COVID-19 IgG/IgM
Rapid Test

CE

(Sangre entera/Suero/Plasma)

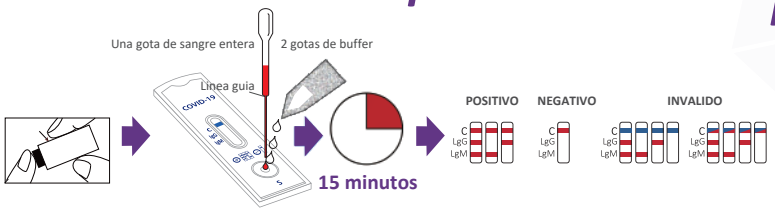
Incluye:

- 20 Tests
- 20 Buffers individuales
- 20 Colectores de sangre
- 20 Lancetas
- 20 Almohadillas de alcohol

Precisión	Sensibilidad	Especificidad
98.20 %	96.25 %	98.90 %

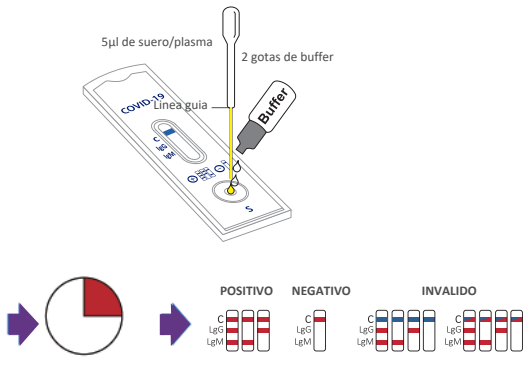
*Fuente: Manual o inserto del test

Procedimiento de prueba:



Para muestras de suero o plasma

Procedimiento de la prueba:



Evaluación clínica de Alta precisión

Para detección IgM:

Método		PCR+	PCR-	Total
COVID-19 IgG/IgM Rapid Test	IgM+	74	2	76
	IgM-	5	225	230
Total		79	227	306

- Sensibilidad relativa: 93.7% (86.0%-97.3%)*
- Especificidad relativa: 99.1% (96.8%-99.8%)*
- Precisión relativa: 97.7% (95.4%-98.9%)*

*95% Intervalo de confianza

Para detección IgG:

Método		Muestras de convalecientes	PCR-	Total
COVID-19 IgG/IgM Rapid Test	IgG+	82	3	85
	IgG-	1	224	225
Total		83	227	310

- Sensibilidad relativa: 98.8% (93.5%-99.8%)*
- Especificidad relativa: 98.7% (96.2%-99.5%)*
- Precisión relativa: 98.7% (96.7%-99.5%)*

*95% Intervalo de confianza

Assure Tech. (Hangzhou) Co.,Ltd.
Building4,No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China

U.S. FOOD & DRUG ADMINISTRATION

September 23, 2020

Frank Lou
Director
Azure Biotech Inc.
Representing: Assure Tech. (Hangzhou) Co., Ltd.
5250 Gulfton St. #2C
Houston, TX 77081

Device:	Assure COVID-19 IgG/IgM Rapid Test Device
Company:	Assure Tech. (Hangzhou) Co., Ltd.
Indication:	Qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, plasma (sodium EDTA) and fingerstick whole blood. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests. This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Mr. Lou:

On July 6, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).[3]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Assure Tech. (Hangzhou) Co., Ltd.
[2] For ease of reference, this letter will use the term "your product" to refer to the Assure COVID-19 IgG/IgM Rapid Test Device for the indication identified above.
[3] The July 6, 2020, authorization was for use of your product for qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, or plasma (sodium EDTA).