

*Pre-analytical:* Handling by staff during separation is another variable, whether centrifuged under standardized conditions or not. Time in contact with blood cells, time out of the fridge, the ambient temperature that day, and so on, are some of the other variables here too, obviously with effects very dependent on the analyte or analytes being measured for Reference Ranges.

*Analytical:* And then there is the method itself. Is it consistent or does it vary some, either a little or a lot? Does it depend on standardization or not, and if so, does the standard have to be reconstituted?

So, this simple example shows that variation is a feature of all such measuring systems, with everything from the patient to the test causing some element of variation. In fact variation is a feature particularly associated with human beings. We are not consistent and will be influenced by moods, caused by a myriad of factors – emotional, financial, stress-related, and others. Some may say that analytical systems are also influenced by moods, but let's leave not consider that for the moment.

The fact is that your final Reference Range or Ranges will include all those variations, and rightly so. Those are the variations that will be relevant when you collect, transport and analyse a patient sample.

But here, in this section, we are really concerned with analytical variation, the changes that take place when you perform repeat measurements, whether on control or patient samples.

Such variation is more accurately called dispersion, a term that describes how dispersed or spread out such results are. It should be appreciated that this result dispersion is natural and inevitable. Many years ago there was an attempt to send out chemistry lab results as a range rather than a single figure, to try and reflect the uncertainty of the measurement. Needless to say it was not popular with doctors when the lab report told them “your patient's sodium is between 136 and 140 mmol/l”! This may have been a more honest reporting system but doctors want a figure, say 138 mmol/l for the sodium example above, rather than a range.

As for patients, so for control samples. The results obtained from your measuring system will vary for your control serum or urine or blood and your function here is to differentiate between normal and acceptable variation – perfectly natural dispersion - and abnormal variation - when something is wrong with either the sample or the test itself. And that is the reason you use statistics - to give you information on which to base your decision.

Now for the thorny issue of what should be done with package insert ranges. Throw them out. They will have been generated by a specific method in several different labs situated in a foreign country. The limits printed will thus include variations between different labs with different conditions to yours, and will almost certainly be too wide for any