Cross Reactivity Study Report

1. Purpose:

The purpose of this study is to know the pathogens that cross-react with Atlas COVID-19 IgG/IgM Rapid Test Device.

2. Materials:

a) Anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-adenovirus, anti-HBsAg, anti-H. Pylori, anti-HIV, anti-HCV, anti-SARS-COV1 serum-based control samples.

a) Three lots of Atlas COVID-19 IgG/IgM Rapid Test device: (20021201, EXP: 12.02.2022, 20021202,EXP: 12.02.2022 & 20021301, EXP: 13.02.2022).

3. Testing Procedure:

3.1 Test the samples using the three batches of Atlas COVID-19 IgG/IgM Rapid test devices according to the product package insert. The reading time is 10 minutes after applying the sample.

4. Data:

The data is presented in Table 1.

Table 1:

Cross Reaction sample	**Test Result**					
	20021201		20021202		20021301	
	IgG	IgM	IgG	IgM	IgG	IgM
Anti-Influenza A	-	-	-	-	-	-
Anti-Influenza B	-	-	-	-	-	-
Anti-RSV	-	-	-	-	-	-
Anti-Adenovirus	-	-	-	-	-	-
Anti-HBsAg	-	-	-	-	-	-
Anti-Syphilis	-	-	-	-	-	-
Anti-HCV	-	-	-	-	-	-
Anti-HIV	-	-	-	-	-	-
Anti-SARS-COV-1	+	+	+	+	+	+

5. Conclusion:

There was no cross-reaction anti-influenza A, anti-influenza B, anti-RSV, anti-Adenovirus, anti-HBsAg, anti-Syphilis, anti-H.pylori, anti-HIV, anti-HCV positive control samples at 10 minutes reading time. Weak Cross reactivity is observed with the serum based sample for SARS-COV-1 antibody.

Stability study Report

1. Purpose:

To investigate the stability of the Atlas COVID-19 IgG/IgM Rapid Test Device Kit related to accelerated and transportation stability studies.

2. Material:

a) Three batches of Atlas COVID-19 IgG/IgM Rapid Test Device Kit: ((20030801, EXP: 08.03.2022, 20030802, EXP: 08.03.2022 & 20030901, EXP: 09.03.2022).
b) Clinical COVID-19 IgG Positive Sample (ELISA confirmed).
c) Clinical COVID-19 IgM Positive Sample (ELISA confirmed).
d) Clinical COVID-19 Negative sample collected from healthy people who have no cold symptoms and are not taking any drugs (ELISA confirmed).

3. Testing Procedure:

Test the negative and positive samples using three batches of Atlas COVID 19 IgG/IgM Rapid Test Device Kit according to the product package insert, each sample is tested three times for each batch.

4. Data:

4.1 Accelerated Stability Study:

Accelerated stability study of Atlas COVID -19 IgG/IgM Rapid Test Device Kit was evaluated using samples from three different batches. These strips were placed in an incubator with the temperature calibrated at 55^0 C and relative humidity calibrated at 60%, the stability testing was performed at 0, 7 and 14 days using negative and positive specimens. The data is presented in table 1.

Table 1: Accelerated Stability Study Test results at 55^0C.

Day	Specimen		Batch #								
			20030801			20030802			20030901		
0	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
7	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-

	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
14	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+

4.2 Transportation stability study:

The Transportation stability study was performed by storing Atlas COVID 19 IgG/IgM rapid test Device for 3 days at extreme low temperature (freezer < -10^{0}C) followed by 3 days at cool temperature (2-8 ^{o}C) followed by 3 days at controlled temperature (20-25 ^{o}C) then followed by 3 days at high temperature (oven (40-45^{o}C)).

Table 2: Transportation stability study test result:

Day	**Specimen**		**Batch #**								
			20030801			20030802			20030901		
0	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
3 (freezer)	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
6 (2-8 ^{o}C)	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
9 (20-25 ^{o}C)	Negative	IgG	-	-	-	-	-	-	-	-	-
		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+
	Negative	IgG	-	-	-	-	-	-	-	-	-

12 (40-45^{o}C)		IgM	-	-	-	-	-	-	-	-	-
	IgG Positive	IgG	+	+	+	+	+	+	+	+	+
		IgM	-	-	-	-	-	-	-	-	-
	IgM Positive	IgG	-	-	-	-	-	-	-	-	-
		IgM	+	+	+	+	+	+	+	+	+

5. Conclusion:

5.1 Accelerated Stability Study:

Atlas COVID 19 IgG/IgM rapid test device is stable at 55 ^{0}C for 14 days and according to the Arrhenius plot the shelf life of Atlas COVID 19 IgG/IgM rapid test device is projected to be at least 24 months from the date of manufacture.

5.2 Transportation Stability study:

Thermal cycling change that could occur during the distribution of Atlas COVID 19 IgG/IgM Rapid Test Device has no effect on product test result.

Sample Correlation Study Report

1. Purpose:

The purpose of this study is to show the relative sensitivity, specificity, and accuracy of Atlas COVID 19 IgG/ IgM Rapid test device when compared to a SARS-COV-2 IgG/IgM ELISA Test Results.

2. Material:

a) Atlas COVID-19 IgG/IgM Rapid Test device: (20021201, EXP: 12.02.2022).
b) COVID-19 Positive Clinical samples: 77 IgG positive and 81 IgM positive (Confirmed by SARS-COV-2 IgG/IgM ELISA).
c) Negative Clinical Samples from healthy people who have no cold symptoms and do not take drugs: 105 samples (confirm by SARS-COV-2 IgG/IgM ELISA test).

3. Testing Procedure:

3.1 Test the samples (positive and negative) and compare the results with the test results of ELISA test.
3.2 Conduct the test as per the Atlas COVID 19 IgG/IgM Rapid test device package insert. Read the test result at 10 minutes.
3.3 The data is presented in tables 1&2.

4. Data:

4.1 IgG Test Result:

Table 1:

Method		**ELISA Results**		**Total Results**
Atlas COVID 19 IgG/IgM Rapid Test Device (IgG Test).	**Results**	**Positive**	**Negative**	
	Positive	74	2	76
	Negative	3	103	106
Total Results		77	105	182

Sensitivity: (74/ (74+3)) = 96.1 % (95%CI: 91.8%~100%).
Specificity: (103/ (103+2)) = 98.1% (95%CI: 95.5%~100%).
Accuracy: (True positive +True Negative /Total) = ((74+103)/182) = 97.2% (95% CI: 94.8%~99.6%).

4.2 IgM Test Result:

Table 2:

Method		**ELISA Results**		**Total Results**
Atlas COVID 19 IgG/IgM Rapid Test Device (IgM Test).	**Results**	**Positive**	**Negative**	
	Positive	76	4	80
	Negative	5	101	106
Total Results		81	105	186

Sensitivity: (76/ (76+5)) = 93.8% (95%CI: 88.6%~99.1%).

Specificity: (101/ (101+4)) = 96.2% (95%CI: 92.5%~99.9%).

Accuracy: (True positive +True Negative /Total) = ((76+101)/186) =95.1% (95% CI: 92%~98.2%).

5. Conclusions:

The obtained data from this study show that Atlas COVID 19 IgG/IgM rapid test device has relatively high sensitivity, specificity and accuracy when compared to SARS-COV-2 IgG/IgM ELISA Test Results.

Interfering substances Study Report

1. Purpose:

The purpose of this study is to identify the substances that do not react with Atlas COVID 19 IgG/IgM rapid Test Device.

2. Material:

a) Various ingestible or physiological substances:

Substance	Concentration
Acetaminophen	20 mg/dl
Caffeine	20 mg/dl
Albumin	2 g/dl
Acetylsalicylic acid	20 mg/dl
Gentisic Acid	20 mg/dl
Ethanol	1%
Ascorbic acid	2 g/dl
Creatinine	200 mg/dl
Bilirubin	1 g/dl
Hemoglobin	1000 mg/dl
Oxalic acid	60 mg/dl
Uric Acid	20 mg/dl

a) Three lots of Atlas COVID-19 IgG/IgM Rapid Test device: (20021201, EXP: 12.02.2022, 20021202, EXP: 12.02.2022 & 20021301, EXP: 13.02.2022).
b) Pooled negative serum sample collected from healthy people who have no cold symptoms and are not taking any drugs.

3. Testing Procedure:

3.1 Test the pooled negative serum sample according to the product package insert to ensure that it gives a negative result.
3.2 Spike Pooled negative serum sample with each ingestible or physiological substance at the above listed concentrations.
3.3 Test the prepared samples using Atlas COVID 19 IgG/IgM Rapid Test device according to Atlas COVID 19 IgG/IgM Rapid Test package insert. Read results at 10 minutes.

4. Data:

The data is presented in Table 1.

Table 1:

Interfering Substances	**Concentration**	**Test Result**					
		20021201		20021202		20021301	
		IgG	IgM	IgG	IgM	IgG	IgM
Acetaminophen	20 mg/dl	-	-	-	-	-	-
Caffeine	20 mg/dl	-	-	-	-	-	-
Albumin	2 g/dl	-	-	-	-	-	-
Acetylsalicylic acid	20 mg/dl	-	-	-	-	-	-
Gentisic Acid	20 mg/dl	-	-	-	-	-	-
Ethanol	1%	-	-	-	-	-	-
Ascorbic acid	2 g/dl	-	-	-	-	-	-
Creatinine	200 mg/dl	-	-	-	-	-	-
Bilirubin	1 g/dl	-	-	-	-	-	-
Hemoglobin	1000 mg/dl	-	-	-	-	-	-
Oxalic acid	60 mg/dl	-	-	-	-	-	-
Uric Acid	20 mg/dl	-	-	-	-	-	-

5. Conclusion:

The above-mentioned substances do not cross react with Atlas COVID -19 IgG/IgM Rapid test device when they are present in samples at the said concentrations after 10 minutes of applying the sample.

Cut-off Value Study Protocol

1. Purpose:

To verify the cut-off value of Atlas COVID-19 IgG/IgM Rapid Test device.

2. Material:

a) 3 lots of Atlas COVID-19 IgG/IgM Rapid Test device: (20021201, EXP: 12.02.2022, 20021202,EXP: 12.02.2022 & 20021301, EXP: 13.02.2022).

a) COVID-19 IgG positive sample and COVID-19 IgM positive sample (Confirmed by ELISA).

b) Pooled negative serum sample collected from healthy people who have no cold symptoms and are not taking any drugs.

3. Testing Procedure:

3.1 Test the pooled negative serum sample according to the product package insert to ensure that it gives a negative result.

3.2 Dilute the positive IgG sample and Positive IgM sample with pooled negative serum sample to make the following concentrations: 1:2,1:4,1:8,1:16,1:32,1:64, 1:128,1:256, 1:512, and 1:1024.

3.3 Test each sample with three lots of Atlas COVID-19 IgG/IgM Rapid Test device according to the product package insert and repeat the test three times for each sample. Read the test result at 10 minutes after applying the sample.

4. Data:

The data is presented in the table below:

COVID IgG/IgM positive sample testing of IgM Test									
Specimen	20021201			20021202			20021301		
Dilution	10 min	10 min	10 min	10 min	10 min	10 min	10 min	10 min	10 min
Original	+	+	+	+	+	+	+	+	+
1:2	+	+	+	+	+	+	+	+	+
1:4	+	+	+	+	+	+	+	+	+
1:16	+	+	+	+	+	+	+	+	+
1:32	+	+	+	+	+	+	+	+	+
1:64	+	+	+	+	+	+	+	+	+
1:128	+	+	+	+	+	+	+	+	+
1:256	±	±	±	±	±	±	+	+	+
1:512	-	-	-	-	-	-	±	±	±
1:1024	-	-	-	-	-	-	-	-	-

COVID IgG/IgM positive sample testing of IgG Test									
Specimen Dilution	20021201			20021202			20021301		
	10 min	10 min	10 min	10 min	10 min	10 min	10 min	10 min	10 min
Original	+	+	+	+	+	+	+	+	+
1:2	+	+	+	+	+	+	+	+	+
1:4	+	+	+	+	+	+	+	+	+
1:16	+	+	+	+	+	+	+	+	+
1:32	+	+	+	+	+	+	+	+	+
1:64	+	+	+	+	+	+	+	+	+
1:128	±	±	±	+	+	+	+	±	±
1:256	-	-	-	±	±	±	±	-	-
1:512	-	-	-	-	-	-	-	-	-
1:1024	-	-	-	-	-	-	-	-	-

5. Conclusion:

The detection limit of Atlas COVID-19 IgG/IgM Rapid Test device is 1:256-1:512 for COVID-19 IgM positive sample and 1:128-1:256 for COVID-19 IgG positive sample.