Reference Material Datasheet

Version:	1
Date:	2023-05-02
Designation:	RM Dw 2023:B
Batch:	385
Date of production:	2023-02-15
Manufacturer:	Swedish Food Agency, Sweden
Storage:	-18 °C or lower (but not lower than -55 °C)
Batch expiry date:	31 December 2024

Manufacturer and contact information

Swedish Food Agency	
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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:B.

Microorganism	Strain*	Parameter
Cladosporium cladosporioides	SLV-488	Microfungi in water (Moulds)
Saccharomyces cerevisiae	SLV-375	Microfungi in water (Yeasts)
Streptomyces sp. (griseus group)	SLV-548	Actinomycetes in water

* Internal strain identification number, Swedish Food Agency

Quality control

The reference material is tested for homogeneity and stability at regular intervals at the Swedish Food Agency.

Homogenity

Table 2. Mean values and measures of homogeneity for RM Dw 2023:B.

Analysis	Volume	Mean value[a]		CV[b]	Homogeneity[c]	
	(ml)	(cfu)	√(cfu)	(%)	I_2	T
Microfungi in water (Moulds)	5	21	4,54	9,19	1,49	1,68
Microfungi in water (Yeasts)	5	28	5,34	6,57	0,99	1,43
Actinomycetes in water	5	48	6,91	4,62	0,77	1,30

[a] Mean value from analysis of 10 vials reconstituted in 300 ml diluent at the Swedish Food Agency. cfu: colony forming units

[b] The coefficient of variation (CV) – expressed as a percentage – is the ratio of the standard deviation to the mean value (square-root transformed values) from the homogeneity analysis of 10 vials.

[c] Homogeneity of a reference material is approved if, for each analysis, the values obtained for the test for "Index of dispersion" between vials ($I2^{\#}$) and the test for reproducibility ($T^{\#\#}$) do not simultaneously exceed 2.0.

[#] Based on calculations of T1 and T2, respectively, according to BCR information, Report EUR 15008 EN, 1993 (Statistical analysis of certification trials for microbiological reference material)

[##] RIVM Report 250935001/2003. KA, Moojman, M During, NJD Nagelkerke. MICROCRM: Preparation and control of batches of microbiological reference material consisting of capsules.

Initial control limits

Table 3 shows the *initial control limits* for each analysis. They can be used as *provisional intervals* until a laboratory has determined its own control limits. The limits indicate where a single result at a laboratory is likely to be obtained. For the individual laboratory, it is here important to note:

- The mean values in Table 3 are from *initial determinations of the concentration* at the Swedish Food Agency. The values do not take in consideration measurement uncertainty in these initial analyses.
- The results of an individual laboratory may be higher or lower than the mean values provided in Table 3, due to random variations between laboratories, methods, media and technicians.
- The standard deviations (s_0) in Table 3 are calculated from repeatability dispersions in the vials at Swedish Food Agency and measures of dispersion, obtained from external laboratories' results (see Table 3, note b) for analyses of the reference material type A.
- The standard deviations s_0 are used to calculate *initial limits of warning and action* ($2s_0$ and $3s_0$, respectively) in Table 3.
- The initial intervals are valid for single analytical values, not mean values.

Control charts

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

www.livsmedelsverket.se/RM-micro

Preparation of simulated water sample

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

Please note that the final **304 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.

Table 3: Mean values and initial control limits for RM Dw 2023:B .

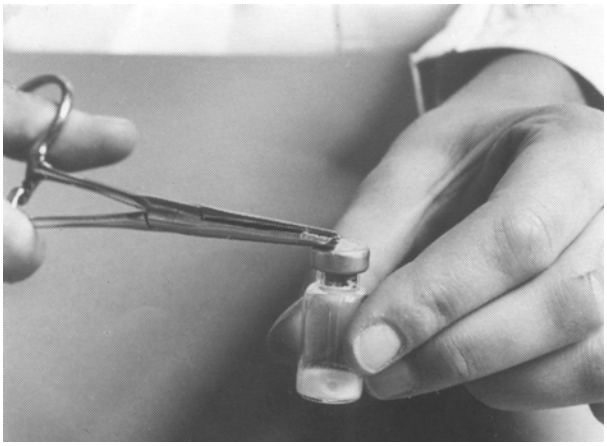
Analysis	Sample volume (cfu)	Mean value[a] (cfu)	Control limits[b] (cfu)				Medium	Reference method
			$-3s_0$	$-2s_0$	$+2s_0$	$+3s_0$		
Microfungi in water (Moulds)	5	21	7	11	33	40	RBCC	SS 02 81 92
Microfungi in water (Yeasts)	5	28	11	16	45	54	RBCC	SS 02 81 92
Actinomycetes in water	5	48	24	31	68	80	ACTA	SS 02 82 12

RBCC: Rose Bengal Agar with both chlortetracycline and chloramphenicol, ACTA: Actinomycete Isolation Agar, cfu: colony forming units

[a] Mean value from analysis of 10 vials reconstituted in 300 ml diluent at the Swedish Food Agency. The mean values are retransformed from square-root transformed results.

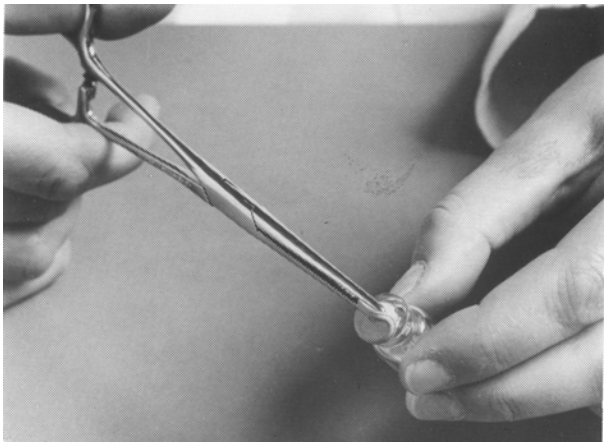
[b] Based on the average from determinations of repeatability standard deviation from duplicate analyses of 5 or 10 vials at Swedish Food agency during several years and on dispersion from reference material used for long time (type A, see that material). From that material the average of dispersion for six parameters are used from analyses during six different days in one year and from 16 laboratories. The intervals are asymmetrical around the mean values, since they have been obtained by retransformation after calculation with square-root transformed results.

Sample preparation of freeze-dried cultures in glass vial

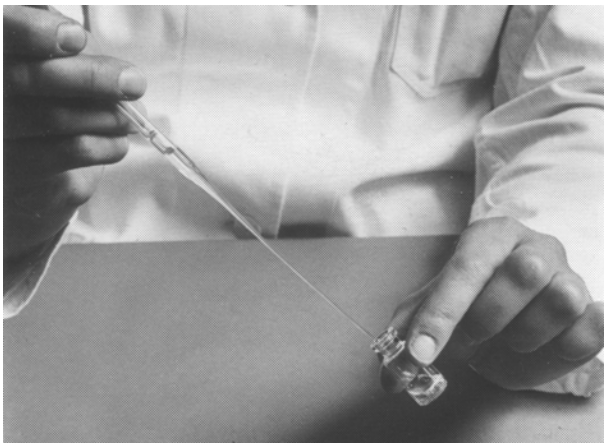


1. Twist the flap on the aluminium cap.

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 300 ml room temperature diluent.

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

8. Transfer the suspension to the bottle containing 301 ml diluent.

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

10. After thorough intermittent mixing, the 304 ml sample is ready for analysis.

11. Perform the analyses within 60 minutes.