

**Photographs of all kit components
(packaged and individually)**

Product: Panbio™ COVID-19 Rapid
Test Device
(Nasopharyngeal)

Reference Number: 41FK10

See Section 2 of Dossier 41FK10_TF01 for device labeling incl. accessory labels.

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1. Kit Box



Figure 1: Closed kit box (reference number 41FK10). Representative picture.

There are two different sizes of kit boxes (A: 230 x 125 x 90 mm and B: 220 x 120 x 90 mm) both of which will have exactly the same labeling information. These kit boxes accommodate 25 test devices packaged in big pouches (A) and small pouches (B), respectively.

Refer to 41FK19 technical dossier labeling section for detailed label information printed on the kit box.

2. Kit Components

2.1. Content Overview



Figure 2: Overview of Panbio™ COVID-19 Ag Rapid Test Device kit components (Ref. 41FK10). Note: in this example, only one packaged test device is shown, while a kit would contain 25.

Upper row from left to right: Buffer (assay diluent) bottle, test device (big pouch) back and front view. Middle row from left to right: Sterilized nasopharyngeal swabs, negative control swab, positive control swab, tube rack. Bottom row from left to right: Quick Reference Guide, Instructions for Use, extraction tubes, extraction tube caps.



Figure 3: Overview of Panbio™ COVID-19 Ag Rapid Test Device kit components (Ref. 41FK10). Note: in this example, only one packaged test device is shown, while a kit would contain 25.

Upper row from left to right: Buffer (assay diluent) bottle, test device (small pouch) back and front view. Middle row from left to right: Sterilized nasopharyngeal swabs, negative control swab, positive control swab, tube rack. Bottom row from left to right: Quick Reference Guide, Instructions for Use, extraction tubes, extraction tube caps.

2.2. Test Device



Figure 4: Closed device pouch (front side, big pouch, initial) containing a Panbio™ COVID-19 Ag Rapid Test Device cartridge and a desiccant bag. The labeling information that is printed on this front side is shown.

Note that this product level (single pouched test device) has been assigned a different reference number 41FK10-P2 to distinguish this product level from the kit with 25 test devices and accessories.



Figure 5: Pictures of back pouch label (big pouch, initial).



Figure 6: Closed device pouch (front and back side, small pouch, initial) containing a Panbio™ COVID-19 Ag Rapid Test Device cartridge and a desiccant bag. The labeling information that is printed on this front side is shown.

Note that this product level (single pouched test device) has been assigned a different reference number 41FK10-P2 to distinguish this product level from the kit with 25 test devices and accessories.



Figure 7: Panbio™ COVID-19 Ag Rapid Test Device (unpacked).

2.3. Accessories

2.3.1 Buffer (Assay Diluent)



Figure 8: Buffer label and buffer vial with attached label (initial version).

2.3.2 Extraction Tubes and Caps

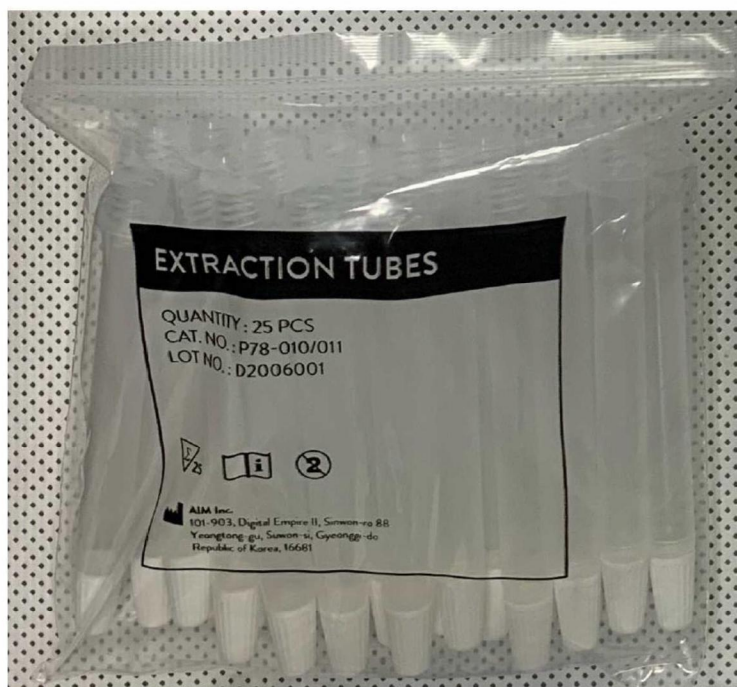


Figure 9: Extraction Tubes (bag with 25 tubes, AIM Inc.).



Figure 10: Extraction Tube Caps (bag with 25 caps, AIM Inc.).



Figure 11: Extraction Tube and Extraction Tube Cap.

Appendix 1 to Dossier 41FK10_TF01

Abbott Rapid Diagnostics Jena GmbH

Product: Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)

2.3.2 Controls

Panbio™ COVID-19 Ag Rapid Test Device Negative Control



Figure 12: Panbio™ COVID-19 Ag Rapid Test Device Negative Control.

Appendix 1 to Dossier 41FK10_TF01

Abbott Rapid Diagnostics Jena GmbH

Product: Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)

Panbio™ COVID-19 Ag Rapid Test Device Positive Control



Figure 13: Panbio™ COVID-19 Ag Rapid Test Device Positive Control.

2.3.4 Sterilized Nasopharyngeal Swab



Figure 14: Bag with 25 individually packaged sterilized nasopharyngeal swabs (Noble Biosciences).



Figure 15: Sterilized nasopharyngeal swab label, Noble Biosciences (front)



Figure 16: Unpacked sterilized nasopharyngeal swab, Noble Biosciences. Breakpoint is indicated by a yellow triangle.

2.3.5 Tube Rack



Figure 17: Picture of Tube Rack.

3. Shipment Box

There are two different sizes of shipment boxes (A: 520 x 470 x 395 mm and B: 505 x 455 x 395 mm) both of which contain 32 product kits per carton (each kit containing 25 test devices packaged in big pouches (A) and small pouches (B), respectively).

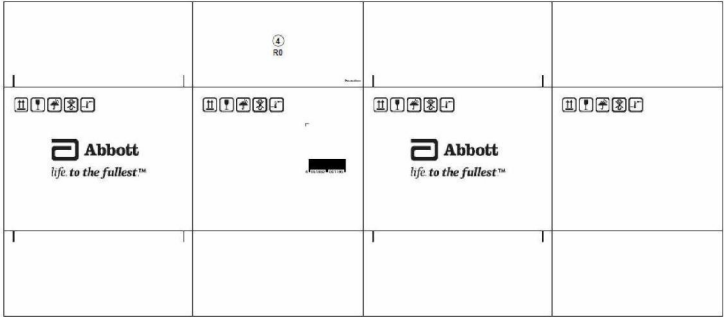


Figure 18: Picture of the shipment box. Representative picture.