



The 5-level diagnostic report model as an essential approach for adding value to laboratory testing

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ABSTRACT

Background: Clinical laboratory results have limited value unless they are appropriately analyzed and interpreted. Clinicians may neglect key abnormal laboratory findings because they lack time or sufficient information to adequately analyze the volume of test results received. It is important that the clinical significance of test results is analyzed and communicated appropriately in the report.

Methods: To maximize the utility of laboratory testing and ensure optimal patient care, we developed the 5-level clinical laboratory diagnostic report. This report includes a comprehensive analysis of all test results, reported step by step according to clinical disease system.

Results: The 5-level model includes description, summary, analysis, and interpretation of test results, all of which help clinicians to develop a thorough, deep, and integrated understanding of the clinical significance of large amounts of complicated and scattered laboratory testing results.

Conclusions: The 5-level report model is an effective and efficient approach to supporting clinical diagnosis and improving the value of clinical laboratory results.

1. The current practice of clinical laboratory medicine

With the evolution of evidence-based medicine to personalized and precision medicine, there is an increasing need for laboratory medicine to provide not only accurate results but greater numbers of more complex tests; even more importantly, there is a greater need for analysis, summarization, integration, and interpretation of test results that reflect the patient's physiological, pathophysiological, and biochemical conditions as well as immune regulation and responses. Such analysis and interpretation can provide clear, concise, accurate, and direct support to physicians for clinical decision making. Unfortunately, the current practice of laboratory medicine in general has not kept up with the demand for this type of service, and this service has not yet become the norm. The main reason is that no system for laboratory diagnostic reporting or report matrix comprising description, analysis, summary, and interpretation of test results is now available [1].

Insufficient and inaccurate laboratory test result reports markedly compromise the accuracy, efficacy, and clinical utility of laboratory tests. It has been reported that up to 45% of laboratory results are inappropriately reported or interpreted in emergency medicine and approximately 25–60% of abnormal laboratory results are neglected by physicians because they lack sufficient information about the test or its interpretation [2]. Laboratory support is becoming increasingly more

necessary for clinicians, especially for applications of precision medicine [3]. Professional interpretation of results by laboratory specialists is particularly needed for complex reports comprising several different types of tests [4].

2. How to improve the current situation

2.1. Developing a laboratory diagnostic report model

How can we fundamentally solve the problem of inadequate or inaccurate laboratory results reporting? Laboratory test results typically reflect pathological and clinical context at multiple levels and multiple dimensions. Simply reporting the result as normal or abnormal isn't sufficient to meet the clinician's need for reliable, integrated information on which to make patient care decision. What is needed, instead, is the extraction of major findings from a large number of complex test results and their presentation in a format that is clinically useful and relevant. The question is how to clearly explain and interpret abnormal test results to meet the needs of clinical practice.

It seems clear that interpretation of test results in conjunction with clinical findings is a minimum standard. We propose a model whereby laboratory physicians systematically analyze, summarize, integrate, consolidate, and interpret the constellation of clinical laboratory test

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results often generated for a specific patient in combination with clinical findings and present them in an accessible format to the clinicians. Based on our experience and practice, we believe that laboratory results reporting stratified into levels combining objective results with pathologic findings, other associated laboratory findings, clinical findings, and changes over time is a practical approach to solving this complex problem. Therefore, we developed a disease-centered 5-level model for laboratory diagnostic test result reporting.

2.2. The 5-level laboratory diagnostic report

The 5-level laboratory diagnostic report we propose is summarized below. For level 1 laboratory diagnostic reporting, the test result is reported directly to the designated clinicians as quickly as is consistent with accuracy and reliability. This type of test result reporting is the model most widely used now in clinical laboratories. The level 2 laboratory diagnostic report includes morphological abnormalities, structural abnormalities, composition changes, pathogens, and other abnormal results, in conjunction with clinical context to provide a descriptive diagnostic conclusion. In the level 3 diagnostic report, a group of laboratory test results related to a type of disease is analyzed and summarized. The association of these abnormal results with pathophysiological status, biochemical changes, and immune regulation and responses is systematically summarized and a conclusive report is issued. The level 4 laboratory diagnostic report is comprehensive, including not only the contents of the level 1–3 reports but also a comprehensive analysis interpreting the associations between the test results and the diagnosis and differential diagnosis as well as the complications of the implicated disease(s) with their potential involvement of multiple organs and multiple systems. The level 4 report is both interpretive and conclusive. The level 5 laboratory diagnostic report details dynamic changes in laboratory test results. The changes in test results over a period of time are plotted and presented for correlation with disease status, therapeutic response, and prognosis. These 5-levels of laboratory diagnostic report, reflecting the complex relationships among test results, pathological changes, clinical status, therapeutic effects, and disease progression during the course of treatment [5], are illustrated in Fig. 1.

2.3. Components and pattern of the 5-level laboratory diagnostic report

The 5-level diagnostic report consists of three parts. Part 1 includes general patient information and basic information on diagnosis and treatment. Part 2 lists laboratory tests and results. Part 3 comprises the laboratory diagnosis or conclusion, including the description of morphological abnormalities, structural abnormalities, composition changes, and pathogens and the comprehensive analysis and interpretation of these abnormal results and their dynamic changes over time to reflect the patient's physiological status, biochemical metabolism, immune regulation and response, and pathophysiological changes.

2.4. Examples of the 5-level laboratory diagnostic report

In actual practice, the 5-level laboratory diagnostic report has begun to be introduced into some hospitals. In a general hospital in Beijing, the itemized and the comprehensive diagnostic reports of hemato-poietic and lymphoid tumor have been applied and warmly welcomed by clinicians. Similar laboratory diagnostic reports have been implemented or are in development for other common diseases. The type of report model is decided by the physicians on their requests and may be recommended by the pathologist if indicated by the patient's condition and clinical needs. The time interval required to issue a 5-level diagnostic report depends on the clinical needs and the time needed to complete the required tests and analyze the results. Here we present details of the 5-levels of diagnostic report.

2.4.1. The level 1 report

The level 1 report, meaning laboratory test result, is released directly to clinicians to meet their immediate needs. The clinical laboratory ensures the accuracy and reliability of the results and reports them to the clinicians as soon as possible (Fig. 2).

2.4.2. The level 2 report

The level 2 diagnostic report with pathologic findings is also reported directly to clinicians for their patient care needs. This report of abnormal results with brief descriptions of the findings provides direct evidence to clinicians for a clinical diagnosis (Fig. 3).

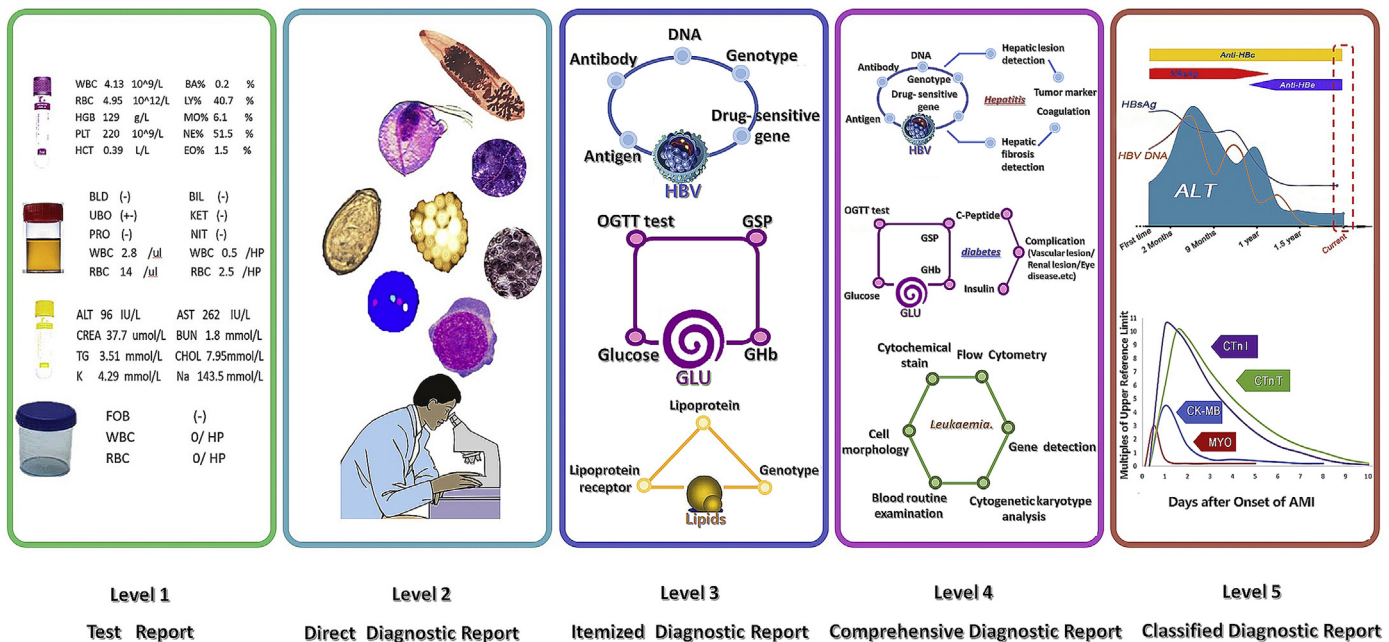


Fig. 1. The contents of each level of the 5-level laboratory diagnostic report.

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