

Atlas Link Technology Co., Ltd

Material Safety Data Sheet

MANUFACTURER:

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1. General Information

Product Name & Synonyms: COVID-19 IgM/IgG Antibody Test (Colloidal Gold)

Trade Name & Catalogue Number: nCov-497

Chemical Family: In-Vitro diagnostics

Formula: Not applicable

Proper DOT Shipping Name(USA): Not applicable

DOT Hazard Classification(USA): Not applicable

2. Precaution

For In-Vitro Diagnostic use only

3. Composition/ Information on ingredients

This product contains a strip sealed in a foil pouch with desiccant. Main substances in the strip are SARS-CoV-2 antigens, monoclonal anti-human IgM antibodies and monoclonal anti-human IgG antibodies

4. Hazards identification

The product does not contain hazardous material(s). This product contains material

of animal origin and should be handled as a potential biohazard. As with all biological material, reduce direct handling to a minimum and wear appropriate protective clothing.

5.Fire and Explosion Hazard Data

N/A

6.Reactivity Hazard Data

- 1)Stability: Stable
- 2)Incompatibility: None
- 3)Hazardous polymerization: Will not occur

7.Health hazard Data

Once the test is performed using human plasma and serum, the product should be handled as though capable of transmitting disease. Although no MSDS is required by the standard, the following general guidelines are given should reagents be inhaled, ingested, or exposed to eyes or skin.

8.Emergency and First-aid procedures

- 1) Inhalation: Provide fresh air. Restore or support breathing.
- 2) Eyes: flush with plenty of water, lifting upper and lower lids from time to time, for at least 15 minutes.
- 3) Skin: flush with plenty of water for 15 minutes. Remove contaminated clothing and shoes.
- 4) Ingestion: Wash out with generous amounts of water. Get medical attention.

9.Special Protection Inhalation

- 1) Ventilation: Good ventilation

2) Gloves: Yes

3) Lab coat: Yes

4) Laboratory precautions: Normal laboratory precautions are recommended.

10.Spill/Leak Procedures

1) Spill Response: Disposables should be made in accordance with existing disposal practices employed for infectious waste.

2) Waste Response: Dispose of a manner consistent with federal, state and local regulation.

11.Handling and storage

Store the material as directed on individual product instructions for use.

12.Stability and reactivity

Stable under normal handling conditions. No further data

13.Toxicological information

This product does not elicit toxicological properties during routine handling and use.

Sensitization No

Teratogenicity No

Reproductive toxicity No

Acute toxicity No

14.Ecological information

Some materials within the cell are bio-accumulative. Under normal conditions, these materials are contained and pose no risk to persons or the surrounding environment.

15.Disposal considerations

This product should be disposed of in accordance with local waste disposal authority guidelines or passed to a chemical disposal company.

16. Transport information

Observe storage requirements. Hazard Class: None. ICAO/IATA class: None

17. Raw Material

Raw Material of the Cassette

Raw material	Application	Characteristics
Glass fiber	Base of sample pad	Thickness 0.3~0.5mm Intensity 50±5g/m ²
Absorbent paper	Base of absorbent pad	Absorbent cotton Thickness: 0.6~0.8mm Intensity: 270±20g/m ²
HauCl ₄	Colloidal gold, bound to SARS-CoV-2 antigens	A.R, Au content > 47.8 %
anti-human IgG	Test line 1 reagent, coated on NC membrane.	Classification: IgG1 Purity: SDS-PAGE >95% Work Concentration: ≥ 1.0mg/ml Preservative: 0.05%NaN ₃ Storage: 4°C

anti-human IgM	Test line 2 reagent, coated on NC membrane.	Classification: IgM1 Purity: SDS-PAGE >95% Work Concentration: \geq 1.0mg/ml Preservative: 0.05%NaN ₃ Storage: 4°C
Goat anti-mouse antibody	Control line reagent, Coated on NC membrane	Classification: IgG1 Purity: SDS-PAGE >95% Work Concentration: \geq 1.5mg/ml Preservative: 0.05%NaN ₃ Storage: 4°C
SARS-CoV-2 antigens	Gold conjugate, bound to colloidal gold	Purity: SDS-PAGE >95% Preservative: 0.05%NaN ₃ Storage: 4°C
Ovalbumin, duck egg	Blocking reagent, for sample pad and membrane treatment	Purity: OD 415 NM (0.1%) \leq 0.06 Protein content: \geq 13.5% MW: 45,000
Nitrocellulose membrane	Immobilize test line and control line	Thickness: 140um \pm 20% Absorption speed: \geq 10mm/min Size of the pore: 5~15um

non-woven cloth	Base of sample pad	washing shrinkage rate: +2/-1 thermal shrinking rate: +3/-2 Inner layer width:18~20mm Outer layer Width:28~30mm Buffer: PBS+0.3~0.5% Tween20
Buffer	Adjust the reaction system	100mM Phosphate buffer, Sodium azide (0.01% w/w)
Cassette cover	hold and protect a strip	(72mmx20mmx6mm), match with strip, cover and plate match well.

Raw Material of the Pack

Desiccant (in pouch)	Keep dry	Silica gel, 0.5g
Pouch	Sealed pouch	Aluminium foil

18.Additional Information

Atlas Link Technology Co., Ltd provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this kit by a properly trained person using this product. Atlas Link Technology Co., Ltd shall not be held liable for any damage resulting from handling or use.