



Technical standards
for
supply related samples
for NAT testing

Tekniske standarder for
leveranserelaterte prøver
til NAT-testing

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1.0 Purpose

The sample is the test equivalent for the corresponding plasma donation and must therefore be clearly assignable to it.

Haemolytic, lipemic or icteric samples must not be supplied.

NAT testing sample must be made available for every plasma donation supplied to Takeda.

Samples need to be taken as part of the blood or plasma collection procedure and need to be stored according to the valid guidelines.

Any contamination or mix up between the samples of different donations must be excluded by appropriate measures.

No testing material must be removed from tubes by suppliers or external laboratories.

Storage and transport of the samples must be performed equally as the plasma donations and in compliance with the specifications of the tube manufacturer.

In case any temperature deviations occur, the contact person at Plasma Logistics & Plasma Analytics must be informed in advance in order to clarify if the samples can still be tested.

N.B.: If a sample cannot be tested, this will lead to the destruction of the corresponding plasma donation.

2.0 Approved plasma sample tubes

Black caps are not allowed.

2.1 Sample tubes 75mm

non ridged, volume 3 ml, no additives

Filling height / filling volume: min. 35 mm / corresponds to min. 2.5 ml
max. 50 mm / corresponds to max. 4 ml

- Greiner Vacuette (red cap) cat. no. 454 224 ¹⁾ or
- Greiner Vacuette (white cap) cat. no. 454 045 ¹⁾ or
- Greiner Vacuette (yellow cap) cat. no. 454 256 ¹⁾ or
- Becton Dickinson Vacutainer (safety grip with red ribbon insert) cat. no. 362 725 ¹⁾ or
- Vacutest Kima cat. no. 149 415 ¹⁾

2.2 Gel sample tubes 100mm

Gel sample tubes are only permitted for the NAT testing of plasma produced from whole blood donation.

When using gel sample tubes, the manufacturer's specifications must be observed in order to avoid haemolytic samples and increased clot formation. Gel sample tubes must be stored in the refrigerator for at least two hours before freezing.

All the sample tubes must be completely filled as the position of the gel layer (among other things) will depend on the filling volume and constitutes a major parameter for the processing.

non ridged, volume 5 ml, with separating gel

Filling height / filling volume: min. 75 mm / corresponds to min. 4.5 ml
max. 85 mm / corresponds to max. 5 ml

- K2E/EDTA K2: Greiner (white safety grip cap with yellow insert) cat. no. 456 058 ¹⁾
- Becton Dickinson (pearly safety grip cap with red insert) cat. no. 362 795 ¹⁾
- Vacutest Kima (white cap) cat. no. 12620 ¹⁾

¹⁾ In case of country-specific deviations of the cat. no. the equivalence of the used sample tube has to be attested by the manufacturer in writing. This confirmation

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must be submitted to the contact person at Plasma Logistics & Plasma Analytics on request.

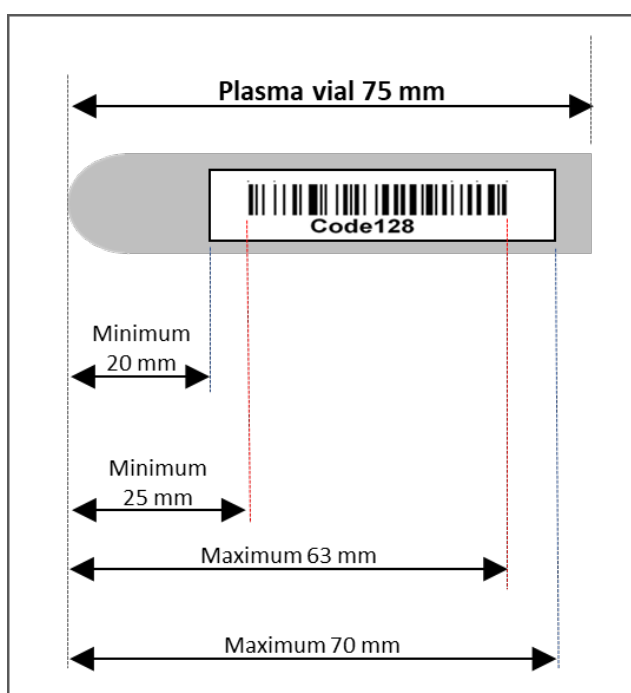
3.0 Barcode position on the sample tube

The beginning of the barcode must be at least 25 mm from the bottom of the tube and the end of the barcode must not be more than 63 mm from the bottom of the tube.

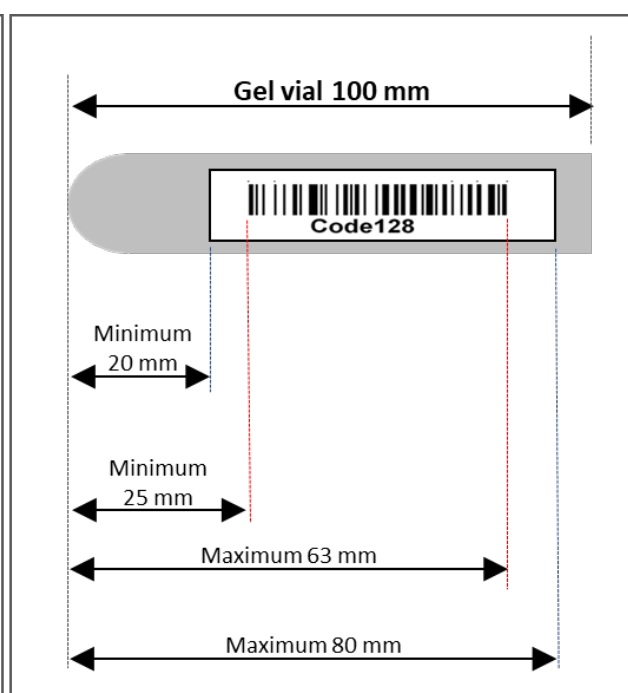
The top-end of the label must not be:

- more than 70 mm from the bottom of the tube (plasma tube 75 mm) (see Picture 1: Position of label/barcode plasma vial).
- more than 80 mm from the bottom of the tube (gel tube 100 mm) (see Picture 2: Position of label/barcode gel vial).

Make sure the labels adhere properly to the tubes and are free of bubbles and/or wrinkles. Make sure the label is straight.



Picture 1: Position of label/ barcode plasma vial



Picture 2: Position of label/ barcode gel vial

4.0 Packing of samples

The NAT sample tubes must be frozen with the caps facing upward and stored at $< -20^{\circ}\text{C}$.

The NAT sample tubes must be put into the labelled box with the nesting insert.

These boxes must be packed into the bigger box. This bigger box must be labelled as well.

Any free space in the bigger box must be filled with filling material.

Either place the bigger box(es) on a separate palette or at the very top of the plasma palette.

No additional paper or electronic documentation must be issued for the delivery of samples that are sent together with plasma shipment.

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5.0 Labels for sample tubes and sample boxes

5.1 NAT sample tubes

Length: 30 to 55 mm

Width: 20 to 35 mm

5.1.1 Minimum requirements of content:

- Bleed number in plain text and barcode

5.2 Box for NAT sample tubes

Length: approx. 105 mm

Width: approx. 70 mm

(e.g.: Zweckform# 3426)

5.2.1 Minimum requirements of content:

- Wording: "Samples for NAT testing"
- Supplier name
- Center code
- Shipment number
- Number of samples
- Wording: "Storage and transportation $\leq -20^{\circ}\text{C}$ "

5.3 Bigger box (outer box for NAT sample tube boxes)

Length: approx. 148 mm

Width: approx. 105 mm

(e.g.: Zweckform# 3483)

5.3.1 Minimum requirements of content:

- Wording "Samples for NAT testing"
- Supplier name
- Center code
- Shipment number
- Wording "Storage and transportation $\leq -20^{\circ}\text{C}$ "

- 2) I tilfelle landsspesifikke avvik i kat. nr., må samsvar med det brukte prøverør bekreftes skriftlig av produsenten. Denne bekreftelsen må sendes til kontaktpersonen i avdelingen «Plasma Logistics & Plasma Analytics» hos Takeda ved forespørsel.

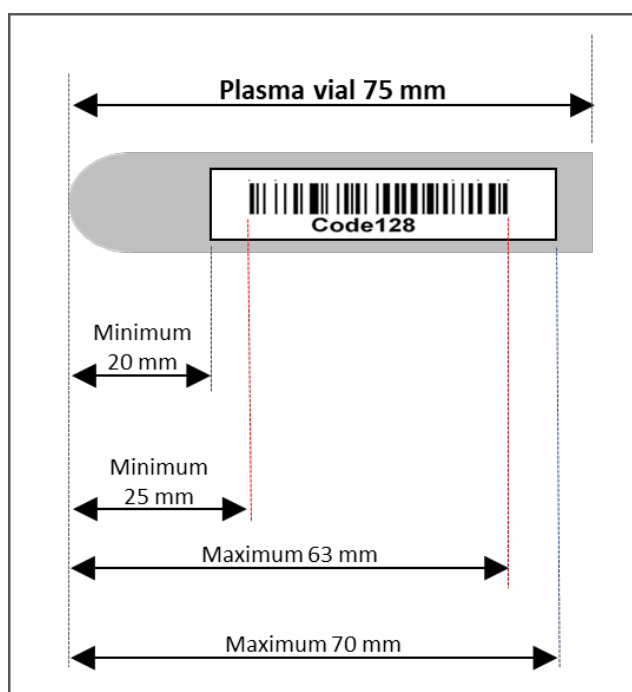
8.0 Plassering av strekkode på prøverør

Starten på strekkoden må være minst 25 mm fra bunnen av røret, og slutten på strekkoden må ikke være mer enn 63 mm fra bunnen av røret.

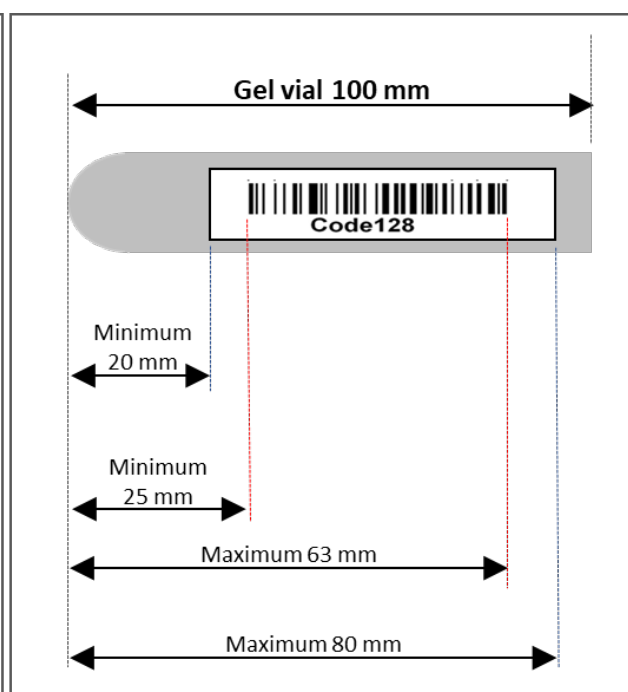
Den øvre enden av etiketten må ikke være:

- mer enn 70 mm fra bunnen av røret (75 mm plasmarør (plasma vial)) (se Figur 1: Plassering av etikett/strekkode på plasmarør).
- mer enn 80 mm fra bunnen av røret (100 mm gelrør (gel vial)) (se Figur 2: Plassering av etikett/strekkode på gelrør).

Sørg for at etikettene fester seg ordentlig til rørene, og er fri for bobler og/eller rynker. Sørg for at etiketten sitter rett.



Figur 1: Plassering av etikett/strekkode på plasmarør



Figur 2: Plassering av etikett/strekkode på gelrør

9.0 Pakking av prøver

NAT-prøverør må fryses med korkene vendt oppover og lagres ved < -20 °C.

NAT-prøverør må settes oppi den etiketterte esken, som inneholder et støttende innlegg.

Disse eskene må igjen pakkes i en større eske. Den store esken må også merkes.

Tomrom i den store esken må fylles opp med et fyllmateriale.

Plasser enten den store esken(e) på en egen pall, eller helt øverst på pallen med plasma.

Det skal ikke utstedes noen ekstra papirer eller elektroniske dokumenter for levering av prøver som sendes sammen med plasmaforsendelsen.

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10.0 Etiketter til prøverør og prøveesker

10.1 NAT-prøverør

Lengde: 30 til 55 mm

Bredde: 20 til 35 mm

10.1.1 Minimumskrav til innhold:

- Tappenummer som vanlig tekst og strekkode

10.2 Eske til NAT-prøverør

Lengde: ca. 105 mm

Bredde: ca. 70 mm

(f.eks.: Zweckform# 3426)

10.2.1 Minimumskrav til innhold:

- Ordlyd: "Samples for NAT testing" eller «Prøver til NAT-testing»
- Navn på leverandør
- Senterkode
- Forsendelsesnummer
- Antall prøver
- Ordlyd: "Storage and transportation ≤ -20 °C" el. "Lagring og transport ≤ -20 °C»

10.3 Stor eske (yttereske til esker med NAT-prøverør)

Lengde: ca. 148 mm

Bredde: ca. 105 mm

(f.eks.: Zweckform# 3483)

10.3.1 Minimumskrav til innhold:

- Ordlyd "Samples for NAT testing" eller «Prøver til NAT-testing»
- Navn på leverandør
- Senterkode
- Forsendelsesnummer
- Ordlyd "Storage and transportation ≤ -20 °C" el. "Lagring og transport ≤ -20 °C»