



# Summary of Results

## External Quality Assessment of Water Microbiology Dialysis Water Scheme

Distribution Number: DW17

Sample Numbers: DW17A, DW17B

Distribution Date:	<b>November 2018</b>
Results Due:	<b>30 November 2018</b>
Report Date:	<b>05 December 2018</b>
Samples prepared and quality control tested by:	<b>Angela Appea Richard Borrill Thomas Harper Margaret Njenga Zak Prior Judith Spellar Lili Tsegaye</b>
Data analysed by:	<b>Joanna Donn Manchari Rajkumar</b>
Report compiled by:	<b>Joanna Donn Manchari Rajkumar</b>
Authorised by:	<b>Nita Patel</b>

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:

$$Z = \frac{(X_i - X_{pt})}{\sigma_{pt}}$$

$X_i$  = participants' result (expressed as a log<sub>10</sub> value)  
 $X_{pt}$  = assigned value (participants' consensus median (expressed as a log<sub>10</sub> 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 cause. 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 LENTICULE® 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 discs, selected randomly from a batch, are examined throughout the distribution period for the enumeration test.

The FEPTU results are determined using a method based on ISO 13959:2014 - Water for haemodialysis and related therapies.

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

Refer to section 17.0 of the Scheme Guide if you have experienced difficulties with any of the examinations .

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

Participants are reminded that reporting incorrect or false negative results for water samples could have serious public health implications.

Please contact FEPTU staff for advice and information:

<b>Repeat samples</b>	Carmen Gomes or Kermin Daruwalla	<b>Tel:</b> +44 (0)20 8327 7119
<b>Data Analysis</b>	Manchari Rajkumar or Nita Patel	<b>Fax:</b> +44 (0)20 8200 8264
<b>Microbiological advice</b>	Nita Patel or Zak Prior	<b>Email:</b> foodeqa@phe.gov.uk
<b>General comments and complaints</b>	Nita Patel or Zak Prior	<a href="#">FEPTU's website</a>
<b>Scheme consultants</b>	Caroline Willis or Julie E. Russell	
<b>Scheme Co-ordinator</b>	Nita Patel	

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



0006

**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

<b>Results</b>	
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	N/A
False positives	11
False negatives	
Your result	
Your interpretation	
Score for performance assessment	
Z-score	

<sup>1</sup> Membrane filtration\* Reference: [https://academic.oup.com/ndt/search-results?f\\_TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity](https://academic.oup.com/ndt/search-results?f_TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity)\*\* Robust  $S^*$  based on median absolute deviation about the participants' median (MADe)

Total sent samples	74
Not examined	2
Non returns	4

**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 ( $\sigma_{pl}$  value) used for calculation of the z-score is **0.35** for this parameter

<b>Results</b>	
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	9
False positives	
False negatives	2
Your result	
Your interpretation	
Score for performance assessment	
Z-score	

<sup>1</sup> Membrane filtration\* Reference: [https://academic.oup.com/ndt/search-results?f\\_TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity](https://academic.oup.com/ndt/search-results?f_TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity)

\*\* Robust S\* based on median absolute deviation about the participants' median (MADe)

Total sent samples	74
Not examined	2
Non returns	4

**Method based presentation**

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

FEPTU Method: Membrane Filtration

Method	Number of Results	Excluded Results	Percentage of the total	Median	Robust S*	Range Reported
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			

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

No data for graph

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 Guidelines	2
Membrane Filtration	TSA	ISO 13959:2014	1
Membrane Filtration	TSA	Other; please state	1
Other	R2A	European pharmacopoeia 5.0	1
Other	YEA	ISO 6222:1999	1
Pour	None	ISO 13959:2014	1
Pour	Other	ISO 6222:1999	1
Pour	R2A	ISO 11663:2014	3
Pour	R2A	ISO 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	YEA	ISO 23500:2014	1
Pour	YEA	ISO 6222:1999	5
Pour	YEA	UK Renal Association Guidelines	4
Spread	R2A	ISO 11663:2014	1
Spread	R2A	ISO 13959:2014	2
Spread	R2A	Other; please state	2
Spread	TGEA	European pharmacopoeia 5.0	1
Spread	TGEA	ISO 11663:2014	1
Spread	TSA	Other; please state	1
Spread	TSA	UK Renal Association Guidelines	1
Spread	YEA	European pharmacopoeia 5.0	1
Spread	YEA	ISO 11663:2014	1

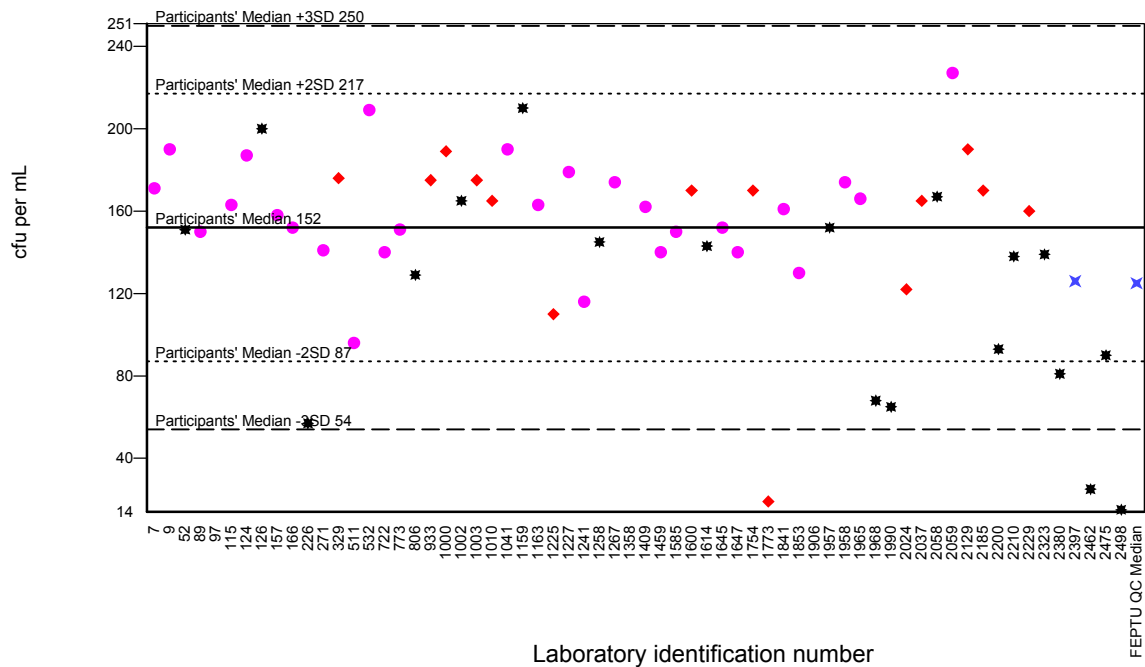
## Method based presentation

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

FEPTU Method: Membrane Filtration

Method	Number of Results	Excluded Results	Percentage of the total	Median	Robust S*	Range Reported
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

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



Key: reported result by method

- ★ Membrane Filtration
- ✕ Not Stated
- ✚ Other
- Pour
- ◆ Spread

Sample: DW17B

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
	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 Guidelines	2
Membrane Filtration	TSA	ISO 13959:2014	1
Membrane Filtration	TSA	Other; please state	1
Other	YEA	ISO 6222:1999	1
Pour	Other	ISO 6222:1999	1
Pour	R2A	ISO 11663:2014	3
Pour	R2A	ISO 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	YEA	ISO 23500:2014	1
Pour	YEA	ISO 6222:1999	5
Pour	YEA	UK Renal Association Guidelines	4
Spread	R2A	European pharmacopoeia 5.0	1
Spread	R2A	ISO 13959:2014	2
Spread	R2A	ISO 23500:2014	1
Spread	R2A	Other; please state	2
Spread	TGEA	European pharmacopoeia 5.0	1
Spread	TGEA	ISO 11663:2014	1
Spread	TGEA	ISO 13959:2014	1
Spread	TSA	Other; please state	1
Spread	TSA	UK Renal Association Guidelines	1
Spread	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	
	DW17B	
DW16	DW16A	
	DW16B	
DW15	DW15A	
	DW15B	
Total maximum possible score		
Total percentage		

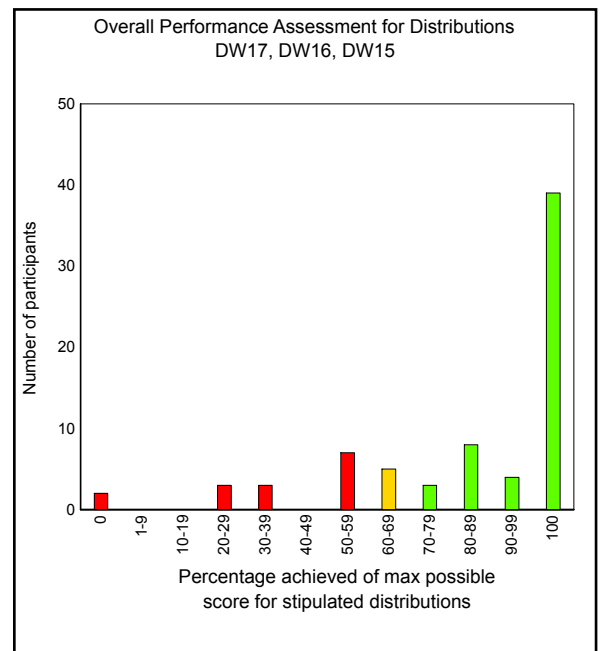
### Performance Assessment Comment:

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-going problems with their examinations and are provided after every distribution. Scores are allocated to results reported for every parameter, for every sample to help assess performance.

Cumulative scores are calculated for the current and previous distribution for the Dialysis Water Scheme. Participants' cumulative scores for each of the examinations are compared with the maximum possible scores after every distribution.

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



### Performance Assessment Comment:

Laboratories that achieve less than 70% of the maximum possible score are likely to be experiencing significant problems with their examinations and are advised to:

- refer to the relevant distribution reports for sample-specific comments
- refer to the website guidance documents:

<https://www.gov.uk/government/collections/external-quality-assessment-eqa-and-proficiency-testing-pt-for-food-water-and-environmental-microbiology>

- contact the organisers for 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)
Count reported 0 Range reported 1 – 6 Censored values of <1 – <10	Satisfactory/Acceptable (28) (4) (7)
Count reported 0 Range reported 1 – 2 Censored value of <1	Not routinely reported (11) (2) (2)
Count reported 555	Unsatisfactory/Unacceptable (1)

DW17B: 54 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)
Count reported 152	Satisfactory/Acceptable (1)
Count reported 0 Range reported 15 – 190 Censored value of > 100	Not routinely reported (2) (12) (1)
Range reported 68 - 110	Breaches action level (2)
Range reported 25 – 227 Censored value of >100 - >1000	Unsatisfactory/Unacceptable (33) (3)

Participants are reminded to only report a conclusion on a test result if this is part of your reporting procedures.

Interpretation of test results can be found in ISO 13959:2014 - Water for haemodialysis and related therapies or the European Best Practice Guidelines for Haemodialysis. The Interpretation/conclusions of microbiological test results in your country may vary to those published in these documents.

#### Method based presentation of results:

Participants are advised if less than 10 laboratories report a result for a method, no data is shown for the Median, Robust SD and the Range Reported in the 'Method based presentation' tables. Numbers shown in the 'Excluded Results' column 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.

