

Biological Factors and the Revelar™ Test

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David Chernoff, MD

A diagnostic test involving human measurement involves factors that can affect the consistency of the measurement. The Revelar device measures mixed aldehydes as an indicator of oxidative stress and free radical activity. When measured in rapid sequence, the Revelar device has shown itself to be consistent—in fact, it is within the range of many laboratory medical devices. However, any effort to measure the effect on a human being over time of certain phenomena, such as the effect of antioxidants, is affected by something known as “biological noise.”

Biological noise creates variability in any test involving human beings; it comes into the picture in a variety of ways, including such things as diurnal patterns, exercise, sleep, gender, age, and even race. Other behaviors, including eating and drinking, also can affect diagnostic device readings. Since this is a typical issue in developing a human diagnostic device, there are commonly accepted approaches to accounting for biological noise so that the device measurements are relevant and useful.

The first step is to conduct research to identify the effects on Revelar of biological noise. There are three elements to this:

- First, Pulse has conducted baseline studies to determine behavior of the device in normal people under controlled circumstances. Factors such as effect of exercise, sleep and diurnal variations have been identified.
- Second, we have identified through our research and via members of the Pulse SAB the key factors endogenous and exogenous factors that further contribute to biological noise. For example, cholesterol levels are reactive to lipids and oxidative stress tends to react in a similar fashion. Therefore, consideration of the effect of a fatty meal is a relevant factor. Other factors we will consider include: (1) age, (2) gender, (3) existence of certain disease states such as COPD's and diabetes; (4) smoking; and (5) consumption of alcohol. We will conduct studies of statistically relevant samples to identify effects of the above factors on Revelar readings.
- Third, within the next year, Pulse will market the Revelar system to a large number of distributors and data will be collected and organized around the above factors so that Pulse can review the effects of these biological noise factors on the mixed aldehyde readings.

The second step is to implement measures so that the biological noise does not interfere with the purpose of the test, ie, to test the effect of supplementation. As an initial matter, Pulse will develop instructions for consumers that will identify best practices for attaining meaningful results and the effects of unavoidable factors on the results.

I previously served for ten years as Medical Director of Chiron, a world leader in blood screening technologies. The development of data and algorithms to address biological noise were routine elements of product evolution at Chiron. For example, when we initially developed our HIV screening assay, there were significant variations within the positive and negative outcome categories. By accounting for a number of recurring factors, we were able to diminish the effects of these factors and develop an extremely useful diagnostic test.

Similarly, the process by which we are engaging at Pulse will take what is already a highly consistent test from a coefficient variation standpoint and will ensure that biological factors will not interfere with the development of meaningful results for the nutrition industry.