

# Deutsche Akkreditierungsstelle GmbH

## Annex to the Accreditation Certificate D-ML-13345-01-00 according to DIN EN ISO 15189:2014

**Valid from: 06.04.2023**

Date of issue: 06.04.2023

Holder of certificate:

**Labor und Praxis Dr. med. Ulrich Pachmann**  
**Kurpromenade 2, 95448 Bayreuth**

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

Medical Laboratory Diagnostics

### **Medical laboratory fields:**

Immunology

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 free choice of standards or equivalent examination procedures.

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

*The management system requirements of DIN EN ISO/IEC 15189 are written in the language relevant to the operations of medical laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.*

*The certificate together with the annex reflects the status as indicated by the date of issue.*

*The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH <https://www.dakks.de/en/content/accredited-bodies-dakks>.*

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

## Medical laboratory field: Immunology

### Type of examination:

#### Microscopy\*\*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Circulating epithelial tumor cells	EDTA blood, ascites-/pleurocentesis material	maintrac (automated microfluorimetric image analysis)
Isolation of single circulating epithelial tumor cells	EDTA blood	Single cell isolation using automated microfluorimetry
Tumorspheres (circulating cancer stemcells)	EDTA blood	stemtrac (suspension cell culture)

### Type of examination:

#### Cell function tests\*\*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Drug testing on circulating epithelial tumor cells	EDTA blood, ascites-/pleurocentesis material	automated microfluorimetric image analysis

### Type of examination:

#### Molecular biological tests (hybridisation procedures)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Human epidermal growth factor receptor 2 (Her-2/new)	EDTA blood	Fluorescence in situ hybridisation (FISH)
Epithelial growth factor receptor (EGFR)	EDTA blood	Fluorescence in situ hybridisation (FISH)
Apoptoses	EDTA-blood	TUNEL