Product Data Sheet

Product:	SARS-CoV-2 Antigen Rapid Test Set (Collodial Gold Immunochromatography)	
Trademark:	Lepu Medical	
REF:	CV03	
Manufacturer:	Lepu Medical Technology (Beijing) Co., Ltd., China	

Classification:	Antigen tests for professional use for the direct pathogen detection of the coronavirus SARS-CoV-2. Not a product according to Annex II List A or List B of Regulation (EU) 98/79 on in vitro diagnostic medical devices. Conformity confirmed according to Annex III, points 2 to 5 of Regulation (EU) 98/79.
Product description:	This product is a professional-grade test for the qualitative detection of SARS-CoV-2 antigens from nasal swabs. This test is intended for use in individuals with symptoms or for other epidemiological reasons for suspected COVID-19 infection. This product is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. ▪ non-invasive ▪ simple application ▪ No electronic devices required ▪ fast result within 15 minutes ▪ high accuracy ▪ inexpensive
Clinical performance:	**Sensitivity:** 95,06% 95% confidence interval: 91.57-97.15% **Specificity:** 99,62% 95% confidence interval: 97,89-99,89% 95,06% 95% confidence interval: 91,57-97,15% **Specificity:** 99,62% 95% confidence interval: 97,89-99,89%

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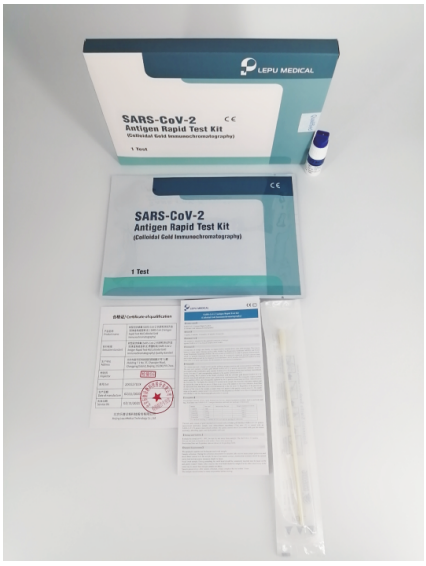
Test kit contents:	 *1 1 Test*  *2 25 Tests*

General Requirements:	**Standard:**	**Description:**
	Regulation (EU) 98/79	Directive (EU) on in vitro diagnostic medical devices
	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 15223-1:2016	Medical devices - Symbols to be used with information to be supplied by the manufacturer

	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
	EN ISO 1041:2008+A1:2013	
	EN ISO 18113:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer
	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
	EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
	EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
Packaging and Variants:	**Packaging**	**Quantity**
	Carton	1 Test
	Carton	5 Tests
	Carton	10 Tests
	Carton	25 Tests
Use:	Single use. Read the instructions for use before use.	
Storage:	Store in a dry place in the original packaging, away from direct sunlight.	
Disposal:	After the test, place the test card, swab and sample treatment solution bottle in the outer packaging and close it tightly. Dispose of the bag in a waste container according to local laws and regulations.	