Accelerated Stability Study

Rapid SARS-CoV-2 Antibody (IgM/IgG) Test（Colloidal Gold）

1. Brief

   The experiment was conducted to study the accelerated stability of Rapid SARS-CoV-2 Antibody (IgM/IgG) Test at 50 ℃. The Quality Control panel was taken as quality control material to assay if the product could meet requirement.

2. Experiment time: 2020.02.21-2020.04.14

3. Operator: Wang Bin

4. Experiment Site: Rapid Test R&D Laboratory, InTec PRODUCTS, INC

5. Acceptance Criteria

   The results of stability study shall meet requirements of the control panel as follows:

5.1 Sensitivity

1) Assay with quality control P-T/M, add specimen and read after 20 minutes, the Test Line color intensity for IgM test strip should be within L6-L8;
2) Assay with quality control P-G, add specimen and read after 20 minutes, the Test Line color intensity for IgG test strip should be within L1-L3.

5.2 Specificity

Assay with SARS-CoV-2 negative controls for 20 samples. Add specimen and read after 20 minutes, the detection rate should be 20/20.

5.3 Repeatability

1) Assay the IgM test strip in 10 replicates with the quality control P-T/M, and the test results should be same. After 20 minutes of specimen addition, all samples were tested positive and the difference in color intensity was not more than one degree.
2) Assay the IgG test strip in 10 replicates with the quality control P-G, and the test results should be same. After 20 minutes of specimen addition, all samples were tested positive and the difference in color intensity was not more than one degree.

6. Experimental protocol

1) Test reagent: Three batches of qualified Rapid SARS-CoV-2 Antibody (IgM/IgG) Test (Colloidal Gold) were produced by standard process, whose batch numbers are S2020021505、S2020030401、GJ20030276
2) Presumed storage conditions: store the kits in 50℃ incubator for 60 days.
3) Quality control: P-T/M、P-G and 20 Negative Samples (N1-N20).
4) Method: Prepare enough Rapid SARS-CoV-2 Antibody (IgM/IgG) Test kits (Colloidal Gold). Store the kits in 50℃ incubator, take out the kits and assay by the quality controls every 7 days. Record the assay results to confirm the accelerated stability of product.

7. Experiment Results

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The experiment results of Lot No. S2020021505 for 7 days

Experiment time: 2020.02.21

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 7	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 2-3	L 2-3	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20

	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 14 days

Experiment time: 2020.02.28

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6-7	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 2-3	L 2-3	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

Panel		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 21 days

Experiment time: 2020.03.06

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6-7	L 6	L 6	L 6	L 7	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 2-3	L 2-3	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

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Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 28 days

Experiment time: 2020.03.13

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6	L 6	L 6	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6-7	L 6	L 6	L 7	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability

	20min TL	IgG	L 2	L 2-3	L 2-3	L 2	L 2	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 30 days

Experiment time: 2020.03.16

	No.		Quality Control P-T/M			Quality Control P-G			/			
Sensitivity	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2	L 2	L 3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6-7	L 6

	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 2	L 2-3	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 35 days

Experiment time: 2020.03.20

	No.		Quality Control P-T/M			Quality Control P-G			/
Sensitivity	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/
	20min TL		L 0	L 0	L 0	L 2	L 2	L 3	/
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/
	20min TL		L 6-7	L 6-7	L 6-7	L 0	L 0	L 0	/

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Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 2	L 2-3	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 42 days

Experiment time: 2020.03.27

Sensi	No.	Quality Control P-T/M	Quality Control P-G	/

tivity	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2	L 2	L 3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6	L 6	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2	L 3	L 2	L 2-3	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

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The experiment results of Lot No. S2020021505 for 49 days

Experiment time: 2020.04.03

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2	L 2	L 2	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2	L 2-3	L 2	L 2	L 2-3	L 2	L 2	L 2	L 2
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 56 days

Experiment time: 2020.04.10

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2	L 2	L 3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 7	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2	L 2	L 2-3	L 2-3	L 1	L 2	L 2	L 1
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

Panel		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020021505 for 60 days

Experiment time: 2020.04.14

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2	L 2	L 2	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6	L 6	L 6	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6-7	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 1	L 2-3	L 2-3	L 2	L 2	L 2	L 2

		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N12	N13	N14	N20	N16	N17	N18	N19	N20
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020030401 for 7 days

Experiment time: 2020.03.10

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6-7	L 6	L 6	L 7	L 6	L 6	L 6

	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 3	L 2-3	L 2-3	L 2-3	L 2-3	L 2	L 2	L 2-3	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020030401 for 14 days

Experiment time: 2020.03.17

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6	L 6	L 6	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

		IgM	L 6	L 6	L 6	L 6-7	L 6	L 6	L 7	L 6	L 6	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 3	L 2-3	L 2-3	L 2-3	L 2	L 2	L 2-3	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020030401 for 21 days

Experiment time: 2020.03.24

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6	L 0	L 0	L 0	/			
Repeatabil	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability

ity	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6-7	L 6	L 6	L 7	L 6	L 6	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 3	L 2-3	L 2-3	L 2	L 2	L 2-3	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020030401 for 28 days

Experiment time: 2020.03.31

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/

	20min TL		L 6-7	L 7	L 7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6-7	L 6	L 7	L 6	L 6	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 2-3	L 2-3	L 2-3	L 2	L 2	L 2-3	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. S2020030401 for 35 days

Experiment time: 2020.04.07

Sensi	No.	Quality Control P-T/M	Quality Control P-G	/

tivity	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2	L 2	L 2	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6	L 6	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6-7	L 6	L 6	L 6	L 6	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 3	L 2-3	L 2-3	L 2-3	L 1	L 2	L 2-3	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

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The experiment results of Lot No. S2020030401 for 42 days

Experiment time: 2020.04.14

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2	L 2	L 2	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6-7	L 6	L 6	L 6	L 6	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 2-3	L 2-3	L 2-3	L 2-3	L 2	L 2	L 1	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. GJ20030276 for 7 days

Experiment time: 2020.03.26

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6	L 6-7	L 6-7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 3	L 3	L 3	L 2-3	L 3	L 2	L 2	L 2-3	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

Panel		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. GJ20030276 for 14 days

Experiment time: 2020.04.02

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 6-7	L 6-7	L 6	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6	L 6
	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 3	L 3	L 2	L 2-3	L 2	L 2	L 2-3	L 2-3

		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

The experiment results of Lot No. GJ20030276 for 21 days

Experiment time: 2020.04.09

Sensitivity	No.		Quality Control P-T/M			Quality Control P-G			/			
	20min CL	IgG	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 0	L 0	L 0	L 2-3	L 2-3	L 2-3	/			
	20min CL	IgM	L 10	L 10	L 10	L 10	L 10	L 10	/			
	20min TL		L 7	L 7	L 7	L 0	L 0	L 0	/			
Repeatability	Assay with quality control P-T/M		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 7	L 7	L 7	L 7	L 7	L 7	L 6-7	L 7	L 7	L 7

	Assay with quality control P-G		Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability	Repeatability
	20min TL	IgG	L 2	L 2-3	L 3	L 3	L 2-3	L 2-3	L 2	L 2	L 2-3	L 2-3
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
Negative Panel	No.		N1	N1	N2	N3	N4	N5	N6	N7	N1	N2
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
	No.		N11	N11	N12	N13	N14	N20	N16	N17	N11	N12
	20min TL	IgG	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0
		IgM	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0	L 0

8 Conclusion

The above experiments results show that the sensitivity and repeatability of Rapid SARS-CoV-2 Antibody (IgM/IgG) Test kits (Colloidal Gold) produced by InTec PRODUCTS, INC. can meet the requirements after accelerated test at 50℃ for 60 days with three batches of kits S2020021505, S2020030401 and GJ20030276. Based on our company's mature colloidal gold platform and the product stability of products of the same type and methodologies that have been certified, it is recommended that the product be valid for at least 12 months.