Interference Substances Study Report for VivaDiag™ SARS-CoV-2 Ag Rapid Test

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Ver1.0

1 Purpose

The purpose of this report is to summarize the potential interfering substances results for the VivaDiag™ SARS-CoV-2 Ag Rapid Test.

2 Scope

Applicable to VivaDiag™ SARS-CoV-2 Ag Rapid Test.

3 References

CLSI EP07 A3：2018 - Interference Testing in Clinical Chemistry; Approved Guideline -Third Edition

4 Responsibilities

R&D Team is responsible for testing.

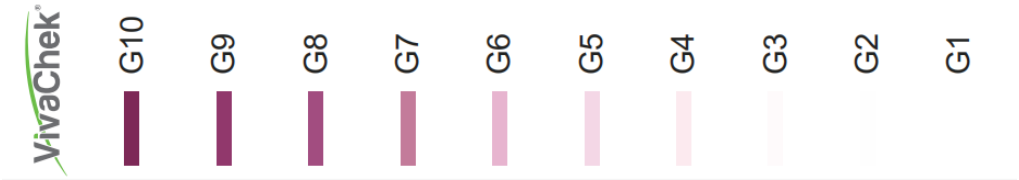
5 Materials and Equipment

5.1 Three (3) VivaDiag™ SARS-CoV-2 Ag Rapid Test Lots

(Lot 1: T2006001, Lot 2: T2006002, Lot 3: T2006003)

5.2 The interfering substances samples

5.3 Color Grade (CF-0021-RE-02 Intensity Grading Card (Rev 0))



6 Acceptance Criteria

6.1 Interference reactivity

According to the color grade interpretation, if there is no difference in the chrominance of the same concentration (with/without the potential interfering substances), the result is acceptable.

7 Procedure

7.1 Interference Reactivity

The potential interfering substance samples are SARS-CoV-2 negative specimens confirmed by PCR test, which are listed in Table 1. And these specimens are tested for 3 times respectively on VivaDiag™ SARS-CoV-2 Ag Rapid Test. Then these specimens mixed the SARS-CoV-2 cultured virus 1/6400 dilution ($1.35x10^3$ $TCID_{50}$/mL) tested for 3 times respectively on VivaDiag™ SARS-CoV-2 Ag Rapid Test.

Table 1- Potential Interfering Substance Samples

Potential Interfering Substance		Concentration
Anti-viral drugs	Zanamivir (Infuenza)	5mg/L
	Oseltamivir (Infuenza)	10mg/mL
	Artemether-lumefantrine (Malaria)	50uM
	Dorxoycline hyclate (Malaria)	70uM
	Quinine (Malaria)	150uM
	Lamivudine (Retroviral medication)	1mg/mL
	Ribavirin (HCV)	1mg/mL
	Daclatasvir (HCV)	1mg/mL
Respiratory Specimens	Mucin:bovine submaxillary gland,type I-S	100ug/mL
	Blood (human), EDTA anticoagulated	5% (v/v)
	Biotin	100ug/mL
Nasal sprays or drops	Neo-Synephrine (Phenylephrine)	10% (v/v)
	Afrin Nasal Spray (Oxymetazoline)	10% (v/v)
	Saline Nasal Spray	10% (v/v)
Homeopathic allergy relief medicine	Homeopathic Zicam Allergy Relief Nasal Gel	5% (v/v)
	Sodium Cromoglycate	20mg/mL
	Olopatadine Hydrochloride	10mg/mL
Anti-inflammato	Acetaminophen	199uM

ry medication	Acetylsalicylic acid	3.62mM
	Ibuprofen	2.425mM
Antibiotic	Mupirocin	10mg/mL
	Tobramycin	5ug/mL
	Erythromycin	81.6uM
	Ciprofloxacin	30.2uM

7.2 Evaluation procedure

The evaluation will be performed in the following sequence.

- Take out the test kit and keep it at room temperature.
- Put a test device on a clean and level surface.
- Gently unscrew the cap of an extraction tube (prefilled with 300μL extraction solution).
- Collect specimen refer to specimen collection, and 10uL of potential interference-reactive samples are inserted into the extubation tube (pre-filled with 300 extraction solution). Mix it thoroughly with the extraction solution, and dispose of the used equipment in biohazard waste.
- Insert a filtered nozzle into extraction tube containing extracted specimen.
- Invert extraction tube and apply 3 drops (about 60μL) of extracted specimen onto the specimen well.
- Read the test result at 15 minutes comparing with Color Grade. Don't read the result after 20 minutes.

8 Results

Interference reactivity	Potential Interference Reactivity																	
Lot	T2006001						T2006002						T2006003					
Sample	Rep.1		Rep.2		Rep.3		Rep.1		Rep.2		Rep.3		Rep.1		Rep.2		Rep.3	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
Zanamivir (Infuenza)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Oseltamivir (Infuenza)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Artemether-lumefantrine (Malaria)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Dorxoycline hyclate (Malaria)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Quinine (Malaria)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Lamivudine (Retroviral medication)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Ribavirin (HCV)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Daclatasvir (HCV)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Mucin:bovine submaxillary gland,type I-S	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Blood (human),EDTA anticoagulated	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Biotin	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Neo-Synephrine (Phenylephrine)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Afrin Nasal Spray (Oxymetazoline)	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Saline Nasal Spray	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Homeopathic Zicam Allergy Relief Nasal Gel	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Sodium Cromoglycate	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Olopatadine Hydrochloride	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Acetaminophen	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Acetylsalicylic acid	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Ibuprofen	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Mupirocin	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Tobramycin	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Erythromycin	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Ciprofloxacin	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1

Interference reactivity	Potential interference substances mixed SARS-CoV-2 cultured virus 1/6400 dilution																	
Lot	T2006001						T2006002						T2006003					
Sample	Rep.1		Rep.2		Rep.3		Rep.1		Rep.2		Rep.3		Rep.1		Rep.2		Rep.3	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
Zanamivir (Infuenza)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Oseltamivir (Infuenza)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Artemether-lumefantrine (Malaria)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Dorxoycline hyclate (Malaria)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Quinine (Malaria)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Lamivudine (Retroviral medication)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Ribavirin (HCV)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Daclatasvir (HCV)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Mucin:bovine submaxillary gland,type I-S	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Blood (human),EDTA anticoagulated	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Biotin	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Neo-Synephrine (Phenylephrine)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Afrin Nasal Spray (Oxymetazoline)	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Saline Nasal Spray	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Homeopathic Zicam Allergy Relief Nasal Gel	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Sodium Cromoglycate	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Olopatadine Hydrochloride	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Acetaminophen	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Acetylsalicylic acid	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Ibuprofen	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Mupirocin	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Tobramycin	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Erythromycin	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
Ciprofloxacin	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3

9 Conclusion

It is shown that there are no interferences for potential interfering substances.