

Certificate of Quality

Product appellation: Lyophilized long-term cell count standards (SCC1 – SCC5)
Charge: D00M07Y20

Product description:

Lyophilized cow milk with Bronopol and Polypropylenglycol.
Samples are only for laboratory usage and not for human consumption!

Packaging:

Glass bottles, sealed with buckler and aluminium cap.
15 mL resuspended sample per packaging unit.

Application:

The materials are suitable for checking accuracy of measurement results in raw milk analysis.

- Comparison in reference analysis, i.e. microscopic methods
- Slope/Intercept calibration and adjustment of analytical instruments in routine analysis

Reference values:

Parameter	Method	Product appellation	Number of results	Reference value \pm expanded uncertainty (k=2)	
Somatic Cells	Flow Cytometry/ microscopy	SCC1	45	117.000 \pm 8.900	cells/mL
		SCC2	45	272.000 \pm 9.400	
		SCC3	45	428.000 \pm 15.600	
		SCC4	45	772.000 \pm 27.100	
		SCC5	45	1.076.000 \pm 44.600	

The somatic cells were analyzed in multiples in 8 different ISO / IEC 17025 accredited laboratories using automated fluorescence optical counting and 1 ISO / IEC 17025 accredited laboratory using microscopic counting. The reference value is the arithmetic mean of all statistically checked measurement results. Accuracy of the reference value was ensured by comparison with the robust mean. In two fluorescence-optical devices used, six results were corrected to the reference values of the Golden Standard ERM BD001 of the European Commission.

The expanded uncertainty (k=2) was determined according to ISO Guide 35, taking into consideration the uncertainty between packaging units and the uncertainty of characterization as well as the uncertainty in two fluorescence-optical devices with regard to the Golden Standard ERM BD001 of the European Commission, the uncertainty of stability is not included. Numerous stability tests have shown that the uncertainty of stability can be neglected for the calculation of extended uncertainty.

The metrological traceability is based on the above-named reference method.

Stability:

Short-term stability under extreme transport conditions and long-term stability of the materials were checked with comparable materials. Stability was confirmed.

The material is best used before:

SCC1 – SCC5

2025-01

Reference values and their uncertainties are guaranteed under the precondition that the material is stored, prepared and used as described below.

Homogeneity:

Homogeneity between packaging units was determined according to ISO Guide 35 on the basis of at least 10 samples taken stratified random from the whole batch. Homogeneity between packaging units is satisfactory.

Parameter	Product appellation	Range of dispersion (95 %)	
Somatic Cells	SCC1	5.900	cells/mL
	SCC2	6.100	
	SCC3	7.600	
	SCC4	16.300	
	SCC5	29.400	

Storage:

Samples must be stored in a suitable refrigerator.

Storage temperature:	≤	6 ± 2 °C
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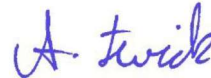
Preparation / Usage:

The samples must be prepared and used according to the “Instruction for preparation of lyophilized long-term cell count standard”. Each sample has to be reconstituted with **14,43 ± 0,07 g** of sterile water. The instruction is enclosed to each delivery. Manifold measurements and calculation of the mean lead to more reliable results.

Notes:

QSE GmbH guarantees the correctness of the somatic cells only if the instruction of preparation and the use of the unchanged material are observed after reconstituted. The material is, in principle, a homogeneous material, on the basis of which no minimum removal rate is specified. The material is suitable for the usual analysis procedures in the dairy industry. On request, the product description and the safety data sheet are available for further information.

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