Reference Material Datasheet

Version:	1.0
Issue date:	2023-10-16
Designation:	**RM Dw 2023:A**
Batch no:	**389**
Date of production:	2023-04-19
Manufacturer:	Swedish Food Agency, Sweden
Storage:	-18 °C or lower (but not lower than -55 °C)
Batch expiry date:	**2025-06-30**

Manufacturer and contact information

Swedish Food Agency	
Company name	Swedish Food Agency (Livsmedelsverket)
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Intended use

This reference material is designed for internal quality control of analytical work at microbiology laboratories. After reconstitution, the test material can be used for control of quantitative drinking water microbiology analyses, as well as for direct or indirect quality control of microbiological media.

Content

Table 1. Microorganisms included in RM Dw 2023:A

Microorganism	Strain*
Escherichia coli	SLV-084
Citrobacter freundii	SLV-424
Enterococcus faecalis	SLV-051
Pseudomonas aeruginosa	SLV-395
Clostridium perfringens	SLV-442

* Internal strain identification number, Swedish Food Agency

Quality control

The reference material is tested for homogeneity at the Swedish Food Agency. No statistically relevant difference has been observed between vials.

Property values

Table 2. Quality control of RM Dw 2023:A. The results are from analysis of 10 individual vials, and are valid for a reconstitution volume of 404 ml. All values are expressed in √ cfu / 5 ml (cfu / 5 ml re-transformed to the cfu scale).

Parameter	x_{RM}	s_{RM}	u_{RM}	Acceptance limits	Method
Coliform bacteria	8.61 (74)	0.38	1.35	5.90 – 11.31 (35 – 128)	EN ISO 9308-1:2014
Escherichia coli 37 °C	6.05 (37)	0.38	1.36	3.34 – 8.76 (11 – 77)	EN ISO 9308-1:2014
Escherichia coli 44 °C	5.86 (34)	0.62	1.47	2.92 – 8.80 (9 – 78)	SS 028167 (m-FC Agar)
Intestinal enterococci	8.42 (71)	0.51	1.38	5.65 – 11.19 (32 – 125)	EN ISO 7899-2:2000
Pseudomonas aeruginosa	5.51 (30)	0.25	1.32	2.87 – 8.14 (8 – 66)	EN ISO 16266:2008
Clostridium perfringens	4.72 (22)	0.73	1.53	1.66 – 7.79 (3 – 61)	EN ISO 14189:2016

x_{RM}: Property value, to be used for start-up control chart.

s_{RM}: Standard deviation of the property value, can be used for start-up control chart.

u_{RM}: Standard uncertainty of the property value (includes uncertainty contributions from characterisation, homogeneity, transportation and method differences).

The lower/upper acceptance limits are calculated as: $x_{RM} \pm 2 * u_{RM}$ (expanded uncertainty at a 95 % confidence interval, with $k = 2$)

Table 3. Quality control of RM Dw 2023:A. The results are from analysis of 10 individual vials, and are valid for a reconstitution volume of 404 ml. All values are expressed in √ cfu / ml (cfu / ml re-transformed to the cfu scale).

Parameter	x_{RM}	s_{RM}	u_{RM}	Acceptance limits	Method
Culturable microorganisms 37 °C, 2 days	5.75 (33)	0.34	1.33	3.10 – 8.41 (10 – 71)	EN ISO 6222:1999
Culturable microorganisms 22 °C, 3 days	5.67 (32)	0,39	1,35	2,98 – 8,36 (9 – 70)	EN ISO 6222:1999

x_{RM}: Property value, to be used for start-up control chart.

s_{RM}: Standard deviation of the property value, can be used for start-up control chart.

u_{RM}: Standard uncertainty of the property value (includes uncertainty contributions from characterisation, homogeneity, transportation and method differences).

The lower/upper acceptance limits are calculated as: $x_{RM} \pm 2 * u_{RM}$ (expanded uncertainty at a 95 % confidence interval, with $k = 2$)

Traceability

Homogeneity, property values, standard deviations and control limits are calculated in accordance with ISO 17034 and ISO Guide 35. All values are metrologically traceable to the respective strains in the Swedish Food Agency's internal culture collection (Table 1).

Preparation of simulated drinking water sample

Reconstitute the vial content according to the instructions on the last page.

Please note that the final **404 ml** corresponds to the undiluted sample to be analysed.

The Swedish Food Agency uses phosphate buffer solution according to SS-EN ISO 8199 as diluent.

Analyses

The analyses should be performed in accordance with the methods used by the individual laboratory.

Acceptance limits for **5 ml** are given in Table 2 (see relevant parameters).

Acceptance limits for **1 ml** are given in Table 3 (see relevant parameters).

Control charts

Instructions for construction of control charts are available at our website:

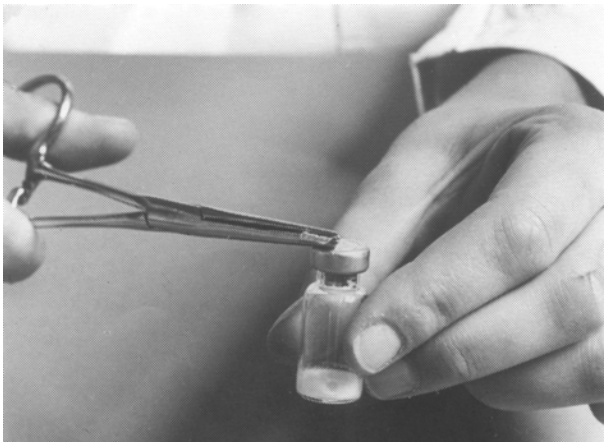
www.livsmedelsverket.se/RM-micro

Approved by

Linnea Blom

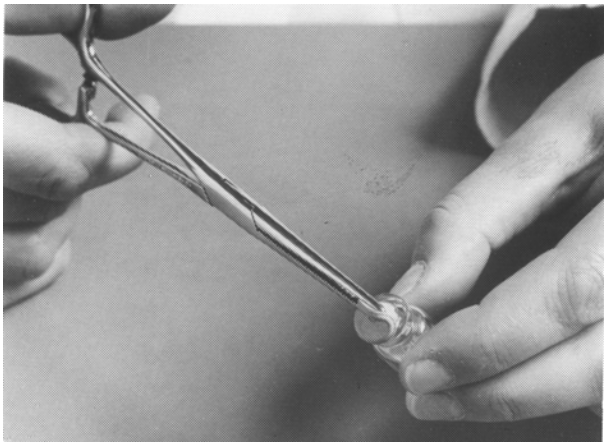
Linnea Blom
PT/RM Drinking water Coordinator

Sample preparation of freeze-dried cultures in glass vial

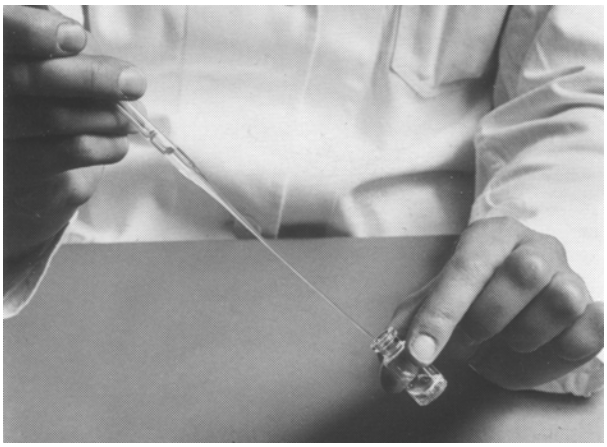


1. Twist the flap on the aluminium cap.

2. Remove the aluminium cap.



3. Remove the rubber plug.

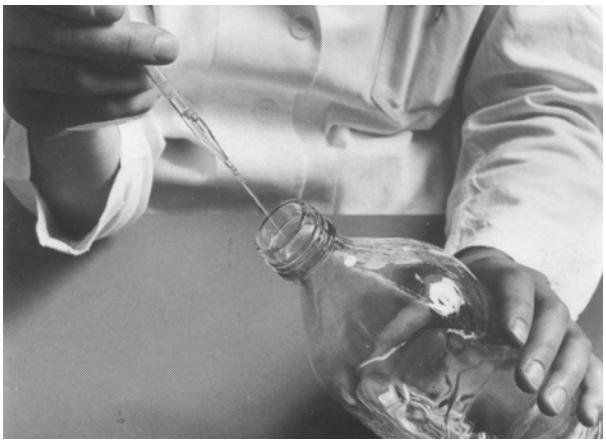


4. Add 1 ml diluent with a sterile pipette.

5. Let the content dissolve (1-5 minutes).

6. Using a sterile pipette, transfer the suspension to a sterile bottle containing 400 ml room temperature diluent.

7. Add another 1 ml and carefully rinse the walls of the vial with the pipette.



8. Transfer the suspension to the bottle containing 401 ml diluent.

9. Repeat steps 7 and 8 two more times with the same pipette.

10. After thorough intermittent mixing, the 404 ml sample is ready for analysis.

11. Perform the analyses within 60 minutes.