正元盛邦（天津）生物科技有限公司

JOYSBIO（Tianjin）Biotechnology Co.,Ltd.

新冠检测试剂检测报告

COVID-19 Test Kit Analysis Report

墨西哥研究对比报告
Mexico INIA Analysis Report

Los resultados obtenidos fueron los siguientes:

Pacientes	*RT-PCR*	*Inmunocromatografía (Prueba rápida)*
Paciente 1	Negativa	Negativa
Paciente 2	Negativa	Negativa
Paciente 3	Positiva	Positiva
Paciente 4	Positiva	Positiva
Paciente 5	No realizada	Negativa

Tabla 1. Comparativa de resultados positivos y negativos en pacientes con realización de RT-PCR y Inmunocromatografía

*El paciente No. 5 no contaba con RT-PCR, [illegible]

INCORPUS MĒDICA
SALUD INTEGRAL

Con esta comparativa preliminar podemos inferir que los resultados obtenidos con las pruebas rápidas de inmunocromatografía concuerdan y sustentan los resultados obtenidos con la prueba de RT-PCR en los pacientes evaluados.

Cabe señalar que en el paciente número cinco, criterio de elegibilidad fue el no presentar ninguna sintomatología respiratoria actual ni en días previas (7 días) ni haber estado en contacto en los días anteriores (15 días) con pacientes con sospecha de infección por COVID-19.

Sin más que agregar, reciba un cordial saludo.

Fraternalmente

与核酸检测试剂盒对比，检测结果基本保持一致。
Compared with the nucleic acid test kit, the detection results were basically consistent.

西班牙INIA检测报告
Spain INIA Analysis Report

与ELISA 检测方法做对比，我公司产品灵敏度达到94.4%，特异性达到92.4%.
Compared with ELISA, the sensitivity of our products can up to 94.4% and specificity can up to 92.4% .

RESULTADOS:

1. Resultados: Lote 2020033006[1]

1.1 Sensibilidad y especificidad:

Tomando el ELISA **INgezim-COVID-DR** como técnica de referencia, el lote del test rápido **JOYSBIO** tiene para las muestras analizadas en este estudio:

- Sensibilidad: 94,4% (5 falsos negativos de 196 muestras analizadas).
- Especificidad (teniendo en cuenta los resultados de IgG e IgM): 92,4 % (8 falsos positivos de 196 muestras analizadas, de los que 1 es IgM+/IgG-).

1.2 Reproducibilidad:

El estudio de la reproduciblidad entre el ELISA **INgezim-COVID-DR** y el test rápido **JOYSBIO** se evaluó mediante el estadístico Kappa para el que se obtuvo el un valor de 0,87±0,04 (teniendo en cuanta para el test rápido los resultados de IgG e IgM)

Este valor indica una **coincidencia casi perfecta** entre ambas técnicas (>0,81).

巴西 ANVISA 检测报告
Brazil ANVISA Analysis Report

Testing name: SENSIBILITY

Start date: 18/06/2020 **End date:** 18/06/2020

Reference	Reference value
ANVISA Resolution RDC nº 379, of 30/04/2020	As stated by the manufacturer in the Instructions for Use.

Method: Quantitative

Result:

Equals **96.0%.** [DECLARED BY THE MANUFACTURER IN THE INSTRUCTIONS FOR USE (% Positive Conformity): **90.66%].**

In 24 clinical samples positive for the marker in question (COVID-19 IgM and IgG), 01 False Negative result was found in the analyzed sample

Trial conclusion: SATISFATORY

我公司产品灵敏度达到96.0%，特异性达到96.92%.
The sensitivity of our products can up to 96% and specificity can up to 96.92% .

Ministério da Saúde

FIOCRUZ
Fundação Oswaldo Cruz
Instituto Nacional de Controle de Qualidade em Saúde

INCQS

Analysis report 1757.1P.0/2020

Testing name: SPECIFICITY

Start date: 18/06/2020 **End date:** 18/06/2020

Reference	Reference value
ANVISA Resolution RDC nº 379, of 30/04/2020	As stated by the manufacturer in the Instructions for Use.

Method: Quantitative

Result:

Equal to **96.92%.** [DECLARED BY THE MANUFACTURER IN THE INSTRUCTION FOR USE (% Negative Compliance): **95.41%**].

In 65 truly negative samples for the marker in question (samples collected between the years 2013 and 2014), 02 false positive results were found in the analyzed sample.

巴塞罗那检测报告
Barcelona Analysis Report

Resultats Obtinguts:

- Anticossos IgG
  - 17 mostres negatives per IgG (Índex <0.9 de les quals 16 han donat negatives i 1 positiva
  - 5 mostres amb índex de la zona indeterminada o positiu dèbil, donant totes elles resultats positius
  - 27 mostres positives amb índex superior a 3 que han donat 26 positives i 1 negativa.

CALCULS:

VP: Verdader positiu

FP: Fals positiu

VPP: Valor predictiu positiu

VPN: Valor predictiu negatiu

IgG

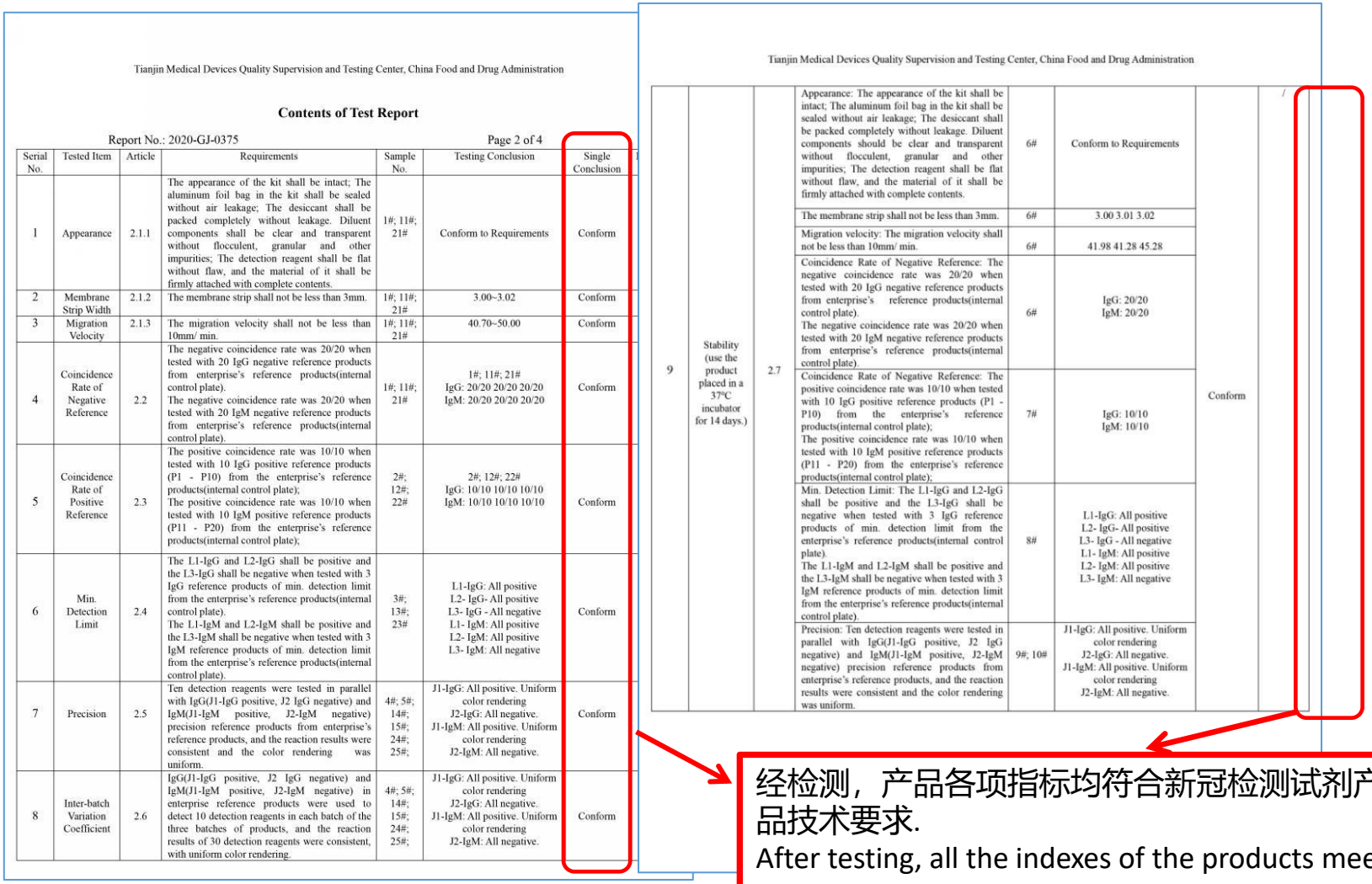
VP	31	FP	1
VN:	16	FN	1
SENSIBILIDAD	VP/ VP+FN	96,88%	
ESPECIFICIDAD:	VN/VN+FP	94,12%	
VPP:	vp/vp+fp	96,88%	
VPN	VN/VN+FN	94,12%	

MOSTRES: 32 PO 17 N

灵敏度达到96.88%，特异性达到94.12%.
Sensitivity can up to 96.88% and specificity can up to 94.12% .

中国国家食品药品监督管理局天津医疗器械质量监督检验中心检测报告

National Medical Products Administration Tianjin Medical Devices Quality Supervision and Testing Center Analysis Report



Tianjin Medical Devices Quality Supervision and Testing Center, China Food and Drug Administration

Contents of Test Report

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Serial No.	Tested Item	Article	Requirements	Sample No.	Testing Conclusion	Single Conclusion
1	Appearance	2.1.1	The appearance of the kit shall be intact; The aluminum foil bag in the kit shall be sealed without air leakage; The desiccant shall be packed completely without leakage. Diluent components shall be clear and transparent without flocculent, granular and other impurities; The detection reagent shall be flat without flaw, and the material of it shall be firmly attached with complete contents.	1#; 11#; 21#	Conform to Requirements	Conform
2	Membrane Strip Width	2.1.2	The membrane strip shall not be less than 3mm.	1#; 11#; 21#	3.00~3.02	Conform
3	Migration Velocity	2.1.3	The migration velocity shall not be less than 10mm/ min.	1#; 11#; 21#	40.70~50.00	Conform
4	Coincidence Rate of Negative Reference	2.2	The negative coincidence rate was 20/20 when tested with 20 IgG negative reference products from enterprise's reference products(internal control plate). The negative coincidence rate was 20/20 when tested with 20 IgM negative reference products from enterprise's reference products(internal control plate).	1#; 11#; 21#	1#; 11#; 21# IgG: 20/20 20/20 20/20 IgM: 20/20 20/20 20/20	Conform
5	Coincidence Rate of Positive Reference	2.3	The positive coincidence rate was 10/10 when tested with 10 IgG positive reference products (P1 - P10) from the enterprise's reference products(internal control plate); The positive coincidence rate was 10/10 when tested with 10 IgM positive reference products (P11 - P20) from the enterprise's reference products(internal control plate);	2#; 12#; 22#	2#; 12#; 22# IgG: 10/10 10/10 10/10 IgM: 10/10 10/10 10/10	Conform
6	Min. Detection Limit	2.4	The L1-IgG and L2-IgG shall be positive and the L3-IgG shall be negative when tested with 3 IgG reference products of min. detection limit from the enterprise's reference products(internal control plate). The L1-IgM and L2-IgM shall be positive and the L3-IgM shall be negative when tested with 3 IgM reference products of min. detection limit from the enterprise's reference products(internal control plate).	3#; 13#; 23#	L1-IgG: All positive L2- IgG- All positive L3- IgG - All negative L1- IgM: All positive L2- IgM: All positive L3- IgM: All negative	Conform
7	Precision	2.5	Ten detection reagents were tested in parallel with IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) precision reference products from enterprise's reference products, and the reaction results were consistent and the color rendering was uniform.	4#; 5#; 14#; 15#; 24#; 25#;	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.	Conform
8	Inter-batch Variation Coefficient	2.6	IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) in enterprise reference products were used to detect 10 detection reagents in each batch of the three batches of products, and the reaction results of 30 detection reagents were consistent, with uniform color rendering.	4#; 5#; 14#; 15#; 24#; 25#;	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.	Conform

Tianjin Medical Devices Quality Supervision and Testing Center, China Food and Drug Administration

9	Stability (use the product placed in a 37℃ incubator for 14 days.)	2.7	Appearance: The appearance of the kit shall be intact; The aluminum foil bag in the kit shall be sealed without air leakage; The desiccant shall be packed completely without leakage. Diluent components should be clear and transparent without flocculent, granular and other impurities; The detection reagent shall be flat without flaw, and the material of it shall be firmly attached with complete contents.	6#	Conform to Requirements	Conform	/
			The membrane strip shall not be less than 3mm.	6#	3.00 3.01 3.02		
			Migration velocity: The migration velocity shall not be less than 10mm/ min.	6#	41.98 41.28 45.28		
			Coincidence Rate of Negative Reference: The negative coincidence rate was 20/20 when tested with 20 IgG negative reference products from enterprise's reference products(internal control plate). The negative coincidence rate was 20/20 when tested with 20 IgM negative reference products from enterprise's reference products(internal control plate).	6#	IgG: 20/20 IgM: 20/20		
			Coincidence Rate of Negative Reference: The positive coincidence rate was 10/10 when tested with 10 IgG positive reference products (P1 - P10) from the enterprise's reference products(internal control plate); The positive coincidence rate was 10/10 when tested with 10 IgM positive reference products (P11 - P20) from the enterprise's reference products(internal control plate);	7#	IgG: 10/10 IgM: 10/10		
			Min. Detection Limit: The L1-IgG and L2-IgG shall be positive and the L3-IgG shall be negative when tested with 3 IgG reference products of min. detection limit from the enterprise's reference products(internal control plate). The L1-IgM and L2-IgM shall be positive and the L3-IgM shall be negative when tested with 3 IgM reference products of min. detection limit from the enterprise's reference products(internal control plate).	8#	L1-IgG: All positive L2- IgG- All positive L3- IgG - All negative L1- IgM: All positive L2- IgM: All positive L3- IgM: All negative		
			Precision: Ten detection reagents were tested in parallel with IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) precision reference products from enterprise's reference products, and the reaction results were consistent and the color rendering was uniform.	9#; 10#	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.		

经检测，产品各项指标均符合新冠检测试剂产品技术要求.

After testing, all the indexes of the products meet the technical requirements of coVID-19 rapid test.