


**WP1 UPDATE STANDARDS // ULRIKE SCHROEDER**

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**All SPIDIA4P aims fulfilled!**

The goal of Work Package 1 (WP 1) was to develop 12 new CEN Technical Specifications (CEN/TS) and 2 new ISO International Standards<sup>1</sup>, thus creating and implementing a portfolio of 22 pre-analytical CEN/TS and ISO Standards (together with the existing standard documents initiated by SPIDIA) for selected pre-analytical workflows needed for personalized medicine. With the publication of CEN/TS 17811:2022 in the beginning of July 2022, this goal has been reached – **all standard documents as envisioned within SPIDIA4P have now been published!**

The working group responsible for the development of the standard documents on European level, CEN/TC 140/WG 3 “Quality management on the medical laboratory”, consisting of a high number of SPIDIA4P partners as well as further pan-European experts, achieved this great progress for the following documents under the main title **“Molecular in vitro diagnostic examinations – Specifications for pre-examination processes...”**:

Task	Project/document title	Status
1.1	...for circulating tumour cells (CTCs) in venous whole blood – Part 1: Isolated RNA	Published as CEN/TS 17390-1 ISO/NP TS 7552-1
1.1	...for circulating tumour cells (CTCs) in venous whole blood – Part 2: Isolated DNA	Published as CEN/TS 17390-2 ISO/NP TS 7552-2
1.2	...for circulating tumour cells (CTCs) in venous whole blood – Part 3: Preparation for analytical CTC staining	Published as CEN/TS 17390-3 ISO/NP TS 7552-3
1.3	...for saliva – Isolated human DNA	Published as EN ISO 4307 (Former CEN/TS 17305)
1.4	...for exosomes and other extracellular vesicles in venous whole blood – Isolated RNA, DNA and proteins	Published as EN ISO 20184-3 (Former CEN/TS 16826-3)
1.5	...for venous whole blood – Isolated circulating cell free RNA from plasma	Published as CEN/TS 17747 Accepted as ISO/PWI TS 18702
1.5	...for urine and other body fluids – Isolated cell free DNA	Published as CEN/TS 17742 Accepted as ISO/PWI 18703
1.6	...for urine and other body fluids – Isolated cell free DNA	Published as CEN/TS 17811 Accepted as ISO/PWI 18704
1.7	...for Fine Needle Aspirates – Part 1: Isolated cellular RNA	Published as CEN/TS 17688-1
1.7	...for Fine Needle Aspirates – Part 2: Isolated proteins	Published as CEN/TS 17688-2
1.7	...for Fine Needle Aspirates – Part 3: Isolated genomic DNA	Published as CEN/TS 17688-3

<sup>1)</sup> On the European level, the standardization projects are developed within the European standard organizations (CEN) Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” as CEN technical specifications (CEN/TS) to be later introduced into the international organization of standardizations (ISO) technical committee ISO/TC 212 “Clinical laboratory testing and in vitro diagnostic test systems” with EN ISO standards as envisioned documents.



1.8	...for human specimen – Isolated microbiome DNA	Published as CEN/TS 17626 Accepted as ISO/PWI TS 18701
1.9	...for metabolomics in urine, venous blood serum and plasma	Published as EN ISO 23118
1.10	...for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 4: In situ detection techniques	Published as EN ISO 20166-4

**Key: NP – New Project; PWI – Preliminary work item**

**All 10 tasks within WP 1 were successfully completed by publishing the according CEN Technical Specifications and EN ISO standards.**

**For most of the published CEN/TS documents, the journey does not stop on the European level, but successfully continues on the International level.**

Supported by decisions of CEN/TC 140, all documents within Tasks 1.1 to 1.8, except for the FNA documents (Task 1.7), were proposed to ISO/TC 212 to be further developed on ISO level under the Vienna Agreement. Their development status now ranges from accepted preliminary work items (Tasks 1.5, 1.6, 1.8) to new projects in development (Tasks 1.1 and 1.2) to already published documents (Tasks 1.3 and 1.4).

Even with SPIDIA4P coming to end, **the standardization work within the according standardization working groups is continuing and will do so in the future.** This does not only hold true for the standards currently in development, but also for those that have been published early on (i.e. within SPIDIA).

To ensure that standards remain up-to-date and globally relevant, they are reviewed at least every five years after publication through the Systematic Review process. Through this process, national standards bodies review the documents and their use in their country (in consultation with their stakeholders) to decide whether they are still valid, should be updated, or withdrawn. The systematic review process will not start before 2024 for documents such as EN ISO series 20166 or 20184, but it is important to note that revisions, based on e.g. new technologies, developments and/or findings, are also possible before the above mentioned five year time frame.

The unparalleled standardization effort achieved within the project time of SPIDIA4P is only possible through the great effort, hard work and continuous engagement of all partners and experts within SPIDIA4P, CEN/TC 140/WG 3 and ISO/TC 212/WG 4. Once again, I would like to express my sincere thanks to everyone involved! SPIDIA4P has been an incredible journey in combining research and innovations with standardization. It will be exciting to see the project outcomes sustainably implemented to reach the overall project goal of improving the global healthcare system.





**THE SPIDIA AND SPIDIA4P PROJECT HAS LED TO THE PUBLICATION OF THE FOLLOWING CEN/TS AND ISO STANDARDS IN 2018–2022**

<b>ISO-series 20166 – FFPE tissue</b>	
<b>ISO 20166-1:2018</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 1: Isolated RNA	<a href="http://www.iso.org/standard/67179.html">www.iso.org/standard/67179.html</a>
<b>ISO 20166-2:2018</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 2: Isolated proteins	<a href="http://www.iso.org/standard/69802.html">www.iso.org/standard/69802.html</a>
<b>ISO 20166-3:2018</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 3: Isolated DNA	<a href="http://www.iso.org/standard/69803.html">www.iso.org/standard/69803.html</a>
<b>ISO 20166-4:2021</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 4: In situ detection techniques	<a href="https://www.iso.org/standard/75442.html">https://www.iso.org/standard/75442.html</a>
<b>ISO-series 20184 – Frozen tissue</b>	
<b>ISO 20184-1:2018</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 1: Isolated RNA	<a href="http://www.iso.org/standard/67215.html">www.iso.org/standard/67215.html</a>
<b>ISO 20184-2:2018</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 2: Isolated proteins	<a href="http://www.iso.org/standard/69801.html">www.iso.org/standard/69801.html</a>
<b>ISO 20184-3:2021</b> , Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue – Part 3: Isolated DNA	<a href="https://www.iso.org/standard/78110.html">https://www.iso.org/standard/78110.html</a>
<b>ISO-series 20186 – Venous whole blood</b>	
<b>ISO 20186-1:2019</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Part 1: Isolated cellular RNA	<a href="http://www.iso.org/standard/67217.html">www.iso.org/standard/67217.html</a>
<b>ISO 20186-2:2019</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Part 2: Isolated genomic DNA	<a href="http://www.iso.org/standard/69799.html">www.iso.org/standard/69799.html</a>
<b>ISO 20186-3:2019</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Part 3: Isolated circulating cell free DNA from plasma	<a href="http://www.iso.org/standard/69800.html">www.iso.org/standard/69800.html</a>
<b>ISO 23118</b>	
<b>ISO 23118:2021</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma	<a href="https://www.iso.org/standard/74605.html">https://www.iso.org/standard/74605.html</a>





**INITIATED BY THE SPIDIA4P PROJECT AND PUBLISHED AS CEN/TS AND ISO STANDARDS – MORE TO COME!**

<b>CEN/TS</b>		
<b>CEN/TS 16826-3:2018</b> , Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 3: Isolated DNA	<a href="http://www.din.de/en/wdc-beuth/din21:281615991">www.din.de/en/wdc-beuth/din21:281615991</a>	
<b>CEN/TS 17390-1:2020</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood – Part 1: Isolated RNA	<a href="https://standards.cencenelec.eu/dyn/www/?p=CEN:35:0:::FSP_SURR_WI,FSP_ORG_ID:65450,6122&amp;cs=1A1C32592109AC94F4B56FCA862D67954">https://standards.cencenelec.eu/dyn/www/?p=CEN:35:0:::FSP_SURR_WI,FSP_ORG_ID:65450,6122&amp;cs=1A1C32592109AC94F4B56FCA862D67954</a>	
<b>CEN/TS 17390-2:2020</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood – Part 2: Isolated DNA	<a href="https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:65452&amp;cs=15F68354250584C9C9EECF2FEC71A0A44">https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:65452&amp;cs=15F68354250584C9C9EECF2FEC71A0A44</a>	
<b>CEN/TS 17390-3:2020</b> : 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	<a href="https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:65451&amp;cs=15E9E8CE0D924716B92532521F07B723C">https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:65451&amp;cs=15E9E8CE0D924716B92532521F07B723C</a>	
<b>CEN/TS 17742:2022</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for venous whole blood – Isolated circulating cell free RNA from plasma	<a href="https://standards.cencenelec.eu/dyn/www/?p=CEN:35:0:::FSP_SURR_WI,FSP_ORG_ID:68138,6122&amp;cs=1EA34F27443FFBE1DF7AA7CBCA6493F24">https://standards.cencenelec.eu/dyn/www/?p=CEN:35:0:::FSP_SURR_WI,FSP_ORG_ID:68138,6122&amp;cs=1EA34F27443FFBE1DF7AA7CBCA6493F24</a>	<b>NEW</b>
<b>CEN/TS 17747:2022</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood - DNA, RNA and proteins	<a href="https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:68137&amp;cs=197A0CEEA18260BFD396E9F8337297837">https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:68137&amp;cs=197A0CEEA18260BFD396E9F8337297837</a>	<b>NEW</b>
<b>CEN/TS 17811:2022</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for urine and other body fluids – Isolated cell free DNA	<a href="https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:67464&amp;cs=11F83CD57162108B9A8AE11ED37111B4B">https://standards.cencenelec.eu/dyn/www/?p=205:35:0:::FSP_SURR_WI:67464&amp;cs=11F83CD57162108B9A8AE11ED37111B4B</a>	<b>NEW</b>
<b>CEN/TS 17626:2022</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for human specimen – Isolated microbiome DNA (German version)	<a href="https://www.beuth.de/de/vornorm/din-cen-ts-17626/330405743">https://www.beuth.de/de/vornorm/din-cen-ts-17626/330405743</a>	<b>NEW</b>
<b>CEN/TS-series 17688 – Fine Needle Aspirates</b>		
<b>CEN-TS 17688-1 :2021</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 1: Isolated cellular RNA	<a href="https://genorma.com/en/project/show/cen:proj:67447">https://genorma.com/en/project/show/cen:proj:67447</a>	<b>NEW</b>
<b>CEN/TS 17688-2:2021</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 2: Isolated proteins	<a href="https://www.nen.nl/nvn-cen-ts-17688-2-2022-en-291143">https://www.nen.nl/nvn-cen-ts-17688-2-2022-en-291143</a>	<b>NEW</b>
<b>CEN/TS 17688-3:2021</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) – Part 3: Isolated genomic DNA	<a href="https://www.nen.nl/nvn-cen-ts-17688-3-2022-en-291145">https://www.nen.nl/nvn-cen-ts-17688-3-2022-en-291145</a>	<b>NEW</b>
<b>ISO 4307</b>		
<b>ISO 4307:2021</b> : Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for saliva – Isolated human DNA	<a href="https://www.iso.org/standard/79865.html">https://www.iso.org/standard/79865.html</a>	<b>NEW</b>