Werkprogramma ISO/TC 212

Documentnummer	Titel
ISO/AWI 15189	Medical laboratories — Requirements for quality and competence
ISO/FDIS 15190	Medical laboratories — Requirements for safety
ISO/NP 16256	Clinical laboratory testing and in vitro diagnostic test systems — Reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases
ISO/FDIS 17511	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
ISO/CD 17593	Clinical laboratory testing and in vitro medical devices — Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy
ISO/DIS 17822-2	In vitro diagnostic test systems — Nucleic acid amplification- based examination procedures for detection and identification of microbial pathogens — Part 2: Laboratory quality practice guide
ISO/AWI 18113-1	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

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ISO/AWI 18113-2	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use
ISO/AWI 18113-3	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use
ISO/AWI 18113-4	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing
ISO/AWI 18113-5	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing
ISO/AWI 20166-4	Molecular in vitro diagnostic examinations — Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 4: in situ detection techniques
ISO/NP 20184-3	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 3: Isolated DNA
ISO/NP 20776-2	Clinical laboratory testing and in vitro diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 2: Evaluation of performance of antimicrobial susceptibility test devices
ISO/DIS 21151	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for international harmonization protocols establishing metrological traceability of values assigned to calibrators and human samples
ISO/DIS 21474-1	In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 1: Terminology and general requirements for nucleic acid quality evaluation
ISO/NP 21474-2	In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 2: Part 2 — Validation and Verification
ISO/FDIS 22367	Medical laboratories — Application of risk management to medical laboratories
ISO/TS 22583	Guidance for supervisors and operators of point-of-care testing (POCT) devices
ISO/CD 23118	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for metabolomics in urine, venous blood serum and plasma
ISO/AWI 23162	Basic semen analysis — Specification and test methods
ISO 35001	Biorisk management for laboratories and other related organisations

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prEN ISO 20776-2 rev	Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 2: Evaluation of performance of antimicrobial susceptibility test devices
prEN ISO 23118	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for metabolomics in urine, venous blood serum and plasma
prEN ISO 23162	Basic semen analysis - Specification and test methods
prEN ISO 6717	In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans
(WI=00140117)	Quality assurance of POCT results - Assessment criteria for comparison measurement and implementation

Documentnummer	Titel
FprCEN/TS 17390-1 (WI=00140123)	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood - Part 1: Isolated RNA
FprCEN/TS 17390-2	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood - Part 2: Isolated DNA.
FprCEN/TS 17390-3	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood - Part 3: Preparations for analytical CTC staining
FprEN ISO 17511	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO/FDIS 17511:2019)
FprEN ISO 22367	Medical laboratories - Application of risk management to medical laboratories (ISO/FDIS 22367:2019)
prCEN/TS xxx	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Isolated circulating cell free RNA from plasma
prCEN/TS xxx	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNA) - Part 2: Isolated proteins
prCEN/TS xxx	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood - Isolated RNA, DNA and proteins
prCEN/TS xxx	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNA) - Part 1: Isolated cellular RNA
prCEN/TS xxx	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA
prCEN/TS xxx	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNA) - Part 3: Isolated genomic DNA
prCEN/TS xxx	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for human specimen — Isolated microbiome DNA
prEN ISO 15189 rev	Medical laboratories - Requirements for quality and competence
prEN ISO 16256 rev	Clinical laboratory testing and in vitro diagnostic test systems - Reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases
prEN ISO 20166-4	Molecular in vitro diagnostic examinations - Specifications for preexamination processes for formalinfixed and paraffin-embedded (FFPE) tissue - Part 4: in situ detection techniques
prEN ISO 20184-3	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 3: Isolated DNA
prEN ISO 20776-1	Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases (ISO/DIS 20776-1:2018)

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