

# ISO 20070:2025-12 (E)

## Biotechnology - Biobanking - Requirements for primary containers for storing biological materials in biobanks

---

### Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Requirements</b> .....	<b>3</b>
4.1 Requirements for the manufacturer.....	3
4.1.1 General.....	3
4.1.2 Product specification.....	4
4.2 Requirements for the primary container.....	4
4.2.1 General requirements.....	4
4.2.2 Suitability for storage conditions and storage duration.....	5
4.2.3 Suitability for transport.....	5
4.2.4 Suitability for the technical methods used.....	5
4.2.5 Suitability for biological material.....	6
4.2.6 Leak-resistance of the primary container.....	7
<b>5 Test methods</b> .....	<b>7</b>
5.1 General.....	7
5.2 Performance of tests and scope of testing.....	7
5.3 Testing stability under storage conditions.....	8
5.4 Testing leak-resistance.....	8
5.5 Testing for the release of substances from the primary container material.....	8
5.6 Testing for adsorption or absorption of components of the biological material by the material of the primary container.....	9
5.7 Testing for changes in the shape and mechanical properties of the primary container.....	9
5.8 Test report.....	9
<b>6 Labelling</b> .....	<b>10</b>
6.1 Identifiability and traceability.....	10
6.2 Testing the labelling.....	10
<b>Annex A (normative) Test method for testing the leak-resistance of primary containers made of plastic</b> .....	<b>11</b>
<b>Annex B (normative) Layouts for SBS microplate format-based racks</b> .....	<b>13</b>
<b>Bibliography</b> .....	<b>16</b>