

## Vitamin K External Quality Assurance Scheme Sample Stability Validation Document

### Background

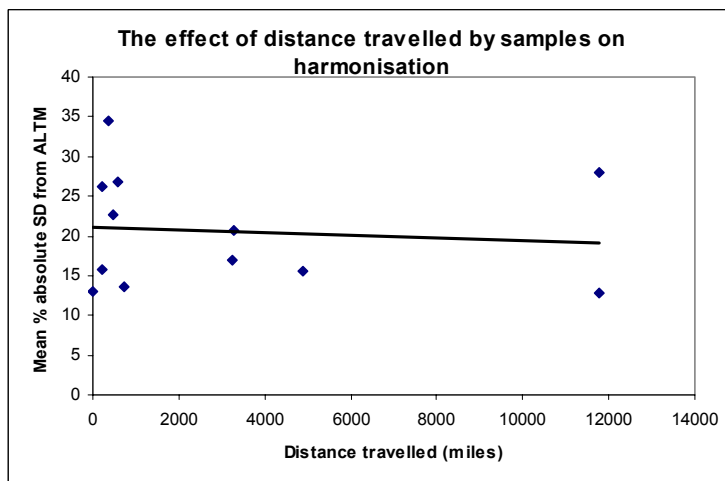
Sample stability in external quality assurance underpins the validity of the entire scheme. Any result alterations due to deterioration of the analyte or sample matrix during transit may adversely effect results. This has two possible consequences; 1) A group may appear to have performed poorly when they have not, 2) Overall variance among groups appears to be greater making the method appear less accurate or precise than it actually is.

KEQAS samples are distributed by courier and can take up to eight days to arrive if they become impeded by customs authorities. Typically they only take a few days, for samples sent during 2007 the average shipping time was 43.2 hours (range = 24-96 hours, n=15). Samples are not shipped on ice but are left at the ambient temperatures they are exposed to during transit. Therefore investigation of possible sample deterioration during transit is an essential validation step for KEQAS.

### Investigation 1: Comparison of laboratory performance with distance travelled by samples.

**Method:** Approximate distance travelled was plotted against each group's mean absolute standard deviation from the all laboratories trimmed mean (ALTM).

### Results:

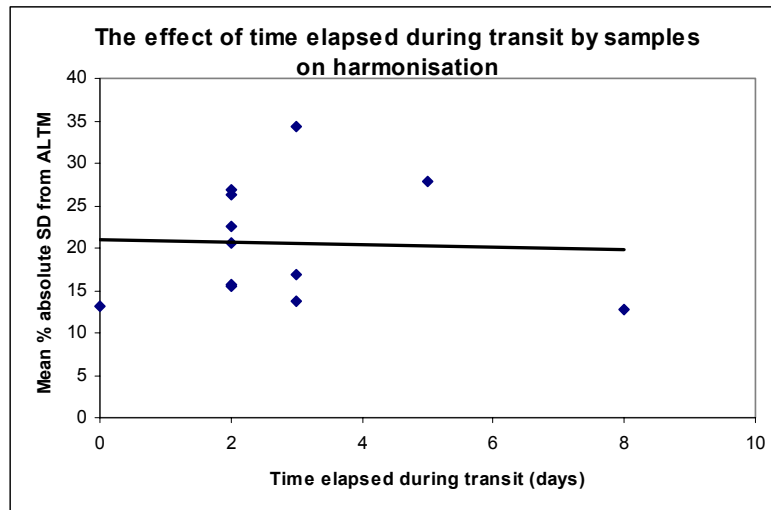


**Conclusion:** Distance travelled does not adversely effect laboratory performance.

**Investigation 2:** Comparison of laboratory performance with time spent by samples in transit.

**Method:** Time in transit was plotted against each group's mean absolute standard deviation from the all laboratories trimmed mean (ALTM).

**Results:**



**Conclusion:** The amount of time spent in transit does not adversely effect laboratory performance.

**Investigation 3:** Simulation of a two-week long sample transit.

**Method:** Three serum vitamin K QC 05/05 samples (1.1ml volume) were packed as usual according to SOP VKQ-001 and left at ambient temperatures in the laboratory for two weeks. The samples were then promptly frozen at -20°C until they were once again thawed for analysis.

**Results:** Six analyses were carried out.

Sample 1: 0.61 and 0.62 µg/L

Sample 2: 0.55 and 0.57 µg/L

Sample 2: 0.61 and 0.59 µg/L

Mean = 0.59 µg/L

QC 05/05 Westguard characteristics:

Mean = 0.63 µg/L

95% CI = 0.50-0.77 µg/L

17 samples analysed

**Conclusion:** There was no significant deterioration of the samples during a two week sample transit simulation.