

## Deutsche Akkreditierungsstelle GmbH

**Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV**

Signatory to the Multilateral Agreements of  
EA, ILAC and IAF for Mutual Recognition

# Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the medical laboratory

**Exosome Diagnostics GmbH**  
**Am Klopferspitz 19a, 82152 Planegg**

is competent under the terms of DIN EN ISO 15189:2014 to carry out examinations in the following field:

**Medical Laboratory Diagnostics**

**Medical laboratory fields:**  
Human genetics (molecular human genetics)

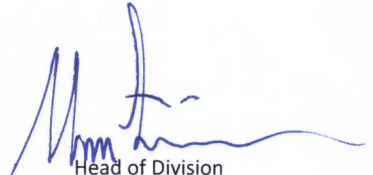
The accreditation certificate shall only apply in connection with the notice of accreditation of 07.06.2018 with the accreditation number D-ML20612-02 and is valid until 10.04.2022. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 2 pages.

Registration number of the certificate: **D-ML-20612-01-00**

Frankfurt am Main,  
07.06.2018

Dipl.-Biol. Uwe Zimmermann  
Head of Division

Translation issued:  
08.06.2018



Head of Division

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf.

## Deutsche Akkreditierungsstelle GmbH

### Annex to the Accreditation Certificate D-ML-20612-01-00 according to DIN EN ISO 15189:2014

Period of validity: 07.06.2018 to 10.04.2022

Date of issue: 07.06.2018

Holder of certificate:

**Exosome Diagnostics GmbH**  
**Am Klopferspitz 19a, 82152 Planegg**

#### **Examinations in the field:**

Medical Laboratory Diagnostics

#### **Medical laboratory fields:**

Human genetics (molecular human genetics)

Within the given type of examination marked with \*\*), the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkKS, the modification, development and refinement of examination procedures.

The listed examination procedures are exemplary. The medical laboratory maintains a current list of all examination procedures within the flexible scope of accreditation.

## Medical laboratory field: Human Genetics (Molecular human genetics)

### Field of examination:

### Molecular biological tests (amplification procedures)\*\*

| Analyte<br>(measurement parameter)   | Test material (matrix)             | Test technique |
|--|------------------------------------|----------------|
| Detection of the presence of biomarkers of lung carcinoma: EML4-ALKv1, v2, v3a-b-c (ExoDx Lung(ALK)) | Human plasma samples, exosomal RNA | RT-qPCR        |