

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

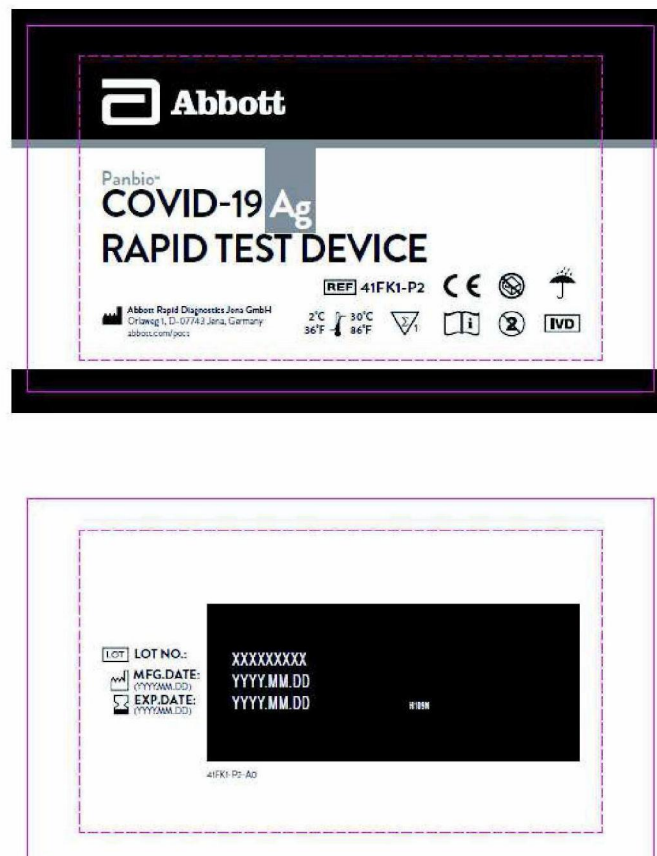


Figure 2-1: Test device labels (front and back side) – big pouch, generic

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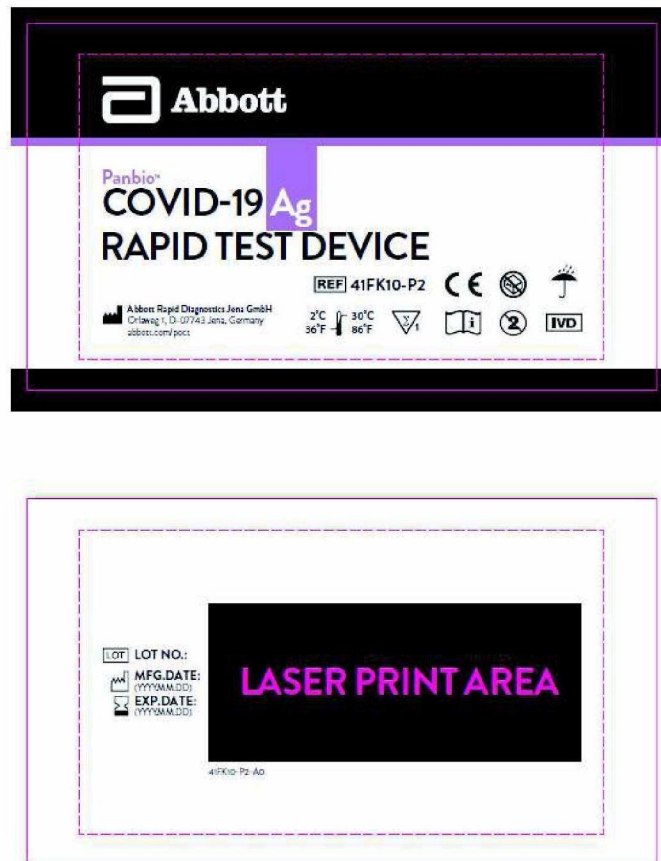


Figure 2-2: Test device labels (front and back side) – big pouch, initial

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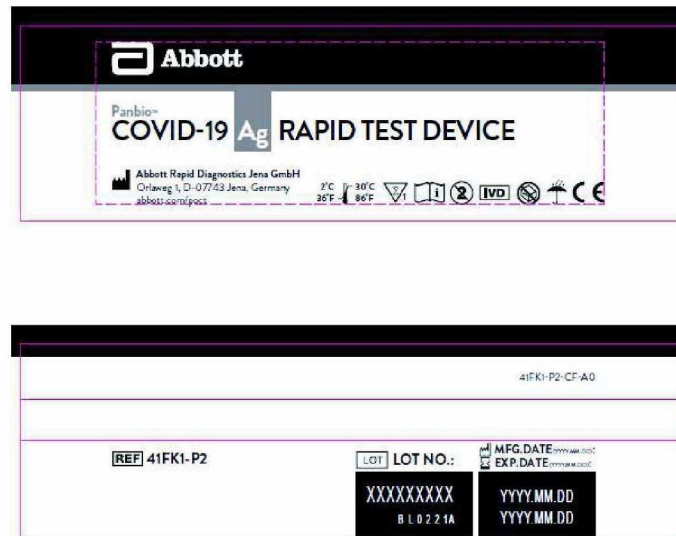


Figure 2-3: Test device labels (front and back side) – small pouch, generic



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

2.1.2.1. Kit Box Label

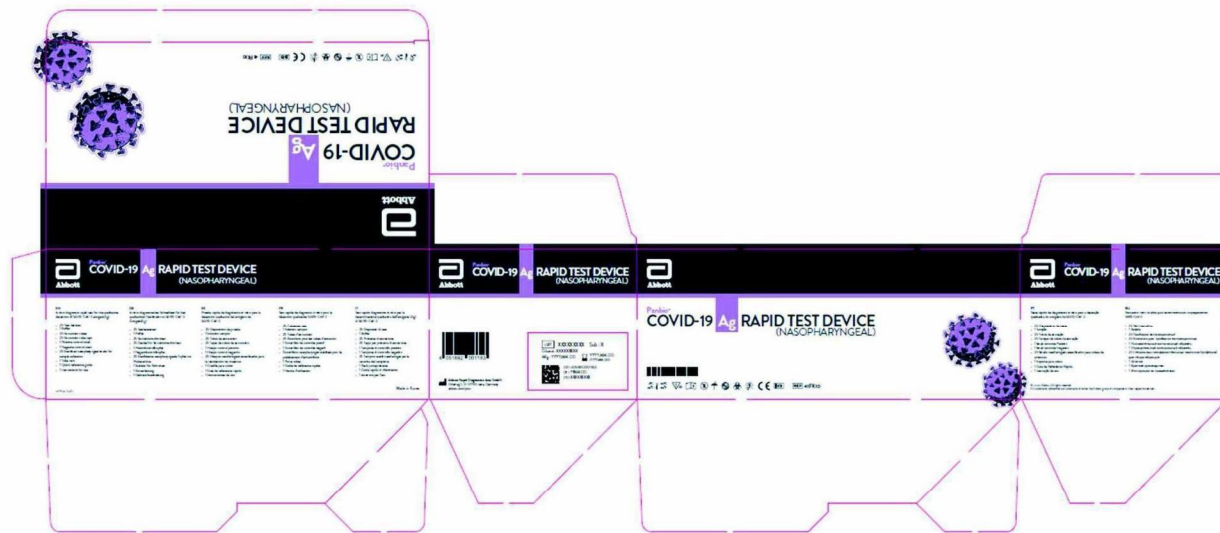


Figure 2-5: Overview: Complete Kit Packaging for Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 incl. printed labeling information (overview). The following Figures 2-6 to 2-10 show enlarged sections of this box label so that the information is readable

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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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Panbio[®] COVID-19 Ag RAPID TEST DEVICE (NASOPHARYNGEAL)

EN
In vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen(Ag)

- 25 Test devices
- 1 Buffer
- 25 Extraction tubes
- 25 Extraction tube caps
- 1 Positive control swab
- 1 Negative control swab
- 25 Sterilized nasopharyngeal swabs for sample collection
- 1 Tubex rack
- 1 Quick reference guide
- 1 Instructions for use

DE
In vitro diagnostischer Schnelltest für den qualitativen Nachweis von SARS-CoV-2 Antigen(Ag)

- 25 Testkassetten
- 1 Puffer
- 25 Extraktionsröhrchen
- 25 Deckel für Extraktionsröhrchen
- 1 Positivkontrolltupfer
- 1 Negativkontrolltupfer
- 25 Sterilisierte nasopharyngeale Tupfer zur Probenahme
- 1 Ständer für Röhrchen
- 1 Kurzanleitung
- 1 Gebrauchsanweisung

ES
Prueba rápida de diagnóstico in-vitro para la detección cualitativa del antígeno de SARS-CoV-2

- 25 Dispositivos de prueba
- 1 Solución tampón
- 25 Tubos de extracción
- 25 Tapas de tubos de extracción
- 1 Hisopo control positivo
- 1 Hisopo control negativo
- 25 Hisopos nasofaríngeos esterilizados para la recolección de muestras
- 1 Gradilla para tubos
- 1 Guía de referencia rápida
- 1 Instrucciones de uso

FR
Test rapide de diagnostic in vitro pour la détection qualitative SARS-CoV-2

- 25 Cassettes test
- 1 Solution tampon
- 25 Tubes d'extraction
- 25 Bouchons pour les tubes d'extraction
- 1 Ecouvillon de contrôle positif
- 1 Ecouvillon nasopharyngés stérilisés pour le prélèvement d'échantillons
- 1 Porte tubes
- 1 Guide de référence rapide
- 1 Notice d'utilisation

IT
Test rapido diagnostico in vitro per la determinazione qualitativa dell'antigene (Ag) di SARS-CoV-2

- 25 Dispositivi di test
- 1 Buffer
- 25 Prewette di estrazione
- 25 Tappi per provetta di estrazione
- 1 Tampone di controllo positivo
- 1 Tampone di controllo negativo
- 25 Tamponi sterili nasofaringei per la raccolta del campione
- 1 Rack portaprovette
- 1 Guida rapida di riferimento
- 1 Istruzioni per l'uso

41FK10-70-A1 Made in Korea

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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Abbott Panbio[™] COVID-19 Ag **RAPID TEST DEVICE**
(NASOPHARYNGEAL)

<p>PT Teste rápido de diagnóstico <i>in vitro</i> para a detecção qualitativa do antígeno de SARS-CoV-2</p> <ul style="list-style-type: none"> • 25 Dispositivos de teste • 1 Tampão • 25 Tubos de extração • 25 Tampas de tubos de extração • 1 Swab controle Positivo • 1 Swab controle Negativo • 25 Swabs nasofaríngeos esterilizados para coleta de amostras • 1 Suporte para tubos • 1 Guia de Referência Rápida • 1 Instrução de uso 	<p>RU Экспресс-тест <i>in vitro</i> для качественного определения SARS-CoV-2</p> <ul style="list-style-type: none"> • 25 Тест-кассеты • 1 Буфер • 25 Пробирки экстракционные • 25 Колпачки для пробирок экстракционных • 1 Положительный контрольный образец • 1 Отрицательный контрольный образец • 25 Стерильных назофарингеальных тампонов (тупферов) для сбора образцов • 1 Штатив • 1 Краткое руководство • 1 Инструкция по применению
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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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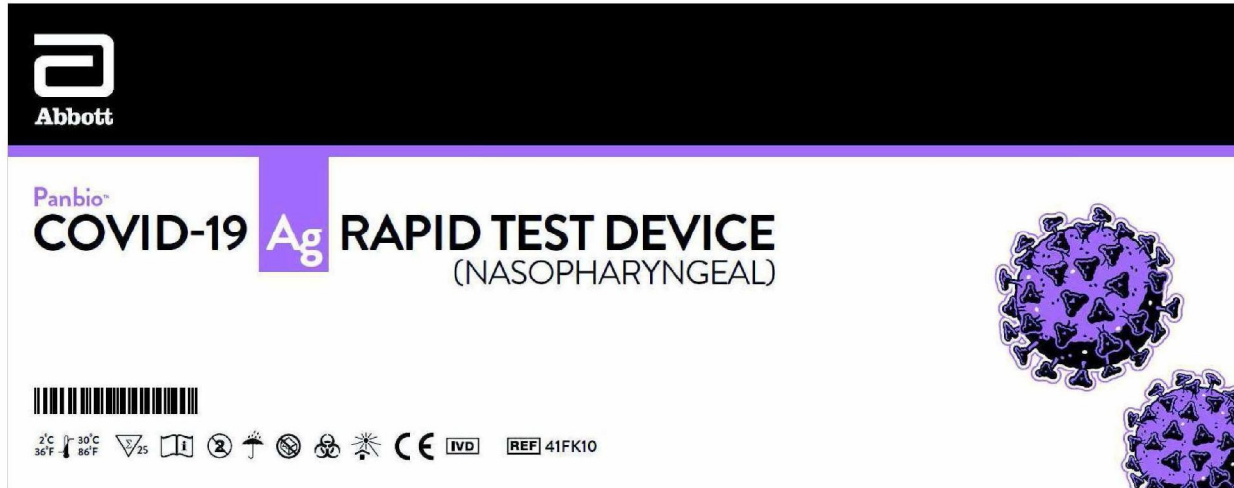


Figure 2-9: Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 specific label information: Reference number, symbols (incl. storage conditions, warnings and precautions, CE, IVD)

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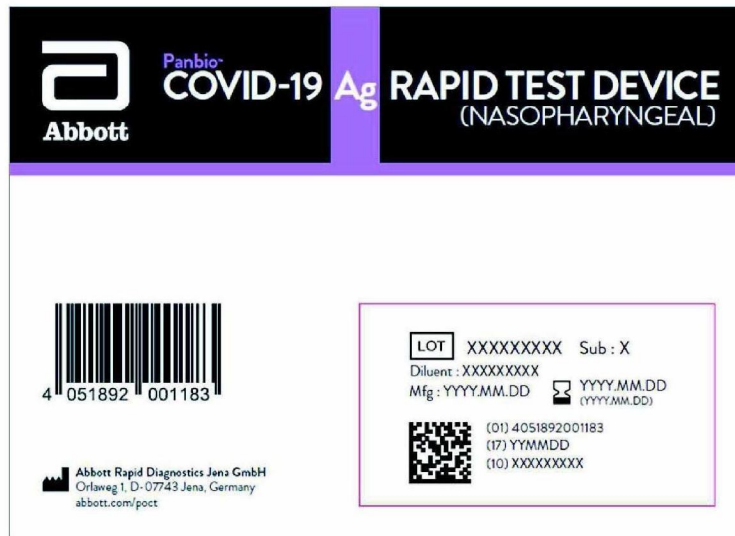


Figure 2-10: Panbio™ COVID-19 Ag Rapid Test Device Ref. 41FK10 specific label information: Manufacturer name and address and label information (incl. storage conditions, lot number, expiry and manufacturing dates, UDI information)

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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.

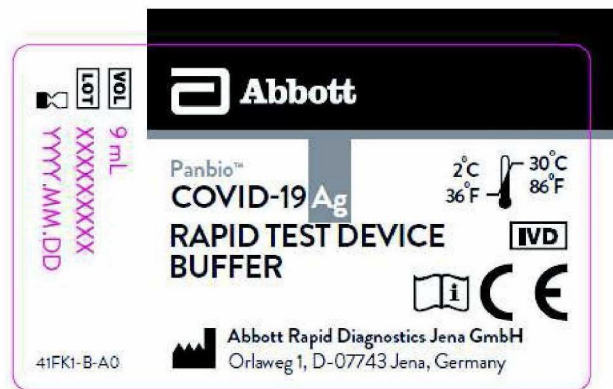


Figure 2-11: Buffer label, generic

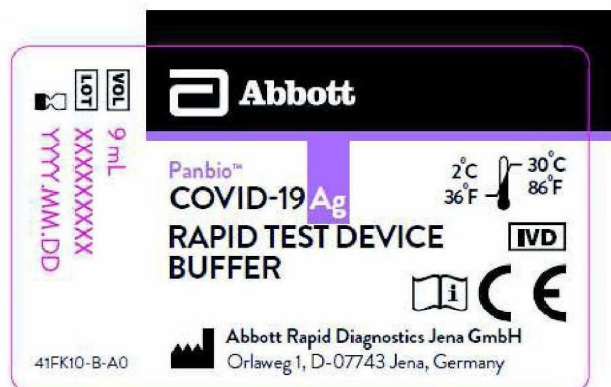


Figure 2-12: Buffer label, initial

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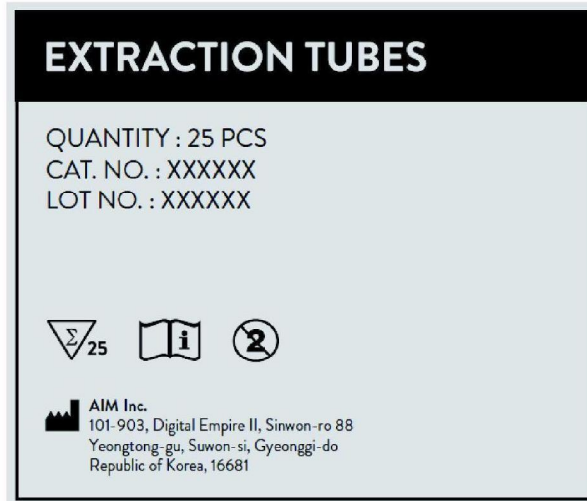
2.1.3.2. Extraction Tubes

Figure 2-13: Extraction tube bag label

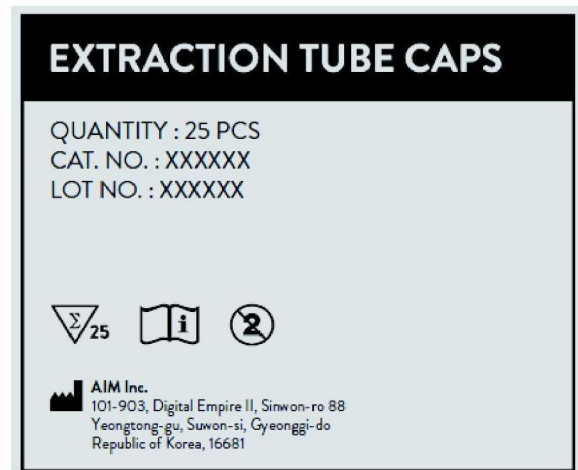
2.1.3.3. Extraction Tube Caps

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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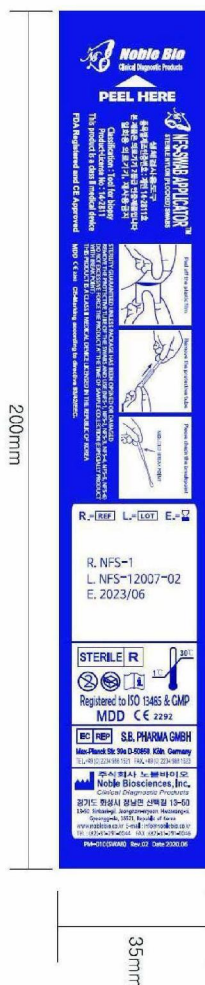


Figure 2-16: Sterilized nasopharyngeal swab label (front; supplier Noble Biosciences

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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.

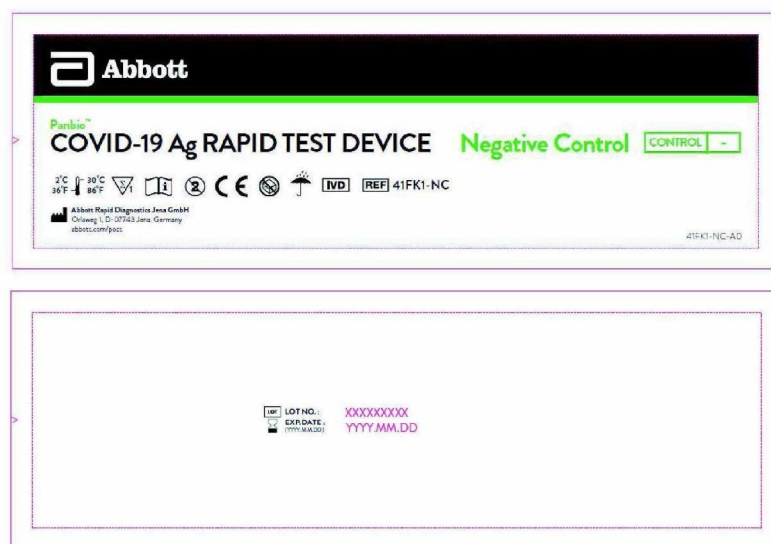


Figure 2-17: Negative Control label, generic

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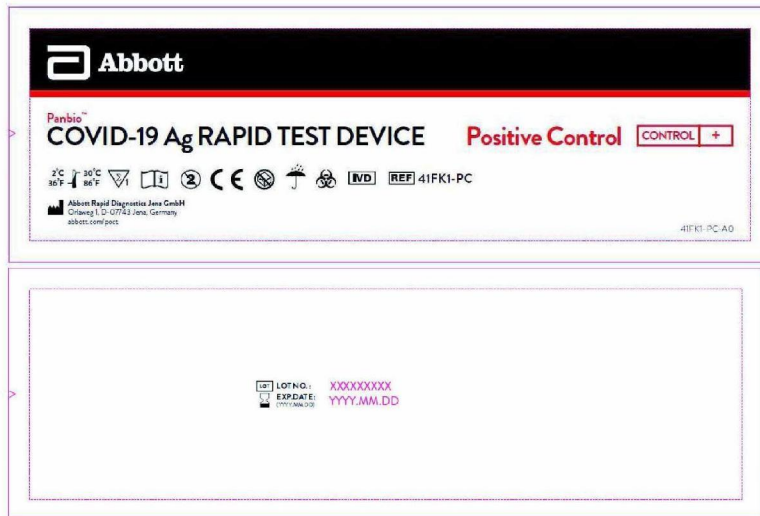


Figure 2-18: Positive Control label, generic



Figure 2-19: Negative Control label, initial

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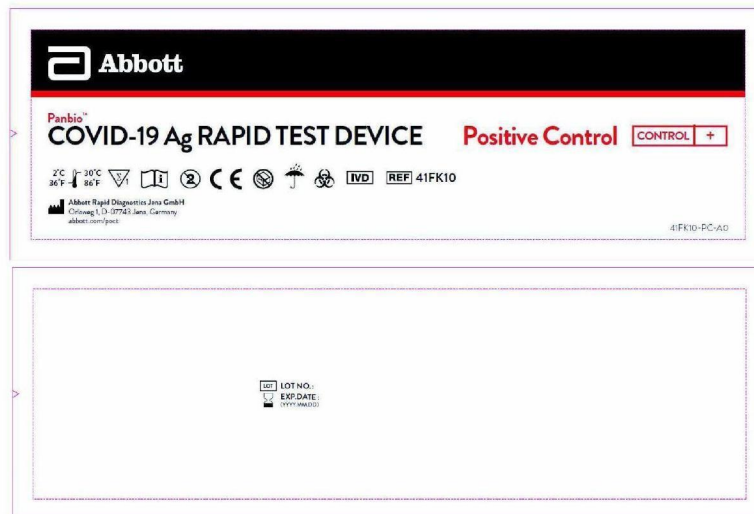


Figure 2-20: Positive Control label, initial

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.