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Deutsche
Akkreditierungsstelle

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# Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that

**INSTAND e.V. - Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e. V.**
**Ubierstraße 20, 40223 Düsseldorf**

as a provider of proficiency testing, fulfills the requirements according to DIN EN ISO/IEC 17043:2023 for those conformity assessment activities specified in detail in the annex listed below. This includes additional existing legal and normative requirements for the proficiency testing provider including those in relevant sectoral schemes, provided that these are explicitly confirmed in the annex listed below.

**D-EP-15027-02-01 Valid from: 07.11.2025**

The management system requirements of DIN EN ISO/IEC 17043 are written in the language relevant to the operations of proficiency testing providers and they conform to the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate only applies in connection with the notice of 07.11.2025 with accreditation number D-EP-15027-02.
It consists of this cover sheet, the reverse side of the cover sheet and the corresponding annex.

Registration number of the accreditation certificate: **D-EP-15027-02-00**

Berlin, 07.11.2025 By proxy Dr.-medic Simona Curelea
Dipl.-Ing. Anna Lewandowski | Head of Technical Unit

Translation issued: 07.11.2025

*This accreditation certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS). It is digital sealed and valid without signature. It reflects the status as indicated by the date of issue. The current status of any valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).*

See notes overleaf

# Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkkS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

Deutsche Akkreditierungsstelle

# Annex to the Accreditation Certificate D-EP-15027-02-00 according to DIN EN ISO/IEC 17043:2023

**Valid from:** **07.11.2025**

Date of issue: 07.11.2025

**This annex is part of the Accreditation Certificate D-EP-15027-02-00.**

Holder of the Accreditation Certificate:

**INSTAND e.V. - Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e. V.**
**Ubierstraße 20, 40223 Düsseldorf**

with the location

**INSTAND e.V. - Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e. V.**
**Ubierstraße 20, 40223 Düsseldorf**

The proficiency testing provider meets the requirements of DIN EN ISO/IEC 17043:2023 to carry out the conformity assessment activities listed in this annex. The proficiency testing provider meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17043 are written in the language relevant to the operations of proficiency testing providers and they conform to the principles of DIN EN ISO 9001.

**Proficiency testing in the field Medical laboratory**



Abbreviations used: see last page

*Within the given types of test parameters /analytes marked with * the proficiency testing provider is permitted, without being required to inform and obtain prior approval from DAkkS, to include of proficiency tests within the scope of accreditation.*
*The proficiency testing provider maintains a current list of all proficiency tests in a flexible scope of accreditation.*

## Proficiency testing in the field Medical laboratory

| Testing field | Matrices/products | Measurands/test parameters | Proficienssy testing schemes |
|---|---|---|---|
| Clinical Chemistry | Plasma, Serum | Hormone* | 294, 295, 297, 298, 300, 301, 302, 304, 305, 306, 309, 625, 626 |
| | Erythrocytes, bone marrow, whole blood | Hematologic parameters* | 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 236, 612, 616, 617, 660 |
| | Plasma, whole blood | Hemostaseologic parameters* | 221, 222, 223, 224, 225, 226, 227, 230, 280, 281, 282, 283, 285, 286, 288, 501, 502, 503, 504, 505, 506, 509 |
| | Serum | IgG subclasses* | 244 |
| | Plasma, serum | Cardiac markers* | 760, 761 |
| | Plasma, serum, whole blood | Conventional clinical chemistry parameters* | 100, 102, 111, 118, 141, 145, 146, 151, 185, 243, 279, 630, 700, 710, 750, 7100 |
| | Liquor, serum | Cerebrospinal fluid (CF) parameters* | 460, 462, 463, 464, 465, 466, 467, 468 |
| | Plasma, serum | Newborn screening paramaters * | 110 |
| | Plasma, serum, whole blood | POCT parameters* | 161, 162, 163, 800, 810 |
| | Plasma, serum, whole blood | Pharmaceuticals* | 190, 191, 192, 193, 194, 195, 197, 198, 199, 200, 201, 202, 203, 601, 602, 850, 860, 861, 862, 863, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 890 |
| | Potassium picrate solution | Wavelength* | 181 |
| | Plasma, serum | Plasma proteins* | 240, 241, 242, 322 |
| | Plasma, serum, whole blood | Trace elements* | 206, 207, 208 |
| | Feces | Stool diagnostics parameters* | 130, 131 |
| | Serum | Tumor markers* | 292, 293, 299 |

| Testing field | Matrices/products | Measurands/test parameters | Proficienssy testing schemes |
|---|---|---|---|
| Clinical Chemistry | Urinary stone, urine | Urine analysis parameter * | 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 182, 204, 205, 500, 751 |
| | Plasma, Serum, whole blood | Vitamins* | 187, 290, 291, 296 |
| Immunology | Serum | Allergy diagnostic parameters* | 720 |
| | Plasma, serum, whole blood | Autoimmune diseases* | 251, 253, 255, 257, 259, 261, 263, 265, 267, 269, 271, 273, 275, 653 |
| | Whole blood | Functional immunologic assays* | 650, 654, 655, 656 |
| | Serum, whole blood | HLA-typing | 440, 441, 443, 445 |
| | Whole blood | Immunophenotyping* | 651 |
| | Plasma, serum | Complement analysis parameters* | 245, 246, 247, 248, 249, 250 |
| Molecular Genetic | Whole blood | Parameters for engraftment- and chimerism diagnostics* | 618 |
| | Genomic DNA, whole blood | Conventional genetics parameters* | 730, 731, 732, 733, 734, 735, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 762, 763, 764, 770, 771, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 786, 787, 788, 790, 791, 792, 793, 794 |
| | Genomic DNA | Oncological parameters* | 738, 765, 766, 767, 768, 769, 795, 796, 797, 798 |
| Transfusion medicine | Plasma, serum, whole blood, genomic DNA | Immunohematologic parameters* | 231, 232, 233, 234, 235, 237, 238, 820 |
| | Serum, whole blood | HLA-typing* | 440, 441, 443, 445 |
| | Whole blood, genomc DNA | Immungenetic parameters* | 234, 235, 442, 444, 772 |

| Testing field | Matrices/products | Measurands/test parameters | Proficienssy testing schemes |
|---|---|---|---|
| Microbiology | Microbiological -/ patient samples | Bacterial genome* | 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548 |
| | Serum, urine | Bacterial infection serology parameters* | 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 334 |
| | Feces | Human microbiome* | 580 |
| | Microbiological -/ patient samples | Conventional bacteriology parameters* | 411, 412, 413 |
| | Microbiological -/ patient samples, mycobacterial cultures, sputum | Mycobacteriological parameters* | 421, 422, 423, 424, 425, 426, 427 |
| | Liquor, microbiological -/ patient samples, serum | Mycological parameters* | 480, 481, 490, 491, 492, 560 |
| | Amniotic fluid, EDTA blood, plasma, serum, feces, whole blood | Parasite diagnostics parameters* | 451, 452, 454, 455, 456, 457, 458, 906, 907 |
| Virology | Liquor, microbiological -/ patient samples, extracts of nucleic acid, plasma, serum, feces, urine, whole blood, genomic DNA | Virus genome* | 340, 349, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 399, 400, 401, 403, 404, 405, 406, 407, 408, 409, 410, 417, 418, 430, 431, 432, 433 |
| | Plasma, serum | Virus immunology parameters* | 335, 336, 337, 338, 339, 341, 342, 343, 344, 345, 346, 347, 348, 350, 351, 352, 353, 354, 355, 356, 357, 358, 402, 415, 416 |

**The requirements for reference institutions in part E of the Guideline of the German Medical Association (Richtlinie der Bundesärztekammer - Rili-BÄK) for the quality assurance of laboratory medical examinations in accordance with the resolution of the Executive Board of the German Medical Association at its meeting on October 18, 2019, last amended by resolutions of the Executive Board of the German Medical Association on April 04, 2023, published in the Deutsches Ärzteblatt on May 30, 2023, are fulfilled in relation to the special parts B1 "Quantitative laboratory medical examinations", B2 for "Qualitative laboratory medical examinations", B3 "Detection and characterization of infectious agents" and B5 for "Molecular genetic and cytogenetic laboratory medical examinations".**

**Abbreviations used:**

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|---|---|
| DIN | Deutsches Institut für Normung e.V. – German institute for standardization |
| EN | Europäische Norm – European Standard |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardisation |
| RV-QM.XX | Instruction of the conformity assessment body |