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# Quality assurance in the medical laboratory: a success story in the health-care system

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Diagnostic lab results are the basis of all rational medical actions. Within diagnostic medicine, there has been a long-standing trend in clinical chemistry/laboratory medicine that it employs the far greatest number of different technologies, analytical laboratory methods and parameters in preparing medical in vitro lab results. It is foreseeable that the sustained rapid technological developments over the past few years, as well as the concept of their application on a more personalized form of medicine, will further intensify the significance of laboratory findings.

Already in the second half of the 20<sup>th</sup> century, the profession recognized, based on its involvement with analytical techniques, that a key prerequisite for properly performing a clinical-chemical analysis and subsequent assessment of its results is first based on the definition of technical measuring equipment terms. We owe today's cornerstones of quality assurance to the desire for comparability of results through standardization of analytic methods and systematic development of their regularities. As a scientific professional association, today's Deutsche Vereinigte Gesellschaft fuer Klinische Chemie und Laboratoriumsmedizin (DGKL) plays a central role here in the establishment and expansion of a reference method concept for clinical-chemical benchmarks as well as in the establishment and dissemination of so-called "Standardized Methods of the Deutsche Gesellschaft fuer Klinische Chemie" (DGKC, one of the two precursor organizations).

A logical outgrowth of the external quality assurance tests performed since the 1960s for standardization of laboratory tests was the first Directive of the German Medical Association (Rili-BAEK) in 1971. Amendments to the directive, the promulgation of EU directives on medical devices (IVDD) and national regulations in the medical products act (MPG) and the Medical Products Operator Ordinance (MP-BetriebV) have further solidified the obligation towards quality assurance for quantitative medical laboratory tests in the Rili-BAEK since 2002.

Thoughts on the formulation of an analogous Rili-BAEK "for the performance of qualitative medical laboratory tests" derived their direct impetus from daily experience in the increasing presence of molecular diagnostics: While legally binding rules for the quantitative tests applied in

medical laboratories according to the Rili-BAEK, quality assurance of nominal or ordinal findings, as is typical for research findings from the field of molecular and cytogenetics, only exists on a voluntary basis. In particular, against the backdrop of the permanence of genetic findings, an increasing number of laboratories felt the need for a set of rules analogous to the existing Rili-BAEK. This was also impressively manifest in the double-digit percentage growth rates of participation in molecular external quality assurance tests from 1998 by the former DGKC.

After acceptance of the advisory board's concept for a comprehensive revision of the Rili-BAEK by the management board of the German Medical Association (BAEK) in 2007, the BAEK advisory board, under the leadership of its Chairman Wolfgang Vogt and BAEK consultant Manfred Brüggemann, established interdisciplinary working groups to formulate special components of qualitative laboratory tests. Upon the recommendation of the German Medical Association (BAEK), and based on the method-oriented classification system of the Rili-BAEK, in 2007 a working group of the Deutsche Vereinigte Gesellschaft fuer Klinische Chemie und Laboratoriumsmedizin (DGKL) prepared an initial recommendation of a directive for "Quality Assurance of Qualitative Medical Laboratory Tests". Due to the Genetic Diagnostics Act that came into effect in the year 2010 and its regulations concerning genetic analytics, it had become necessary, however, to regulate the molecular-genetic tests contained in B2 in a separate Section B5. As a result of the interdisciplinary effort, the new Rili-BAEK is complete and encompasses all the working areas of laboratory medicine. In addition to a section on "Qualitative Medical Laboratory Tests" (B2, published in 2011) with the additional special directive sections "Ejaculate Tests" (B4, published in 2011), it also includes "Molecular and Cytogenetic Tests" (B5, published in 2011) and "Medical Laboratory Tests for the Direct Detection and Characterization of Infectious Agents" (B3, published in 2013).

Now that an initial English translation is available, it is our hope that this set of rules will also be perceived as helpful and inspiring in other countries and will thus facilitate the strengthening of the high quality of laboratory diagnostics in diagnostic medicine.

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