

Scientific Test Summary - Quality

Background

FlexiQuot™ shall be tested for the possibility of sample contamination with plastic particles from the cracking of the tube at the kinks when separating the FlexiQuot™ segments. If any contamination with plastic particles occurs, it should have the highest occurrence when FlexiQuot™ is frozen at a temperature where the risk of porosity is at maximum (in this case minus 80 degrees). Also the FlexiQuot™ tool shall be tested for presence of plastic particles after performing the cracking operation. Further the shedding of plastic particles during cracking of FlexiQuot™ with the tool will be “provoked” by twisting motions with the tool during cracking. The test shall compare FlexiQuot™ to standard commercial cryo tubes.

Hypothesis

Generally, a larger amount of particles is expected in FlexiQuot™ because of (1) the larger surface area compared to a standard cryo tube and (2) the fact that the current FlexiQuot™ is a prototype and not yet manufactured under industrial conditions with full purity requirements. Contamination of the FlexiQuot™ tool with plastic particles is expected when cracking FlexiQuot™.

Testing

Several test series of FlexiQuot™ were filled with coloured liquid and stored at minus 20 and minus 80 degrees Celsius for 24 to 48 hours. The frozen test tubes were cracked with the FlexiQuot™ tool. The cracking motion was either performed with or without trying to provoke shedding of plastic particles from the kink. The sample was thawed, centrifuged and the resulting pellet and the supernatant were examined for the presence of particles visually and by microscopy. In all settings microscopic particles can be found in the pellet of all sample containers. FlexiQuot™ is in greater exposure to particles than standard cryo tubes. The FlexiQuot™ tool is contaminated with particles from the FlexiQuot™ cracks.

Conclusion

No identification of plastic particles was possible despite repeated procedures.

With regard to microscopic particles we found as follows:

- Unidentified particles in the water solution, in FlexiQuot™ and in standard cryo tubes were found. To identify the particles would require a sterile FlexiQuot™.
- Higher incidence of particles in FlexiQuot™ than standard cryo tubes were found, which is expected because of the bigger surface area of FlexiQuot™, but also because the current FlexiQuot™ is a prototype, which is produced in a special workshops, but without the need of purity inside the tube as opposed to the standard commercial cryo tubes, which are industry-produced with full purity requirements.
- The FlexiQuot™ tools can be contaminated by particles from the FlexiQuot™ cracks. Also this is considered most likely due to the current non-sterile manufacture of FlexiQuot™ without purity requirements.

In general, FlexiQuot™ was found to be a valid alternative to the standard cryo tube with major additions: It is easy to handle and a sensible solution to storing a sample in one tube, while giving full flexibility to the choice of analyses to perform on various aliquots of the sample.