



# The add value of laboratory diagnostics: the many reasons why decision-makers should actually care

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**Abstract:** The role and responsibilities of laboratory professionals are impressively changing. Clinical and technical background is no longer sufficient, since laboratory activity is now increasingly committed to manage organizational, administrative and economic concerns. Although the relationship between costs, revenues and profits is indeed straightforward for public laboratories, with much larger profitability than many other industries, laboratory professionals are still struggling to survive. While most public hospitals are besieged to reach the break-even and stay afloat, public laboratories only receive a fraction of what they bill, but are largely contributing to generate economic revenues that will ultimately contribute to offset the hospital losses. Whatever profitability analyst would hence see as quite masochistic to kill the golden goose. In this dissertation, we are hence aiming to provide some useful elements to convince decision-makers that laboratory medicine is not a deadwood, but is probably the key for a patient-centered and sustainable future of health care.

**Keywords:** Laboratory medicine; economics; patient safety; quality

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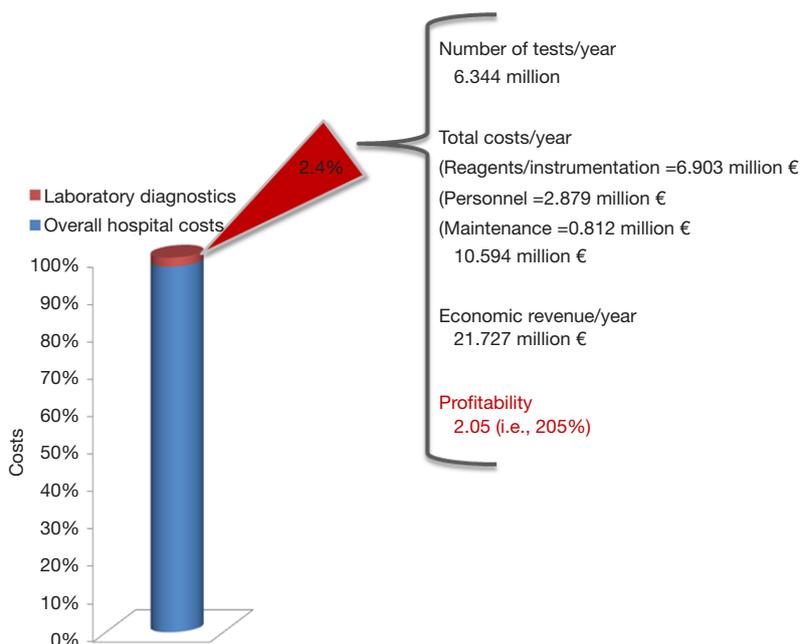
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The landscape of laboratory medicine, within the increasingly complexity of the third millennium healthcare, is multifaceted (1). On one hand, the core of our daily work as laboratory professionals can be straightforwardly summarized in a pivotal sentence captured from the preface of *Tietz's Applied Laboratory Medicine*, "Laboratory medicine plays an integrated role in the diagnosis, prognosis, treatment, and long-term management of disease". Most of us would hence agree that, throughout its long history, laboratory medicine has represented an essential and virtually unavoidable milestone for the clinical decision making. This influential statement is supported by a bout of evidence clearly attesting that laboratory testing generates fundamental, "clinically-usable" information for management of most human pathologies and for the progress of science and medicine (2). There are also some notable (and positive) exceptions to this rule, since laboratory testing is now the one and only means for the diagnosis of certain diseases.

Cardiac troponins testing, by using the novel high-sensitivity immunoassays, is the benchmark for diagnosing non-ST elevation myocardial infarction (NSTEMI), which now represents up to 60–70% of all cases of acute coronary syndromes (3). Molecular testing is also the core for diagnosing monogenetic disorders (4), whilst the personalized treatment of many cancers is now profoundly based on results of specific diagnostic tests (i.e., Her2/neu status in breast cancer) (5). Even diabetes mellitus, one of the most common human disorders, cannot be diagnosed without measurement of fasting plasma glucose or glycated hemoglobin (HbA1c) (6).

Albeit the over millenary history of laboratory medicine has finally contributed to entrench a positive culture on how this clinical branch is perceived by its many stakeholders, a number of challenges are plaguing the efficiency, even the outliving, of our profession. These include increasing complexity and volume management, enhanced demand



**Figure 1** Net profit analysis of a medium-sized European public laboratory.

of care, liability, inappropriateness, professional decline, direct-to-consumer testing, reimbursement policies and, last but not least, shortage of public funding. This last aspect is especially concerning, since over 50% of the budget of a medium-sized public laboratory actually relies on costs for instrumentation and reagents, so paving the way to some important reflections on the future of our discipline.

The first standpoint, that needs to be reaffirmed, is that the overall cost of laboratory testing is a drop in the ocean of the global healthcare expenditure. Recent statistics indicates that laboratory diagnostics contributes for only 1.4–2.8% to the overall balance of most national healthcare services around the world (7). These figures are globally in accordance with those calculated for a medium European public laboratory (*Figure 1*). Nevertheless, when the number of tests and their related costs are compared to the overall economic revenue calculated according to local reimbursement policies, the conclusion is that laboratory diagnostics actually erodes less than 2.5% of the total hospital expenditures, but ensures a profitability exceeding 300%. Obviously, this figure only considers costs for consumable and reagents, but when even total costs are included in the calculation (i.e., personnel and maintenance), the profitability remains well above 200% (*Figure 1*).

According to the prestigious journal *Forbes* (8), the top five most profitable worldwide industries include the generic pharmaceutical industry (30% net profit margin), followed by investment (29.1% net profit margin), tobacco (27.2% net profit margin), internet software/services (25% net profit margin) and biotechnology (24.6% net profit margin). Realistically, public clinical laboratories can hence ensure a net profit margin that is nearly 7-fold higher than whatever other industry, and would actually be approximately 10-fold larger than banks and information technology (both 23% net profit margin). Now, imagine to bring these figures to some experts of human capital management. No doubts, they will remain simply... fascinated. Notably, the impact of some capital costs (i.e., rent or purchase of buildings, national or local taxes) is virtually null for public laboratories, so that it should not surprise that the return of investment will be more favorable than for other industries. Nevertheless, this aspect does not actually overturn the former concept that laboratory medicine is indeed profitable for public hospitals and for the healthcare system as a whole, especially in those countries where public healthcare coverage is lower and/or insurance coverage is vast. To put this simply, laboratory diagnostics is a high-profitably enterprise (9).

Albeit laboratory medicine largely contributes to

accountable care, this discipline has now become a prime target for cuts. While most public hospitals are still struggling to reach a break even and stay afloat, public laboratories only receive a fraction of what they bill, but are largely contributing to generate economic revenues that will ultimately contribute to offset the hospital losses. It is also quite bizarre that some credible, evidence-based efficiency analyses are completely overlooked while planning consolidation policies and scale economy (10). In view of this, whatever profitability analyst would consider quite masochistic to kill the golden goose. This springs to mind the question about why many decision-makers are still placing laboratory medicine in the firing line, by imposing huge economic constraints? Maybe because laboratory budgets are much more transparent than those of other healthcare disciplines [most often expressed in terms of diagnosis related groups (DRGs)], and it is hence much simpler to cut what you can precisely measure? Or maybe because laboratory medicine is still regarded as a commodity by many decision-makers and hospital administrators, and there is poor consciousness (if any...) about the negative consequences on the daily managed care from limiting diagnostic testing? Or, even worse (and this is our responsibility), because we have been unable to promote ourselves, and our essential activity, like many other clinical colleagues more efficiently do?

Last but not least, quality of testing is another foremost aspect (11). Cutting down the budgets of tenders will bring modest instrumentation and poor reagents into the laboratory. Quality does not come for free, and decision-makers should have already learnt that each money spent on quality will bring many savings afterwards as a consequence of a more efficient or timely diagnostic support and a lower risk of harm for the patients.

The role of laboratory managers has consistently changed over the last decades. Clinical and technical background is no longer sufficient, since the time spent in the laboratory is now increasingly committed to organizational, administrative and economic concerns. Although the relationship between costs, revenues and profits is indeed straightforward for *in vitro* diagnostic testing, many laboratory professionals are still struggling to keep their public labs afloat. This is quite inexplicable and unwarranted from both a clinical and a genuinely economic perspective. Our best weapon to reverse this trend is knowledge dissemination. In the era of personalized (laboratory) medicine (12), decision-makers will need a wealth of knowledge that laboratory medicine is not a

deadwood, but is probably the key for a patient-centered and sustainable future of health care.

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## Footnote

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