PROJECT CODE	PRODUCT DESIGNATION	REFERENCE
NA	BIOSYNEX COVID-19 BSS	SW40005

Content

I. Precision

1. Repeatability

Completion date: 2020/02/25

➢ Objective

The objective is to assess the intra lot and inter lot repeatability of the test.

➢ Material

✓ Description of component

3 lots of the COVID-19 rapid test: Lot1#: COV2002001-R, Lot2#: COV2002002-R, Lot3#: COV2002003-R

✓ Samples

Negative and positive (P1) specimen

➢ Method

Negative and positive (P1) specimens were run in replicates of 10 in three separate lots of products. Results were read as positive or negative at 10 minutes after specimen application.

➢ Results

	Lot1#: COV2002001-R			Lot2#: COV2002002-R			Lot3#: COV2002003-R		
Times	Neg	IgG Pos	IgM Pos	Neg	IgG Pos	IgM Pos	Neg	IgG Pos	IgM Pos
	10min	10min	10min	10min	10min	10min	10min	10min	10min
1	-	+	+	-	+	+	-	+	+
2	-	+	+	-	+	+	-	+	+
3	-	+	+	-	+	+	-	+	+
4	-	+	+	-	+	+	-	+	+
5	-	+	+	-	+	+	-	+	+
6	-	+	+	-	+	+	-	+	+
7	-	+	+	-	+	+	-	+	+
8	-	+	+	-	+	+	-	+	+
9	-	+	+	-	+	+	-	+	+
10	-	+	+	-	+	+	-	+	+

➢ Conclusion

100% of actual results were consistent with expected results. No distinct difference was detected in intra lots and inter-lot.

2. Reproducibility

2.1. Inter Days Reproducibility

No data available. Study in progress

2.2. Inter Lots reproducibility

See §1.

2.3. Inter places

No data available. Study in progress

2.4. Inter persons

No data available. Study in progress

II. Analytical sensitivity

Completion date: *2020.03.02*

- Objective

The objective is to determine the level of detection of the test.

- Material
  - ✓ Product Information:
    COVID-19 IgG/IgM Rapid Test
    Lot No.1: COV2002001-T
    Lot No.2: COV2002002-T
    Lot No.3: COV2002003-T
  - ✓ Sample Information:
    COV-IgG-IgM positive (P1) 20200302-01

- Method

A COV-IgG-IgM positive (P1) specimen was diluted to the following concentrations: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256 and 1:512, with the same negative serum.
Different diluted positive specimens were tested by COVID-19 IgG/IgM Rapid test. The diluted positive samples were randomized and run blind-coded in replicates of 3. Interpret the results at 10 minutes.

- Results

COV-IgG-IgM positive (P1) for IgM test									
Specimen Dilution	COV2002001-T			COV2002002-T			COV2002003-T		
	10min	10min	10min	10min	10min	10min	10min	10min	10min
original	+	+	+	+	+	+	+	+	+
1:2	+	+	+	+	+	+	+	+	+
1:4	+	+	+	+	+	+	+	+	+
1:8	+	+	+	+	+	+	+	+	+
1:16	+	+	+	+	+	+	+	+	+
1:32	+	+	+	+	+	+	+	+	+
1:64	+	+	+	+	+	+	+	+	+
1:128	+	+	+	+	+	+	+	+	+
1:256	+	+	+	+	+	+	+	+	+
1:512	-	-	-	-	-	-	-	-	-

COV-IgG-IgM positive (P1) for IgG test									
Specimen Dilution	COV2002001-T			COV2002002-T			COV2002003-T		
	10min	10min	10min	10min	10min	10min	10min	10min	10min
original	+	+	+	+	+	+	+	+	+
1:2	+	+	+	+	+	+	+	+	+
1:4	+	+	+	+	+	+	+	+	+
1:8	+	+	+	+	+	+	+	+	+
1:16	+	+	+	+	+	+	+	+	+
1:32	+	+	+	+	+	+	+	+	+
1:64	+	+	+	+	+	+	+	+	+
1:128	-	-	-	-	-	-	-	-	-
1:256	-	-	-	-	-	-	-	-	-

Comment: - means negative result and + means positive result.

➢ Conclusion

From the above study results, the detection level of COVID-19 IgG/IgM Rapid Test is 1:256 for COVID-19 IgM positive specimen and 1:64 for COVID-19 IgG positive specimen with the COV-IgG-IgM positive (P1).

III. Analytical specificity

1. Interference Testing

Completion date: *2020.02.20*

➢ Objective

To evaluate the possible interference between the test and different analytes.

➢ Material

✓ Description of component

3 lots of the COVID-19 rapid test: Lot1#: COV2002001-R, Lot2#: COV2002002-R, Lot3#: COV2002003-R

➢ Method

Analytes were spiked into negative serum (product confirmed) at the concentrations listed. The specimens were tested in triplicate with visual interpretations occurring at 10minutes after specimen application. Results are presented in table below.

➢ Results

COVID-19 IgG/IgM		COV2002001-R			COV2002002-R			COV2002003-R		
Analytes	**Concentration**	**Negative**			**Negative**			**Negative**		
Acetaminophen	20 mg/dL	1	1	1	1	1	1	1	1	1
Caffeine	20 mg/dL	1	1	1	1	1	1	1	1	1
Albumin	2 g/dL	1	1	1	1	1	1	1	1	1
Acetylsalicylic Acid	20 mg/dL	1	1	1	1	1	1	1	1	1
Gentisic Acid	20 mg/dL	1	1	1	1	1	1	1	1	1
Ethanol	1%	1	1	1	1	1	1	1	1	1
Ascorbic Acid	2g/dL	1	1	1	1	1	1	1	1	1
Creatine	200mg/d	1	1	1	1	1	1	1	1	1
Bilirubin	1g/dL	1	1	1	1	1	1	1	1	1
Hemoglobin	1000mg/dl	1	1	1	1	1	1	1	1	1
Oxalic Acid	60mg/dL	1	1	1	1	1	1	1	1	1
Uric acid	20mg/ml	1	1	1	1	1	1	1	1	1

➢ Conclusion

No substances showed any interference with the test. There were no differences observed between the results at 10 minutes

2. Cross reactivity

Completion date: *2020.02.20*

➢ Objective

The aim of this study is to evaluate whether cross-reaction occur with specimens: anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV, HAMA, SARS-CoV antibody and Rheumatoid Factor positive specimens.

➢ Material

✓ Description of component

3 lots of the COVID-19 rapid test: Lot1#: COV2002001-R, Lot2#: COV2002002-R, Lot3#: COV2002003-R

➢ Method

The COVID-19 IgG/IgM Rapid Test has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV, anti-SARS-COV, HAMA and rheumatoid factor positive specimens. Visual interpretations were recorded at 10 minutes after specimen application.

➢ Results

COVID-19 IgG/IgM / Specimens	COV2002001-R			COV2002002-R			COV2002003-R		
	Neg. Serum			Neg. Serum			Neg. Serum		
3 anti-influenza A virus	-	-	-	-	-	-	-	-	-
3 anti-influenza B virus	-	-	-	-	-	-	-	-	-
3 anti-RSV	-	-	-	-	-	-	-	-	-
3 anti-Adenovirus	-	-	-	-	-	-	-	-	-
3 HBsAg	-	-	-	-	-	-	-	-	-
3 anti-Syphilis	-	-	-	-	-	-	-	-	-
3 anti-H. Pylori	-	-	-	-	-	-	-	-	-
3 anti-HIV	-	-	-	-	-	-	-	-	-
3 anti-HCV	-	-	-	-	-	-	-	-	-
1 anti-SARS-COV	+			+			+		
10 HAMA	10 -			10 -			10 -		
30 RF	23-, 7+			23-, 7+			23-, 7+		

➢ Conclusion

There was no cross-reaction with anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV and HAMA positive specimens at 10minutes. Some cross reactivity was observed with samples positive for SARS-CoV antibody and Rheumatoid Factor.

IV. Robustness

1. Temperature flex study

Completion date: *2020.02.24*

➢ Objective

The objective is to evaluate the impact on the test results when the test is stored at different temperatures (-20°C, 2~8°C, RT, 37°C and 45°C)

➢ Material

✓ Description of component

3 lots of the COVID-19 rapid test: Lot1#: COV2002001-R, Lot2#: COV2002002-R, Lot3#: COV2002003-R

✓ Samples

10 negative serum samples

➢ Method

10 negative serum samples will be tested with COVID-19 IgG/IgM Rapid test product stored at -20°C, 2~8°C, RT, 37°C and 45°C. The results have been read at the prescribed read time.

➢ Results

Treatment temperature(°C)	COV2002001-R									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	1	1	1	1	1	1	1	1	1	1
2~8	1	1	1	1	1	1	1	1	1	1
RT	1	1	1	1	1	1	1	1	1	1
37	1	1	1	1	1	1	1	1	1	1
45	1	1	1	1	1	1	1	1	1	1
Treatment temperature(°C)	COV2002002-R									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	1	1	1	1	1	1	1	1	1	1
2~8	1	1	1	1	1	1	1	1	1	1
RT	1	1	1	1	1	1	1	1	1	1
37	1	1	1	1	1	1	1	1	1	1
45	1	1	1	1	1	1	1	1	1	1
Treatment temperature(°C)	COV2002003-R									
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
-20	1	1	1	1	1	1	1	1	1	1
2~8	1	1	1	1	1	1	1	1	1	1
RT	1	1	1	1	1	1	1	1	1	1
37	1	1	1	1	1	1	1	1	1	1
45	1	1	1	1	1	1	1	1	1	1

➢ Conclusion

The data showed that COVID-19 IgG/IgM Rapid test product can yield correct results when tested from -20°C to 45°C at 30 minutes with the samples for serum samples. But the sensitive of product will influence significantly at -20℃ and 2~8℃ . Performing the test at RT will be better.

2. Anti-coagulant study

Completion date: *2020.02.21*

➢ Objective

The aim of this study is to evaluate whether the use of different anticoagulants on specimen has an impact on the performances of the test.

➢ Material

✓ Description of component

COVID-19 rapid test: Lot#COV2002001-R

✓ Samples

Samples collected from 10 volunteers with COVID-19.

➢ Method

To test the samples collected from 10 volunteers with COVID-19 (Whole blood/Serum/plasma) respectively. From each healthy volunteer, 6 kinds of anticoagulants are used to collect whole blood samples. Namely K2EDTA treated plasma, Sodium / Potassium citrate treated plasma, Sodium / Lithium heparin treated plasma and Sodium oxalate treated plasma was collected respectively. One test was run for each sample.

*Direction for testing:

For Whole blood/serum/plasma: 1 drop (approximately 10µl) of Serum/Plasma+2drops (approximately 80ul) of buffer. Read the results at 10 min.

➢ Results

Item	Time	Serum		K_2EDTA				Sodium citrate				Potassium citrate				Sodium heparin				Lithium heparin				Sodium oxalate			
				Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB		Plasma		WB	
		IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
1	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
2	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
3	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
4	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
5	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
6	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
7	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
8	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
9	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			
10	10mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	20mins	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Background	Clear		Clear				Clear				Clear				Clear				Clear				Clear			

➢ Conclusion

The result showed no difference among different anticoagulant tube to collect Whole blood/serum/plasma samples in this study.

V. Measuring range of the assay (hook effect)

No data available. Study in progress.

VI. History (changes)

Revision	Date	Part	Reason/Changes
01	2020-03-19	NA	Creation of the document