

Mission

Biospecimens stored in biorepositories are intended to be used for biomarker identification and validation. The performance of such biomarkers greatly depends on the pre-analytical variations of the samples having been used for the biomarkers' initial identification. Quality Assurance on this issue is therefore of the outmost importance and allows us to establish the right correspondence between processing methods and end-use biomarkers. The mission of this Working Group is to address the challenges of biospecimen research by 1. developing tools for efficient preanalytical tracking, observational biospecimen research and biospecimen quality control, 2. experimental work on validation of novel biospecimen processing and characterization methods, and 3. Developing proficiency testing programs for biorepositories.

Chair: Fay Betsou, Co-Chair: Elaine Gunter

2011 members of ISBER Working Group on Biospecimen Science

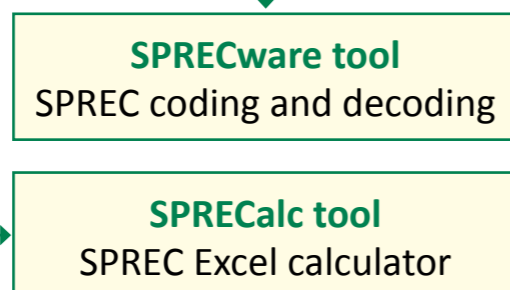
Garry ASHTON
Mike BARNES
Erica BENSON
Fay BETSOU
Rodrigo CHUAQUI
Judith CLEMENTS
Domenico COPPOLA
Yvonne DESOUZA
James ELIASON
Barbara GLAZER
Katrina GODDARD
Fiorella GUADAGNI
Elaine GUNTER
Keith HARDING
Jae Pil JEON
Jo KESSLER
Olga KOFANOVA
Iren KOPPANDI
Theresa KOKKAT
Conny MATHAY
Anne Mieke DE WILDE
Francesca POLONI
Kathi SHEA
Amy SKUBITZ
Stella SOMIARI
Gunnel TYBRING

Current Projects

1 SPREC implementation and update

Examples of successful SPREC implementation

- Prostate Cancer Bioresource, Australia
- BioBIM, San Raffaele, Italy
- IBBL, Luxembourg
- Seracare, USA
- Quintiles, USA
- Lifegene, Sweden
- Lifelines, The Netherlands
- TMF, Germany
- Biobank software providers



SPREC beyond humans...

"Standard PREanalytical Codes (SPREC): A New Paradigm for Environmental Biobanking Sectors Explored in Algal Culture Collections", *Biopreservation Biobanking*, 2011;4:399-410

Publication

SPREC version 2.0

"Standard preanalytical coding for biospecimens: Review and implementation of the Sample PREanalytical Code", submitted

Publication

More options

Implementation tools

3 Study of robustness and reproducibility of RT RNA Storage

Comparison of RNA stored and shipped at RT (BioMatrica, GenVault, Imagene, without stabilizer) and dry ice/-80°C

- 7 samples,
- 5 conditions,
- 5 participant labs,
- 3 testing labs

For detailed results see poster no. BSS 14

Assessment by yield, RIN, qRT-PCR (GAPDH, ACTB, IL1, ORM1, PLAUR)

Application in PT Schemes

"Short term stability study of RNA at room temperature", in preparation

Publication

4 Study of robustness and reproducibility of viable cell shipping at frozen or RT

Comparison of LN, dry ice, and RT shipment

High and low viability PBMCs and Jurkat cells

- 4 samples,
- 3 media,
- 3 shipment conditions,
- 3 testing labs

For detailed results see poster no. BSS 05

Assessment by Trypan blue, CASY, flow cytometry (Cytex, Annexin V, Hoescht), ELISPOT

"Impact of shipment and storage conditions on cell viability and function assessed by different testing methods", in preparation.

Publication

5 Development of a Proficiency Testing Program

Partnership Agreement ISBER-IBBL, signed

Business plan and budget, established

SOPs (ISO17043:2010), User Manual, Quality Manual, written, reviewed, released

PT software, configured, implemented

DNA quantification and purity scheme, run

RNA integrity scheme, run

Statistical approach:

ISO/IEC 17043:2010: Conformity assessment – General requirements for Proficiency testing

IUPAC Technical Report (Pure Applied Chem 2006:78:145-196)

For detailed results see poster no. QAC 16

2 Quality Control tool identification through literature data mining

Update of the biospecimen science literature compilation (100 new references)

<http://www.isber.org/wg/BS-WG-LitComp.html>

Long term storage and freeze-thaw stability literature information

Critical reading of ~600 publications to identify biospecimen QC tools (markers/assays) that can be used to define sample quality

Eventual implementation in PT schemes!

"Identification of evidence-based biospecimen quality control tools", submitted

Publication

Examples of findings

QC tool	Sample type	QC scope	Applicability grade	Accessibility grade	Future research required
1K+	Serum	Precentrifugation delay at 4°C	Immediately applicable	Readily accessible	Plasma
2Truncated cystatin C	CSF	Storage conditions	Not immediately applicable	Not immediately accessible	Produce MABs once confirmation in other sample types.
3DUSP1 expression	Prostate fresh tissue	Warm ischemia time	Immediately applicable	Readily accessible	other tissue types
4Myosin heavy chain	Prostatic tissue	Cold ischemia	Not immediately applicable	Potentially accessible	Other tissue types, ref values

Significant contributions to the works of the group were also made by

Kristine DAVIS
Sara DEMIROGLU
Jacko DUKER
Sabine LEHMANN
Helen MOORE
Umberto NANNI
Wusheng YAN
and Trina YEADON

Future Projects

Validation of newly identified biospecimen quality control tools

Development of new Proficiency Testing schemes:

- Cell viability
- Tissue histology
- Tissue antigenicity

Validation of innovative tissue stabilisation technologies

Previous Publications

"Standard preanalytical coding for biospecimens: defining the sample PREanalytical code", *Cancer Epidemiol Biomarkers Prev* 2010;19:1004-1011.

Publication

"Human biospecimen research: experimental protocol and quality control tools", *Cancer Epidemiol Biomarkers Prev.* 2009 Apr;18(4):1017-25

Publication

Experimental projects; Stability, robustness studies

In silico research; new QC tools

Proficiency Testing Present schemes

Proficiency Testing future schemes

Integration of the activities of the working Group