

Disclosure Information

I hereby declare that I have had business or personal interests in the following industrial enterprises since 1 September 2020:

Name of the enterprise / Nature of the interest

Enterprise | Interest

Truckee Applied Genomics, LLC|Formalin free TAG-1 fixative to test

Lyme Diagnostics Ltd|Vials for Lyme disease testing

SPIDIA:

The SPIDIA project has received funding under the Seventh Research Framework Programme of the European Union, FP7-HEALTH-2007-1.2.5 under grant agreement no. 222916.

SPIDIA4P:

The SPIDIA4P project receives/ received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112.

Biobanking in general and the use of autopsy tissue

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Learning objectives

- ✓ **Bio-samples quality**
- ✓ **Standardization of pre-analytical processes**
- ✓ **Autopsy tissues quality- how to manage**

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Collection

Management

Storage



Governance

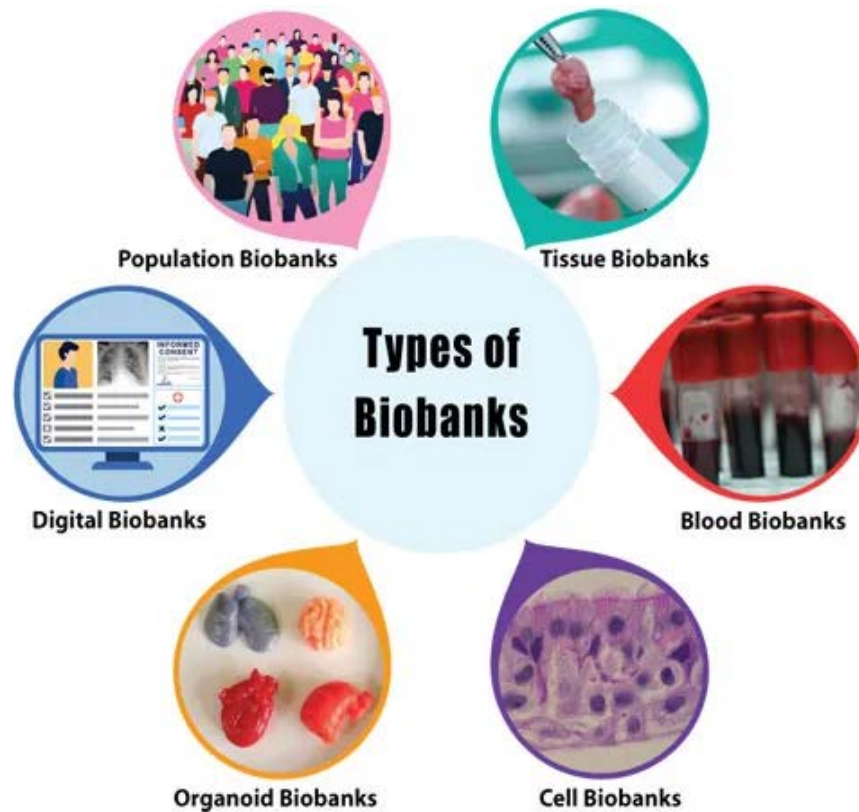
Ethical/Legal Issues

Quality Control

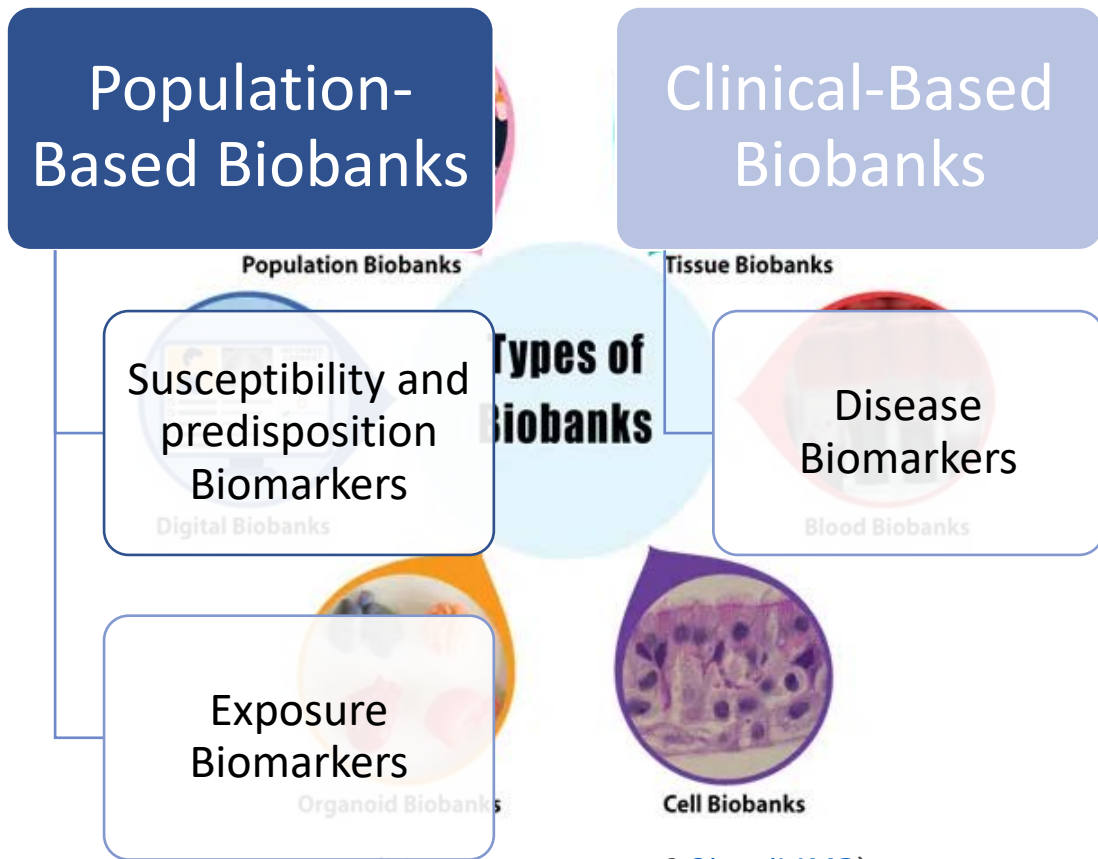
Data Management

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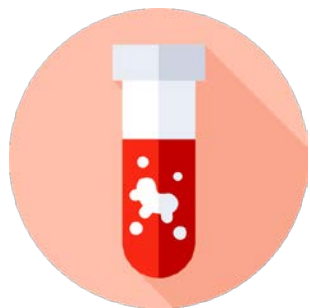
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(Figure courtesy of [CloudLIMS](#))



(Figure courtesy of [CloudLIMS](#))



Biobanks are responsible for providing **high-quality biosamples** that are linked to comprehensive clinical information to support research

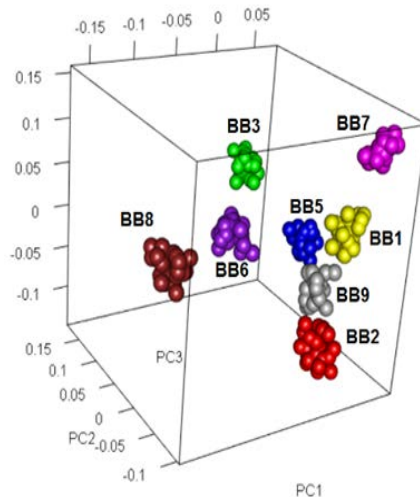
- Standardization of pre-analytical processes is key to guarantee reliability of analytical results
- Same requirements for diagnostics and biobanks

Sample source determines the metabolome signature

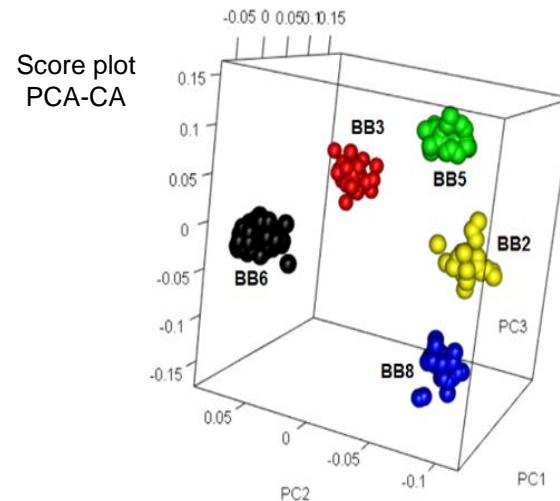
European healthy subjects

Courtesy of CERM-Florence

EDTA-plasma from 9 biobanks



Serum from 5 biobanks



Preanalytical phase

Biological/environmental factors



Technical factors



1. Mostly outside the laboratory
2. Harder to Control
3. Different health care professionals
4. Biomolecules analysis (DNA, RNA, protein, ccf-DNA, miRNA...) requires dedicated pre-analytical processes

Use of Standards

As a reference model to which you may conform.

They establish technical specifications for pre-analytical processes in IVD, clinical and preclinical research

ISO and CEN documents

INTERNATIONAL
STANDARD

ISO
20166-1

First edition
2018-12

Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue —

**Part 1:
Isolated RNA**

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour les tissus fixés au formol et inclus en paraffine (FFPE) —

Partie 1: ARN extrait

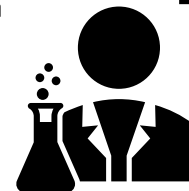
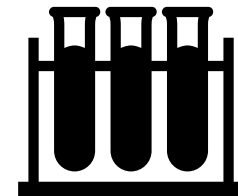
Major efforts for improvement

- **Technologies** for securing high quality samples
- **International Standards** for pre-analytical workflows (new documents)



Education and Training

- **Multi-disciplinarity**-ongoing education on correct sample collection and handling procedures and on the implications of errors in the preanalytical phase.
- **EQA** for pre-analytical processes





QUALITY MANAGEMENT TOOLS SELF ASSESSMENT SURVEY

ACCESS TO BBMRI-ERIC SAS

- **GO TO**
bbmri-eric.eu/services/self-assessment-survey/
- **FILL OUT**
Request form / tick off pre-conditions / send
- **GET STARTED**
Receive @ with the link to SAS

EVALUATION OF SPECIFICATIONS

- **COMPLETION**
of BBMRI-ERIC SAS
- **SUBMIT REPORT**
to BBMRI-ERIC
- **BE REVIEWED**
by BBMRI-ERIC (remote or on-site)

AWARD Q-LABEL IN BBMRI-ERIC DIRECTORY

- **SAMPLE COLLECTION**
Assessed according to relevant standards
- **BIOBANK**
Internal audit based on ISO 20387 and ISO 9001
- **ENHANCE VISIBILITY**
Q-Label in the Directory directory.bbmri-eric.eu

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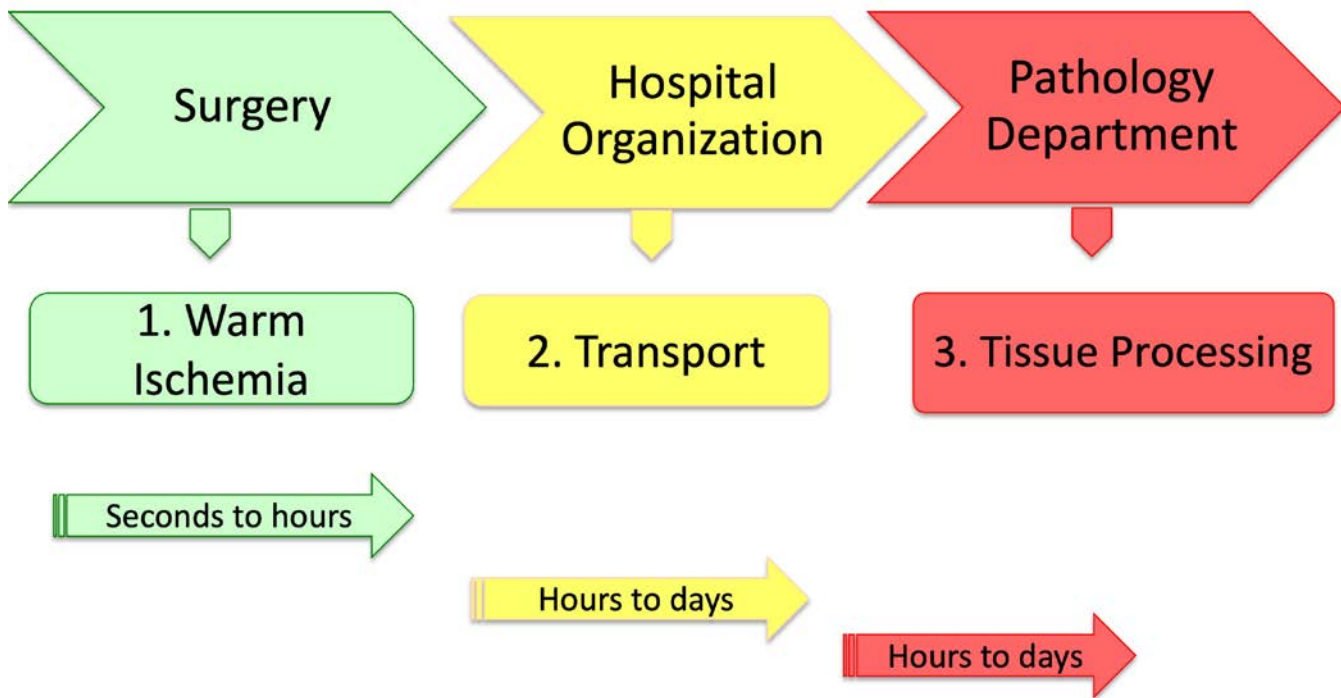
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* Have you purchased the required ISO and CEN/TS standards, as the basis for your biobanking and specimen handling procedures? See <http://www.bbmri-eric.eu/services/standardisation/>

Yes No

* Please select the required BBMRI-ERIC Self-Assessment Surveys from the list below:

- Quality Management Systems - General Requirements for Biobanking; ISO 20387:2018
- Specifications for pre-examination processes for frozen tissue - Part 1: Isolated RNA; ISO 20184-1:2018
- Specifications for pre-examination processes for frozen tissue - Part 2: Isolated proteins; ISO 20184-2:2018
- Specifications for pre-examination processes for FFPE tissue - Part 1: Isolated RNA; ISO 20166-1:2018
- Specifications for pre-examination processes for FFPE tissue - Part 2: Isolated proteins; ISO 20166-2:2018
- Specifications for pre-examination processes for FFPE tissue - Part 3: Isolated DNA; ISO 20166-3:2018
- Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA; ISO 20186-1:2019
- Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA; ISO 20186-2:2019
- Specifications for pre-examination processes for venous whole blood - Part 3: Isolated ccfDNA from plasma; ISO 20186-3:2019
- Specifications for pre-examination processes for metabolomics in urine; CEN/TS 16945:2016
- Specifications for pre-examination processes for metabolomics in serum and plasma; CEN/TS 16945:2016



Surgical Tissue Workflow



Highly degraded biomolecule

- Post mortem Interval for autolysis and microbial activity

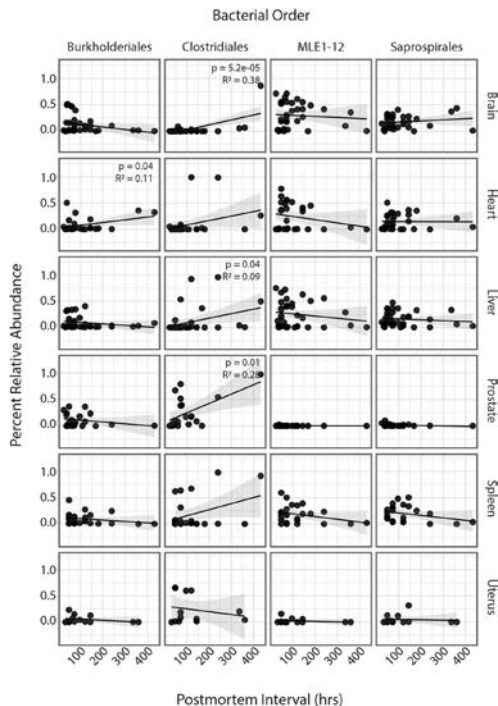
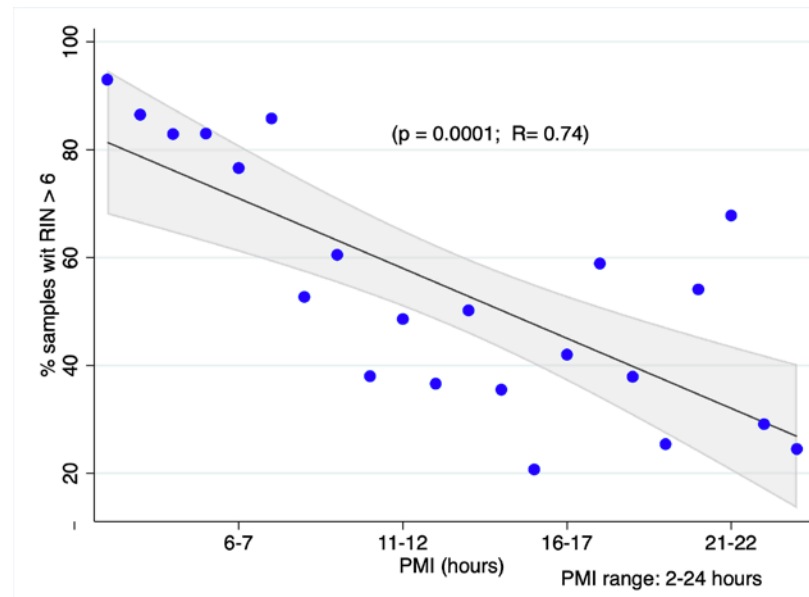


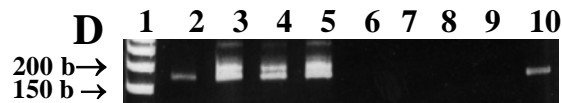
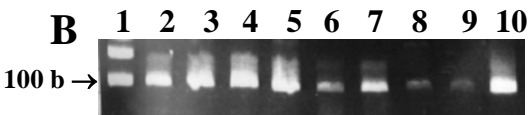
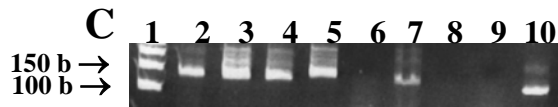
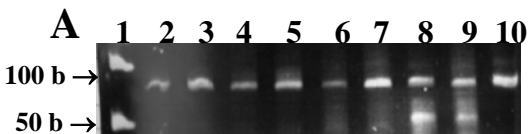
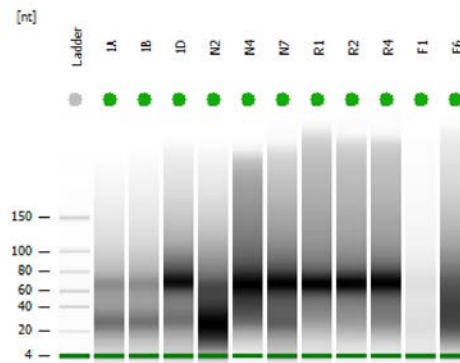
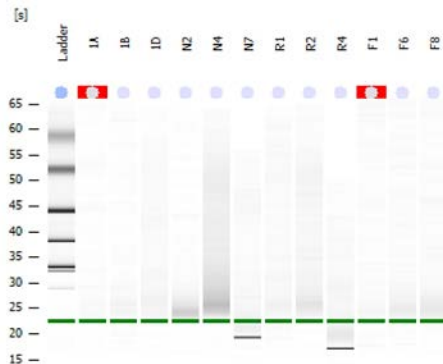
Image from Lutz Het al, 2020, Front Microbiol



Data from Carithers LJ et al, 2015, Biopreserv Biobank

Thanatomicrobiome and epinecrotic microbiome develop in postmortem human body and vary during PMI.

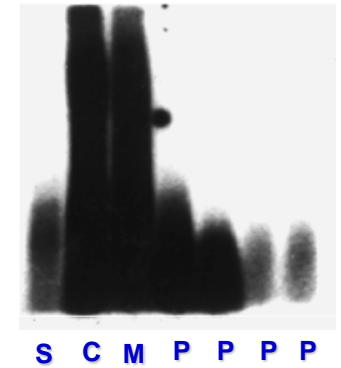
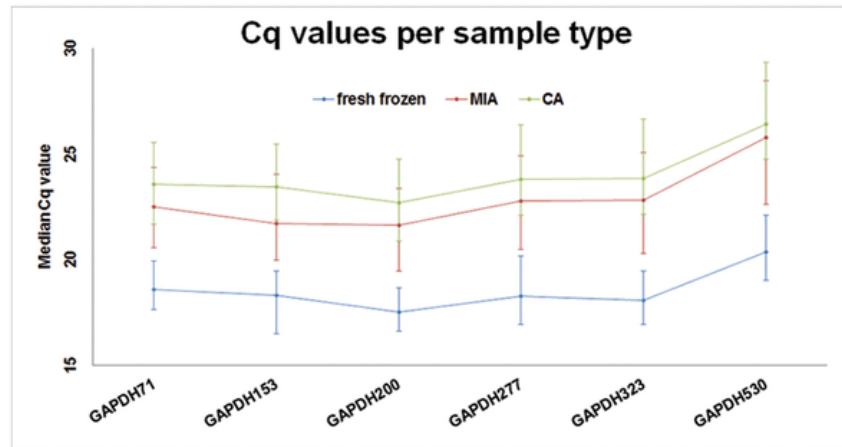
- Postmortem microbial communities predict accurate PMI.



Highly degraded biomolecule In
FFPE
- Extensive fixation time



GAPDH size assay in fresh frozen, MIA and CA samples.



van der Linden A, Blokker BM, Kap M, Weustink AC, Riegman PHJ, et al. (2014) PLOS ONE 9(12): e115675. <https://doi.org/10.1371/journal.pone.0115675>



MAIN RESOURCE FOR:

- ✓ HUMAN NORMAL TISSUES
- ✓ NEUROSCIENCE RESEARCH
- ✓ CARDIOLOGICAL DISEASES

AUTOPSY TISSUE
BIOBANKS

HIGHER QUALITY

SPECIFIC
WORKFLOW FOR
BIOBANKING

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NeuroBioBank

Facilitating Research and Creating Awareness

Best Practices for Postmortem Recovery of Normal Human Tissue for Research

https://biospecimens.cancer.gov/global/pdfs/caHUB_ANTWG_Postmortem_BPs.pdf

Autopsy and tissue collection **within 24h** from death

Documentation of cause of death, agonal state, PMI...

Standardized sectioning, processing and storage of the tissues

Tissue pathological assessment

Molecular QC: RNA Integrity, gene expression, pH...



Anatomy Lesson of Dr. Tulp

- ✓ CT guided biopsies for MIA (alternative to conventional autopsy where it is not possible)
- ✓ Rigorous procedures and documentation allow analyzing long RNA stretches from autopsy tissues (even FFPE)

CONTROLLING PRE-ANALYTICAL PROCESSES IN AUTOPSY TISSUES ALLOWS THE COLLECTION OF HIGH QUALITY BIOMOLECULES FOR BIOBANKING AND FOLLOWING RESEARCH.

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Thank you for your attention