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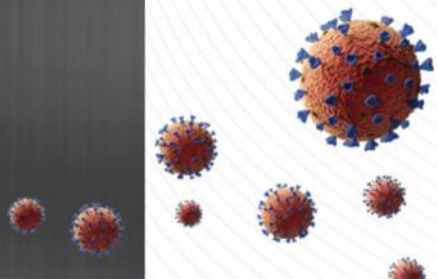
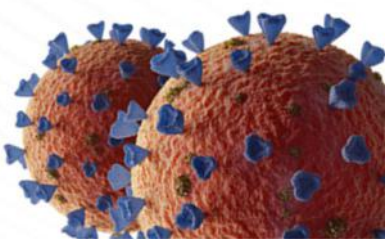
BOAS PRÁTICAS DE ARMAZENAMENTO E DISTRIBUIÇÃO
Certificação
ANVISA
RDC 16/2013
8.04.472-2

Teste Rápido **COVID-19** para IgG/IgM

SUMÁRIO

FABRICANTE COM **30 ANOS** DE EXPERIÊNCIA NO **MERCADO EUROPEU**





4 MILHÕES DE TESTES

COVID-19 COMERCIALIZADOS, **ESPECIALMENTE NA EUROPA**:

PRODUTOS VENDIDOS EM MAIS DE **11 PAÍSES**

REGISTRO

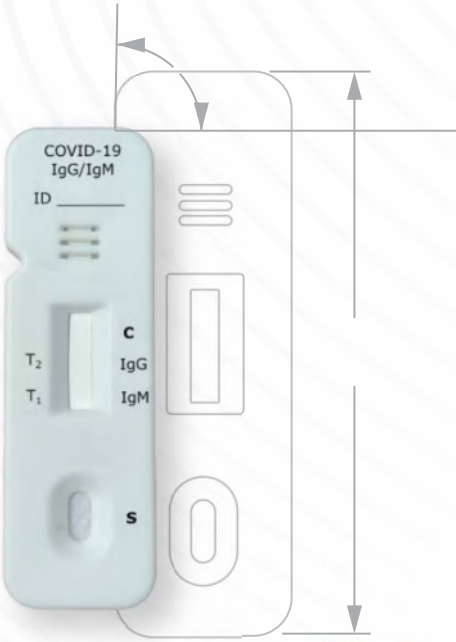
ANVISA
Agência Nacional de Vigilância Sanitária

Nº 80262280027

PRODUTO

ASSUT EUROPE
SUTURE CHIRURGICHE
unotec®
More than surgery

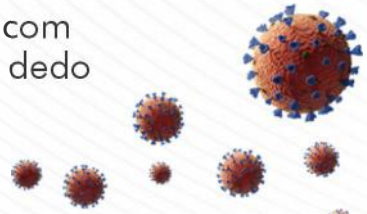
COVID-19
TESTE RÁPIDO IgG/IgM

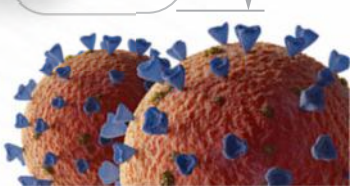


EXATO
Anticorpo de alta pureza com alta precisão

EFICAZ
Resultado do teste disponível en 15 minutos

ACESSÍVEL
Adequado com punção do dedo





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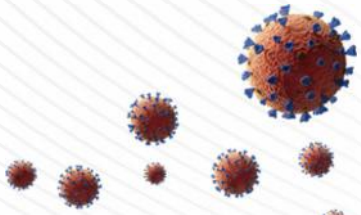
INFORMAÇÕES **GERAIS**

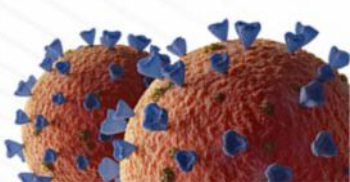
Certificado de Boas Práticas de Fabricação ANVISA
Registro ANVISA
Certificado ISO 13.485
Certificado CE

INFORMAÇÕES **DO PRODUTO**

CADA KIT CONTÉM:

1 Cartão de detecção.
1 Diluente de amostra (0,3 ml).
1 Conta gotas.
1 Dispositivo de amostra de sangue.
1 Haste de algodão com iodo.





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ANÁLISE DO TESTE
(com 17 páginas)

ASSUT EUROPE
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Clinical Validation Report

Product Name: Covid-19 IgG/IgM Rapid Test
Product Code: COVID-19/20
Model and Specifications: tests packed independently

Abstract of Research

To evaluate clinical applications of the COVID-19/20 manufactured by Assut Europe SpA, to in-vitro qualitative tests on the content of the Covid-19 antibody in clinical samples (serum/plasma/whole blood), a clinical research has been made for this test strip.

In total, 220 serum samples were selected as research object, of them, 93 cases were diagnosed as positive according to the novel coronavirus pneumonia treatment plan, 127 cases were diagnosed as negative according to the novel coronavirus pneumonia treatment plan.

The research objects were classified into the IgG and IgM of positive group and negative group by comparing test results of these products. Meanwhile, these samples were tested via a test card, to compare the test results of the tested product and those of the reference product, with statistical analysis being made. The coincidence rate of positive/negative and the total coincidence rate of both products were proven higher than 90% in comparison, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent. The tested product is applicable to auxiliary clinical diagnosis.

As a large family of virus, coronavirus is a single plus strand RNA virus featured by envelopes. As known to us, such virus can trigger major diseases such as cold, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). COVID-19 was identified in the cases of viral pneumonia in Wuhan, 2019 and was named officially by WHO on January 12, 2020. As a core protein of COVID-19, N protein (Nucleocapsid) is a component inside the virus, and is relatively conservative among category-p coronaviruses and is a common tool for diagnosis on coronaviruses. As a key receptor for COVID-19's entry in the cell, ACE2 is of great significance for research on the virus infection mechanism.

To validate the applicability and accuracy of such test strip on clinical applications, a systematic research is required for its clinical properties. In total, 220 samples were involved in this clinical research.

The purpose of research of this clinical test is: calculate the consistency percentage of negative/positive and the total consistency percentage and the Kappa coefficient by making statistics of and analyzing test results through comparative experimental research for the followings for the same clinical sample: the COVID-19/20 produced by Assut Europe SpA, the tested product, and the 2019-nCoV antibody test kit (colloidal-gold). The equivalence between the tested product and the reference product is verified according to the results of statistical analysis, so as to validate the applicability and accuracy of the tested product in auxiliary clinical diagnosis.

ASSUT EUROPE spa - Sede legale: Via Giuseppe Gregoraci, 12 - 00173 Roma - Tel. +39 06 72677348 - Fax +39 06 72675380
Stabilimento di produzione: Zona Industriale • 67062 Magliano dei Marsi (AQ) • Tel. +39 0863.517956-515000 - Fax +39 0863.570084-515209
Codice Fiscale e Partita IVA n. 01262470667 - R.E.A. n. 1153837 Roma - Capitale sociale € 6.416.457,00 i. v.
www.assuteurope.com • www.unotecsrl.com Soggetto a direzione e controllo e-mail: customerservice@assuteurope.com

RESULTADO FINAL
DO TESTE

antibody fixed into the test zone M and corresponding antibody in the quality control area (C). It can be used for rapid tests on the COVID-19 antibody in the serum/plasma specimen as well as auxiliary clinical screening of those suffering from pneumonia triggered by Covid-19. This clinical test aims at evaluating the clinical properties of such product. The test conditions are concluded as follow

Test results of the serum sample of the tested product and the reference product: both the coincidence rate of negative/positive and the total coincidence rate are larger than 90%, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent.

The comparison result of test device and
specificity are both more than 90%, indicating good consistency with the nucleic acid test results.

(II) Test conclusions

By analyzing the test results of the tested product and the reference, the consistency percentage of negative/positive and the total consistency percentage are proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of two such systems. Meanwhile, the diagnostic sensitivity and specificity of test device are both more than 90% compared with the detection results of nucleic acid method, indicating good consistency with the nucleic acid test results.

Annex I: Data of Clinical Tests

Sample No.	Gender	Age	Tested product Results	Reference Product Results	Nucleic acid test results
1	F	45	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
2	M	66	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	
3	M	36	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
4	F	44	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
5	F	54	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
6	M	65	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	

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QUALIFICAÇÕES DO FABRICANTE

CE **MARK**

ASSUT EUROPE SUTURE CHIRURGICHE

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EC Declaration of Conformity

Manufacture Address:	**Assut Europe SpA** **Via G. Gregoraci, 12** **00173 Roma** **Italy**
Product Information:	**COVID-19 IgG/IgM Rapid test Cassette**
Product Code:	**Covid-19**
Classification:	**Others** **according to article 9 of directive 98/79/EC**
Conformity Assessment Route:	**Annex III of Directive 98/79/EC** **We hereby declare, under our sole responsibility, that the above mentioned products meets the provisions of the directive 98/79/EC implemented by Legislative Decree 332/2000**
General Applicable Directive:	**Directive 98/79/EC on *in vitro* diagnostic medical devices**
Standards Applied	**All applicable harmonized standards**
Place, date of issue	**Rome, 24.03.2020**
Signature of Management Representative	Mimmo Carducci, MD

CE

CERTIFICAÇÃO **ISO**

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CERTIFICATO N. / *CERTIFICATE N.* **9124.ASS2**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

ASSUT EUROPE SPA

VIA GIUSEPPE GREGORACI 12 - 00173 ROMA (RM)

UNITA' OPERATIVE / *OPERATIVE UNITS*

ZONA INDUSTRIALE - 67062 MAGLIANO DE' MARSI (AQ)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, fabbricazione e sterilizzazione interna ed esterna di suture chirurgiche ed altri dispositivi medici non attivi, impiantabili e non impiantabili. Commercializzazione di suture chirurgiche ed altri dispositivi medici non attivi, impiantabili e non impiantabili

Design, manufacture and internal /external sterilization of surgical sutures and others not active, implantable and not implantable medical devices. Sale of surgical sutures and others not active, implantable and not implantable medical devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION*	EMISSIONE CORRENTE / *CURRENT ISSUE*	SCADENZA / *EXPIRY*
	2001-04-24	2018-10-17	2021-11-26

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Dinaga

ACCREDIA
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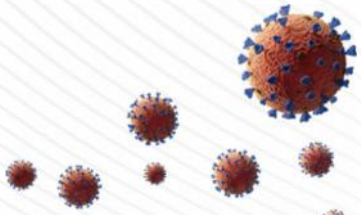
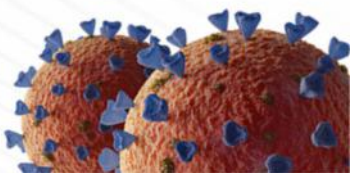
CISQ is the Italian Federation of management System Certification Bodies.





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CARTA DE **CREDENCIAMENTO** DA CARE MED

ASSUT EUROPE unotec
SUTURE CHIRURGICHE

Rio de Janeiro,22 de maio de 2020.

CARTA DE CREDENCIAMENTO

A empresa **ASSUT EUROPE LATINO AMÉRICA IMPORTAÇÃO E EXPORTAÇÃO LTDA, CNPJ: 07.032.636/0001-64,** com sede à Rua Professor Alfredo Gomes, 18 - Botafogo – Rio de Janeiro – RJ, declara, para os devidos fins, que a empresa **CARE MED DISTRIBUIDORA DE MATERIAIS CIRÚRGICOS EIRELI CNPJ:09.272.750/0001-97,**com sede à A Rua Ernesto da Fontoura 1479 conj 703/704/706/707 São Geraldo-RS Cep:90230-090 está cadastrada, credenciada e autorizada à comercializar o produto **COVID-19 IgG/IgM Rapid Test, para todo território nacional sem exclusividade.****************

Tal cadastro e credenciamento não conferem exclusividade à empresa **CARE MED DISTRIBUIDORA DE MATERIAIS CIRÚRGICOS EIRELI** .A empresa **ASSUT EUROPE LATINO AMÉRICA IMPORTAÇÃO E EXPORTAÇÃO LTDA** declara ainda, que este credenciamento **é valido até dia 22/08/2020**. Esta declaração cancela e substitui qualquer declaração emitida anteriormente a esta data.************************************

Ana Venâncio
Diretora Geral

15º OFÍCIO DE NOTAS - FERNANDA DE FREITAS LEITÃO - TABELIÃ
Rua do Ouvidor, nº 86, Centro (21) 3233-2000 - Rio de Janeiro/RJ
Reconheço por SEMELHANÇA as firmas de
ANA DOLORES BEIXAS VENANCIO
Rio de Janeiro, 22 de maio de 2020
CRISTIANE SEIXAS VENANCIO - ESCREVENTE - Mat.
Selo(s): EDKZ41265-RFA
Consulte em https://www3.trj.jus.br/sitepublico
OFÍCIO DE NOTAS
Cristiane Seixas Venancio
Tabeliã Substituta
Mat. 94/5183

CONTATO EXECUTIVO

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+55 (51) 9 8110 0349 (What's)
sandro@care.med.br