

Ring test

Cereulide in infant formula (quantification LC-MS/MS)

P2627-RT



Summary

The entire report is available to participants only.

The ring test is designed, realised, evaluated, and authorised on behalf of PROOF-ACS GmbH by

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Project coordinator

The report is approved by

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PROOF-ACS is a DAkkS accredited proficiency testing provider according to DIN EN ISO 17043:2023 (D-EP-22211-01-00). This ring test is covered by the scope of accreditation.

PROOF-ACS GmbH does not have any analytical laboratory facilities of its own. Homogeneity testing and stability testing are subcontracted to laboratories, accredited according to DIN EN ISO 17025. The subcontracted laboratory may also participate in the ring tests. If so, the laboratory is treated in the same way as other participants and the same rules of confidentiality apply.

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The proficiency test evaluates the performances of laboratories with respect to their ability to quantify cereulide in infant formula. Recent recalls showed the importance of valid analytical results related to cereulide at low concentration levels. Even though the standardised analytical method DIN EN ISO 18465:2017-05 is available, adjustments are needed for the matrix infant formula.

36 laboratories across 13 countries world-wide took part in the proficiency test. 34 labs reported results and are considered for evaluation.

Two different test materials as well as a blank material are provided. Test material 1 consists of commercially available infant formula with a contamination with cereulide. Test material 2 is spiked with an analytical standard of cereulide.

Test material 1 is more challenging, as the contamination with cereulide is due to contaminated arachidonic acid, which is bound to a maltodextrin substrate. The challenge is to reconstitute the sample properly to ensure an adequate extraction of cereulide from the powder.

Test material 2 is used to check whether the analytical standards, which are applied by the labs world-wide are comparable, and if the analytical method is set up properly in general. The additional challenge of proper extraction is excluded for this material, as the material is spiked with the analytical standard on the surface of the powder. Extraction of cereulide from the spiked powder of test material 2 is thus less difficult compared to test material 1.

All labs kept the term of submission of results and are considered for evaluation. The deadline for results reporting is extended for two laboratories due to delays during the shipment.

The report contains an assessment related to

- the *comparability* of the results. The evaluation of the comparability is based on the z-score model. The absolute values of z-scores should be at least ≤ 2 . The comparability criterion is applied to both test materials.
- the *trueness* of the results. The trueness is expressed as the coverage of the spiked level in %. The coverage should be at least between 70 and 120 % of the spiked level. The trueness criterion is applied to test material 2 only.

Results

Material	Spiked level [µg/kg]	Assigned value [µg/kg]	Assigned value in % of the spiked level	No. of results	No. of results with z-score ≤ 2	No. of results within 70-120 % of the spiked level
Cereulide test material 1	unspiked, contaminated	0.815	-	34	28	not applicable
Cereulide test material 2	1.6	1.36	85	34	33	33

To summarise:

- 36 laboratories took part in the tests. 34 labs reported results and are considered for evaluation.
- Most of the labs are aware, that reconstitution of the infant formula is necessary for an adequate extraction of cereulide from the powder.
- One of the labs mixed-up the samples and reported invalid results related to all three materials.
- None of the other labs reported false positive results related to the blank material.
- 28 labs reported comparable results related to test material 1. 6 labs failed. 5 of them did not reconstitute the powder with water.
- 33 out of 34 labs reported comparable and true results related to test material 2.
- A comparable and true analysis of cereulide in infant formula is possible if the powder is reconstituted properly.