

Abbott Rapid Diagnostics Jena GmbH

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.

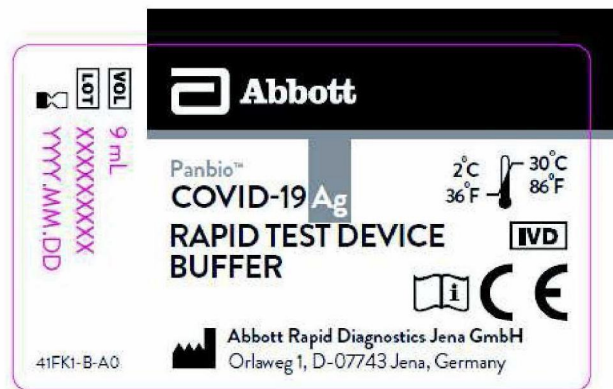


Figure 2-11: Buffer label, generic

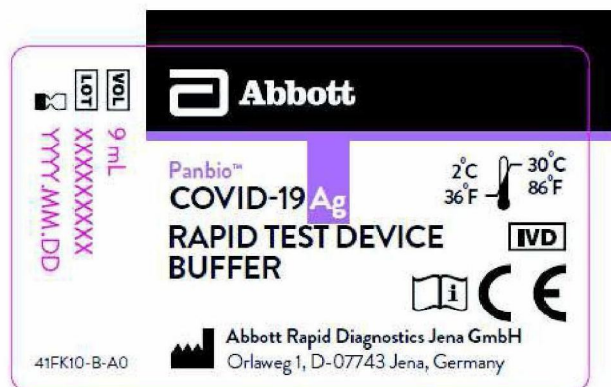


Figure 2-12: Buffer label, initial

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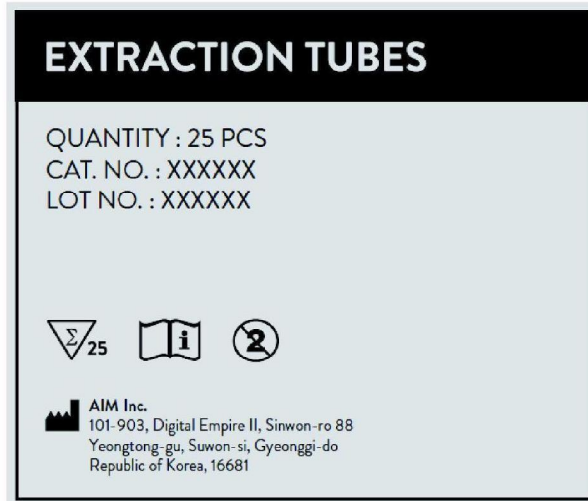
2.1.3.2. Extraction Tubes

Figure 2-13: Extraction tube bag label

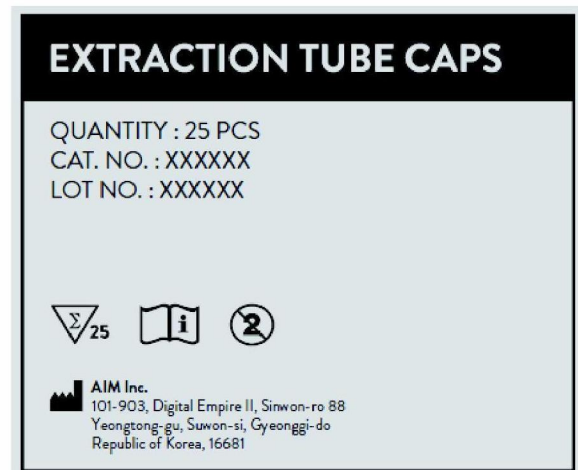
2.1.3.3. Extraction Tube Caps

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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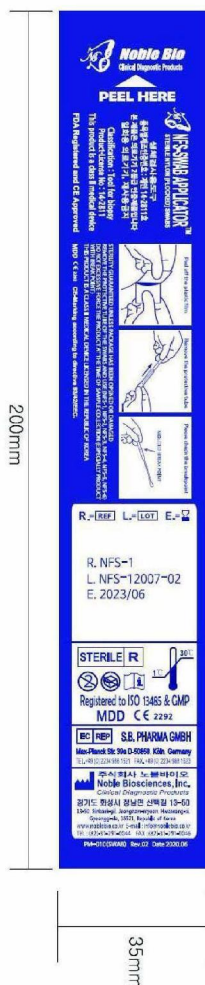


Figure 2-16: Sterilized nasopharyngeal swab label (front; supplier Noble Biosciences

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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.

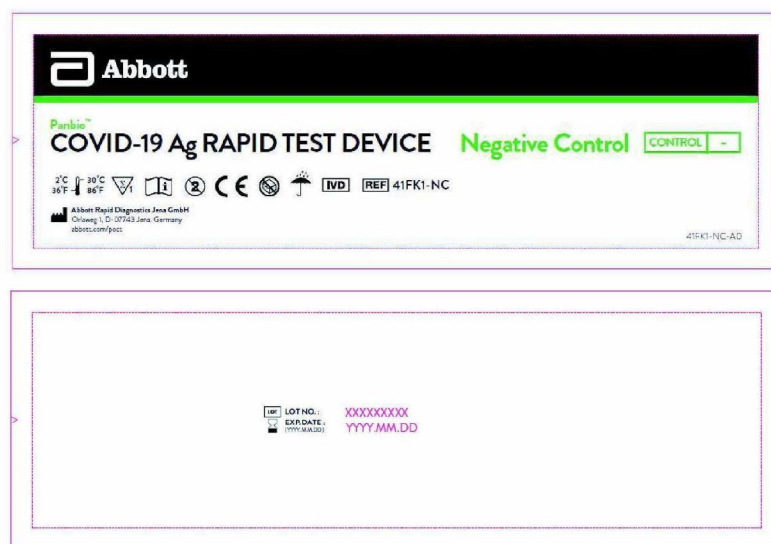


Figure 2-17: Negative Control label, generic

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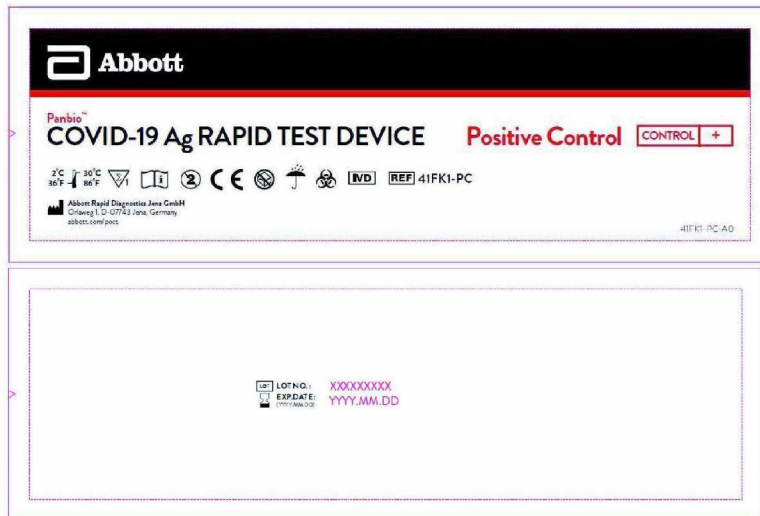


Figure 2-18: Positive Control label, generic



Figure 2-19: Negative Control label, initial

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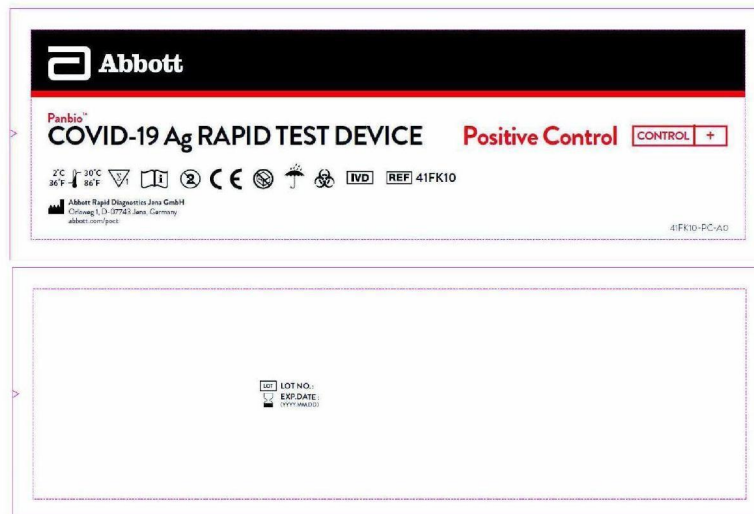


Figure 2-20: Positive Control label, initial

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.