

Biospecimen Science Literature Compilation

Second Edition

February 2010

I. Biospecimen research is not a new discipline

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II. Studies in a Clinical setting

A. Normative documents

1. ISO17025:2005, General requirements for the competence of testing and calibration laboratories.
2. ISO/DIS 6710. Single-use containers for human venous blood specimen collection. Draft 2001.
3. EN/ISO15189:2007, Medical laboratories: particular requirements for quality and competence. *Published in 2003, the ISO 15189 quickly became a widely accepted standard to be used for accreditation of clinical laboratory competence. The ISO15189 standard is divided in two parts, management requirements and technical requirements related to activities carried out by clinical laboratories. Importantly, the last ISO15189, 2007 version establishes responsibility of the clinical laboratory for all preanalytical steps, including ordering and sampling. However, detailed technical preanalytical requirements are absent from normative documents.*
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B. General Guidelines

1. OECD guidelines on Good Laboratory Practice and Compliance Monitoring (ENV/MC/CHEM(98)17) *have been issued following international collaboration (http://www.oecd.org/document/63/0,2340,en_2649_34381_2346175_1_1_1_1,00.html) between scientific*

societies. These are being increasingly implemented and propagated by organization of the national Clinical Chemistry societies under the umbrella of the EFCC: European Federation of Clinical Chemistry and Laboratory Medicine.

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7. Chronolab's databank
8. "Recommendations for detection and management of unsuitable samples in clinical laboratories" by the same Working Group (Clin Chem Lab Med 2007; 45: 728-36)
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C. Domain-specific

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4. CLSI, MM13-A: Collection, transport, preparation and storage of specimens for molecular methods.
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C.1. Hematology

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C.2. Bone

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C.3. Immunology

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C.4. Endocrinology

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C.5. Nutrition

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C.6. Clinical chemistry

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D. Analyte-specific

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E. Meetings

The following documents have been elaborated by meetings held either by scientific or by normative bodies / working groups. Scientific workgroups include:

1. Symposium on the impact of the preanalytical phase on the quality of laboratory results in Haemostasis (Montpellier, 1996).
2. The impact of the preanalytical phase on the quality of laboratory results (Basel, 1997).
3. Session on “Extra-analytical variability and quality in laboratory medicine” at the National Congress of SIBioC, Rimini October 4th, 2007.
4. Variabilité biologique : la phase préanalytique. 24ème Congrès annuel de la Société Québécoise de Biologie Clinique. 47ème Congrès annuel de la Société Canadienne de Biologie Clinique, Saint Sauveur 1-5 juin 2003.
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10. *The main normative working group is the ISO Technical Committee 212 which is devoted to clinical laboratory testing and in vitro diagnostic test systems. To our knowledge, ISO/TC 212 has not yet undertaken a project development on preanalytics standardisation.*

III. Studies in a Research setting

A. Proteomics

A.1. Serum, plasma

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C. Transcriptomics: RNA

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Special contribution from Dr Erica E Benson & Dr Keith Harding

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