



PREFEITURA MUNICIPAL DE PELOTAS
C.N.P.J. - 87455531000157

OR 013577120

5-435805

Número : E007742/2020
Empenho de Despesa
Data Empenho : 07/04/2020

Unidade Administrativa : 2.08.00.00.000.00.00.00 - Secretaria Municipal de Saúde
U.O. 208
Fonte Recursos 4511 0
Projeto/Atividade 10.305.0101.2045.00
Natureza Despesa 3.3.90.30.00.00.00.00

Valor Empenho: DUZENTOS MIL REAIS
Licitação: Dispensa de Licitação
Motivo: INC. IV, ART. 24, LEI N. 8.666/93
Tipo Licitação: Material de Consumo
Característica Peculiar: Não se Aplica

Saldo Anterior 380.524,80
Valor Empenho 200.000,00
Saldo Atual 180.524,80

Nome: QUALYPROT COMERCIO E CONFECÇÃO DE UNIFORMES
Endereço: SIRA, 256
Complemento:
C.G./C.I.C: 13259812000106
Inscr. Estadual:
Bairro: SAO JOAO
Cidade: São Paulo-São Paulo

Banco: 001 BANCO DO BRASIL
Conta Corrente : 393487
Especificações

Item	Unidade	Classif. Despesa	Qtd	VI Unitário	Valor
1	Unidade	3.3.90.30.36.00.00.00 - MATERIAL HOSPITALAR	2000	100,0000	200.000,00
Teste Covid-19 rápido (15 minutos IgG/IgM Cassete)					
Total ==> 200.000,00					

Observação do Empenho: Justificativa: Teste para aplicar nos suspeitos de COVID-19.
SIS: 3765/2020
Solicitante: Diretoria Administrativa e Financeira / Unidade Atendida: Diretoria de Ações em Saúde

Endereço de entrega: Almoxxarrado da SMS - Rua Barão de Santa Tecla 313 (quase esquina)
Tiradentes) Centro Pelotas/RS CEP 96010-160.
PROJETO/ATIVIDADE: 10.305.0101.2045.00 - VIGILÂNCIA EPIDEMIOLÓGICA
DEBITO: AG-29-9 C/C:43580-5 BB
FONTE: 4511 - COVID 19

Local de Entrega:



Recebi os materiais e/ou serviços constantes nesta Nota
Assinatura: *[Signature]* Data: 15/04/2020
Assinatura: *[Signature]* Data: / /
Autorizo Pagamento

Emittido por: *[Signature]*
Assinatura: *[Signature]* Data: / /
Assinatura: *[Signature]* Data: / /

Confira a documentação. Despesa em condições de Pagamento
Confira o valor discriminado. Pelo qual dou plena e total quitação
Emp. 8888/2020
Clarice Silva de Avila
Emp. 8888/2020
LUGÃO M. Gomes
Contador

de de de
Assinatura
Página: 1

INFORMAÇÕES COMPLEMENTARES
 Empenho número: E00742/2020 de 07/04/2020 - Observação do empenho: Teste para aplicar nos suspeitos de COVID-19.
 RESERVADO AO FISCO

DADOS ADICIONAIS

CODIGO PRODUTO	DESCRICO DO PRODUTO / SERVICO	NCM/SH	CST	CEP	UNID.	Q.TDE.	VALOR UNITARIO	VALOR DESCONTO	VALOR LIQUIDO	BASE DE CALC. ICMS	VALOR ICMS	VALOR IPI	ALIQ. %
339030360000	MATERIAL HOSPITALAR-Teste Covid-19 rápido(15 minutos)	30021590	020	6102	UN	2000	100,00	0,00	200.000,00	140.000,00	5.600,00	4,00	0,00

DADOS DOS PRODUTOS / SERVIÇOS

QUANTIDADE: 80
 CAIXA
 MARCA: _____
 NUMERAÇÃO: _____
 PESO BRUTO: 40,000
 PESO LIQUIDO: 40,000
 ENDEREÇO: _____
 MUNICIPIO: _____ UF: _____
 INSCRIÇÃO ESTADUAL: _____
 FRETE POR CONTA: 3 - PROP/REMT
 CODIGO ANTI: _____
 PLACA DO VEICULO: _____ UF: _____
 CNPJ / CPF: _____

TRANSPORTADOR / VOLUMES TRANSPORTADOS

VALOR DO FRETE: 0,00
 VALOR DO SEGURO: 0,00
 DESCONTO: 0,00
 OUTRAS DESPESAS ACESSÓRIAS: 0,00
 VALOR DO IPI: 0,00
 VALOR TOTAL DA NOTA: 200.000,00
 VALOR TOTAL DOS PRODUTOS: 200.000,00
 BASE DE CALCULO DO ICMS: 140.000,00
 VALOR DO ICMS: 5.600,00
 BASE DE CALCULO DO ICMS SUBST.: 0,00
 VALOR DO ICMS SUBST.: 0,00

CALCULO DO IMPOSTO

Valor: R\$ 200.000,00
 Número: 001
 Vencimento: 08/04/2020

PARCELAS

PELOTAS
 UF: RS
 TELEFONE / FAX: 0930323092
 INSCRIÇÃO ESTADUAL: _____
 HORA DA SAÍDA: 16:23:50
 PC CEL PEDRO OSORIO, 101
 BAIRRO / DISTRITO: CENTRO
 CEP: 96015-010
 DATA DA SAÍDA: 08/04/2020
 MUNICIPIO DE PELOTAS
 CNPJ / CPF: 87.455.531/0001-57
 DATA DA EMISSÃO: 08/04/2020

DESTINATARIO / REMETENTE

147830250110
 INSCRIÇÃO ESTADUAL
 Venda de mercadoria adquirida ou recebida de terceiros
 INSCRIÇÃO ESTADUAL DO SUBSTITUTO TRIBUTARIO
 CNPJ / CPF: 13.259.812/0001-06
 PROTOCOLO DE AUTORIZAÇÃO DE USO
 135200282436280 08/04/2020 16:40:03



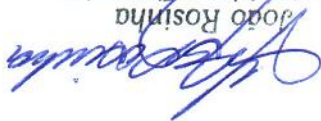
QUALYPROT COMERCIO E CONFECÇÃO DE UNIFORMES
 R SIRIA, 256, SALA 01, JARDIM SÃO JOSE, SÃO PAULO - SP
 Fone: (11) 2092-8648
 - CEP: 03086-040
 www.qualyprot.com
 falecomviva_contabilidade@outlook.com

DANFE
 Documento Auxiliar da Nota Fiscal Eletrônica
 0 - ENTRADA
 1 - SAÍDA
 Nº 000.000.355
 Série 001
 Folha 1/1

Consulta de autenticidade no portal nacional da NF-e
 www.nfe.fazenda.gov.br/portal ou no site da Sefaz autorizadora
 3520 0413 2598 1200 0106 5500 1000 0003 5514 6973 1773
 CHAVE DE ACESSO

Recebemos de QUALYPROT COMERCIO E CONFECÇÃO DE UNIFORMES CORPORAATIVOS EIR os produtos e/ou serviços constantes da Nota Fiscal Eletrônica ind
 Emissão: 08/04/2020 Des/Rem: MUNICIPIO DE PELOTAS Valor Total: 200.000,00
 DATA DO RECEBIMENTO: _____
 IDENTIFICAÇÃO E ASSINATURA DO RECEBEDOR: _____
 NF-e Nº 000.000.355 Série 001

3MS Pelotas/RS
Matrícula: 31068
Diretor Adm. e Financeiro

João Rosinha


Ass.: _____
Data: 15/04/2010
recebi os Materiais e/ou Serviços
constantes nesta NOTA.



www.qualyprot.com

06 de Abril de 2020.

Proposta nº 1246/2020

Para: Prefeitura Municipal de Pelotas

A/C Sr João Rosinha - Secretaria de Saúde

Prezado Sr João Rosinha,

Conforme solicitado, segue proposta comercial para o fornecimento dos seguintes materiais:

NR	PRODUTO	QTDE	VALOR	VALOR TOTAL R\$
01	Teste rápido COVID-19 (15 minutos IgG/IgM Cassete)	2.000 (80 caixas com 25un)	100,00	200.000,00

- Condição de entrega: CIF Município de Pelotas

- Prazo de entrega: 10 dias, após a confirmação da compra

- Condição de pagamento: 100% na entrega (pedido expedido após envio de empenho)

Atenciosamente,


Eduardo Tavares



Ruasiria, 256 | Sala 1
São Paulo | 03086-040



mail@qualyprot.com
www.qualyprot.com



+55112941-5625
+55113522-4129

615 3765/2020

CERTIFICATE OF REGISTRATION

Biocan Diagnostics Inc

This is to certify that the management system of:

Main Site: 55a & 53b Fawcett Road, Coquitlam, British Columbia,
V3K6V2, Canada
(DUNS # 203720904)

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

The management system is applicable to:

The design and development, manufacture and distribution of in vitro diagnostic rapid test kits used in diagnosis, detection of cancer, cardiac markers, Inflammatory & Tumor markers, fecal antigens, drugs of abuse, fertility testing, pregnancy testing, sexually transmitted, parasitology, infectious diseases, respiratory, hormone, neonatal, serology, clinical chemistry, urinalysis; and the manufacture and distribution of in-vitro diagnostic analyzers including home use, near patient/point of care in vitro diagnostic devices.

Certificate Number: 0073670-02

Initial Certification Date: 2018-03-22

Certification Effective Date: 2018-07-04

Certification Expiry Date: 2021-03-21




Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at <http://www.intertek.com/business-assurance/certificate-validation/>



		Revision	2020-02	APPROVED	File ID.	COVID-GM
		Technical Dossier Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test				

Technical Dossier


Product Name:

**Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM
Antibody Test**

Cassette Format (Serum/Plasma/Whole blood)

Catalogue No. B215C

Manufacturer: Biocan Diagnostics Inc.
 Products manufactured in an ISO13485 certified facility
 Manufacturer Address:
 55A-53B Fawcett Road, Coquitlam, B.C Canada
 Postcode: V3K6V2
 Website: www.rapidtest.ca

		Technical Dossier Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test		
		Revision	2020-02	APPROVED
		File ID.	COVID-GM	

I. Products Description:

A rapid test for the qualitative detection and differentiation of novel coronavirus (COVID-19) IgG & IgM antibodies in human whole blood, serum and plasma samples. For presumptive preliminary screening use only. All results should be confirmed with other qualified assays.

Biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of a pink colored conjugate pad containing recombinant COVID-19 antigen conjugated with colloid gold (COVID-19 conjugates) and quality control antibody gold conjugates and a nitrocellulose membrane strip containing two test lines (T1 and T2) and a control line (C). The T1 line is pre-coated with monoclonal anti-human IgG for the detection of IgG anti-COVID-19, T2 line is pre-coated with reagents for the detection of IgM anti-COVID-19 and the C line is pre-coated with quality control antibody. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. COVID-19 IgM antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a pink colored T2 line, indicating COVID-19 IgM positive test result. COVID-19 IgG antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a pink colored T1 line, indicating a COVID-19 IgG positive test result. Absence of any test lines (T1 and T2) suggests a negative result. The test cassette also contains a quality control line C. Regardless of the presence or absence of a detection band, the red quality control band C should appear. If the quality control band C does not appear, the test result is invalid, and the sample needs to be tested again with another test cassette.

II. Intended Use:


Biocan Tell Me Fast Coronavirus (COVID-19) IgG/IgM Antibody Test is a rapid, qualitative, membrane-based immunochromatographic in vitro assay intended for detection and differentiation of novel coronavirus (COVID-19) IgG & IgM antibodies with human serum, plasma or whole blood samples. This test is intended for laboratory in vitro diagnostic use and is a preliminary screening presumptive test and final diagnosis should be based after examination with other qualified assays

III. Product Components

Active Ingredients:

- (1) Coated Antibodies and Antigen:
 Control region: Goat anti-mouse (IgG) polyclonal antibody
 Test region (IgG): Mouse Anti-Human IgG Antibody
 Test region (IgM): Mouse Anti-Human IgM Antibody
- (2) Labeled Antibody:
 Colloidal gold conjugate of recombinant COVID-19 antigen
- (3) Sample Diluent (Phosphate Buffer) containing sodium azide.

IV. Storage: 2 to 30°C

	Technical Dossier Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test		
	Revision	2020-02	APPROVED
		File ID.	COVID-GM

V. Expiration Dating: 24 months from date of manufacture

VI. Method of Manufacture & Materials:

6.1 Nitrocellulose Membrane Manufacture:

The purified antibodies, diluted in phosphate buffer saline, is coated on the test region. Simultaneously, Goat anti-mouse (IgG) polyclonal antibody, diluted in phosphate buffer saline, is coated on the control region.

6.2 The coated membrane is dried for a minimum of 24 hours then sealed in an aluminum bag which contains silica gel desiccant.

6.3 Colloidal gold conjugate of recombinant COVID-19 antigen pad manufacture:
 A buffer solution containing recombinant COVID-19 antigen colloidal gold conjugate is coated onto glass fiber sheets.

The coated glass fiber sheet is dried for minimum 24 hours then sealed in an aluminum bag which contains desiccant.

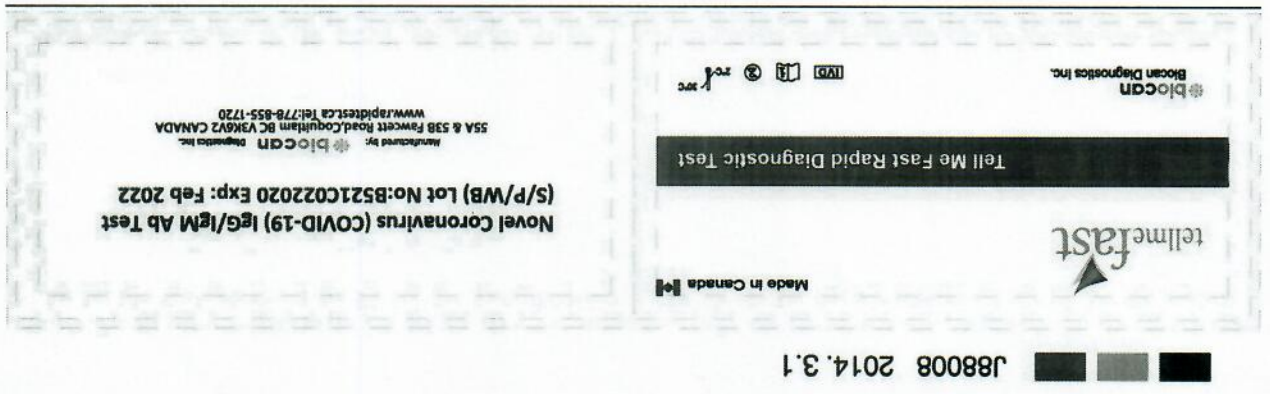
8.4 Test Device Assembly:
 The coated membrane, the conjugate pad, and an absorbent pad is applied to an adhesive-coated backing.

A 2-part waterproof label is applied over the conjugate pad and the absorbent pad, the assembled sheet of material is cut into strips. The test strips are then vacuum-dried for a minimum of 4 hours.

The assembled test strip is sealed within a plastic cassette casing. The cassette is sealed in an aluminum pouch along with a desiccant packet.

VII. Certificate

- Manufactured in a Quality Management System-ISO 13485:2003 certified facility
- CE Declaration of Conformity




Pouch labeling for Novel Coronavirus (COVID-19) IgG/IgM Antibody Cassette packaging


For Carton: Carton Specification: 57x43x38 cm
 One Carton can fully pack 40 COVID-19 IgG/IgM Antibody Cassette Boxes

For Biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Cassette Test:
 Pouch: 6.5cm x 13.5cm
 Product Packing Box: 19.5x13.5x6.5cm
 COVID-19 IgG/IgM Antibody Diluent Buffer 1 Bottle/box
 COVID-19 IgG/IgM Antibody Cassette Instruction (B215C) 1 test instruction/box



Package Information
 For individual packed Cassette test, each test kit is packed along with one desiccant into an aluminum foil pouch.

	Technical Dossier Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test		
	Revision	2020-02	APPROVED
	File ID.	COVID-GM	

	Technical Dossier Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test		
	Revision	2020-02	APPROVED
		File ID.	COVID-GM

STABILITY AND REACTIVITY DATA Stability: Stable in Normal Conditions. Conditions to Avoid: None known. Materials to Avoid: Not applicable. Hazardous Decomposition Products: None know	DISPOSAL CONSIDERATIONS Disposal of Preparation Left: Dispose according to current regional and national rules.
---	---

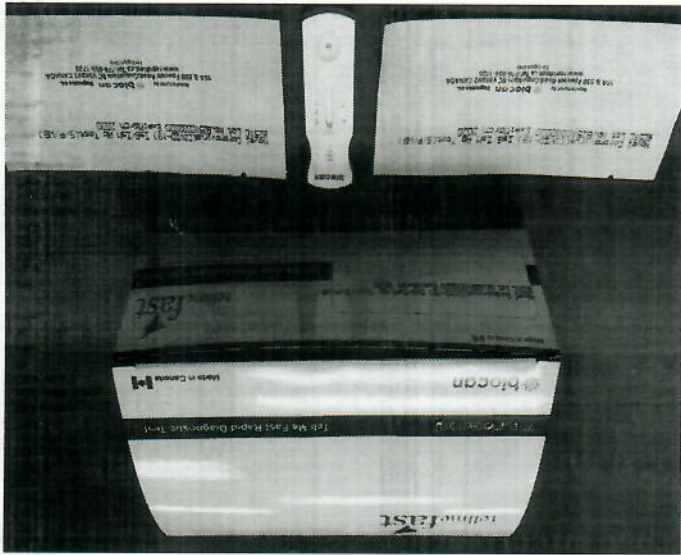
TRANSPORTATION INFORMATION

Road / Railway Haulage ADR/RID: Not restricted. Sea Freight IMO (IMDG): Not restricted. Air Freight IATA (CAO): Not restricted. UN Number: Not applicable.	Symbols of Danger: None. "R" Phrases Indicating Specific Risks: None. "S" Phrases Indicating Caution: None.
---	---

OTHER REGULATORY INFORMATION


The product is manufactured in accordance with Good Manufacturing Practice (GMP) for IVD – Ordinance n° 686 of 27/08/98, Directive 98/79 – CE, Quality Management System NBR ISO 13485:2004 (EN ISO 13485:200) and labelling and symbols information in accordance with Ordinance 206 of 17/11/06, NBR ISO 15223:2004, EN 980:2008.

- Test Requires only 10µL of human serum, plasma or whole blood (including finger prick)

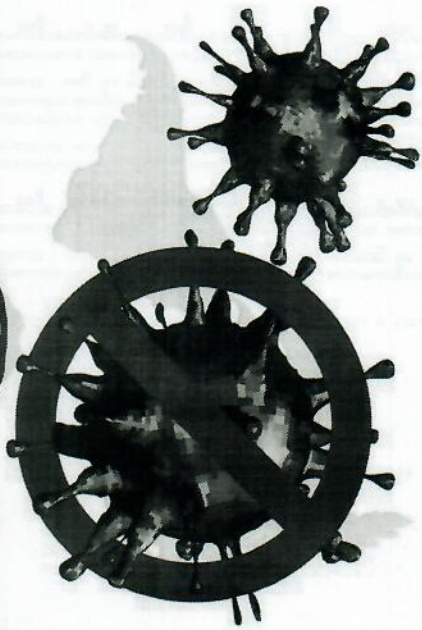


Responding fast to Coronavirus (COVID-19) outbreak Biocan has a launched a rapid test capable of delivering fast results in just minutes to detect the Coronavirus COVID-19 IgG/IgM Antibodies in human whole blood, plasma or serum sample. This test is easy to use and cost effective.

Now detect Novel Coronavirus (COVID-19) infection in just minutes with the Biocan Tell Me Fast COVID-19 IgG/IgM Antibody Test.

bioCAN
 A Message from
 Biocan Diagnostics Inc.  Canada

**TEST & TREAT TO
 STOP
 COVID-19**



Proudly Canadian 

bioCAN 



- Detects and differentiates between an IgM and IgG COVID-19 virus infection for a primary and past infection.

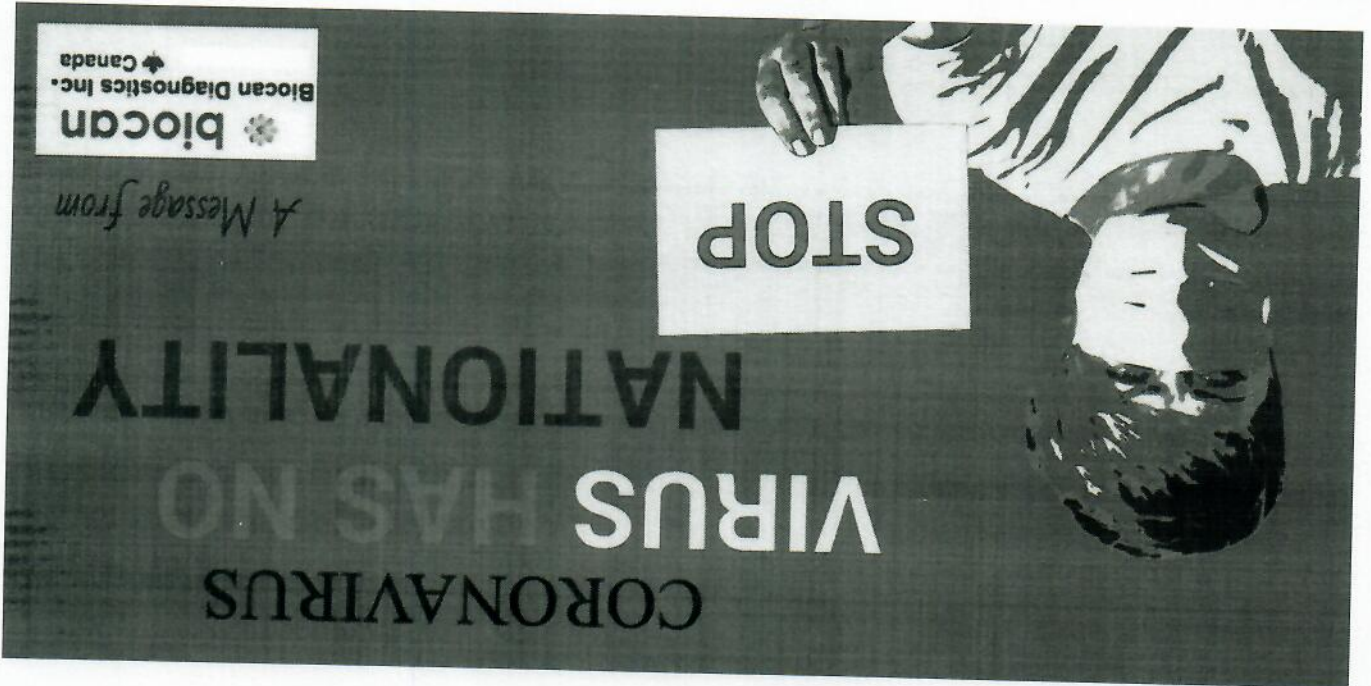
- Easy to use and results in 10 minutes

- Cost effective and no instruments needed to perform the test. Test be performed at doctor's office, clinics, labs, field setting, mobile testing, hospitals, labs, cruise ships, airports, ports etc.

- Stable at 2 to 30 C. No cold chain needed for transportation.

PERFORMANCE:

Currently we only recommend using this test for presumptive preliminary screening purposes only. The expected sensitivity of test for IgM & IgG should be 92% and specificity at 99.5% when compared to PCR. In comparison to PCR test specimens tested from 1 to 3 days of infection the IgM positive rate should be 16% and the IgG positive rate should be 16%. Specimens tested from 4 to 7 days, the IgM positive rate should be 85.7% and the IgG positive rate 92.8%. Specimens in the range of 8 days to 14 days the IgM & IgG positive rate should be 90%. IgG can be detected for a longer period of time. *More testing data to be available soon.*



Biocan Diagnostics Inc based in Canada has a launched a rapid test for easy and fast detection of the highly contagious Coronavirus (COVID-19). Biocan is an ISO 13485:2016 MDSAP certified manufacturer of various rapid in vitro diagnostics tests made under stringent quality control in our facility near Vancouver, Canada. As part of our corporate mission we have launched the COVID-19 IgG/IgM Ab Rapid Test at a very reasonable cost to make it affordable to where it is need most to stop the spread of this novel coronavirus, which has now affected a very large number of people worldwide and is spreading at a very fast rate.



DECLARATION OF CONFORMITY



Biocan Diagnostics Inc.
55A & 53B Fawcett Road
Coquitlam, British Columbia
Canada, V3K6V2

Biocan Diagnostics Inc. hereby declares and ensures that the products listed below comply with the requirements of the European Union in Vitro Diagnostics Medical Device Directive 98/79/EC.

Product Brand: Tell Me Fast™

RAPID TESTS

Catalogue	Description	Format
B700C/B700S	Malaria Pf Antigen	Cassette/Strip
B701C/B701S	Malaria Pf/Pv Antigen	Cassette/Strip
B702C/B702S	Malaria Pf/Pan Antigen	Cassette/Strip
B704C/B704S	Malaria Pf/Pv Antibody	Cassette/Strip
B801C/B801S	S:Typhi (Typhoid) Antigen	Cassette/Strip
B802C	S:Typhi/Para Typhi ABC (Typhoid) Antigen	Cassette/Strip
B808C	Typhoid IgG/IgM Ab	Cassette
B809C	S:Typhoid IgG/IgM Ab & S:Typhi/Para Typhi ABC Ag Combo	Cassette
B803C/B803S	Dengue IgG/IgM Antibody	Cassette/Strip
B805C	Dengue IgG/IgM Antibody & NS 1 Antigen Combo	Cassette/Strip
B806C	Dengue NS1 Antigen	Cassette
B810	Dengue IgA/IgM/IgG (Triplex)	Cassette
B811	Dengue IgA/IgM/IgG Antibody & NS1 Antigen (Fourplex)	Cassette
B103C	Herpes Simplex Virus 1 IgG/IgM Antibody	Cassette
B104C	Herpes Simplex Virus 2 IgG/IgM Antibody	Cassette
B200C	Leptospira IgG/IgM Antibody	Cassette
B201C	Leptospira IgG/IgM Antibody	Cassette
B807C	Chikungunya IgG/IgM Antibody	Cassette
B815C	Zika IgG/IgM Antibody Test	Cassette
B571C/B571S	Fecal Occult Blood (FOB)	Cassette/Strip
B511C	Transferrin	Cassette
B512C	Lactoferrin	Cassette
B514C	Calprotectin	Cassette
B515C	FOB-Lactoferrin Combo	Cassette
B517C	Procalcitonin	Cassette
B519C	Clostridium difficile GDH	Cassette
B521C	E.Coli O157	Cassette
B523C	Entamoeba	Cassette
B525C	C. difficile Toxin A	Cassette
B526C	C. difficile Toxin B	Cassette
B527C	C. difficile Toxin A/B	Cassette
B219C/B291S	Influenza A & B Antigen Test	Cassette/Strip
B908C/B908S	Treponema Pallidum (Syphilis)	Cassette/Strip
B909C/B909C	Treponema Pallidum (Syphilis)	Cassette/Strip

MHRA Unique Registration Number: IVD000772
(Medicines & Healthcare Products Regulatory Agency, UK)
CEA Countries Reference Number: GB/CA01/IVD000774





DECLARATION OF CONFORMITY

MHRA Unique Registration Number: IVD000772
(Medicines & Healthcare Products Regulatory Agency, UK)
EEA Countries Reference Number: GB/CA01/IVD000774

B590C/B590S	Neisseria Gonorrhoeae	Cassette/Strip
B219C/B219S	Influenza A & B Antigen Test	Cassette/Strip
B401C/B401S	Respiratory Syncytial Virus (RSV) Antigen Test	Cassette/Strip
B814C/B814S	Chagas Ab (<i>Trypanosoma cruzi</i>)	Cassette/Strip
B521C	Novel Coronavirus (COVID-19) IgG/IgM Ab Test	Cassette

Catalogue	Description	Format
B402C	H. Pylori Antibody	Cassette
B403C	H. Pylori Antigen	Cassette
B411C	H. Pylori IgG/IgM Antibody	Cassette
B500C	Myoglobin	Cassette
B502C	Troponin I	Cassette
B501C	Creatine Kinase Isoenzymes	Cassette
B503P	Cardiac Combo (Trop I, CK-MB, Myoglobin)	Cassette
B600C/B600S	hCG (Pregnancy) Serum/Urine Combo	Cassette
B601C/B601S	Human Chorionic Gonadotropin (Pregnancy)	Cassette/Strip
B602M	Human Chorionic Gonadotropin (Pregnancy)	Midstream
B603C/B603S	hCG Ultrasensitive Early Detection	Cassette/Strip
B604M	hCG Ultrasensitive Early Detection	Midstream
B605C/B605S	hCG Ultrasensitive Early Detection Combo	Cassette/Strip
B607C/B607S	Luteinizing Hormone	Cassette/Strip
B607M	Luteinizing Hormone	Midstream
B609C/B609S	FSH	Cassette/Strip
B214C/B214S	Adenovirus Antigen Test	Cassette/Strip
B215C/B215S	Rotavirus Antigen Test	Cassette/Strip
B216C/B216S	Adenovirus/Rotavirus Antigen Combo Test	Cassette/Strip
B300C/B300S	Leishmania (Kalaazar)	Cassette/Strip
B580C/B580S	Prostate Specific Antigen (PSA)	Cassette/Strip
B582C/B582S	Carcinoembryonic Antigen (CEA)	Cassette/Strip
B584CB584C	Alpha-Fetoprotein (AFP)	Cassette/Strip
B301C	Giardia Ag Test	Cassette
B302C	Norovirus Ag Test	Cassette
B417C/B417S	Strep A Antigen Test	Cassette
B418C/B418S	Strep B Antigen Test	Cassette
B820C/B820S	Filaria IgG/IgM Ab Test	Cassette/Strip
B304C	Ebola Virus IgG/IgM Ab Test	Cassette/Strip
B826C	Zika IgG/IgM Ab & Chikungunya IgG/IgM Ab Test	Cassette
B828C	Dengue IgG/IgM Ab & Zika IgG/IgM Ab Test	Cassette
B830C	Dengue IgG/IgM Ab & Chikungunya IgG/IgM Ab Test	Cassette
B832C	Dengue IgG/IgM Ab - NS1 Ag & Chikungunya IgG/IgM	Cassette
B834C	Dengue IgG/IgM Ab - NS1 Ag & Zika IgG/IgM Ab Test	Cassette
BF500	Vitamin D Fluorescence	Cassette
BF301	Troponin I Fluorescence	Cassette
BF304	NT Pro BNP Fluorescence	Cassette
BF305	CK-MB Fluorescence	Cassette
BF307	Myoglobin Fluorescence	Cassette
BF309	D-Dimer Fluorescence	Cassette
BF401	CRP Fluorescence	Cassette
BF700	Procalcitonin Fluorescence	Cassette
BF203	Ferritin Fluorescence	Cassette
BF801	Parathyroid Fluorescence	Cassette



MHRA Unique Registration Number: IVD000772
 (Medicines & Healthcare Products Regulatory Agency, UK)
 EEA Countries Reference Number: GB/CA01/IVD000774

DECLARATION OF CONFORMITY

DOA (RAPID TESTS)

Catalogue	Description	Format
B721C/B721S	Amphetamine (AMP)	Cassette/Strip
B722C/B722S	Barbiturates (BAR)	Cassette/Strip
B723C/B723S	Benzodiazepine (BZO)	Cassette/Strip
B724C/B724S	Cocaine (COC)	Cassette/Strip
B726C/B726S	Methylenedioxymethamphetamine (MDMA) (Ecstasy)	Cassette/Strip
B727C/B727S	Methamphetamine (MET)	Cassette/Strip
B728C/B728S	Morphine (MOR)	Cassette/Strip
B729C/B729D	Opiates (OPI)	Cassette/Strip
B730C/B730S	Methadone (MTD)	Cassette/Strip
B731C/B731S	Tricyclic Antidepressants (TCA)	Cassette/Strip
B732C/B732S	Tetrahydrocannabinol (THC)	Cassette/Strip
B733C/B733S	Buprenorphine (BUP)	Cassette/Strip
B734C/B734S	Oxycodone (OXY)	Cassette/Strip
B735C/B735S	Phencyclidine (PCP)	Cassette/Strip
B736C/B736S	Tramadol (TML)	Cassette/Strip
B737C/B737S	Ketamine (KET)	Cassette/Strip
B738C/B737S	Cotinine (COT)	Cassette/Strip
B739C/B739S	Synthetic Cannabis (K2)	Cassette/Strip
B740C/B740S	Fentanyl (FYL)	Cassette/Strip
B741C/B741S	Methaqualone (MQL)	Cassette/Strip
B742C/B742S	Propoxyphene (PPX)	Cassette/Strip
B743C/743S	EDDP	Cassette/Strip
BMDP	Multi Drug Panel (2,3,5,6 &10)	Dip Card/Cassette

Class: Other

Regulation Scope: 98/79/EC Annex III

Applicable AB Directives: 98/79/EC

Applicable Harmonized Standards: ISO 9001, ISO 13485:2016, TS EN 375, TS EN 376, TS EN 591, TS EN 592, TS EN 1041, TS EN 13532, TS EN 14971,

CE Authorized Representative:

Welkang Teach Consulting
 Suite B, 29 Harley Street LONDON W1G 9QR England, United Kingdom

Declaration Date/Place: 26th Feb 2020, Vancouver, BC, Canada

The undersigned hereby declares, under the sole responsibility of the manufacturer, that the medical device as specified above conforms to the essential requirements listed in the Annex I of the European in vitro Medical Device Directive 98/79/EC (IVD).



Signature:

Authorized Signatory, Name: Bhayjit Jauhar

