

Customer Letter

Issue Date: September 6, 2021

Subject: Release the Cut-off value for Covi-FERON FIA

Dear Valued Customer,

We are pleased to inform you that we release the cut-off value for STANDARD F Covi-FERON FIA (Cat No. 13COVF20G, 13COVF20G-RUO) as following.

Nil (IU/mL)	SP Antigen*-Nil (IU/mL)	NP Antigen-Nil (IU/mL)	Mitogen-Nil (IU/mL)	Result
≤ 8.0	< 0.30	< 0.30	≥ 0.5	Non-Reactive
	≥ 0.30 and <25% of Nil value	≥ 0.30 and <25% of Nil value	≥ 0.5	Non-Reactive
	≥ 0.30 and ≥ 25% of Nil value	Any	Any	Reactive
	Any	≥ 0.30 and ≥ 25% of Nil value	Any	Reactive
	< 0.30	< 0.30	< 0.5	Indeterminate
	≥ 0.30 and <25% of Nil value	≥ 0.30 and <25% of Nil value	< 0.5	Indeterminate
> 8.0	Any	Any	Any	Indeterminate

* Either Original SP Antigen or Variant SP Antigen

NOTE:

- A 'Reactive' result indicates that the sample contains effector T cells-mediated immune response to SARS-CoV-2.
- A 'Non-Reactive' result indicates that no effector T cells-mediated response to SARS-CoV-2 was detected.
- Incorrect performance of the assay may cause false reactive or false non-reactive responses.
- A false non-reactive result can be caused by incorrect blood sample collection or improper handling of the specimen, affecting lymphocyte function.
- A false reactive result may be obtained for the Covi-FERON FIA test when tested in subjects previously exposed to non SARS-CoV-2 human coronaviruses. Alternative tests would be required if these infections are suspected.

Kindly note that the above cut-off criteria has NOT been thoroughly verified by R&D team. Hence, this can be modified in accordance with the results of clinical evaluation study in the future.

Yours faithfully,

Sora Choi
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