

Cross Reactivity Study Report of COVID-19 Antigen Rapid Test

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Cross Reactivity Study Report of COVID-19 Antigen Rapid Test

1. Purpose

Evaluate Cross Reactivity for COVID-19 Antigen Rapid Test .

2. Material

ICOV-502 Lot1: COV20060001-T
 Lot2: COV20060002-T
 Lot3: COV20060003-T

Bacteria

3. Test methods

Insert cotton swabs into 1E+08org/ml concentrations of bacterial solution to complete the swab sampling operation. Then insert the swab specimen into the specimen Extraction tube and tested according to the package insert in triplicate. Read the results at 15 minutes. Different concentrations of bacterial solution are as follows:

Arcanobacterium	Concentration: 1E+08org/ml
Candida albicans	Concentration: 1E+08org/ml
Corynebacterium	Concentration: 1E+08org/ml
Escherichia coli	Concentration: 1E+08org/ml
Moraxella catarrhalis	Concentration: 1E+08org/ml
Neisseria lactamica	Concentration: 1E+08org/ml
Nesseria subllava	Concentration: 1E+08org/ml
Pseudomonas aeruginosa	Concentration: 1E+08org/ml
Staphylococcus aureus subspaureus	Concentration: 1E+08org/ml
Staphylococcus epidermidis	Concentration: 1E+08org/ml
Streptococcus pneumoniae	Concentration: 1E+08org/ml
Streptococcus pygenes	Concentration: 1E+08org/ml
Streptococcus salivarius	Concentration: 1E+08org/ml
Streptococcus sp group F	Concentration: 1E+08org/m

4. Acceptance Criteria

No cross-reaction. Different substances were added to the test and the results were still negative.

5. Result

Table: Cross Reactivity Result

Treatment	ICOV-502		
	L	COV20060002-T	COV20060003-T

	15 minutes			15 minutes			15 minutes		
Arcanobacterium	-	-	-	-	-	-	-	-	-
Candida albicans	-	-	-	-	-	-	-	-	-
Corynebacterium	-	-	-	-	-	-	-	-	-
Escherichia coli	-	-	-	-	-	-	-	-	-
Moraxella catarrhalis	-	-	-	-	-	-	-	-	-
Neisseria lactamica	-	-	-	-	-	-	-	-	-
Nesseria subllava	-	-	-	-	-	-	-	-	-
Pseudomonas aeruginosa	-	-	-	-	-	-	-	-	-
Staphylococcus aureus subspaureus	-	-	-	-	-	-	-	-	-
Staphylococcus epidermidis	-	-	-	-	-	-	-	-	-
Streptococcus pneumoniae	-	-	-	-	-	-	-	-	-
Streptococcus pyogenes	-	-	-	-	-	-	-	-	-
Streptococcus salivarius	-	-	-	-	-	-	-	-	-
Streptococcus sp group F	-	-	-	-	-	-	-	-	-

Note: “-” means negative result

As can be seen from the above table, the results were all negative after different concentrations of bacterial were tested. So the addition of the bacteria has no influence on the test result.

6. Conclusion

There was no cross-reaction with the substances above at 15 minutes.

