

SEKBIO



SARS-CoV-2 Rapid Ag Test Uncut Sheet

| Committed to make diagnostics more accurate |



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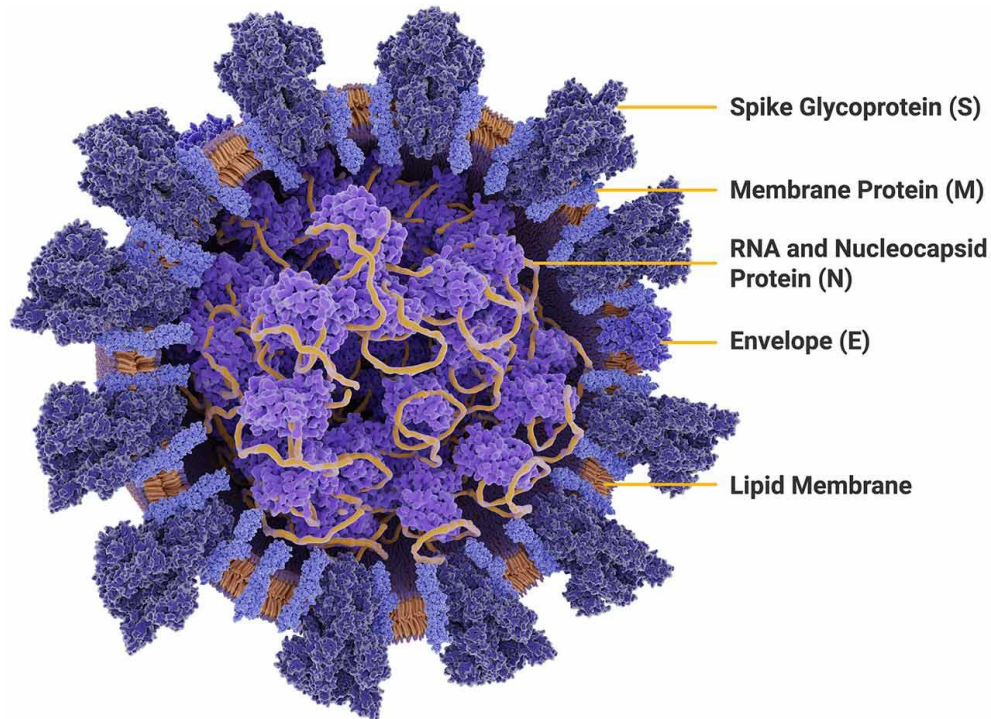
04

Comparison

Part 01

SARS-CoV-2

- SARS-CoV-2
Structure
- Nucleocapsid
Protein



Nucleocapsid Protein

The nucleocapsid protein is the most highly expressed of the four major coronavirus structural proteins, is a structural protein that creates a capsid around the enclosed nucleic acid. And plays role of:

- Interacting with the viral membrane protein during viral assembly;
- Assisting in RNA synthesis and folding;
- Playing a role in virus budding;
- Affecting host cell responses, including cell cycle and translation.

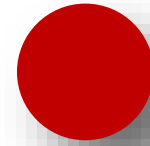
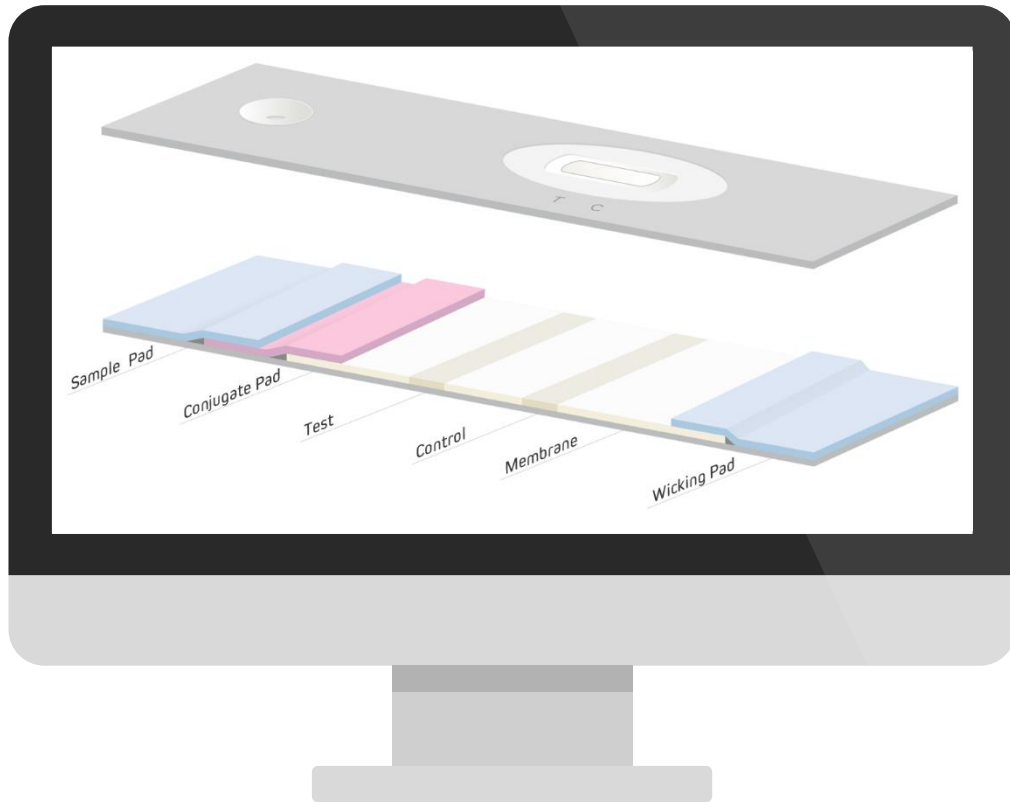
Part 02

Components

- Components
- Principle

Uncut Sheet Components

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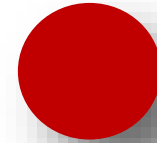
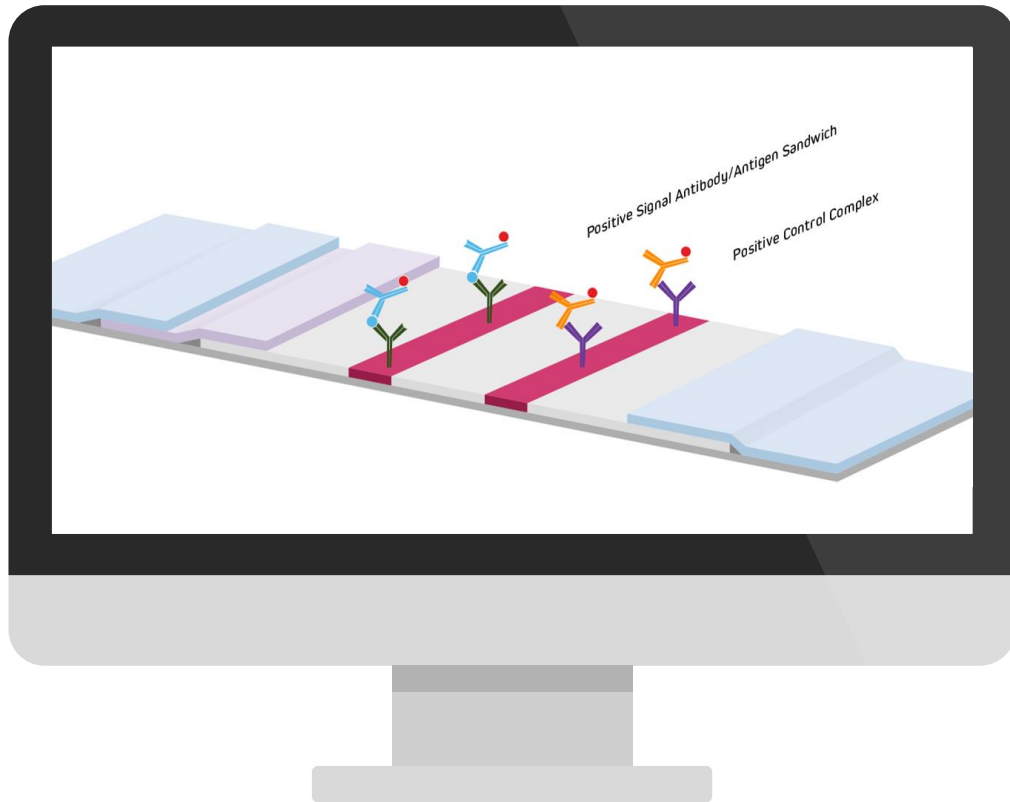
This uncut sheet is consist of Sample Pad, Conjugate Pad, NC Membrane, Wicking Pad, and antibody printed T Line and C Line.

The T Line is coated with Recombinant Rabbit Anti-SARS-CoV-2 NP Antibody;

The Conjugate Pad is coated with nanoparticle-labeled SARS-CoV-2 NP antibody.

Test Principle

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If NP antigen is present, it will bind to the colored antibody-nanoparticle conjugate forming an immunocomplex.

The immunocomplex will then migrate on the membrane via capillary action. And then will bind to the antibody on T Line, forming a visible red band to an positive result.

The absence of the colored band in the test region suggests a negative result. A colored band always appears on C Line serving as procedural control regardless of the specimen contains NP antigen or not.

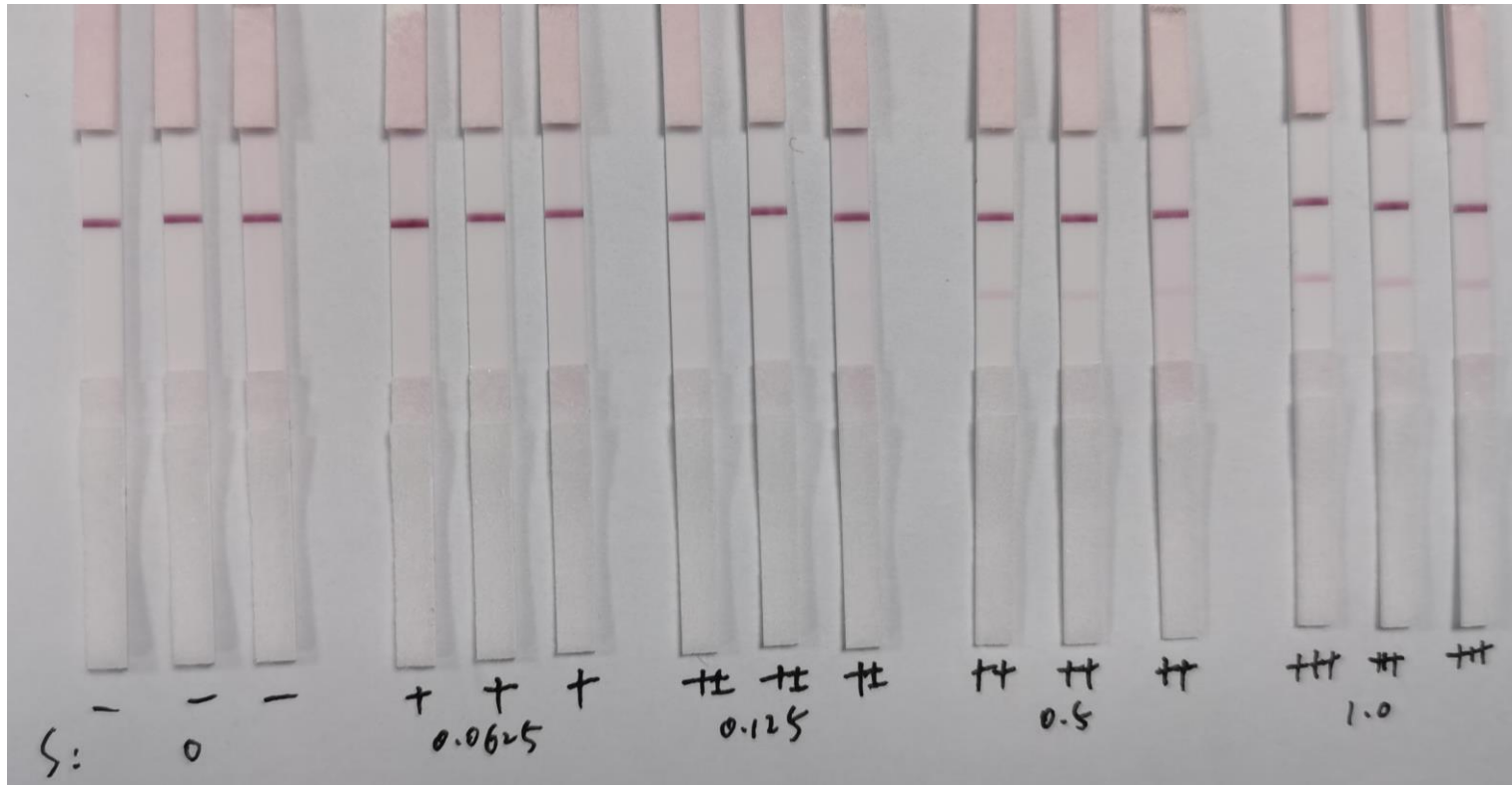
Part 03

Performance

- Sensitivity
- Specificity

Sensitivity

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Detect the recombinant nucleocapsid (N) protein of SARS-CoV-2 virus, the Limit of Detection (LoD) was confirmed to be 62.5pg/mL.

Sensitivity

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Detect the SARS-CoV-2 Pseudovirus, the Limit of Detection (LoD) is 1:10000

Specificity

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Test on more than 300 negative clinical samples, no false-positive results were observed.

Part 04

Comparison

- Clinical Study
- Competitive Analysis

Swab eluted with sample extraction solution

- Positive Percent Agreement =
 $57 / (57 + 8) \times 100\% = 87.7\%$
(95% CI: 79.7% - 95.7%)
- Negative Percent Agreement =
 $343 / (343 + 10) \times 100\% = 97.2\%$
(95% CI: 95.5% - 98.9%)

Nucleic acid detection SARS-CoV-2 antigen detection	Positive	Negative	Total
	Positive	57	10
Negative	8	343	351
Total	65	353	418

Swab kept in UTM

- Positive Percent Agreement =
 $56 / (56 + 9) \times 100\% = 86.2\%$
(95% CI: 77.7%-94.7%)
- Negative Percent Agreement =
 $361 / (9 + 361) \times 100\% = 97.6\%$
(95% CI: 96.0%-99.2%)

SARS-CoV-2 antigen detection	Nucleic acid detection		Total
	Positive	Negative	
Positive	56	9	77
Negative	9	361	378
Total	65	370	455

Competitive Analysis

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Competitor	Method
Sekbio	Colloidal Gold
Competitor 1	Colloidal Gold
Competitor 2	Colloidal Gold
Competitor 3	Latex
Competitor 4	Latex



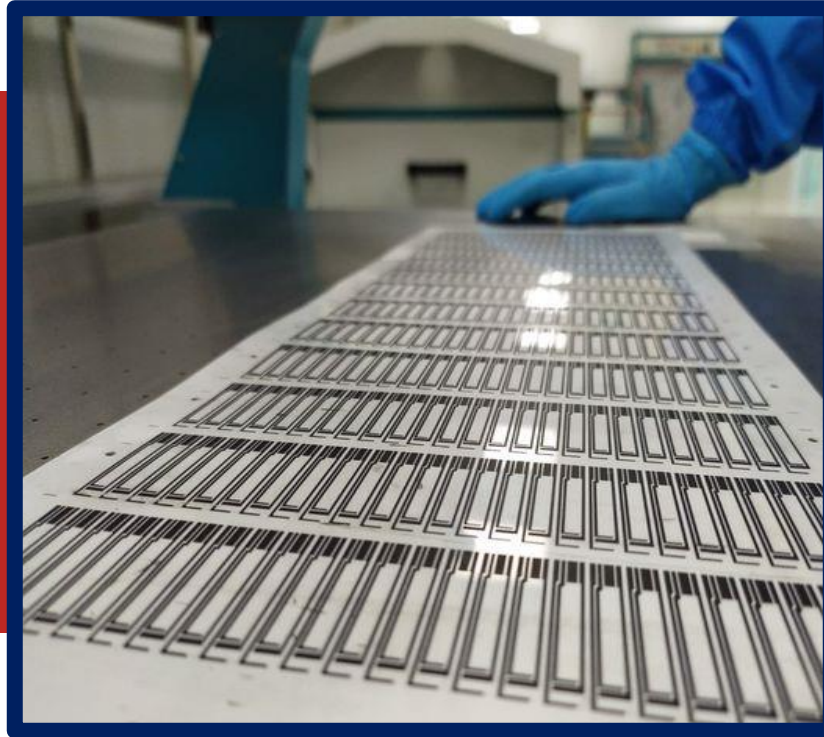
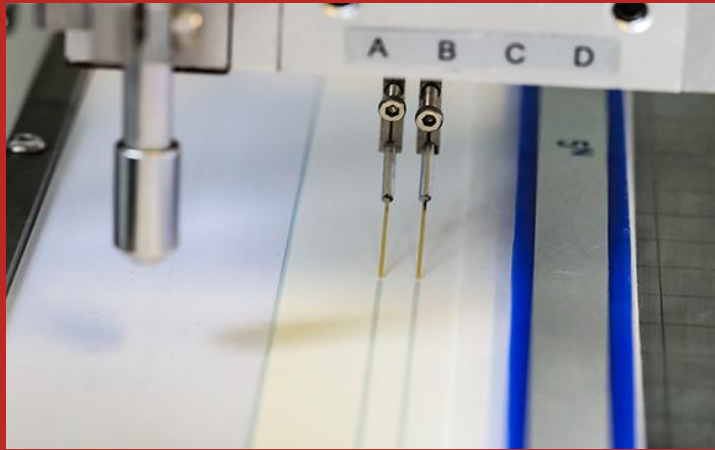
Research & Development

Since the COVID-19 pandemic broke out, SEKBIO has been working around the clock to provide the highest-quality antibody pair and uncut sheet to detecting nucleocapsid protein. We have developed and launched several well-performing pairs to multiple mutants.



Highlights

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Our strong development capacity and large-scale production with comprehensive QC platforms play a role in many R&D work of our clients and helped manufacturers around the world to fight against disease.

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