Association Guidelines	4
Spread	R2A	European pharmacopoeia 5.0	1
Spread	Rz	ISO 13959:2014	2
Spread	R2A	ISO 23500:2014	1
Spread	K2A	Other; please state	2
Spread	TGEA	European pharmacopoeia 5.0	1
Spread	TGEA	ISO 11663:2014	1
Spread	TGEA	ISO 13959:2014	1
Sprear'	TSA Other; please state		1
Sp ad	TSA UK Renal Association Guideline		1
Spreau	YEA European pharmacopoeia 5.0		1
Spread	YEA	ISO 11663:2014	1

#### **Performance Assessment Sheet**

Distribution	Sample	Total Viable Counts 17°C - 23°C for 7 days score
DW17	DW17A	
DWI7	DW17B	
DW16	DW16A	
DWIG	DW16B	
DW15	DW15A	
DW15	DW15B	
Total maximum possible score		
Total percentage		

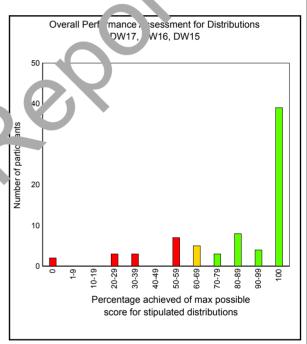
#### **Performance Assessment Comment:**

Participants are reminded that to take advantage of the performance assessment overtime tool provided in the reports they need to take part in more than one distribution a year.

Performance assessments are designed to alert participants to on-grang problems with their examinations and are provided after every distribution. Scores are allocated to results reported for ver parameter, for every sample to help assess performance.

Cumulative scores are calculated for the current ar previous distribution for the Dialysis Water Scheme. Participan if umilative scores for each of the examinations are compared with the maximum possible scores after every distribution.

Your overall performance with the enumerations of the dialysis water proficiency testing samples for the current artageneous distributions is collated in the chart to the right.



## Performance Assessment Commer

Laboratories that achieve less that 70% of  $t^i$  e maximum possible score are likely to be experiencing significant problems with their examinations and are accised to.

- a) refer to the relevant distribution epons for sample-specific comments
- b) refer to the webstle guid frice do liments:

  <a href="https://www.gov.uk.gov
- c) contact the organisers advice

#### Sample specific comment

#### DW17A -no micro-organisms

11/68 (16%) of the laboratories reported a false positive for this sample when no micro-organisms were presented in the sample. Therefore 95% confidence interval around the participants' median has been used to score the sample. The expected range is 0 - 3 cfu per 1mL and scores have been awarded accordingly. Participants are reminded that it is important to process all samples using aseptic techniques to reduce the likelihood of environmental contamination.

DW17A: 55 laboratories provided a conclusion on the results reported, responses are shown in the table below:

Colony forming counts reported per mL	Conclusion reported by the laboratories (number of laboratories)
	Satisfactory/Acceptable
Count reported 0	(28)
Range reported 1 – 6	(4)
Censored values of <1 - <10	(7)
	Not routinely reported
Count reported 0	(11)
Range reported 1 – 2	(2)
Censored value of <1	(2)
	Unsatisfactory/Unacceptable
Count reported 555	(1)

#### DW17B: 54 labor atories provided a conclusion on the results reported, respons so, sh, and the table below:

Colony forming counts reported per mL	Conclusion reporte, by the laboratories (number of laboratories)
Count reported 152	Satisfactory/Acce, 'ab' (1)
Count reported 0 Ranged reported 15 – 190 Censored value of >100	Not routinely reported (2) (
Range reported 68 - 110	Br. Che action level (2)
Range reported 25 – 227 Censored value of >100 - >1000	(35, (3)

Participants are reminder to the vita conclusion on a test result if this is part of your reporting procedures.

Interpretation of test 'esults can' e found in ISO 13959:2014 - Water for haemodialysis and related therapies or the European Best Practice Gu,  $a^{\mu}$  es for Haemodialysis. The Interpretation/conclusions of microbiological test results in your coupt' y magnetic to those published in these documents.

# Meth. \bas \_a presentation of results:

Particip. is are actived if less than 10 laboratories report a result for a method, no data is shown for the Median, Robust Suind to a Range Reported in the 'Method based presentation' tables. Numbers shown in the 'Excluded Results' cold of are laboratories that reported a censored value.

## General comment:

If you do not return a result for a distribution, you will not be able to view all the participants' results data in your individualised report. Therefore, we will post generic reports on the website, which will be available for 12 months after the distribution has closed, so you can access the missing data.

End of report.

