Austrian Standards to provide significant discounts on international standards and technical specifications associated with the IVDR

Until November 20, 2020, you can save up to 50% on pre-analytical ISO standards & ISO 15189!

Sep 2020

Image by Austrian Standards

On the initiative of the Austrian Biobanking infrastructure BBMRI.at, Austrian Standards is offering international standards and technical specifications associated with the In vitro Diagnostic Regulation (IVDR) at a greatly reduced price. This promotion is on the occasion of the "LISAvienna Regulatory Conference for Medical Devices and In-Vitro Diagnostics" which is co-organized by LISAvienna, BBMRI.at and en.co.tec and on the occasion of the "BBMRI.QM webinar series on sample pre-analytic standards" from BBMRI-ERIC.

In the **promotional period from September 23 to November 20, 2020** , you will benefit from the following price reduction when ordering the standards mentioned:

- **50% discount** on the ISO standards and CEN technical specifications **"Molecular in vitro diagnostic examinations — Specifications for pre-examination processes"**
- **50% discount** o n **ISO 15189:2014 "Medical laboratories - Requirements for quality and competence"**
- **20% discount** on **ISO 20387:2018 „General requirements for biobanking"**

The discounts are already taken into account and are valid for all language versions.

Did you know that all national versions of the European standards are identical in content?
European standards are marked with the abbreviation "EN" - this means that all members of the European standardization organizations CEN and CENELEC have to adopt the standard nationally. Except for the language, the national versions of the European standards are identical in content (e.g.. ÖNORM EN ISO 15189 = BS EN ISO 15189 = DIN EN ISO 15189).

SELECT STANDARDS AND ORDER

Order the standards (in German and/or English versions) at Austrian Standards at the reduced rate here:

- **ISO 20184-1:2018**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 1: Isolated RNA
  Link to the already discounted ÖNORM EN ISO 20184-1:2019 06 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für gefrorene Gewebeproben - Teil 1: Isolierte RNS
  Link zur bereits rabattierten ÖNORM EN ISO 20184-1:2019 06 01

- **ISO 20184-2:2018**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 2: Isolated proteins (ISO 20184-2:2018)
  Link to the already discounted ÖNORM EN ISO 20184-2:2019 04 15
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für gefrorene Gewebeproben - Teil 2: Isolierte Proteine (ISO 20184-2:2018)
  Link zur bereits rabattierten ÖNORM EN ISO 20184-2:2019 04 15

- **CEN/TS 16826-3:2018**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 3: Isolated DNA (CEN/TS 16826-3:2018)
  Link to the already discounted ONR CEN/TS 16826-3:2018 10 15
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 3: Isolierte DNA (CEN/TS 16826-3:2018)
  Link zur bereits rabattierten ONR CEN/TS 16826-3:2018 10 15

- **ISO 20166-1:2018**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 1: Isolated RNA (ISO 20166-1:2018)

Link to the already discounted ONORM EN ISO 20166-1:2019 04 15
Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für formalinfixierte und paraffineingebettete (FFPE)-Gewebeproben - Teil 1: Isolierte RNS (ISO 20166-1:2018)
Link zur bereits rabattierten ÖNORM EN ISO 20166-1:2019 04 15

- **ISO 20166-2:2018**

  Molecular in vitro diagnostic examinations - Specifications for pre-examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 2: Isolated proteins (ISO 20166-2:2018)
  Link to the already discounted ÖNORM EN ISO 20166-2:2019 04 15
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für formalinfixierte und paraffineingebettete (FFPE)-Gewebeproben - Teil 2: Isolierte Proteine (ISO 20166-2:2018)
  Link zur bereits rabattierten ÖNORM EN ISO 20166-2:2019 04 15

- **ISO 20166-3:2018**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 3: Isolated DNA (ISO 20166-3:2018)
  Link to the already discounted ÖNORM EN ISO 20166-3:2019 06 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für formalinfixierte und paraffineingebettete (FFPE)-Gewebeproben - Teil 3: Isolierte DNS (ISO 20166-3:2018)
  Link zur bereits rabattierten ÖNORM EN ISO 20166-3:2019 06 01

- **ISO 20186-1:2019**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA (ISO 20186-1:2019)
  Link to the already discounted ÖNORM EN ISO 20186-1:2019 08 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 1: Isolierte zelluläre RNA (ISO 20186-1:2019)
  Link zur bereits rabattierten ÖNORM EN ISO 20186-1:2019 08 01

- **ISO 20186-2:2019**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic RNA (ISO 20186-2:2019)
  Link to the already discounted ÖNORM EN ISO 20186-2:2019 08 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 2: Isolierte genomische DNA (ISO 20186-2:2019)
  Link zur bereits rabattierten ÖNORM EN ISO 20186-2:2019 08 01

- **ISO 20186-3:2019**

  Molecular in-vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 3: Isolated circulating cell free DNA from plasma (ISO 20186-3:2019)
  Link to the already discounted ÖNORM EN ISO 20186-3:2020 03 15
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 3: Aus Plasma isolierte zirkulierende zellfreie DNA (ISO 20186-3:2019)
  Link zur bereits rabattierten ÖNORM EN ISO 20186-3:2020 03 15

- **CEN/TS 17390-1:2020**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood - Part 1: Isolated RNA (CEN/TS 17390-1:2020)
  Link to the already discounted ONR CEN/TS 17390-1:2020 05 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für zirkulierende Tumorzellen (CTC) in venösen Vollblutproben - Teil 1: Isolierte RNA (CEN/TS 17390-1:2020)
  Link zur bereits rabattierten ONR CEN/TS 17390-1:2020 05 01

- **CEN/TS 17390-2:2020**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood - Part 2: Isolated DNA (CEN/TS 17390-2:2020)
  Link to the already discounted ONR CEN/TS 17390-2:2020 05 01
  Molekularanalytische in vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für zirkulierende Tumorzellen (CTC) in venösen Vollblutproben - Teil 2: Isolierte DNA (CEN/TS 17390-2:2020)
  Link zur bereits rabattierten ONR CEN/TS 17390-2:2020 05 01

- **CEN/TS 17390-3:2020**

  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 (CEN/TS 17390-3:2020)
  Link to the already discounted ONR CEN/TS 17390-3:2020 05 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für zirkulierende Tumorzellen (CTC) in venösen Vollblutproben - Teil 3: Vorbereitungen für die analytische CTC-Färbung (CEN/TS 17390-3:2020)
Link zur bereits rabattierten ONR CEN/TS 17390-3:2020 05 01

- **CEN/TS 169485:2016**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for metabolomics in urine, venous blood serum and plasma (CEN/TS 169485:2016)
  Link to the already discounted ONR CEN/TS 16945:2016 10 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für Metabolomuntersuchungen in Urin, venöses Blutserum und -plasma (CEN/TS 169485:2016)
  Link zur bereits rabattierten ONR CEN/TS 16945:2016 10 01

- **CEN/TS 17305:2019**

  Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for saliva - Isolated human DNA (CEN/TS 17305:2019)
  Link to the already discounted ONR CEN/TS 17305:2019 08 01
  Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für Speichel - Isolierte menschliche DNA (CEN/TS 17305:2019)
  Link zur bereits rabattierten ONR CEN/TS 17305:2019 08 01

- **ISO 15189:2014**

  Medical laboratories - Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)
  Link to the already discounted ÖNORM EN ISO 15189:2014 12 01
  Medizinische Laboratorien - Anforderungen an die Qualität und Kompetenz (ISO 15189:2012, korrigierte Fassung 2014-08-15)
  Link zur bereits rabattierten ÖNORM EN ISO 15189:2014 12 01

- **ISO 20387:2018**

  Biotechnology -- Biobanking -- General requirements for biobanking
  (available only in English version, German-language ISO standard version not yet pubished)
  Link to the already discounted ISO 20387:2018 08 15

Why are the pre-analytics standards relevant?

The European Parliament passed a new EU regulation for in vitro diagnostics (IVDR) in 2017. The transition period runs until May 2022. By then at the latest, manufacturers of in-vitro diagnostics will have to adapt to regulatory changes in order to secure access to the European market.

The new regulations affect not only products that are still in the development stage, but also all products already available on the market. In addition, products manufactured and used in healthcare facilities (so-called Laboratory Developed Tests (LDT), "in-house" tests) are also affected. The IVDR requires addressing the sample pre-analytics to describe it in the technical documentation. In this context the pre-analytics standards "Molecular in vitro diagnostic examinations — Specifications for pre-examination processes" represent the state-of-the-art and are relevant norms.

Did you know that ....
... compromised patients' samples are often making in vitro diagnostic and research test results unreliable or even impossible?

To tackle this, the EU Horizon2020 SPIDA4P consortium (www.spidia.eu) is working on the development and implementation of 22 pan-European pre-analytical CEN/Technical Specifications and ISO/International Standards for workflows applied to personalized medicine, but also to biobanking for research purposes. Corresponding External Quality Assurance (EQA) Schemes have also been developed, aiming to survey the resulting quality of samples. SPIDIA4P is ensuring information of stakeholders, their involvement, training, education, and counselling for implementation.

Read the Special Edition in New Biotechnology "Standardisation of generic Pre-analytical Procedures for In vitro Diagnostics for Personalised Medicine" >>

Bundesministerium Bildung, Wissenschaft und Forschung

Funded by
GZ 10.470/0016-II/3/2013 (2013-2018)
BMBWF-10.470/0010-V/3c/2018 (2018-2023)