

 Genmark Sağlık Ürünleri <small>ITH. İHR SAN. TIC. LTD.</small>	Technical File	Docum No: F-ÜR-13
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RV2-RT100/RV2-RT500 - geneM.A.P™ geneMAP™ Respiratory Viral Panel 2 (2019-nCoV, Inf A/B, RSV A/B)

The all studies has been performed / performing with 1 day bottled 3 different lot number kits. Various aliquots has been keep in freezer at $-20 \pm 5^{\circ}\text{C}$

- Sample type:Recombinant virus RNA

1-Freeze-Thawing Stability Test

t: Freeze-Thaw Repeat Number	Detected x / 5 replicates		
	Lot01	Lot02	Lot03
0	5/5	5/5	5/5
1	5/5	5/5	5/5
2	5/5	5/5	5/5
3	5/5	5/5	5/5
4	5/5	5/5	5/5
5	5/5	5/5	5/5
6	5/5	5/5	5/5
7	5/5	4/5	4/5
8	5/5	4/5	4/5

2- Room Temperature Stability Test (30°C)

t: Days	Detected x / 5 replicates		
	Lot01	Lot02	Lot03
0	5/5	5/5	5/5
1	5/5	5/5	5/5
2	5/5	5/5	5/5
3	5/5	5/5	5/5
4	5/5	5/5	5/5
5	5/5	5/5	5/5
6	5/5	5/5	5/5
7	5/5	4/5	5/5
8	5/5	4/5	4/5
9	4/5	4/5	4/5

3-Shipping Stability Test:

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The study has been done with 3 kg Blue Ice Bags in Styrofoam box in room temperature (30°C)

t: Days	Detected x / 5 replicates		
	Lot01	Lot02	Lot03
0	5/5	5/5	5/5
1	5/5	5/5	5/5
2	5/5	5/5	5/5
3	5/5	5/5	5/5
4	5/5	5/5	5/5
5	5/5	5/5	4/5
6	4/5	5/5	4/5
7	4/5	4/5	4/5

4- Shelf-Life Stability Test Unopened: (The kit is stable for 12 months at:-20 ±5°C -OneStep Enzyme System)

t: Dates	Detected x / 5 replicates		
	Lot01	Lot02	Lot03
01.01.2020	5/5	5/5	5/5
01.02.2020	5/5	5/5	5/5
01.03.2020	5/5	5/5	5/5
01.04.2020	5/5	5/5	5/5
01.05.2020	5/5	5/5	5/5
01.06.2020	5/5	5/5	5/5
01.06.2020	5/5	5/5	5/5
01.07.2021	5/5	5/5	5/5
01.08.2021	5/5	5/5	5/5
01.09.2021	5/5	5/5	5/5
01.10.2021	5/5	5/5	5/5
01.11.2021	5/5	5/5	5/5
01.12.2021	5/5	5/5	5/5

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5-In-use/Opened Kit Stability: (@ 4±2 °C)

t=days	Detected x / 5 replicates		
	Lot01	Lot02	Lot03
0	5/5	5/5	5/5
1	5/5	5/5	5/5
2	5/5	5/5	5/5
3	5/5	5/5	5/5
4	5/5	5/5	5/5
5	5/5	5/5	5/5
6	5/5	5/5	5/5
7	5/5	5/5	5/5
8	5/5	5/5	5/5
9	5/5	5/5	5/5
10	5/5	5/5	5/5
11	5/5	5/5	5/5
12	5/5	5/5	5/5
13	5/5	5/5	5/5
14	5/5	5/5	5/5
15	5/5	5/5	5/5
16	5/5	5/5	5/5
17	5/5	5/5	5/5
18	5/5	5/5	4/5
19	4/5	4/5	5/5
20	4/5	4/5	4/5

Evaluation:

Burcu SEBİT



Approved by:

Barbaros ERATAK

