

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13269-01-00 according to DIN EN ISO/IEC 17025:2005

Valid from: 08.11.2019

Date of issue: 08.11.2019

Certificate holder:

Epiontis GmbH

Barbara-McClintock-Straße 6, 12489 Berlin

Tests in the field:

Healthcare (Medical Laboratory Testing within Clinical Trials)

Test area:

Immunology

For the test fields marked with ** the laboratory is permitted to modify and develop new test procedures without obtaining prior notification and consent from the Deutsche Akkreditierungsstelle GmbH.

The test procedures are given by way of an example. The laboratory has an up-to-date list of all test procedures within the flexible accreditation range.

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH. <https://www.dakks.de/en/content/accredited-bodies-dakks>

Test area: Immunology

Type of test:

Molecular Biological Analysis (Amplification)**

Norm / Date of issue / In House Method / Version	Analyte / Norm title / Sample preparation details / Test technology	Test material (matrix)
QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-2_8e_Rev00, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu FoxP3 / quantitative RT-PCR	Human Tissue and Suspension cells
QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-2_8e_Rev00, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu CD3 / quantitative RT-PCR	Human Tissue and Suspension cells
QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu CCR6 / quantitative RT-PCR	Human Tissue and Suspension cells

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QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu NK Cells/ quantitative RT-PCR	Human Tissue and Suspension cells
QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-2_8e_Rev00, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu B Cells / quantitative RT-PCR	Human Tissue and Suspension cells

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QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu naive CD8-T+ Cells/ quantitative RT-PCR	Human Tissue and Suspension cells
QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-2_3_Rev01, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu Th17 Cells / quantitative RT-PCR	Human Tissue and Suspension cells

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QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-2_8e_Rev00, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu CD8 Cells / quantitative RT-PCR	Human Tissue and Suspension cells
QMA 504-1_1e_Rev06, QMA 504-1_4e_Rev04, QMA 504-1_7_Rev01, QMA 504-1_8_Rev02, QMA 504-2_1e_Rev07, QMA 504-2_8e_Rev00, QMA 504-4_Rev00, QMA 504-5e_Rev04, QMA 504-6_Rev01, QMA 510-1e_Rev06, QMA 510-2_Rev00; QMA 510-3e_Rev00	hu TFH Cells/ quantitative RT-PCR	Human Tissue and Suspension cells

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Abbreviations used:

DIN	Deutsches Institut für Normung e.V.
EN	European Standard
hu	human
ISO	International Organization for Standardization
RT-PCR	Real-Time Polymerase Chain Reaction
IEC	International Electrotechnical Commission
QMA xxx-xe	In House Method