PREMIA®

MEDICAL

BIOZEK COVID-19 IgG/IgM Rapid Test

For Reliable Coronavirus Disease 2019 (COVID-19) Diagnosis

* The novel coronavirus pneumonia (NCP), or "COVID-19"(Corona Virus Disease), was discovered from the 2019 Wuhan Viral Pneumonia case in China and was named by the World Health Organization on January 12, 2020.
* COVID-19 is caused by 2019 novel coronavirus (COVID-19),mainly transmitted through respiratory droplets.
* On January 30, 2020, WHO released the new coronavirus infection pneumonia epidemic as a public health emergency of international concern.
* Currently , the COVID-19 is occurring in many parts of the world, especially in China, which has the largest population in the world.

BIOZEK COVID-19 IgG/IgM Rapid Test Offers:

- √ *High Accuracy with more than 92.9%*
- √ *Fast Results with 10 minutes Assay Time*
- √ *Simple Operation without Equipment Required*

Single use kit with fingerstick whole blood specimen is also available !

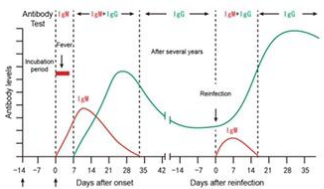
CE

www.biozek.com info@biozek.com

BIOZEK COVID-19 IgG/IgM Rapid Test

For Reliable Coronavirus Disease 2019 (COVID-19) Diagnosis

* BIOZEK COVID-19 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimen with only 10 minutes assay time.
* The combination use of IgM and IgG test can reflect virus infection and the immune status of the body effectively.

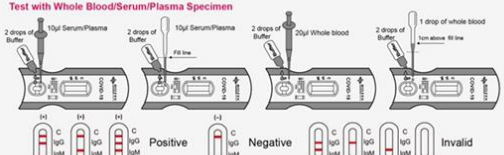


Applications:

√ Doctors/ Nursing Homes/ Polyclinics engaged in Infectious Diseases or Respiratory Department.
√ Labs getting prescription from such doctors/ hospitals/ Nursing Homes.
√ Specially designed COVID-19 epidemic centric hospitals in China or other countries.
√ Emergency Department

Convenient Operation

Test with Whole Blood/Serum/Plasma Specimen



Test with Fingerstick Whole Blood Specimen

Ordering Information

Cat.no.	Product	Format	Specimen	Pack	CE Status
BNCP-402	COVID-19 IgG/IgM Rapid Test	Cassette	WB/S/P	30T	CE
BNCP-402S	COVID-19 IgG/IgM Rapid Test (Single Use Kit)	Cassette	Fingerstick Whole Blood	20T	CE

www.biozek.com info@biozek.com Inzek International Trading Vissenstraat 32, 7324 AL, Apeldoorn, The Netherlands

EC Declaration of Conformity

Manufacturer:

Name: Inzek International Trading
Address: Vissenstraat 32, 7324AL – Apeldoorn, The Netherlands

Product Name and Models(s):

COVID-19 IgM/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

REF BNCP-402

Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: 15 70 90 90 00

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro* diagnostic medical devices

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN ISO, EN 13641:2002, ISO 15223-1:2012

CE After preparation of the necessary technical documentation as well as the conformity declaration the required CE marking can be affixed on the product. Other relevant directives must be observed.

Place, Date of Issue: Apeldoorn on 20/02/2020

Signature: _____

Name: Z. Hamid

Position: Manager

Certificate of Approval

This is to certify that the Management System of:

Inzek International Trading B.V.

Vissenstraat 32, 7324 AL Apeldoorn, Netherlands

has been approved by LRQA to the following standards:

ISO 13485:2016

P.G. Cornelissen - Area Manager North Europe

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

Current issue date: 9 March 2019
Expiry date: 8 March 2022
Certificate identity number: 10177988

Original approval(s):
ISO 13485 – 9 March 2019

Approval number(s): ISO 13485 – 00019238

The scope of this approval is applicable to:
Design, development, production and distribution of In Vitro Diagnostics Medical device - reagents and instrument for point of care testing.

UKAS MANAGEMENT SYSTEMS
001

› My cases
› Notify medical devices
› Change products
› Apply for certificate of free sale

› Find products

Notify medical devices and IVDs

Product

Status	BEV - Notification confirmed
Brand name	Biozek medical
Alternative brand name	
Group name	
Article number(s)	BNCP-402
Model(s)	COVID-19 IgG/IgM rapid test cassette
Class	Other in-vitro medical devices
Notified body	
Classification rule	
Type	CE-markering
Category/Categories	06 - In vitro diagnostic devices
GMDN Code	
Other nomenclature	EDMA: 15 70 90 90 00
Brief description (in English)	A rapid test for the qualititative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimens.
Brief description (in Dutch)	Een sneltest voor de kwalitatieve detectie van IgG of IgM antilichamen van COVID-19 in bloed, serum en plasma
New product	Yes
CE mark valid through	
Name of manufacturer	Inzek International Trading

Print Ok

Inzek International Trading B.V.,	Document No.: ZTC-QC-005-R-003
COA The DOA COA	Effective Date: 2018-07-02

Certificate Of Analysis

Product Name:	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)			**Catalog No.:**	INCP-402
Batch No.:	BNCP40200074	**Date of Sampling:**	2020-02-01	**Quantity:**	3000PCS
Expiry Date:	2022.02	**Date of Analysis:**	2020.02.01	**Specification:**	
Other information:/					
Buffer Lot:BNCP40200074B, EXP: 2022.02					

QC ITEM		QC Criterion	QC Result	Conclusion
Physical	Appearance	Good	Good	Pass
Functional Performance	Positive Sample	Positive	100% Positive	Pass
	Negative Sample	Negative	100% Negative	Pass

Others:	/

Final QC Conslusion:	This batch of product met the QC Criteria

QC superviser:

Date: 2020.03.01

Revision: 03	**Page 1 of 1**