



























## Limit of Detection (LoD) Study Results

Concentration TCID <sub>50</sub> /mL	Number Positive/Total	% Detected
140.6	20/20	100%

## Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross reactivity and potential interference of BinaxNOW™ COVID-19 Ag Card was evaluated by testing 37 commensal and pathogenic microorganisms (8 bacteria, 14 viruses, 1 yeast and pooled human nasal wash) that may be present in the nasal cavity. Each of the organism, viruses, and yeast were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (45 TCID<sub>50</sub>/swab). No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Potential Cross Reactant		Test Concentration
Virus	Adenovirus	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human metapneumovirus (hMPV)	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Rhinovirus	1.0 x 10 <sup>5</sup> PFU/mL
	Enterovirus/Coxsackievirus B4	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human coronavirus OC43	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human coronavirus 229E	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human coronavirus NL63	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 1	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 2	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 3	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Human parainfluenza virus 4	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Influenza A	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Influenza B	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Respiratory Syncytial Virus A	1.0 x 10 <sup>5</sup> PFU/mL
Bacteria	<i>Bordetella pertussis</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Chlamydia pneumoniae</i>	1.0 x 10 <sup>6</sup> IFU/mL
	<i>Haemophilus influenzae</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Legionella pneumophila</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Mycoplasma pneumoniae</i>	1.0 x 10 <sup>6</sup> U/mL
	<i>Streptococcus pneumoniae</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Streptococcus pyogenes (group A)</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Mycobacterium tuberculosis</i>	1.0 x 10 <sup>6</sup> cells/mL
	<i>Staphylococcus aureus</i>	1.0 x 10 <sup>6</sup> org/mL
	<i>Staphylococcus epidermidis</i>	1.0 x 10 <sup>6</sup> org/mL
Pooled human nasal wash	N/A	
Yeast	<i>Candida albicans</i>	1.0 x 10 <sup>6</sup> cells/mL

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45% homology across 18% of the sequence, making cross-reactivity in the BinaxNOW™ COVID-19 Ag Card highly unlikely.
- No protein sequence homology was found between *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein, MERS-CoV and human coronavirus HKU1 revealed that cross-reactivity cannot be ruled out. Homology for HKU1 and MERS-CoV is relatively low, at 37.8% across 95% of the sequence and 57.14% across 87% of the sequence, respectively.

### High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of  $1.6 \times 10^5$  TCID<sub>50</sub>/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW™ COVID-19 Ag Card.

### Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the BinaxNOW™ COVID-19 Ag Card at the concentrations listed below and were found not to affect test performance.

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconium (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkalol	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v
Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin <sup>1</sup>	0.25% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v

<sup>1</sup> Testing demonstrated false negative results at concentrations of 5 mg/mL (0.5% w/v). Standard dose of nasal ointment: 20 mg (2% w/w) of mupirocin in single-use 1-gram tubes.

## SYMBOLS

<b>R<sub>x</sub></b> Only	Prescription Only
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## ORDERING AND CONTACT INFORMATION

### Reorder Numbers:

195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)

195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit

**US +1 877 441 7440**

### Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

**US**

+ 1 800 257 9525

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