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Monitoring the patient response as an alternative to commercial negative quality control in infectious serology

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ABSTRACT

Background: Traditional internal quality control schemes for qualitative infectious serology mostly rely on the use of commercial positive and negative quality control materials. However, with respect to the negative control, target values provided by the manufacturer are often poorly defined and non-commutability of the commercial materials further complicates correct interpretation of control results.

An alternative quality control procedure using the median patient seronegative response is presented.

Study design: Daily patient median responses were calculated for our Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C antibody and HIV antigen/antibody test systems. Because of the low prevalence of these viruses in our area, most patient responses are negative. A minimum of 5 patient samples per day was required to generate a stable daily median. Control limits were calculated and daily patient medians were plotted against commercial quality control results.

Results: Commercial negative controls and daily patient medians mostly behaved in the same way. Nevertheless, for the Hepatitis B surface antigen test, patient medians frequently exceeded the calculated control limit in contrast to commercial quality controls. This confirms that target ranges provided by the manufacturer are not always adequate. Moreover, an important matrix-related interference occurred on our HIV antigen/antibody test system and correct interpretation was only possible using daily patient median results.

Conclusion: Monitoring the daily patient median response can be a valuable alternative to traditional commercial negative quality control. It's easy to perform, cost-free, provides additional information with respect to matrix effects and allows for the establishment of well-defined control limits.

1. Background

Practical guidelines regarding the internal quality control of qualitative infectious serology tests are scarce [1]. In contrast to other fields of laboratory medicine, such as clinical chemistry or immunochemistry, there are no elaborated theoretical models available from which suitable quality control strategies can be derived. The most common practice used for monitoring the test performance is the quantitative follow-up of the signals obtained with commercial positive and negative quality control materials [2]. However, with respect to the negative control, there are two important intrinsic disadvantages related to the use of such commercial quality materials.

Firstly, the purpose of the negative control is to quantify the 'noise', which can be regarded as a measure of the aspecific, matrix-induced response. However, in order to obtain maximum stability and good solubility, matrices of commercial controls are thoroughly altered, to an extent that they are no longer comparable to the matrices of native patient samples. By consequence, the commutability of such negative controls cannot automatically be assumed [3,4].

Secondly, the target values that come with these commercial materials are often poorly defined. The negative controls are supposed to generate signals in the range below the cut-off. However, if we do not know how the signal of the commercial control relates to the signals of our seronegative patients, we cannot define an appropriate limit for the quality control that avoids an increased risk of reporting false positive results on our patient samples [5].

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2. Objectives

We present a novel approach to monitor the performance of qualitative infectious serology tests that does not rely on the use of commercial negative quality control materials. This alternative method uses the daily median of the measurement signals of patient samples [6], a parameter that can easily be calculated by most of the current laboratory information systems. The value of monitoring the patient median response was evaluated with our Hepatitis B surface antigen (HBsAg), Hepatitis B core antibodies (HBcAb), Hepatitis C antibodies (HCV) and HIV antigen/antibodies (HIV) test systems.

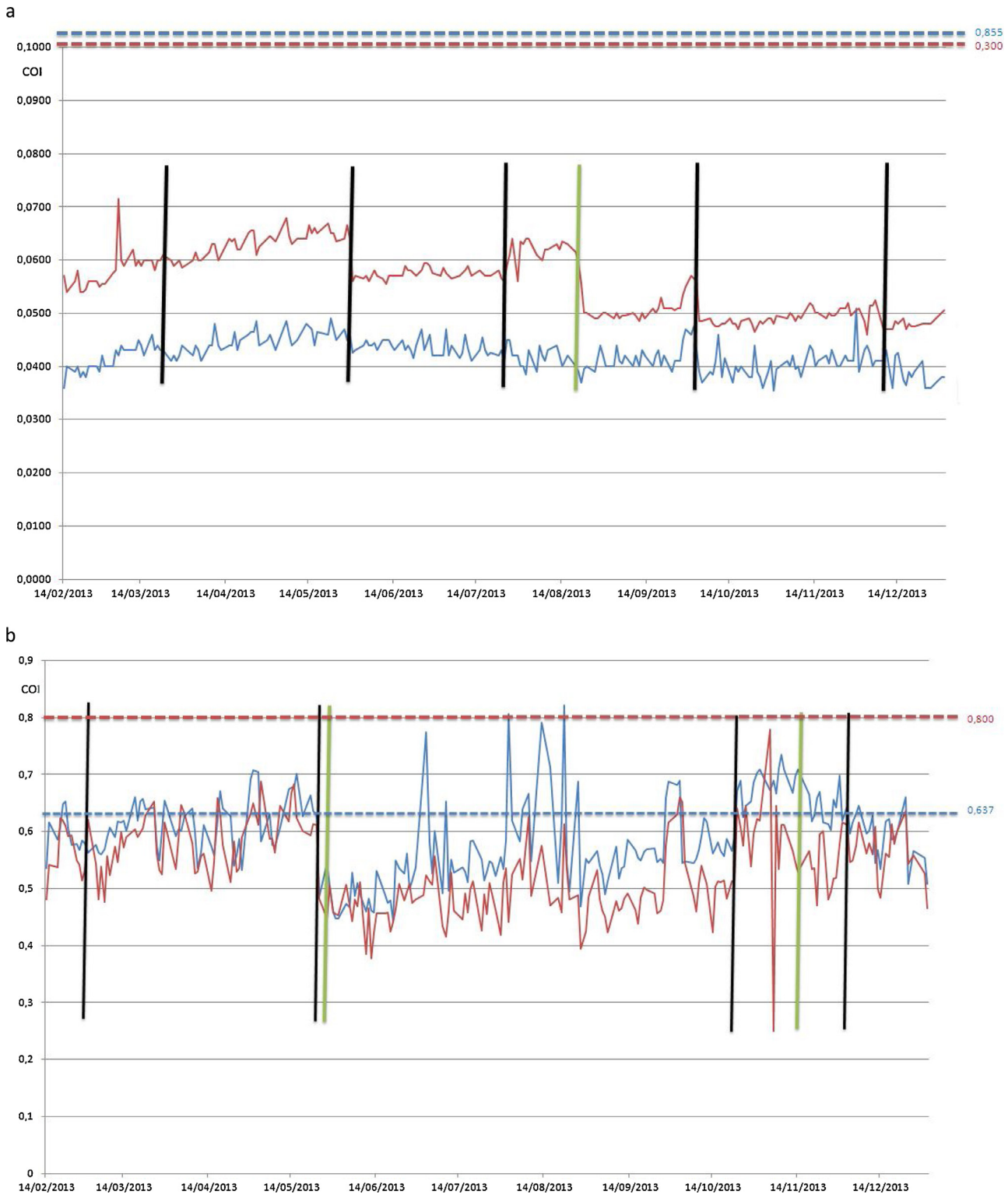

Fig. 1. Chronological overview of the commercial negative control results (red lines) and daily patient medians (blue lines) with their corresponding limit values (dotted lines) for HCV (1a), HBsAg (1b), HBcAb (1c) and HIV (1d). Reagent lot changes are indicated with black bars, QC lot changes are indicated with green bars. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)