



Paul-Ehrlich-Institut Postfach D-63207 Langen

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Roßlau
DE Deutschland

Administrative Code:
Reference Number:
Date of Release of Certificate:

N2.04.01.0107
21002/20
26.03.2020

**EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE
FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS**

Examined under Article 82 of Directive 2001/82/EC as amended by Directive 2004/28/EC

Trade name:	Rabitec
International non-proprietary name / Ph. Eur. name / common name:	Live rabiesvirus (GMO)
Name and address of manufacturer responsible for batch release:	IDT Biologika GmbH / 06861 Dessau-Roßlau
Marketing authorisation number (Member State / EC):	EU/2/17/219/002
Manufacturer's batch number(s): - final bulk no - final lot no - batch number	0271019 0271019-B
Batch number of diluent (where appropriate):	
Type of container:	bait-coated blister pack
Total number of containers in this batch:	122681
Number of doses/volume per container:	1
Date of start of period of validity:	28.10.2019
Expiry date:	21.10.2021



This batch has partly been examined using testing procedures for which the Paul-Ehrlich-Institut has been accredited. The accredited test procedures are shown on www.pei.de/qm-en.

This batch has been examined in conformity with Article 82. The examination is based on review of the manufacturer's protocol and repetition of the appropriate control laboratory tests.

This batch is in compliance with the approved specifications laid down in the above-mentioned marketing authorisation. Technical details for these compliance results are attached to this form.

Fees are laid down separately.



Dr. Daniela Külbs
Division 4 Veterinary Medicine

This document was issued electronically and is therefore valid without signature.





AUTHORITY'S TEST REPORT

Lot Number: **0271019-B**
Product: **Rabitec**
Marketing
Authorization
Number: **EU/2/17/219/002**
Expiry Date: **21.10.2021**

Test	Test Procedure	Test Date	Specification	Assessment Pass / Fail
Appearance	Abt.4-V-021	18.02.2020	Bait: solid, not easily moulded, fatty, brown, fish-like intensive odour	PASS
Titration live virus	4/3-S-040	18.02.2020	7.0 -7.9 log10 FFU/ml	PASS

Remark / further tests:

Report authorised by:



Dr. Daniela Külbs
Division 4 Veterinary Medicine

Date: **26.03.2020**

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