

PACKING LIST MANUAL

for DIAGNOVITAL SARS-CoV-2 Real Time PCR Kit CE-IVD

Section I. The kit box

Products	Image/Kit	Materials Provided/Kit	
A1-09065100 DIAGNOVITAL SARS-CoV-2 Real Time PCR Kit CE-IVD (100 tests) A1-09065050 DIAGNOVITAL SARS-CoV-2 Real Time PCR Kit CE-IVD (50 tests)	Image 1.1. Image showing A1-09065100, A1-09065050, A1-09065010 kit box	DIAGNOVITAL SARS-CoV-2 Real Time PCR Kit CE- IVD is provided in the form of 10, 25, 50 or 100 Tests. All forms are maintained in the same inner kit box (image 1.1). Only the volumes of tube contents alter according to the test size of the kit (either 10,25,50 or 100 tests).	
A1-09065025 DIAGNOVITAL SARS- CoV-2 Real Time PCR Kit (25 tests) A1-09065010 DIAGNOVITAL SARS- CoV-2 Real Time PCR Kit (10 tests)	Image 1.2. Image showing the kit content	Green tube-50X VitaScript TM Reverse Transcriptase Yellow tube I - Diagnovital® 2X qPCR Mastermix E Yellow Tube II - Diagnovital® 2X qPCR Mastermix RdRP Yellow Tube II - Diagnovital® 2X qPCR Mastermix HEC Red Tube - SARS-CoV-2 Target Positive Control (TPC) Blue Tube I - Nuclease-free dH ₂ O Blue Tube II - Nuclease-free dH ₂ O	



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Section II. Styrofoam Box Dimensions

Image	Styrofoam Box Type	Dimensions	Dry Ice Net Qty / Box	Kit / Box	Shipping Temperature
Image 2.1Image showing the styrofoam above view, please refer to image 2.2 and 2.3 for further detail.	Standard#1	38x43x47cm	15,00 kg (Approx 8 blocks)	28 kits	-15°C / -25°C
	Standard#2	30x30x33cm	7,50 kg (Approx 3 blocks)	3 kits	-15°C / -25°C



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Image 2.2. 2.3 2.4. Image showing the styrofoams (38x43x47 cm and 30x30x33 cm respectively). As can be seen in image 2.3, the dry ice blocks are put into the medial split of the box while keeping the kit boxes on edge splits of the styrofoam. The standard#1 styrofoam (38x43x47 cm) is recommended for remote area shipments (38x43x47 cm) dry ice net quantity of which is 15 kg (8 block dry ices). After the specially designed styrofoam cover is placed in to the edge recesses of the lower box, its junction is also taped twice by duct tape ensuing the air-proof environment. The described system is reported to maintain product sustainability for 4,5 days when exposed to constant 40 °C degrees outside temperature. (Ref. RTA Laboratories The Cold Chain Transport Validation Project, Nov 2017; achieved with 38x43x47 cm box including 15,00 kg dry ice)



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Section III. Exterior Boxes

Exterior Box Dimensions

Image	Product	Dimensions	Shipment Temperature
Image 3.1 Image showing the exterior boxes that contains related styrofoams Cold chain transport labels are applied to each side of the boxes and the dry ice net quantity in terms of kg is written on the dry ice label above. Please refer to below images for further details.	Exterior Box for Standard#1 Styrofoam	38x43x47cm	-15°C / -25°C
	Exterior Box for Standard#2 Styrofoam	30x30x33cm	-15°C / -25°C



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Image 3.1, 3.2 and 3.3 Images from left to right showing the exterior boxes of standard#1 and standard#2 and the cold chain transport labels. Dry ice newt quantity label is attached above side of each box and the dry ice net quantity is manually written accordingly. Time & Temperature Sensitive Labels are applied onto each side of the box.