

LightMix[®] Modular Positive Control Respiratory Panel

Cat.-No. 90-0100-01

Roche SAP n° 08 285 365 001

Positive Controls for 2 x 32 PCR reactions (32 plates) for ModularDx Respiratory Kits [lyophilized]

1. Content and

- 1 Vials transparent cap Mix I (lyophilized), 32 reactions
- 1 Vials transparent cap Mix II (lyophilized), 32 reactions

Storage at Arrival:

Store cooled or at ambient temperature
Do not freeze the lyophilized reagents.

2. Storage and Expiry

- Lyophilized product is stable for at least 6 months (4°C to 25°C in the dark). See lot-specific expiry.
- Dissolved controls are not long-term stable. For daily use store cooled (4°C), long-term-use store frozen.

3. Introduction and Intended Use

This product is intended to be used as **Control Reagent** for **ModularDx Respiratory** kits. The amount of target NA included in the reagents are adjusted to yield a defined Cp range (see table). **Mix 1** gives signals in channels 500, 580, and 640 while working as **Negative Control** for 530, 610, and 660, **Mix 2** yields signals in 530, 610, eventually 640 (melting) and 660 and is negative for 500, 580, and 640.

4. Instructions for Use

See Multiplex PCR instruction delivered with the ModularDx kits.

4.1. Preparation of the Positive Control

Add 160 µl PCR-grade water to each vial. Mix by pipetting the solution up and down 10 times.

Note: Opening of these vials may cause contaminations of the work-space (aerosol).

► **Use 5 µl** positive **Positive Control** per 20 µl PCR reaction.

5. Material Safety Data (MSDS)

According to OSHA 29CFR1910.1200, Australia [NOHSC:1005, 1008 (1999)] and the EU Directives 67/548/EC and 1999/45/EC any products which do not contain more than 1% of a component classified as hazardous or classified as carcinogenic do not require a Material Safety Data Sheet (MSDS).

Product is not hazardous, not toxic, not IATA-restricted. Product is not from human, animal or plant origin.

Certificate of Analysis (CoA)	
Lot n° 3759	
Expiry :	
Dilution	H1 IB H5 H7 MP IC EV HK NL OC P1 P4 BV PC Bp Sp Lp psi Hi
Cp range	✓ ✓
passed	
Dilution	IA H3 H9 RS AD HR PE 2E ME SA P3 P2 Ma Mp Bt Cp Ld EA
Cp range	✓
passed	
QC Acceptance Date:	
We, the undersigned, certify that the product designated above has been obtained in accordance with the rules of production and quality control.	
Name(s) :	
<i>Name 1</i>	<i>Name 2</i>

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Distributed by Roche - www.lifescience.roche.com

6. Description : Positive Control Mix I and Mix II

Respiratory Mix I **blue pellet** contains target DNA for the following ModularDx Kits

Kit n°	Roche SAP	Target (Pathogen)	CP range
50-0100-96	07792204001	InfA H1 (H1N1)	28-30
50-0114-96	07683324001	PIV-4	29-31
50-0115-96	07730497001	Corona HKU	28-30
50-0128-96	07766262001	allPIV	29-31
50-0129-96	07766254001	allCorona	29-31
50-0656-96	07730454001	Enterovirus	28-30
50-0678-96	07730004001	B. paraptussis	28-30
50-0683-96	07730586001	Legionella pn (MIP)	29-31
50-0689-96	07730632001	Pneumocystis	29-31
50--96	-	Moraxella	29-31
53-0634-96	07041578001	InfA H7 (H7N9)	29-31
58-0102-96	07792212001	Influenza B	29-31
58-0105-96	07548087001	InfA H5	28-30
58-0117-96	07548087001	Corona OC43	28-30
58-0125-96	07730446001	hMPV	28-30
58-0643-96	07414013001	S. pneumoniae	29-31
58-0679-96	07730543001	B. pertussis	29-31
58-0686-96	07730578001	C. psittaci	29-31
64-0104-96	-	InfC	28-30
64-0111-96	07683332001	PIV-1	29-31
64-0119-96	07730489001	Corona NL63	29-31
64-0134-96	07730420001	Picornia HRV+EV	28-30
64-0634-96	07548079001	InfA H7 (H7N9)	29-31
64-0646-96	07548079001	H. influenzae	29-31
64-0656-96	07396805001	Enterovirus	28-30
64-0682-96	07730608001	Legionella pn.	28-30

Respiratory Mix II **green pellet** contains target for the following ModularDx Kits

50-0128-96	07766262001	allPIV	29-31
50-0129-96	07766254001	allCorona	29-31
53-0101-96	07792182001	Influenza A	29-31
53-0109-96	07548095001	InfA H9	29-31
53-0116-96	07683316001	PIV-3	29-31
53-0116-96	-	Coronavirus MERS	29-31
53-0120-96	-	Bocavirus	28-30
53-0122-96	-	Enterovirus D68	not contained
53-0126-96	07730438001	hPeV	29-31
53-0680-96	07730616001	M. pneumoniae	29-31
58-0120-96	07730527001	Bocavirus	28-30
61-0103-96	07548109001	InfA H3	29-31
61-0110-96	07766343001	RSV	29-31
61-0112-96	07683308001	PIV-2	29-31
61-0118-96	07730519001	hCoV 229E	29-31
61-0121-96	07730535001	AdV	29-31
61-0126-96	07766319001	hPeV	29-31
61-0681-96	07730551001	C. pneumoniae	29-31
64-0111-96	07683332001	PIV-1	29-31
64-0123-96	07730420001	HRV	28-30
64-0126-96	07766297001	hPeV	29-31
64-0682-96	07730608001	Legionella spp.	29-31
66-0909-96	07396805001	EAV (control RNA)	24-28

Note: The crossing point (Cp) values will vary from instrument to instrument by up to 2 cycles.

7. Version History

V170606 Revised version

2017-06-06