

Summary of Results

External Quality Assessment of Water Microbiology Dialysis Water Scheme

Distribution Number: DW35 Sample Numbers: DW35A, DW35B

Distribution Date:	February 2025
Results Due:	14 March 2025
Report Date:	18 March 2025
Samples prepared and quality control tested by:	Divya George Nafeesa Hussain Afifa Halim Sabine Naujokat Zak Prior Jake Videlefsky
Data analysed by:	Nita Patel Hiten Pragji
Report compiled by:	Nita Patel Hiten Pragji
Authorised by:	Nita Patel

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

UK Health Security Agency
Food and Environmental Proficiency Testing Unit (FEPTU)

61 Colindale Avenue London NW9 5EQ

Tel: +44 (0)20 8327 7119

Fax:

For further information about the scheme please refer to:

Scheme Guide: https://www.feptu.org.uk/schemes/scheme-guide/

Guide to Scoring and Statistics: https://www.feptu.org.uk/schemes/scoring/

General guidance for z-scores:

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

xi = participants' result (expressed as a log 10 value)

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

 σ_{pt} = the fixed standard deviation for the examination (calculated by FEPTU)

The σ_{pt} -value expresses the acceptable difference between the individual participant's result and the participants' consensus median. The σ_{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, UKHSA 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 23500-3:2019 Preparation and quality management of fluids for haemodialysis and related therapies - part 3 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 19.0 of the Scheme Guide if you have experienced difficulties with any of the examinations.

https://www.feptu.org.uk/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:

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

Data Analysis Nita Patel Fax:

Email: foodeqa@ukhsa.gov.uk

Microbiological advice Nita Patel or Zak Prior <u>FEPTU's website</u>

General comments and complaints Nita Patel or Zak Prior

Scheme consultants Caroline Willis
Scheme Co-ordinator Nita Patel

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



0006

Sample: DW35A

Contents: Candida famata (30) (wild strain), Enterococcus faecium (11) (wild strain), Kocuria kristinae

(15) (wild strain)

Expected Results:

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

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

Results		
FEPTU median (MF)¹	64	
No. results returned	57	
Assigned value (Participants' median all results)	70	
Interpretation based on assigned value*	Satisfactory/Triggers action level	
Uncertainty of assigned value	2	
Participants' mean (all results)	70	
Expected Range	40 - 99	
Standard deviation**	15	
No of outlying counts	9	
False positives		
False negatives	0	
Your result		
Your interpretation		
Score for performance assessment		
Z-score		

¹ Membrane filtration

^{**} Robust S^* based on median absolute deviation about the participants' median (MADe)

Total sent samples	59
Not examined	1
Non returns	1

^{*} Reference: https://academic.oup.com/ndt/search-results?f_TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity

Sample: DW35B

Contents: No micro-organisms

Expected Results:

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

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

Results		
FEPTU median (MF) ¹	0	
No. results returned	57	
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	5	
False negatives		
Your result		
Your interpretation		
Score for performance assessment		
Z-score		

¹ Membrane filtration

^{**} Robust S^* based on median absolute deviation about the participants' median (MADe)

Total sent samples	59
Not examined	1
Non returns	1

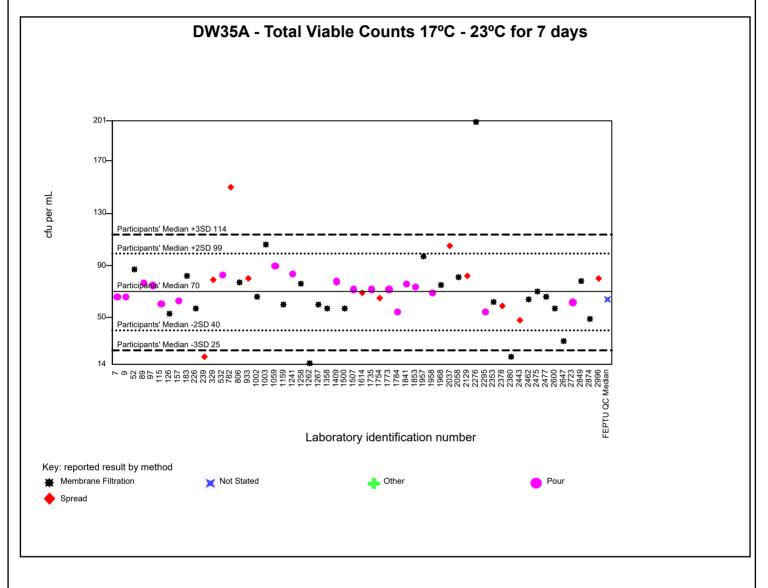
^{*} Reference: https://academic.oup.com/ndt/search-results?f_TocHeadingTitle=SECTION%20IV:%20Dialysis%20fluid%20purity

Method based presentation

DW35A: Total Viable Counts 17°C - 23°C for 7 days

FEPTU Method: Membrane Filtration

Method	Number of	Excluded	Percentage	Median	Robust S*	Range Reported
	Results	Results	of the total			
Membrane Filtration	26	1	46	65	0	15 - 200
Not Stated	0	1	0			
Other	0	0	0			
Pour	19	0	33	72	0	55 - 90
Spread	11	0	19	79	0	20 - 150
IDEXX EasyDisc YEA	0	0	0			



Sample: DW35A

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	Other	ISO 23500-5:2019	1
Membrane Filtration	Other	Other; please state	1
Membrane Filtration	R2A	European pharmacopoeia 5.0	1
Membrane Filtration	R2A	ISO 23500-3:2019	5
Membrane Filtration	R2A	ISO 23500-5:2024	1
Membrane Filtration	R2A	Other; please state	6
Membrane Filtration	TGEA	European pharmacopoeia 5.0	2
Membrane Filtration	TGEA	ISO 23500-3:2019	1
Membrane Filtration	TGEA	ISO 23500-3:2024	2
Membrane Filtration	TGEA	Other; please state	1
Membrane Filtration	TGEA	UK Renal Association guideline	1
Membrane Filtration	TSA	ISO 23500-3:2019	1
Membrane Filtration	TSA	Other; please state	2
Membrane Filtration	YEA	ISO 6222:1999	1
Pour	Other	ISO 6222:1999	1
Pour	R2A	ISO 23500-3:2019	1
Pour	R2A	ISO 23500-3:2024	3
Pour	R2A	ISO 23500-5:2024	2
Pour	R2A	UK Renal Association guideline	4
Pour	TGEA	ISO 23500-3:2019	2
Pour	YEA	ISO 23500-3:2019	1
Pour	YEA	ISO 6222:1999	2
Pour	YEA	Public Health England guideline	1
Pour	YEA	UK Renal Association guideline	2
Spread	R2A	ISO 23500-3:2019	5
Spread	R2A	ISO 23500-3:2024	1
Spread	R2A	Other; please state	1
Spread	TGEA	ISO 23500-5:2019	1
Spread	TSA	ISO 23500-3:2019	1
Spread	TSA	UK Renal Association guideline	1

Method based presentation

DW35B: Total Viable Counts 17°C - 23°C for 7 days

FEPTU Method: Membrane Filtration

Method	Number of	Excluded	Percentage	Median	Robust S*	Range Reporte	d
	Results	Results	of the total				
Membrane Filtration	20	7	44	0	0	0 - 3	
Not Stated	0	1	0				
Other	0	0	0				
Pour	17	2	37	0	0	0 - 0	1
Spread	8	3	17				
IDEXX EasyDisc YEA	0	0	0				

DW35B - Total Viable Counts 17°C - 23°C for 7 days

No data for graph

Sample: DW35B

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 17ºC - 23ºC for 7 days Standard Method	Count
Membrane Filtration	Other	ISO 23500-5:2019	1
Membrane Filtration	Other	Other; please state	1
Membrane Filtration	R2A	European pharmacopoeia 5.0	1
Membrane Filtration	R2A	ISO 23500-3:2019	5
Membrane Filtration	R2A	Other; please state	6
Membrane Filtration	TGEA	European pharmacopoeia 5.0	2
Membrane Filtration	TGEA	ISO 23500-3:2019	1
Membrane Filtration	TGEA	ISO 23500-3:2024	2
Membrane Filtration	TGEA	Other; please state	1
Membrane Filtration	TGEA	UK Renal Association guideline	1
Membrane Filtration	TSA	ISO 23500-3:2019	1
Membrane Filtration	TSA	Other; please state	2
Membrane Filtration	YEA	ISO 6222:1999	1
Pour	Other	ISO 6222:1999	1
Pour	R2A	ISO 23500-3:2019	1
Pour	R2A	ISO 23500-3:2024	3
Pour	R2A	ISO 23500-5:2024	2
Pour	R2A	UK Renal Association guideline	4
Pour	TGEA	ISO 23500-3:2019	1
Pour	TGEA	ISO 23500-5:2019	1
Pour	YEA	ISO 23500-3:2019	1
Pour	YEA	ISO 6222:1999	2
Pour	YEA	Public Health England guideline	1
Pour	YEA	UK Renal Association guideline	2
Spread	R2A	ISO 23500-3:2019	4
Spread	R2A	ISO 23500-3:2024	1
Spread	R2A	ISO 23500-5:2024	1
Spread	R2A	Other; please state	1
Spread	TGEA	ISO 23500-5:2019	1
Spread	TSA	ISO 23500-3:2019	1
Spread	TSA	UK Renal Association guideline	1

Performance Assessment Sheet

Distribution	Sample	Total Viable Counts 17°C - 23°C for 7 days score
DW35	DW35A	
DWSS	DW35B	
DW34	DW34A	
DVV34	DW34B	
DW33	DW33A	
DWSS	DW33B	
Total maximum possible score		
Total percentage		

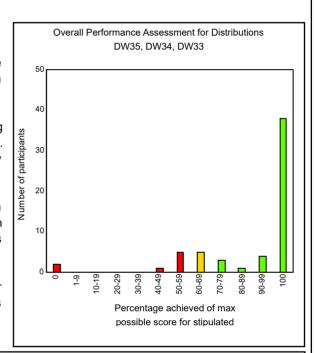
Performance Assessment Comment:

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:

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

Scheme Guide - FEPTU and Scoring - FEPTU

c) contact the organisers for advice

Sample specific comment

<u>DW35B: Total viable count</u>
For the statistical analysis 95% confidence interval was used. Therefore the actual range calculated was 0 - 3 colony forming units per mL, this changes the number of false positive to 0 and not 5 as shown on page 4 of this report.

DW35A: 32 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)
Range reported 48 – 1.06x10 ²	Satisfactory/Acceptable (13)
Range reported 60 – 2.00x10 ²	Satisfactory/Triggers action level (2)
Range reported 53 - 87	Borderline (5)
Range reported 20 – 1.50x10 ² High censored value >150	Unsatisfactory/Unacceptable (9) (1)
Range reported 75 - 80	Breaches action level (2)
Range reported 15 - 90	Not routinely reported (12)

DW35B: 33 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)
Range reported 0 – 3 Low censored value	Satisfactory/Acceptable (28) (5)
Range reported 0 or low censored value	Not routinely reported (12)

One participant's result for DW35A was changed to >150 from 500 cfu per mL.

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

Interpretation of test results can be found in ISO 23500-3:2019 - Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies. The Interpretation/conclusions of microbiological test results in your country may vary to those published in this document.

Method based presentation of results:

Participants are advised if less than 10 laboratories report a result for a method, no data are 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

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. To access the missing data contact us on foodeqa@ukhsa.gov.uk.

New website

We are pleased to announce the launch of our new website: https://www.feptu.org.uk/. Please refer to this website to obtain the latest information for your proficiency testing.

Information of importance

- To understand more about the proficiency testing schemes, please use the following links for information on:
- 1. Report format explained: Annotated report
- 2. Performance rating: Performance-over-time and Scheme guide (section 16.0)
- Scoring and statistics used: Scoring information and stats
 Homogeneity and stability: Scheme guide (section 9.0)
- 5. Complaints and appeal process: Scheme guide (section 20.0 and 21.0)

For further information about the operation of the service including confidentiality and terms of participation, please refer to the Scheme Guide: Scheme guide

End of report.

