

3rd, revised edition 2003

Samples: From the Patient to the Laboratory

***The impact of preanalytical variables
on the quality of laboratory results***

W. G. Guder · S. Narayanan · H. Wisser · B. Zawta



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Front Cover: Fractal image from Mandelbrot's non linear mathematics.
Stephen Johnson; Tony Stone Bilderwelten, Munich

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The authors having known each other for many years decided to summarize their experience of preanalytical variables in 1992 after observing an increasing contribution of these factors on laboratory results. They agreed to summarize their knowledge in a short and understandable form aiming to increase the awareness of these factors among all professions involved in the preanalytical phase of the laboratory diagnostic process. This idea was generously supported by Becton Dickinson, Europe.

After the style and general contents of the book were agreed upon in a first meeting of the authors together with the publisher, the manuscripts were completed by the authors in a short time with the help of many collaborators and colleagues. The authors would especially like to thank Heidrun Dürr and Edith Rothermel, Heidelberg, Klaus Krischok, Munich, Ulrich Wurster, Hannover for providing and designing figures. Thanks also to Ingrid Freina, Ulrike Arnold and Patrick Bernhard, Munich, Carol Pirello, New Jersey, Kerstin Geiger, Marion Wajda and Helga Kallmeyer, Mannheim, Annelies Frim, Stuttgart for their expert secretarial help. David J. Purnell, Plymouth, Wolfgang Heil, Wuppertal, and James Brawley, Gaiberg/Heidelberg greatly supported our work by critically reading the manuscripts. We would like to thank Alois Jochum for translation support.

The present 3rd version includes a special edition of "The Quality of Diagnostic Samples" as CD-ROM, containing all Recommendations of the Working Group on Preanalytical Quality, updated May 2003, kindly provided by Chronolab AG, Zug, Switzerland. Several Figures have been replaced by the newest versions available and references adapted to more recent publications.

In continuation of a 10 years collaboration with the Publisher GIT we thank A. Pillmann (Wiley-VCH) for her experienced support in editing this new version in close collaboration with all contributors.

The authors do hope that the new version will help to continuously increase the awareness of preanalytical variables as a possible source of laboratory errors. As the previous editions it is devoted to all professions involved in the organization and performance of preanalytical steps. The authors would be pleased if this work helps to improve the quality of patient care by increasing knowledge on preanalytical variables in the laboratory diagnostic process.

Walter G. Guder Sheshadri Narayanan Hermann Wisser Bernd Zawta

May 2003

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The impact of preanalytical variables on the quality of laboratory results

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The Quality of Diagnostic Samples CD-Rom

Annex

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The optimal sample volume
Analyte stability in sample matrix
The haemolytic, icteric and lipemic sample
Samples and stability of analytes in blood, urine and CSF

Laboratory tests generally provide a more sensitive indicator of the state of a patient's health than the patient's account of how he or she feels. This has prompted an increasing emphasis on laboratory tests in the diagnosis and management of the patient's disease. Major decisions about the management of a patient are being made on small changes in laboratory data. Thus, a decision to change the dose of a patient's drug is often made on its plasma concentration.

Laboratories have long been aware that many non-disease factors may affect clinical laboratory test values. These include the potential effect of drugs, either through an effect on the physiological function of various organs, or an interference with an analytical method.

Whereas the laboratorian may be aware of the possibility of an analytical interference, clinicians are largely unaware of these effects and the available resources to help them interpret test values correctly. When this information is not given with the result, clinicians may misinterpret test values and take an inappropriate action with their patients.

Clinical decisions based on laboratory test values are correctly made only when the conditions under which blood or other specimens are properly identified and standardized, or when the lack of standardization is recognized and allowances are made for some lack of comparability with previous test values. While laboratorians are aware of the concepts of intra- and interindividual variation as they affect laboratory data, many colleagues are unfamiliar with all but the most obvious causes of differences in test values, such as gender and age.

An understanding of intraindividual variation of test values is important if appropriate clinical decisions are to be made when serial data are being followed. The new concepts of critical differences or reference changes are now important. For proper interpretation of the typically small differences between laboratory data obtained on successive specimens from patients, the variables affecting the test values need to be standardized wherever possible, but first the pertinent variables need to be identified.

These are the issues that prompt the need to revisit all the factors related to preanalytical variables. It is thus particularly timely for this book to be published. The authors hope to reach a broader audience than the laboratorians who are probably quite familiar with many of the factors affecting test results. Since 1956, when Roger Williams published his pioneering studies on the differences between people in a book entitled "Biochemical Individuality", physiologists have been concerned with the differences between people. Now that we have a broader understanding of the genetic influence on human physiology and behavior and a greater need to extract more information from small changes in laboratory data, the publication of a new book concerned with preanalytical variables which contribute to intra- and interindividual variability is both timely and welcome. This book is intended not just for laboratorians but also for physicians, nurses and everyone involved in the chain of events from the decision to order a laboratory test to the interpretation of its results. Proper application of the information contained in this book should lead to less unnecessary testing, reduced costs and a better understanding of the results.

Philadelphia, April 1996

Donald S. Young M.D., Ph.D.