

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13269-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 17.09.2020

Date of issue: 17.09.2020

Certificate holder:

Precision for Medicine GmbH

Barbara-McClintock-Straße 6, 12489 Berlin

Tests in the field:

Healthcare (Medical Laboratory Testing within Clinical Studies)

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 DAkkS 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 management system requirements in DIN EN ISO/IEC 17025 are written in language relevant to operations of testing laboratories and operate generally in accordance with the principles of DIN EN ISO 9001.

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:

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| 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 |