

LightMix® Modular Positive Controls Gastro Panel

Cat.-No. 90-0600-01

Roche SAP n° 07 932 146 001

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

1. Content and

- 1 Vial transparent cap Mix I (lyophilized), 32 reactions
- 1 Vial 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 **Positive Control** for ModularDx Gastro kits (Gastro Bacteria, Gastro Parasites, and Gastro Viruses). The amount of the different targets included in the reagents (pDNA) are adjusted to be in a defined Cp range.

4. Instructions for Use

See instruction delivered with the ModularDx kits.

4.1. Preparation of the Positive Control DNA

Add **160 µl** RNase/DNase-free Tris buffer or water to the vial with the **black** cap, for 10 µl sample add **320 µl**. Mix the solution by pipetting up and down 10 times. If vortexing spin down to collect the solution.

Notes: Opening of this vial may cause contaminations of the work-space (aerosol). Use of Tris buffer pH 8.0-8.5 increases the long-term stability in solution. Store dissolved controls frozen.

► Use **5 µl** positive control for a 20 µl PCR reaction (or 10 µl if using 10 µl sample).

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.

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We, the undersigned, certify that the product designated above has been obtained in accordance with the rules of production and quality control.																																												
Name(s) :																																												

6. Description : Gastro Mix Control DNA (Mix I and Mix II)

Gastro Mix I contains target DNA for the following ModularDx Kits

Kit n°	Roche SAP	Target (Pathogen)	CP values
Gastro Bacteria Panel			
50-0601-96	07041837001	<i>Yersinia enterocolitica</i>	27-29
58-0603-96	07041853001	<i>Shigella</i> / EIEC	26-28
64-0600-96	07041829001	<i>Aeromonas</i> spp	28-30
64-0605-96	07041870001	<i>Plesiomonas</i>	28-30
64-0619-96	08022801001	<i>C. diff. Tox B</i>	25-27
Gastro Parasites Panel			
50-0611-96	07041896001	<i>Entamoeba hist.</i>	27-29
58-0613-96	07042248001	<i>Dientamoeba</i>	26-28
64-0615-96	07042264001	<i>Blastocystis</i> spp	28-30
Gastro Virus Panel			
50-0656-96	07730454001	Enterovirus	27-29
50-0652-96	07374348001	Norovirus GG1	29-31
53-0652-96	07374321001	Norovirus GG1	29-31
58-0654-96	07374313001	Rotavirus A	28-30
64-0656-96	07396805001	Enterovirus	27-29
64-0657-96	07374291001	Astrovirus	26-28

Gastro Mix II contains target DNA for the following ModularDx Kits

Kit n°	Roche SAP	Target (Pathogen)	CP values
Gastro Bacteria Panel			
53-0602-96	07041845001	<i>Campylobacter</i>	28-30
61-0604-96	07041861001	<i>Salmonella</i> spp	27-29
64-0616-96	08022771001	<i>C. diff. Tox A</i>	25-27
66-0901-96	07093802001	PhHV (control)	28-30
Gastro Parasites Panel			
53-0612-96	07042230001	<i>Giardia</i>	27-29
61-0614-96	07042256001	<i>Cryptosporidium</i>	24-26
Gastro Virus Panel			
53-0653-96	07374364001	Norovirus GG2	28-30
61-0655-96	07374305001	Adenovirus F	28-30
66-0909-96	07396805001	EAV (control)	28-30

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

7. Version History

V151001	Release version	2015-10-15
V151111	<i>C. diff</i> ToxA moved to MixII and Noro GG1 removed from MixI	2015-11-18
V160313	Roche SAP number	2016-08-08

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