

Abbott Rapid Diagnostics Jena GmbH

2. Information Supplied by the Manufacturer

2.1. Labels and Packaging

The following Sections show the pouch and kit box labels for the product configurations Ref. Ref. 41FK10.

2.1.1. Test Device Labelling

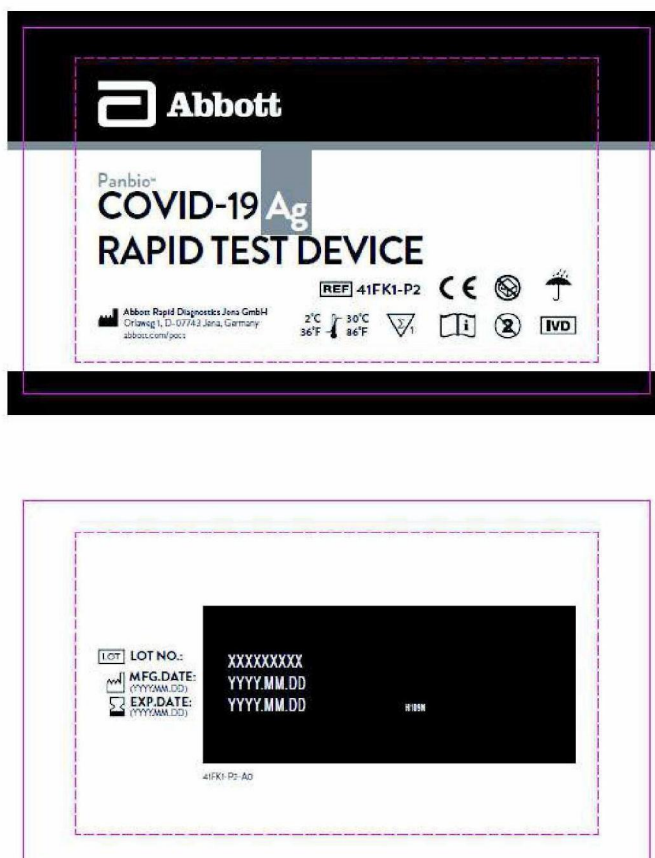


Figure 2-1: Test device labels (front and back side) – big pouch, generic

Extract from 41FK10_TF01 Version 01

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Panbio™ COVID-19 Ag RTD (NP)

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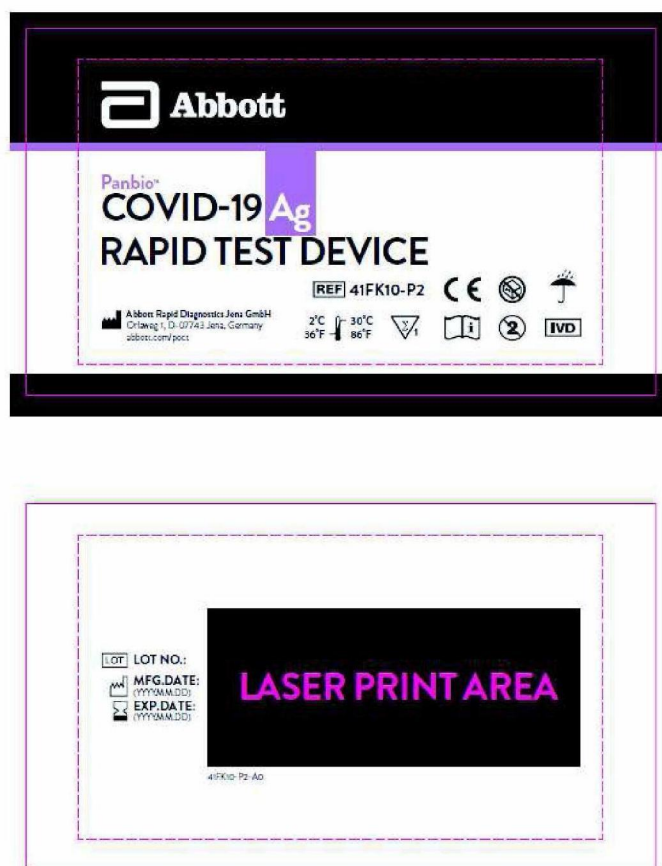


Figure 2-2: Test device labels (front and back side) – big pouch, initial

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Figure 2-3: Test device labels (front and back side) – small pouch, generic

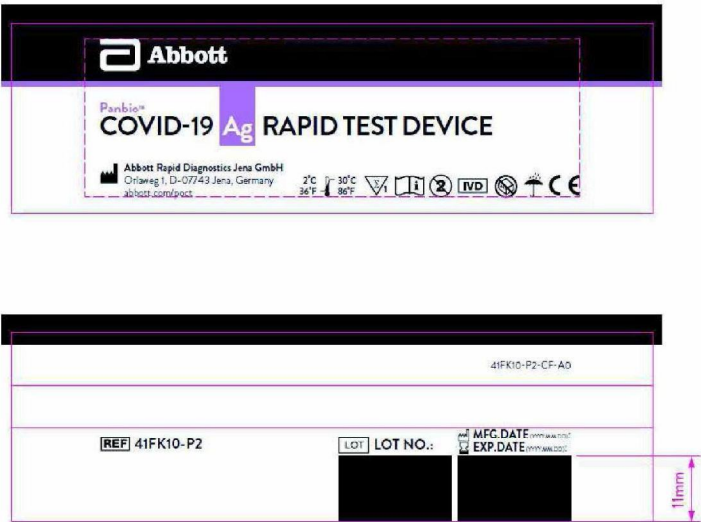


Figure 2-4: Test device labels (front and back side) – small pouch, initial

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2.1.2. Kit Labelling and Packaging

The following GTIN codes have been procured from GS1 Germany for this product:

Product	Product Reference Number	Kit Level GTIN (former EAN-13)	Barcode
Panbio™ COVID-19 Ag Rapid Test Device	41FK10	4051892001183	

Shipment Level GTINs

EAN-13 code on the shipment box containing 32 kits (each with 25 tests) is as follows: 4051892001190

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2.1.2.1. Kit Box Label

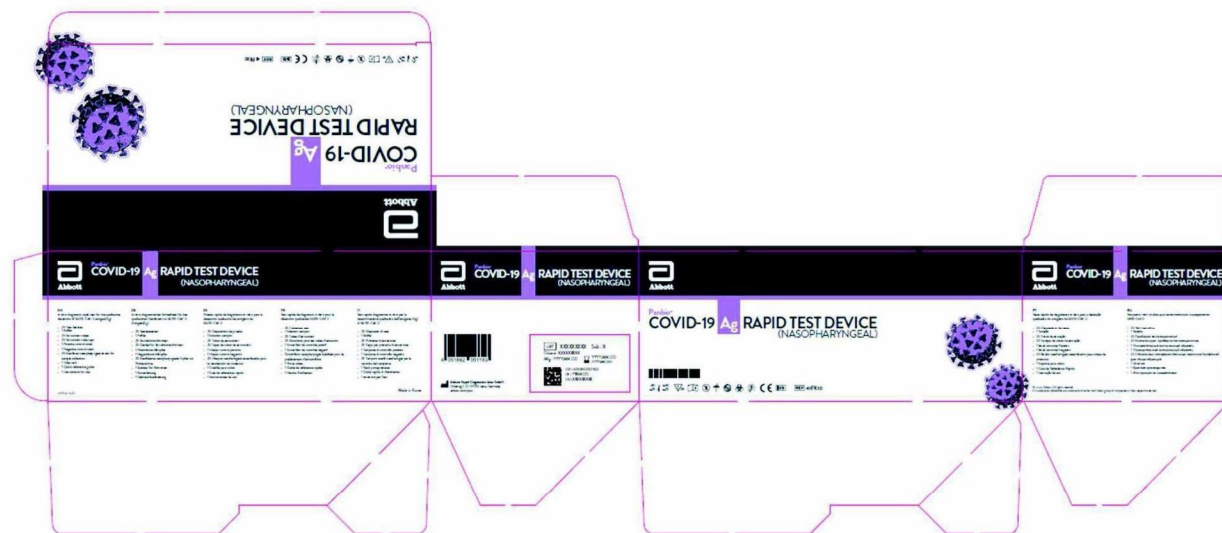


Figure 2-5: Overview: Complete Kit Packaging for Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 incl. printed labeling information (overview). The following Figures 2-6 to 2-10 show enlarged sections of this box label so that the information is readable

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Figure 2-6: Kit Packaging for Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 incl. printed labeling information (product name and symbols).

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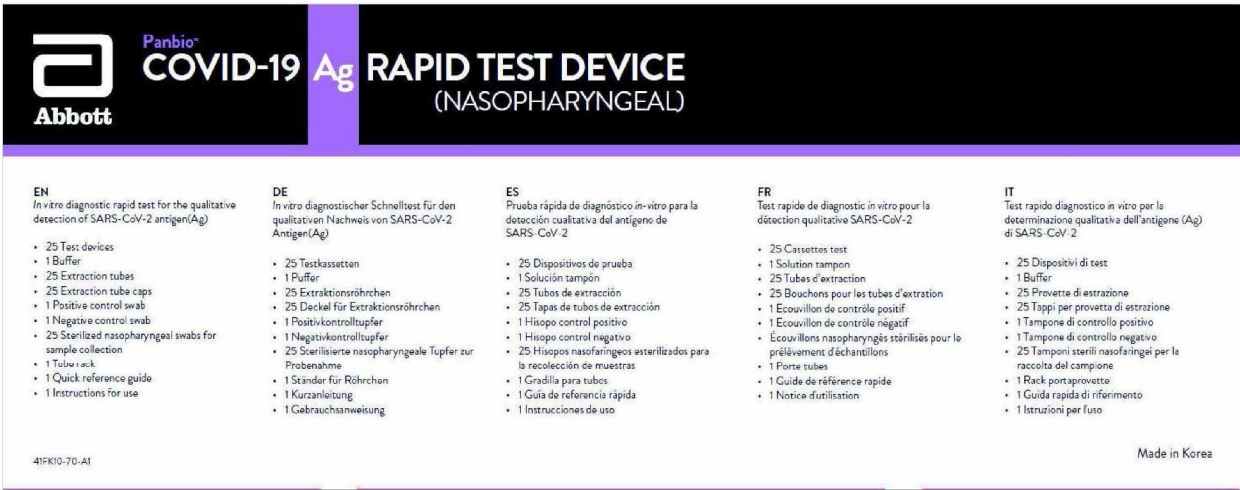


Figure 2-7: Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 specific label information: Kit contents (in EN, DE, ES, FR and IT)

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Figure 2-8: Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 specific label information: Kit contents (in PT, RU)

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Figure 2-9: Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 specific label information: Reference number, symbols (incl. storage conditions, warnings and precautions, CE, IVD)

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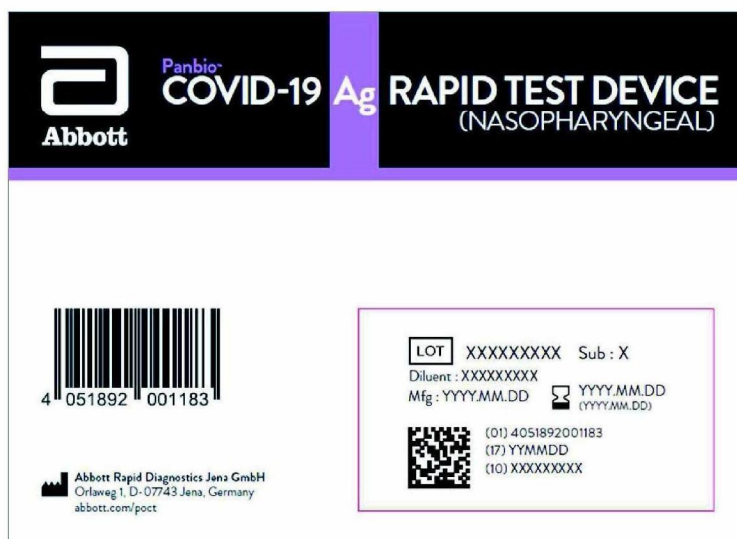


Figure 2-10: Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 specific label information: Manufacturer name and address and label information (incl. storage conditions, lot number, expiry and manufacturing dates, UDI information)

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2.1.3. Accessory Labelling

2.1.3.1. Buffer

Within this section pictures of the buffer label are shown. There are 2 different versions of buffer labels that will be used that have the same label content but differ slightly regarding branding.

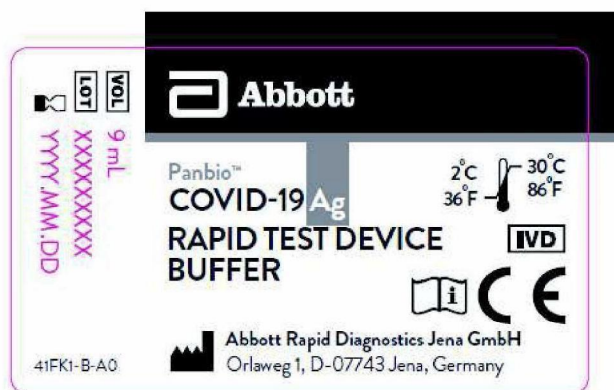


Figure 2-11: Buffer label, generic

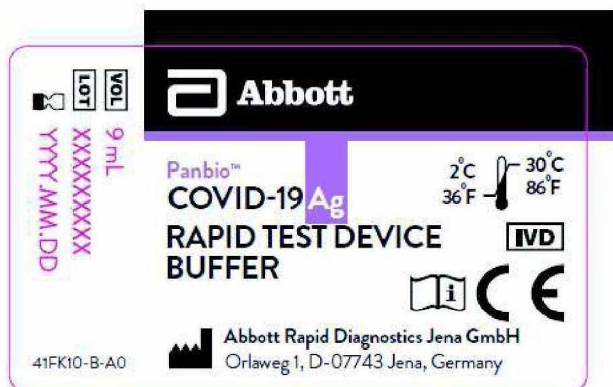


Figure 2-12: Buffer label, initial

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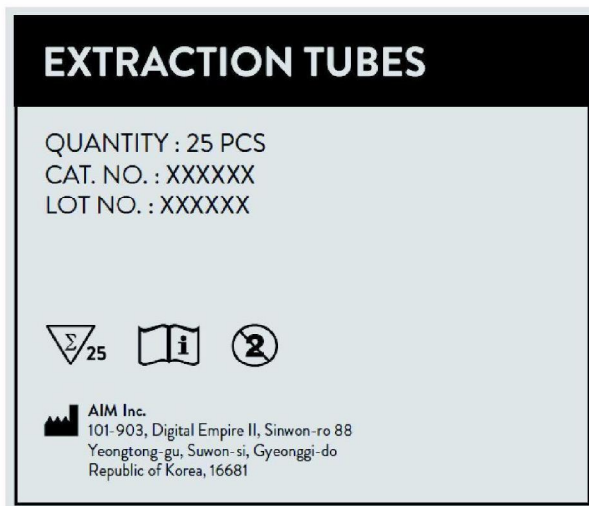
2.1.3.2. Extraction Tubes

Figure 2-13: Extraction tube bag label

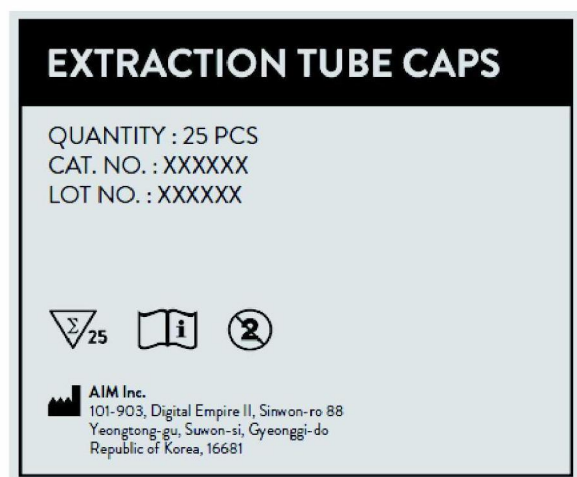
2.1.3.3. Extraction Tube Caps

Figure 2-14: Extraction tube cap bag label

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2.1.3.4. Sterilized Swabs



Figure 2-15: Sterilized nasopharyngeal swab bag label

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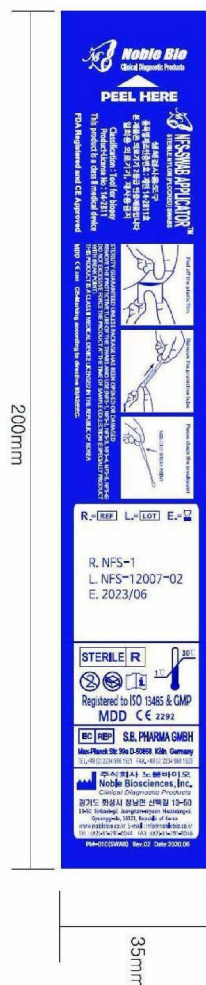


Figure 2-16: Sterilized nasopharyngeal swab label (front; supplier Noble Biosciences)

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2.1.3.5. Control Swabs

Within this section pictures of the positive and negative control swab labels are shown. There are 2 different versions of these labels that will be used and have the same label content but differ regarding assigned reference number. Initially, the pouch versions with document numbers 41FK10-NC and 41FK10-PC will be used. At a later point in time a generic version of the label indicating reference numbers 41FK1-NC and 41FK1-PC will be used.



Figure 2-17: Negative Control label, generic

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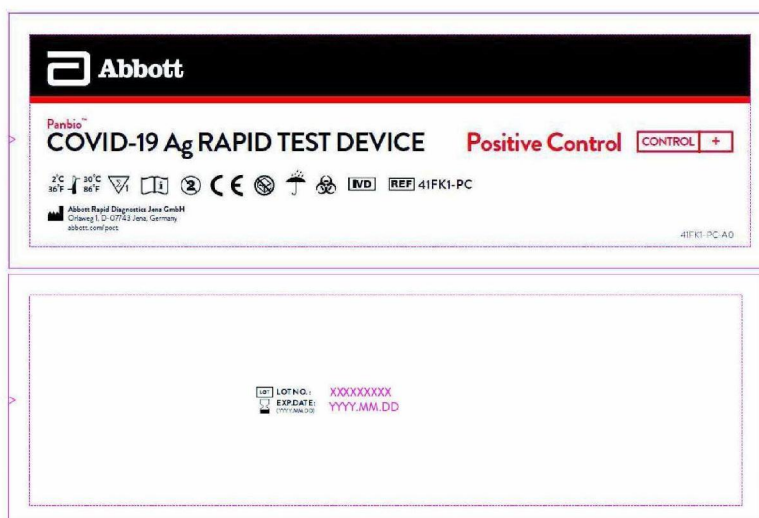


Figure 2-18: Positive Control label, generic



Figure 2-19: Negative Control label, initial

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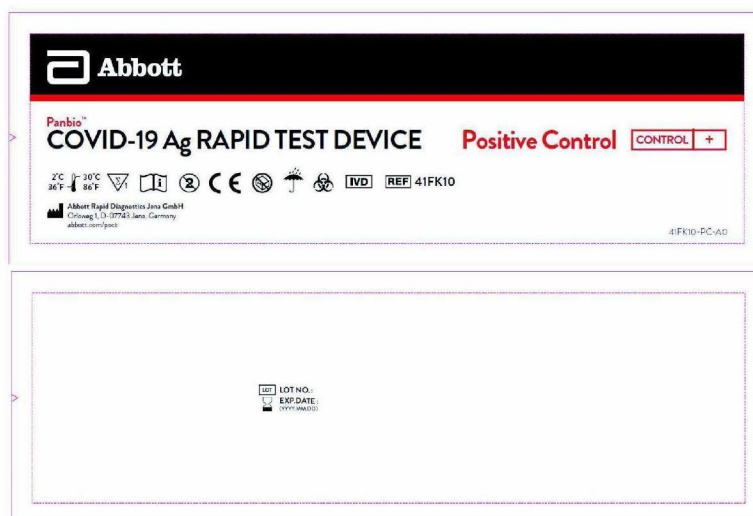


Figure 2-20: Positive Control label, initial

2.2. Instructions for Use

A comprehensive IFU was developed and qualified by Abbott Rapid Diagnostics Jena GmbH in collaboration with ADK in compliance with the following regulatory requirements, standards and guidance documents: DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013 and DIN EN ISO 18113-2:2013.

A copy of the current Instructions for Use for Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10-A0 is provided in Appendix 2.

Currently, the Instructions for Use are available as a multi-language booklet including the following languages: English, German, French, Spanish, Portuguese, Italian, and Russian.

It will be translated into the languages required by the individual target countries prior to launch in these countries and in agreement with applicable regulations.