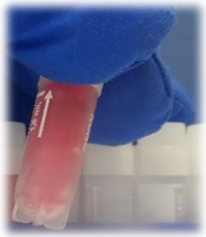
Object of investigation

Resealable packaging material for the preservation and (long term-)storage of liquid biological samples, e.g. cellsuspensions, blood, blood components or DNA.



Requirements:
Tightness against
- sample contamination
- contamination of the environment

State of the art / Problems

- Lack of standardized methods or test procedures for tightness assessment
- Existing methods far away from real-world storage- and transport conditions
  - ➢ No comparability for the end user

High demands on packaging material

I. Pressure differences & temperature changes
II. Direct contact to dry ice (saturated CO_2-atmosphere)
III. Direct contact to liquid nitrogen

Developed methods

I. Gravimetric leak tightness test
II. Tightness against CO_2 after dry-ice shipping
III. LN_2-tightness after contact with liquid nitrogen

I. Gravimetric leak tightness test

Examines the transport safety of biological samples by evidence of tightness of the primary packaging

Scenario

Verification of the tightness of primary packaging in accordance with

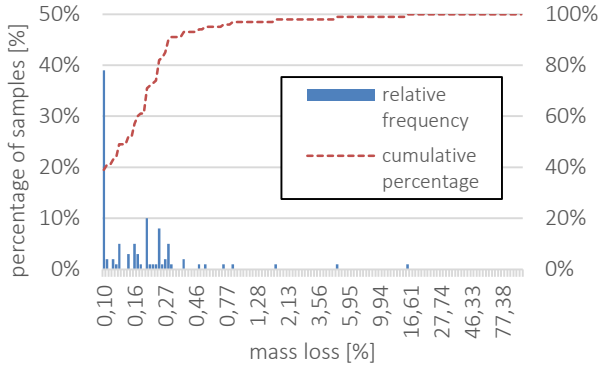
- IATA
  (International Air Transport Association)
- ADR
  (European Agreement concerning the International Carriage of Dangerous Goods by Road)

Parameters

- Pressure difference of 95 kPa between sample and ambient atmosphere
- Temperature range −40 °C to +55 °C

Result

Quantitative statement of mass loss of the primary packaging in the required pressure and temperature range by means of relative frequency and cumulative percentages.



II. Tightness against CO_2

Proves the tightness against the penetration of CO_2 into the packaging material.

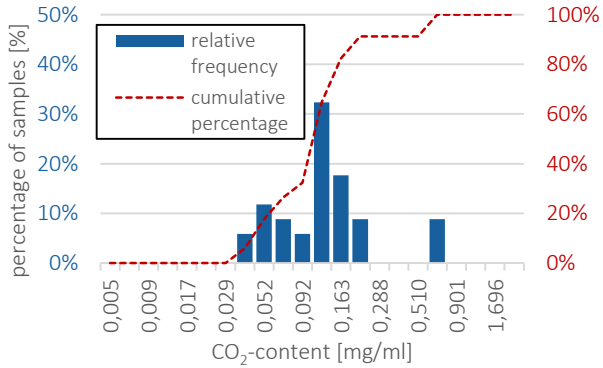
Scenario

Transport of frozen samples on dry-ice leads to saturated CO_2-atmosphere.

- In case of leakage CO_2 penetrates the packaging
  - ➢ Accumulation in the headspace
- CO_2 diffuses after thawing into the liquid sample
  - ➢ Reaction to carbonic acid
- Changes in the pH value:
  risk for the stability of the samples
  - ➢ Impact on analyses

Result

Quantitative statement to the absorbed mass of CO_2 depending on storage or shipping period by means of relative frequency and cumulative percentages.

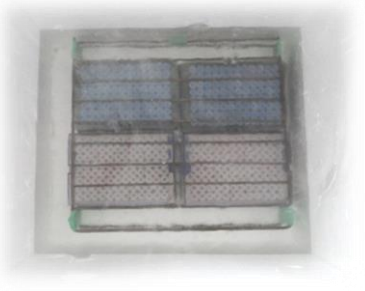


III. Tightness against LN_2

Evidence of tightness against penetration of liquid nitrogen into the packaging material.

Scenario

- Packaging material is immersed into liquid nitrogen for fast freezing
- Packaging material is stored in the liquid phase of N_2
- Direct contact of the packaging material with LN_2 while filling the tank.



Risks

- Contamination of the environment
- Cross contamination of the samples if several packaging are leaking
- Bursting of the packaging during rewarming
  - ➢ Dangerous for employees
  - ➢ Irretrievable loss of the sample

Result

Qualitative statement to the performance of the packaging material after contact to respectively storage in liquid nitrogen.

Advantages of our methods

- ✓ Assessment under real-world conditions
- ✓ Extensive, quantitative evaluation of obtained test results
- ✓ Proof of tightness by an independent institute

Further services

Thermal cycles / Aging-Tests

- Artificial aging of the packaging material by repeated freezing and rewarming
- Heating rate up to 60 K/min
- Freezing rate up to −100 K/min
- Temperature range −180 °C to +40 °C

Bursting pressure test

- Determination of the inner pressure until component failure
- Temperature range −180 °C to +40 °C

Nitrogen permeation test

- Determination of the permeation rate of N_2
- Temperature range −180 °C to +40 °C

Leaching studies

- Proof of leaked substances of the primary packaging material after extraction
- E.g. amides, esters, aldehydes or fatty acids

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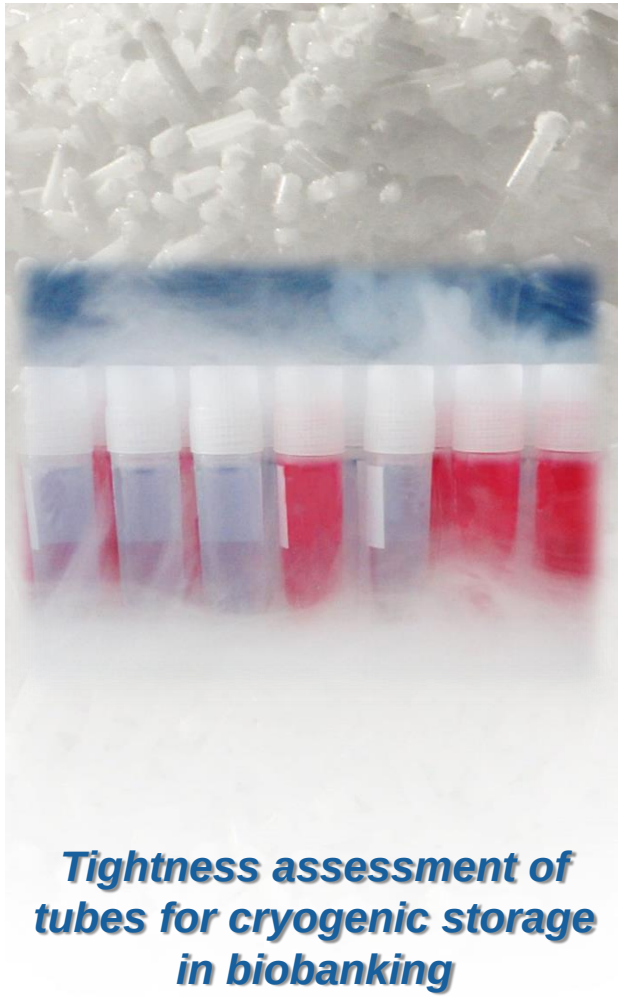

Tightness assessment of tubes for cryogenic storage in biobanking

ILK Dresden