Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Co-funded by the European Union

Proficiency test for Official Residue Control Laboratories

Beta-agonists in tissue (BETA0324)

PROTOCOL

General Information

This exercise shall assist the participating laboratories in verifying their analytical proficiency. Therefore the selected methods, the number of parallel analyses performed and the analytical procedures used should closely correspond to those normally applied in routine analyses. Each laboratory can freely choose which methods to apply (screening and confirmatory methods). Laboratories only performing a screening analysis are requested to indicate how a positive result is confirmed (by means of which method and in which laboratory). Each participant receives 2 samples of lyophilised bovine lung and 2 samples of lyophilised bovine liver (each corresponding to about 20 g reconstituted material). Only the results submitted for the liver samples will be considered for the overall proficiency assessment. The results for the lung samples will be evaluated for information only.
We kindly ask you to confirm the receipt of all samples immediately using the online form:
https://ec.europa.eu/eusurvey/runner/BETA0324SampleReceipt
password: @6goWgzUcCs4%f

Any consultation with other participants is against professional scientific conduct and impairs the intended purpose of this study. Thus, the participants themselves are responsible for gaining a genuine idea of their proficiency in routine analysis. First information on laboratory performance will be provided in the form of a preliminary report. Participants are asked to confirm that all results transferred to the proficiency testing provider have been correctly reproduced in the preliminary report and point out any errors. The final report containing detailed information on the proficiency test and the participants' performance will be prepared from these (corrected) data. The participants' performance will be evaluated based on the principles described in the *Common Protocol for Proficiency Testing* available from the FIS-VL. The following modifications will be made:

- One point will be deducted from a participant's total score if they submit one or two false positive results. If more than two false positive results are submitted by a participant, two points will be deducted from their overall point score.
- To pass the proficiency test a minimum of two thirds of the maximum possible point score needs to be achieved.

Apart from a listing of all participants which will in no way correlate participants to their results, the participants will only be referred to by their lab codes in any of the reports. The participants consent to the publication of their results in an anonymised form by the organiser of the proficiency test. In addition, the results of the NRLs participating in this proficiency test may be provided in a non-anonymised form to the European Commission (DG SANTE) for internal use, as well as to the competent authorities of the Member States (according to Article 94, 2.(c), Regulation (EU) 2017/625). Analogously, the results of the German Official Control Laboratories may be provided in a non-anonymised form to the German competent authorities for internal use (according to Article 101, 1.(c), Regulation (EU) 2017/625).

To give feedback on the proficiency test, please contact eurlvetdrug@bvl.bund.de for the feedback form. For further information on the conduction of EURL proficiency tests, including details on the point score system used for performance evaluation, please refer to the Common Protocol for Proficiency Testing available from the EURL-website: https://eurl-residues.eu/eurl-bvl/bvl-proficiency-tests/.

General information on the samples and their stability

The matrix samples consist of incurred material which was produced in co-operation with the holding for test animals of the Federal Institute for Risk Assessment (BfR). The material was produced by mixing incurred materials with blank material, homogenisation of the total batch, lyophilisation, re-homogenisation and portioning. The samples are shipped at room temprature and should be stored at -20 °C immediately upon receipt. The stability of the samples was checked for -20 °C, +4 °C and room temperature. The samples are stable for at least seven days at room temperature (dark) and for at least three months when kept at -20 °C. The stability tests for longer storage periods are currently underway. If a significant instability is detected, its influence on the participants' results will be respected by adequate means.

Remarks on the analysis

The samples are to be examined for the presence of beta-agonists by applying your laboratory's routine test methods. If required, a method description for the determination of beta-agonists in lung and liver is available from the EURL Berlin. The homogeneity of the samples was assessed for a quantity of 2 g reconstituted sample and hence we recommend to use no less than this quantity for a single analysis. All samples shall be reconstituted considering the dry mass given in Table 1. Further information on reconstitution is provided in the EURL's reconstitution protocol.

Table 1: Sample coding, matrix and dry masses of the sample types included in BETA0324.

Sample code prefix	Matrix	Dry mass /%
LI	Bovine liver	30.2
LU	Bovine lung	20.6

Any detected analytes are to be quantified and confirmed. For this purpose the criteria of Commission Decision 2002/657/EC or Commission Implementing Regulation 2021/808[1] are to be taken into account. If screening, as well as confirmatory analysis are carried out, the analyses should be performed independently from one another on separate aliquots. Furthermore, if you are planning to participate in the screening and the confirmation assessment, we recommend to subject the samples to confirmation analysis regardless of the results of your screening analyses.

Please note that participants shall analyse for the minimum required, as well as the recommended substances as specified in Table 2. For the performance assessment the marker residues laid down in Commission Regulation (EU) No 37/2010, if available, are relevant. Results for other metabolites can be provided additionally but will not be part of the proficiency assessment. However, if a sufficient amount of results is provided by the participants, the proficiency test parameters will be calculated.

Table 2: Current classification of beta-agonists as minimum required, recommended, and optional analytes. Minimum required and recommended analytes are relevant for the proficiency assessment.

minimum required	recommended	optional
Please refer to the FIS-VL for the complete list of analytes.		

Report of the analytical results

The deadline for submitting the test results is 30th April 2024. Please exclusively use the provided result files and/or result form to indicate your results. Contact the proficiency testing provider if there are any difficulties. The information has to be filled in completely and unambiguously. If you would like to use the proficiency test as a tool to test the adequacy of more than one analytical method, please contact the proficiency testing organiser prior to submitting your results.

[1] If your method has been validated in accordance with CD 2002/657/EC, you should refer to the identification criteria listed in this document. Likewise, if your method has been validated in accordance with CIR 2021/808, you should refer to the identification criteria listed in this regulation.

There are

- 2 result files (LA2 and LAB) for the submission of the results of the confirmatory analysis. Save them to the same folder and use the same names for both files. Only one file can be opened. Still, both files (LA2 and LAB) need to be submitted.
- 1 result / method description form for the submission of screening results.
- Optional: 1 result form for the reporting of additional analytes, available upon request.

For the final report, the results will be used exactly as given by the participants in the result files and screening result form. Necessary recovery corrections have to be carried out by the participants themselves.

Indicating your results

- It is essential for the evaluation of the proficiency test to state the results of parallel determinations separately and not as mean values. For the confirmatory analysis a maximum of six separate results should be provided. If you routinely conduct more parallel analyses, please contact the proficiency testing organiser prior to submitting your results.
- If a recovery correction is required, it is to be carried out by the participants themselves. The kind of recovery correction applied is to be stated on the result forms. Correction by application of a suitable internal standard is not considered a recovery correction for the purpose of this proficiency test.
- The quantitative results should be expressed by an analytically justifiable number of significant digits.
- The indicated results should refer to the active drug without counter ions in the fresh material using the unit ng/g or µg/kg.
- The investigated and detected analytes are to be referred to by the names given in the result forms. In addition, the CCα (confirmatory methods) and CCβscreening (for analytical methods validated in accordance with CD 2002/657) or the Screening Target Concentration and the CCβ (for analytical methods validated in accordance with CIR 2021/808) of the applied test methods are to be indicated.
- The proficiency testing organiser recommends reporting confirmed analytical results if they are below CCα.
- The requested validation parameters are to be indicated for all analytes detectable with the applied method.
- Participants are asked to submit an associated measurement uncertainty, coverage factor k and coverage probability for all analytes.

Supplementary Information (only upon request)

The EURL may contact you for additional information like raw data or a copy of your method description.

Attachments

Time schedule
Result form for screening results
Reconstitution protocol
Instructions for use of result files
RingDat files for confirmatory results (by separate email)