

ISO 6717:2021 (E)

In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

Contents

	Foreword
1	Scope
2	Normative references
3	Terms and definitions
4	Materials
5	Filling capacity/draw volume
6	Graduation lines
7	Design
8	Construction
9	Sterility and special microbiological states
10	Additives
11	Marking and labelling
Annex A	(normative) Tests for filling capacity and/or graduation lines for non-evacuated specimen container
A.1	Reagents and apparatus
A.2	Test conditions
A.3	Test procedure
A.4	Test criteria
Annex B	(normative) Draw volume test for evacuated containers
B.1	Reagents and apparatus
B.2	Test conditions
B.3	Test procedure
B.4	Test criteria
Annex C	(normative) Test for leakage from the closure of a container
C.1	Reagents and apparatus
C.2	Test procedure for non-evacuated containers intended for storage above 0 °C
C.3	Test procedure for non-evacuated containers intended for storage at 0 °C or below
C.4	Test procedure for evacuated containers
C.5	Test criteria
Annex D	(normative) Test for the robustness of a container that is intended for centrifugation
D.1	Reagents and apparatus
D.2	Test conditions
D.3	Test procedure
D.4	Test criteria