General Information

MiniCollect® Tubes are plastic, non-evacuated, non-sterile low sample volume tubes with integrated collection devices. The closure is color coded to identify the additives which are present in varying concentrations depending on the tube type and stated volumes.

Components

The tube consists of the following components:

- MiniCollect® Tube: With an integrated scoop for easier blood collection.
- Cap with pierceable membrane
- Additive
- MiniCollect® Carrier Tube
- Label with filling mark(s).

Component	Material
MiniCollect® Cap	PE TPE
MiniCollect® Tube	PP
MiniCollect® Carrier Tube 13/75mm (only for MiniCollect® Complete)	PET
Tube label	PP

Cautions / Precautions

- Do not use tubes if foreign matter is present.
- Handle all biological samples and blood collection devices according to the policies and procedures of your facility.
- Obtain appropriate medical attention in the case of any exposure to biological samples.

- Check all tubes to verify appropriate product and shelf-life before use. Do not use tubes after the expiration date.
- It is the laboratory's ultimate responsibility to verify that a change from one tube to another does not significantly affect analytical results obtained from patient samples.
- Single use only.

Sterility

Not applicable, since the product is not sterile.

Labelling

Symbol	Title of symbol	Norms / Directives	Tube label	Rack label	Inner carton label	Outer carton label
☒	Catalogue number	EN 980 ISO 15223-1	X	X	X	X
☒	Batch code	EN 980 ISO 15223-1	X	X	X	X
☒	Use-by date	EN 980 ISO 15223-1	X	X	X	X
☒	Communauté Européenne	Directive 98/79/EC	X	X	X	X
	Do not re-use	EN 980 ISO 15223-1	X	X	X	X

☒	In vitro diagnostic medical device	EN 980 ISO 15223-1	X	X	X	X
	Temperature limitation	EN 980 EN ISO 15223-1	-	X	X	X
☒	Consult instructions for use	EN 980 EN ISO 15223-1	-	X	-	-
☒	Manufacturer	EN 980 EN ISO 15223-1	-	X	X	X

UDI attributes

For the UDI-marking the GS1 UDI barcode is used. A GS1-128 barcode is printed on the carton label and a GS1 DataMatrix is printed on the rack label.

Both codes consist of:

(01) GTIN of the packaging unit, (17) expiration date, (10) batch number

1. GTIN (Global Trade Item Number) of the packaging unit – 14 digits (01)
2. Expiration date – 6 digits (YYMMDD) (17)
3. Batch number – 8 characters (10)

Labeling the product with a UDI Barcode is only required by the US-FDA so far.

Packaging

MiniCollect®		MiniCollect® Complete	
Packaging	Amount of tubes	Packaging	Amount of tubes

Rack	50 Tubes	Rack	50 Tubes
Inner box	500 Tubes (= 10 racks)	Inner box	500 Tubes (= 10 racks)
Outer box	2000 Tubes (= 4 inner boxes)	Outer box	2000 Tubes (= 4 inner boxes)

Shipping stability - DROP TEST

The function of the package was verified in a drop test under transport conditions. Results: The outer boxes and the inner boxes did not tear or break and the product was not damaged. The packaging has passed all requirements of the drop test.

Recommended Order of Draw (based on CLSI GP42-A6)

If multiple specimens are to be collected, including EDTA specimens, the EDTA specimen is drawn first to ensure adequate volume and accurate haematology test results. Specimens with other additives are collected next; serum specimens are collected last.

1. EDTA
2. Heparin / Heparin Sep
3. Glycolytic inhibitor tubes
4. Serum / Serum Sep

Literature

GP42-A6 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Sixth Edition.