

# DIN 13279:2022-05 (E)

## Biotechnology - Requirements for sample containers for storing biological materials in biobanks

---

<b>Contents</b>		<b>Page</b>
Foreword .....		3
Introduction .....		4
1	Scope .....	5
2	Normative references .....	5
3	Terms and definitions .....	5
4	Requirements .....	8
4.1	Requirements for the manufacturer .....	8
4.1.1	General .....	8
4.1.2	Product specification .....	9
4.2	Requirements for the sample container .....	9
4.2.1	General requirements .....	9
4.2.2	Suitability for storage conditions and storage duration .....	9
4.2.3	Suitability for transport .....	9
4.2.4	Suitability for the technical methods used .....	10
4.2.5	Suitability for biological material .....	10
4.2.6	Leak-tightness of the sample container .....	11
5	Test methods .....	11
5.1	General .....	11
5.2	Performance of tests and scope of testing .....	11
5.3	Post-market surveillance .....	12
5.4	Testing stability under storage conditions .....	12
5.5	Testing leak-tightness .....	13
5.6	Testing for the release of substances from the sample container material .....	13
5.7	Testing for adsorption or absorption of sample components from the material of the sample container .....	13
5.8	Testing for changes in the shape and mechanical properties of the sample container .....	14
5.9	Test report .....	14
6	Labelling .....	15
6.1	Identifiability and traceability .....	15
6.2	Testing the labelling .....	15
Annex A (normative)	Recommended test method for testing the leak-tightness of sample containers made of plastic .....	16
A.1	Leak-tightness test .....	16
A.2	Storage temperatures between -40 °C and 55 °C .....	16
Bibliography .....		17