

3 February, 2022

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## Homogeneity of reference material Dw 2021:C

Homogeneity is evaluated by use of some different measures, both decisive ones and other to understand the result distribution. Duplicate analyses from 10 vials have been used.

**Test 1** is a numerical check to see if the cfu results *within the vials* are randomly distributed as expected by a Poisson distribution. The ratio between variance/mean is used as the test value for an "Index of dispersion". This value is compared with what is expected from a  $\chi^2$  distribution. If the value is higher than expected there is an over dispersion, if the value is lower than expected there is an under dispersion" (**I<sub>1</sub>**).

**Test 2** is similar to test 1 but here the "Index of dispersion" compares the results *between vials* (**I<sub>2</sub>**). [**Decisive**]

**Test 3** is a one way analysis of variance (**ANOVA**) to check if the variance (= the squared standard deviation) is larger between vials than within. If there is strong under dispersion in test 1 (unusually small variation due to chance) the variation between vials will, relatively seen, be reckoned as large. This situation may result in a high F-value even when variation between vials is not unusually large. *This test is a traditional one in e.g. chemistry.*

**Test 4** is a separate test for reproducibility *between vials* (**T** according to the RIVM Report 250935001/2003) that has the property to be insensitive to the cfu values (in contrast to **I<sub>2</sub>**, where high cfu results will more easily be deemed inhomogeneous than low cfu results). [**Decisive**]

**The homogeneity** is judged as satisfactory when the two decisive criteria, **I<sub>2</sub>** and **T**, not simultaneously have values larger than 2.

### Mean values and measures of homogeneity for RM Dw 2021:C<sup>1</sup>

Analysis	Volume (ml)	Mean value		CV <sup>2</sup> (%)	Homogeneity <sup>4</sup>				
		(cfu)	$\sqrt{(cfu)}$		I <sub>1</sub>	AN <sup>3</sup>	I <sub>2</sub>	T	
Slow growing bacteria 22 °C, 7d (Yeast extract Agar, YeA)	0.1	82	9.053	7.5	5	1.98	NS	1.70	1.32
Slow growing bacteria 22 °C, 7d (R2A agar)	0.1	87	9.301	5.9	1.20	NS	1.20	1.27	

- Results from 10 vials in duplicate dissolved in 300 ml diluent 12 weeks after freeze-drying. For more information see INSTRUCTIONS.
- Coefficient of variation (CV) is SD as per cent of the mean (square-root transformed values), where SD is the pooled standard deviation from the ANOVA with a degree of freedom of 19.
- ANOVA: NS: not significant F-test; \*, \*\*, \*\*\*: F-test significant on the levels 5, 1 and 0.1%, respectively.
- The decisive tests of homogeneity, **I<sub>2</sub>** and **T**, together clearly indicate homogeneity.