

## Scientific Test Summary - Sedimentation

### Background

The new FlexiQuot™ cryo tubes shall be tested for their ability to provide homogeneous samples: It shall be investigated, if the larger volume of liquid sample in the FlexiQuot™ would lead to sedimentation of small or large molecules in the tube during storage at various temperatures, in particular during freezing. It is an important parameter to establish that the five segments of FlexiQuot™ would contain homogeneous sample aliquots.

### Hypothesis

It is not expected that samples stored in and aliquoted by means of cracking the FlexiQuot™ into its segments will result in inhomogeneous samples.

### Testing

An exhaustive series of tests was performed to address potential sedimentation of small and large molecules in a liquid sample in FlexiQuot™. As representative test solution human plasma was used. To test for potential sedimentation of large molecules, the concentration of the biomarker IP10 was measured by ELISA; to test for potential sedimentation of small molecules, the concentration of electrolytes (such as glucose and sodium) in plasma were measured on the ABL 800 Flex. Concentration measurements were performed after sample storage in FlexiQuot™ for 24 to 48 hours at different temperatures (4, minus 20, minus 80 and minus 196 degrees Celsius), and with the tubes in horizontal and vertical position. The same test liquids from a standard cryo tube served as control.

### Conclusion

The test series confirms that aliquotation with FlexiQuot™ results in homogeneous samples and no sedimentation can be observed in any of the various tested subgroups at any of the applied storage temperatures. If any sedimentation were present in FlexiQuot™, an increase of concentration down through the segments FlexiQuot™ would be detected. The performed tests show clearly that this is not the case: Neither small nor big molecules sediment over the length of the new FlexiQuot™ tube, all concentrations were found to be homogenous and just subject to standard variations.

In detail, it was determined that in the plasma pools tested:

- Electrolytes, representing small molecules, show no sedimentation in FlexiQuot™.
- The biomarker IP-10, representing large molecules, shows no sedimentation in FlexiQuot™.

The test series further confirmed that FlexiQuot™ is easy to store and thaw. There were no uncontrolled cracks observed because of the new kink design. The workload is clearly reduced by not having to perform four repetitive movements, but only one (transferring the bulk solution for the test into one FlexiQuot™), which also reduces the risk of work injuries.