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Pneumatic Tube System Validation

Blood-based vs Vital**QC**

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A Better Way to Validate Your PTS

Pneumatic tube systems are traditionally validated for blood sample transport by measuring hemolysis on a selection of samples before and after transport. In most cases, this approach will not provide meaningful results because the sample size is insufficient.

A blood-based validation approach often relies on a selection of 10-20 samples per line. However, like many health-outcome variables, the distribution of clinical blood hemolysis is both wide and skewed (Figure 1). As a result, a selection of a few dozen samples is insufficient to draw meaningful conclusions.

As an example, for the distribution shown in Figure 1, a statistical analysis[1] shows that identifying a change of 10% would require at least 200 samples. In general, *many hundreds of samples are needed to draw meaningful conclusions about blood hemolysis caused by PTS transport*.

Motryx's Vital**QC** models are developed using thousands of clinical blood samples paired with vibration measurements and do not suffer from a lack of statistical significance. Vital**QC** models utilize the full population distribution to validate PTS lines, making its projections statistically significant and grounded in observations. For this reason, Vital**QC** provides results that more meaningful reflect reality than a typical blood-based validation does.

Blood-based validations are also highly susceptible to error from preanalytical hemolysis caused by poor patient health or a bad blood draw. Vital**QC** models, on the other hand, are not susceptible to individual preanalytical errors. They are subject to statistical uncertainty inherent in the modelling, but Motryx's testing shows that this uncertainty is often less than the uncertainty introduced through preanalytical errors.

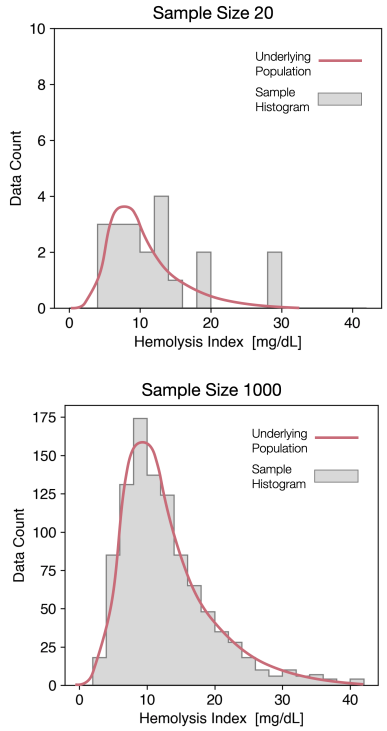

Figure 1: Hemolysis Index of a random selection of blood samples from a lognormal distribution. Notice how a small selection of samples (top) does not accurately reflect the underlying population distribution. Many samples (bottom) are needed to meaningfully represent the true population distribution.

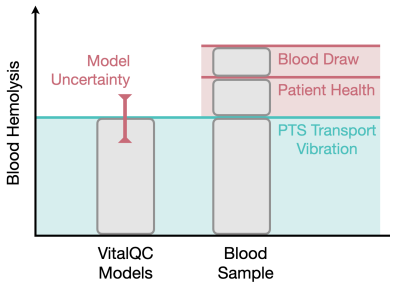

Figure 2: Preanalytical uncertainty in blood-based validations often outweighs statistical uncertainty in VitalQC models

[1] Standard t-test modified for lognormal distributions, using 90% power and 5% significance. See Equation 4 in *O'Keeffe, A.G., Ambler, G. & Barber, J.A. Sample size calculations based on a difference in medians for positively skewed outcomes in health care studies. BMC Med Res Methodol 17, 157 (2017)*