



March 09, 2021

Urgent Field Safety Notice – FSN-2101

Coronavirus Ag Rapid Test Cassette (Swab) IFU

Product Name	REF	LOT	EXP
Coronavirus Ag Rapid Test Cassette(Swab)	GCCOV-502a	SEE Attached LOT LIST	SEE Attached LOT LIST

To whom it may concern,

Orient Gene Biotech is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention

ISSUE	<ul style="list-style-type: none">● Currently we add nasal specimen and extend intended use from healthcare professionals to trained operators in the package insert(B22060-03)● The nasal swab and extended intended use are applicable to the products lot mentioned above.● The product lot mentioned above used the previous package insert(B21935-04) along with nasopharyngeal swab instruction and healthcare professionals
IMPACT	<ul style="list-style-type: none">● The product lot mentioned above along with the previous package insert (B21935-04) has no impact to the Orient Gene Coronavirus Ag Rapid Test Cassette (Swab) performance using nasopharyngeal swab.● The nasal swab improves the usability of the test and the extended intended use allow more people participate in the regular testing so as to help monitor individual health condition systematically and fight COVID-19 efficiently.
ACTION	<ul style="list-style-type: none">● The updated IFU will be sent to the distributor, who will send it onto any end customers who are affected. These customers should then take actions to ensure that the instructions in the updated package insert are followed, in place of the previous package insert.● Post the updated package insert (B22060-03) on website where the user can achieve.
RESOLUTION	<ul style="list-style-type: none">● Orient Gene no longer distributes Coronavirus Ag Rapid Test Cassette (Swab) along with package insert (B21935-04).● Future Coronavirus Ag Rapid Test Cassette (Swab) will include a appropriate package insert.



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

The national competent authority has been informed of this field safety corrective action.

Please share this information with your user and retain this notification as part of your Distribution System documentation. If you have forwarded any of the affected product(s) Listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed response form within 10 days so that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact tina@orientgene.com and melinda@orientgene.com

We apologize for the inconvenience that this caused your testing

Yours sincerely,

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