GESPRIN

MATERIAL SANITARIO

TEST RÁPIDO DE ANTÍGENOS 25 ud.

Polígono Espíritu Santo
Parcela 12
Oviedo - 33010

TLF:608 134 210
648 654 347
info@gesprin.es

www.gesprin.es

Flowflex™

GESPRIN
MATERIAL SANITARIO

> Resultados en 15 minutos

> Sensibilidad de 97,1%

> Especificidad de 99,3%

> Tubos precargados de reactivo monodosis

'Flowflex™. SARS-COV-2

Prueba rápida de antígeno

Proporciona ayuda en el diagnóstico de la infección por SARS-COV-2 a personas sospechosas de tener una infección activa por COVID-19.

RÁPIDO

SIMPLE

PRECISO

ACON®

ACON Laboratories, INC.

Flow*flex* SARS-CoV-2 Prueba rápida de Antígeno

La prueba rápida de Antígeno Flowflex SARS-CoV-2 es una prueba inmunocromatográfica para la detección cualitativa del antígeno de la proteína nucleocápsida del SARS-CoV-2, en muestras de hisopos nasales de individuos sospechosos por COVID-19.

- Muestra de hisopo nasal
- Resultados en 15 minutos
- Excelente desempeño en comparación con los métodos moleculares.
- Sensibilidad de 97,1%. Especificidad de 99,3%
- Almacenamiento a temperatura ambiente
- Caducidad 2 años
- Tubos precargados de reactivo monodosis

Validación Clínica

La validación clínica de la eficacia de la prueba rápida de Antígeno Flowflex se ha llevado a cabo a base de un estudio de 304 muestras de hisopos nasales de pacientes sospechosos por COVID-19 en los últimos 7 días. Todos los resultados obtenidos de la prueba rápida de Antígeno Flowflex SARS-CoV-2 se han correlacionado con los resultados del RT PCR.

Fiabilidad clínica de Flowflex SARS-CoV-2

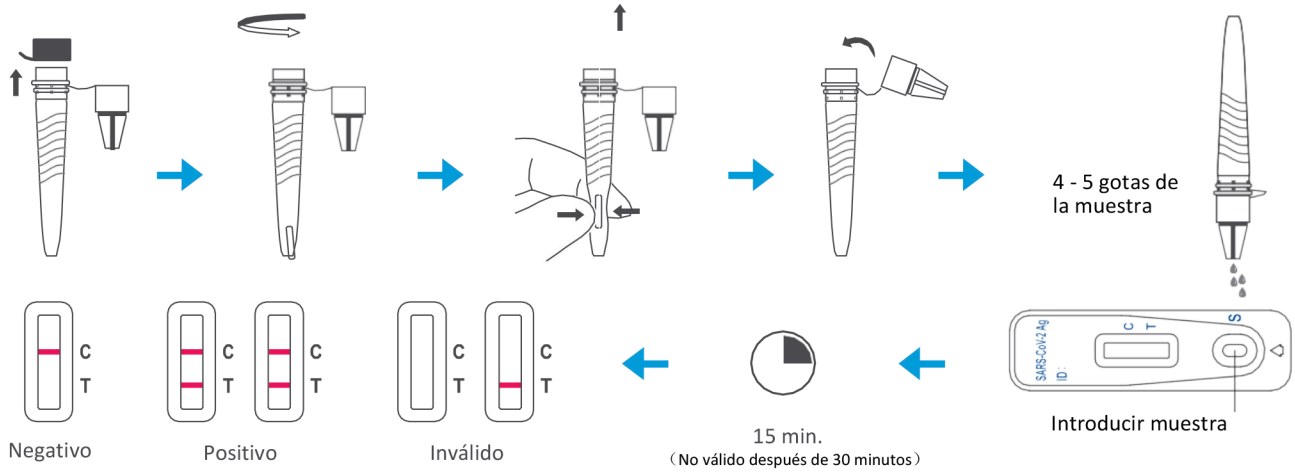
Método		RT-PCR		Total
	Resultado	Negativo	Positivo	
Flow*flex* SARS-CoV-2	Negativo	269	1	270
	Positivo	1	33	34
Total		270	34	304
PEP: 97.1% (83.8%- 99.9%)*	PEN: 99.6% (97.7%- 99.9%)*	PG: 99.3% (97.5% -99.9%)*		

PEP- Prueba de ensayo positivo; **PEN** – Prueba de ensayo Negativo; **PG** – Porcentaje General, *95% Fiabilidad

Componentes de la caja

- 25 Cassettes de Prueba
- 1 Instrucciones de uso
- 25 tubos precargados de reactivo
- 1 Hisopo de control negativo
- 1 Hisopo de control positivo
- 25 bastoncillos de algodón desechables
- 1 estación de trabajo

Preparación de Muestra e Interpretación de Resultados



Información

Nombre de producto	Código de producto	Formato	Tipo de muestra	Embalaje
Flowflex SARS-CoV-2 prueba rápida de Antígeno	L031-11815	Casete	Hisopo nasal	Caja de 25 Kits

CE

GESPRIN MATERIAL SANITARIO
Polígono Espíritu Santo
Parcela 12 - 33010 Oviedo
985 986 346/648 654 347
info@gesprin.es
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ACON Laboratories, Inc.
Oberlin Drive, # 340
San Diego, CA 92121, USA
aconlabs.com

Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC and the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Acon Laboratories, Inc.
5850 Oberlin Drive, #340
San Diego, CA 92121
USA

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and medical devices and has allocated registration numbers shown in:

Annex A dated 2020-10-26

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices and medical devices fulfill the applicable requirements of Directives 98/79/EC and 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2020-10-26

Dr. Philipp Hohenbrink
Senior Consultant
MDSS GmbH

Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
C131-1011	Mission® ALT Alanine Aminotransferase Test Strips		11 01 01 03	Alanine Amino-Transferase	"Other"	N/A	DE/CA09/0170/A10/IVD/022-01
C131-1021	Mission® AST Aspartate Aminotransferase Test Strips		11 01 01 10	Aspartate Amino-Transferase	"Other"	N/A	DE/CA09/0170/A10/IVD/077-01
G134-10D, G134-11D	On Call® Blood Uric Acid Test Strip	(OGS-201)	11 02 01 32	Uric Acid	Self-Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/082-01
G134-10D, G134-11D	On Call® Blood Uric Acid Test Strip	(OGS-201)	11 02 01 32	Uric Acid	"Other"	N/A	DE/CA09/0170/A10/IVD/087-01
G126-121	On Call® A1c HbA1c Control Solution		11 50 02 05	Diabetes Controls	"Other"	N/A	DE/CA09/0170/A10/IVD/002-01
G124-12D	On Call® Uric Acid Control Solution		11 50 02 05	Diabetes Controls	"Other"	N/A	DE/CA09/0170/A10/IVD/088-01
G124-12D	On Call® Uric Acid Control Solution		11 50 02 05	Diabetes Controls	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/080-01
U021-011, U021-021, U021-031	Mission® Liquid Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-015, U021-025, U021-035	Insight® Liquid Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-071, U021-081, U021-091	Mission® Liquid Diptube Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-075, U021-085, U021-095	Insight® Liquid Diptube Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-041, U021-051, U021-061	Mission® Dry Strip Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-045, U021-055, U021-065	Insight® Dry Strip Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
C121-1051	Mission® ALT Control Solution		11 50 02 90	Other Specific Control (CC)	"Other"	N/A	DE/CA09/0170/A10/IVD/016-02
G134-106, G134-116	On Call® Chosen Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G135-102, G135-112	On Call® Vivid Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G135-109, G135-119	D-ONE Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G135-105, G135-115	On Call Sharp Blood Glucose Test Strips	(OGS-121)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G133-11C, G133-10C	On Call Plus II Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G135-10H, G135-11H	On Call Extra Blood Glucose Test Strips	(OGS-191)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G135-10U, G135-11U	On Call® Sure Blood Glucose Test Strip	(OGS-211)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
24118, 24119, 24120	GIMA Blood Glucose Test Strips	(OGS-211)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G134-906A	Go-Keto Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G133-11x	On Call® Plus Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G134-101, G 134-111	On Call® Advanced Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G134-102, G134-112	On Call® Platinum Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G133-10D, G133-11D	On Call® Redi II Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G135-10H, G135-11H	On Call® Extra Blood Glucose Test Strips	(OGS-191)	11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G135-10U, G135-11U	On Call® Sure Blood Glucose Test Strip	(OGS-211)	11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
24118, 24119, 24120	GIMA Blood Glucose Test Strips	(OGS-211)	11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G134-101, G134-111	On Call® Advanced Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G134-106, G134-116	On Call® Chosen Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G134-906A	Go-Keto Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
C131-5011	Mission® Ultra CHOL Total Cholesterol Test Strips		11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-04
C131-2011; C131-2061	Mission® Cholesterol CHOL Total Cholesterol Test Device	(CCS-111)	11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-04
C131-2013	LipidScan Lipid Profile Test Device Total Cholesterol	(CCS-111)	11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-04
C131-2011; C131-2061	Mission® Cholesterol CHOL Total Cholesterol Test Device	(CCS-111)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/069-07
C131-5011	Mission® Ultra-CHOL Total Cholesterol Test Strips	(CCS-101)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/069-07
C131-2013	LipidScan Lipid Profile Test Device Total Cholesterol	(CCS-111)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/069-07
C131-2031; C131-2081	Mission® Cholesterol HDL High Density Lipoprotein Test Device	(CCS-113)	11 70 01 03	HDL Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/012-02
C131-2033	LipidScan Lipid Profile Test Device High Density Lipid Protein (HDL)	(CCS-113)	11 70 01 03	HDL Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/012-02
C131-2031; C131-2081	Mission® Cholesterol HDL High Density Lipoprotein Test Device	(CCS-113)	11 70 01 03	HDL Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/067-05
C131-2033	LipidScan Lipid Profile Test Device High Density Lipid Protein (HDL)	(CCS-113)	11 70 01 03	HDL Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/067-05
C131-2021; C131-2071	Mission® Cholesterol TRIG Triglyceride Test Device	(CCS-112)	11 70 01 05	Triglyceride Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/013-02
C131-2023	LipidScan Lipid Profile Test Device Triglycerides (TRIG)	(CCS-112)	11 70 01 05	Triglyceride Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/013-02
C131-2023	LipidScan Lipid Profile Test Device Triglycerides (TRIG)	(CCS-112)	11 70 01 05	Triglyceride Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/068-05
C131-2021; C131-2071	Mission® Cholesterol TRIG Triglyceride Test Device	(CCS-112)	11 70 01 05	Triglyceride Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/068-05

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G136-111	On Call® A1c HbA1c Test Kit		11 70 01 07	Glycosylated/Glycated Haemoglobin Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/003-02
G136-112	On Call® MultiPro HbA1c Test Kit	OGS-221	11 70 01 07	Glycosylated/Glycated Haemoglobin Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/003-02
GK134-10A, GK134-11A	On Call® Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/098
GK134-90AA	Go-Keto Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/098
GK134-10A, GK134-11A	On Call® Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/008-05
GK134-90AA	Go-Keto Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/008-05
C131-2041; C131-2051	Mission® Cholesterol 3-in-1 Lipid Panel Test Device	(CCS-114)	11 70 01 30	Multiple parameter blood test	"Other"	N/A	DE/CA09/0170/A10/IVD/011-02
C131-2043	LipidScan Lipid Profile Test Device Combo Lipid Profile	(CCS-114)	11 70 01 30	Multiple parameter blood test	"Other"	N/A	DE/CA09/0170/A10/IVD/011-02
C131-2041; C131-2051	Mission® Cholesterol 3-in-1 Lipid Panel Test Device	(CCS-114)	11 70 01 30	Multiple parameter blood test	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/066-05
C131-2043	LipidScan Lipid Profile Test Device Combo Lipid Profile	(CCS-114)	11 70 01 30	Multiple parameter blood test	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/066-05
C121-5011	Mission® Ultra Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
C121-2011	Mission® Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
C121-2023	LipidScan Lipid Profile Control Device		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
C121-2021	Mission® Cholesterol CTRL Control Device		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G125-12H	On Call® Extra Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G125-12U	On Call® Sure Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
24121	GIMA Glucose Control Solution	(OGC-211)	11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G126-122	On Call® MultiPro HbA1c Individual Controls	OGC-221	11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G124-121	On Call® Advanced Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G124-126	On Call® Chosen Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06

MDSS
Medical Device Safety Service

Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G124-12A	On Call® Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
GK124-92AA	Go-Keto Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G124-126	On Call® Chosen Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-122	On Call® Vivid Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-129	D-ONE Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-125	On Call® Sharp Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G123-12C	On Call® Plus II Blood Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-12H	On Call® Extra Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-12U	On Call® Sure Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
24121	GIMA Glucose Control Solution	(OGC-211)	11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G124-121	On Call® Advanced Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G124-122	On Call® Platinum Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G123-311	On Call® Plus Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G123-371	On Call® Redi Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G123-12D	On Call® Redi II Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
C121-5011	Mission® Ultra Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
C121-2011	Mission® Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
C121-2023	LipidScan Lipid Profile Control Device		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
C121-2021	Mission® Cholesterol CTRL Control Device		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06

MDSS
Medical Device Safety Service

Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G124-12A	On Call® Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
GK124-92AA	Go-Keto Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U033-XX1, U034-XX1	Mission® Expert Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U033-XX5, U034-XX5	Insight® Expert Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
49110000xx	Blaas Check Urineweginfectie Thuistest		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
4911000xxx	Totaal Check Thuistest Voor urine		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
49110000xx	Blaas Check Urineweginfectie Thuistest		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
4911000xxx	Totaal Check Thuistest Voor urine		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
U031-XX3	MiTest Urinary Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
U033-XX1, U034-XX1	Mission® Expert Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
U033-XX5, U034-XX5	Insight® Expert Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
I031-1011	Foresight® Allergen Test Kit		12 02 01 06	Immunoglobulin E - Screen	"Other"	N/A	DE/CA09/0170/A10/IVD/009-02
I231-2021	Foresight® CEA EIA Kit		12 03 01 31	Carcinoembryonic Antigen	"Other"	N/A	DE/CA09/0170/A10/IVD/043-03
I231-2022	Incontrol® CEA EIA Kit		12 03 01 31	Carcinoembryonic Antigen	"Other"	N/A	DE/CA09/0170/A10/IVD/043-03
I231-2031	Foresight® Total PSA EIA Test Kit		12 03 01 32	Total Prostatic Specific Antigen	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/015-06
I231-2032	Incontrol® Total PSA EIA Test Kit		12 03 01 32	Total Prostatic Specific Antigen	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/015-06
I231-2011	Foresight® AFP EIA Kit		12 03 90 01	Alphafetoprotein	"Other"	N/A	DE/CA09/0170/A10/IVD/061-03
I231-2012	Incontrol® AFP EIA Kit		12 03 90 01	Alphafetoprotein	"Other"	N/A	DE/CA09/0170/A10/IVD/061-03

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I231-3051	Foresight® Free T3 EIA Test Kit		12 04 01 01	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-04
I231-3052	Incontrol® Free T3 EIA Test Kit		12 04 01 01	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-04
I331-4051	Foresight® Free T3 CLIA Test Kit		12 04 01 01	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-04
I231-3031	Foresight® Free T4 EIA Test Kit		12 04 01 02	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-04
I231-3032	Incontrol® Free T4 EIA Test Kit		12 04 01 02	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-04
I331-4031	Foresight® Free T4 CLIA Test Kit		12 04 01 02	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-04
I231-3041	Foresight® Total T3 EIA Test Kit		12 04 01 05	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-04
I231-3042	Incontrol® Total T3 EIA Test Kit		12 04 01 05	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-04
I331-4041	Foresight® Total T3 CLIA Test Kit		12 04 01 05	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-04
I231-3021	Foresight® Total T4 EIA Test Kit		12 04 01 07	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-04
I231-3022	Incontrol® Total T4 EIA Test Kit		12 04 01 07	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-04
I331-4021	Foresight® Total T4 CLIA Test Kit		12 04 01 07	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-04
I231-3011	Foresight® TSH EIA Kit		12 04 01 11	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-04
I231-3012	Incontrol® TSH EIA Kit		12 04 01 11	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-04
I331-4011	Foresight® TSH CLIA Test Kit		12 04 01 11	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-04
I231-4031	Foresight® FSH EIA Test Kit		12 05 01 04	Follicle Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/014-02
I231-4032	Incontrol® FSH EIA Test Kit		12 05 01 04	Follicle Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/014-02
I231-4021	Foresight® LH EIA Test Kit		12 05 01 05	Luteinising Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/021-02
I231-4022	Incontrol® LH EIA Test Kit		12 05 01 05	Luteinising Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/021-02
I231-4041	Foresight® PRL EIA Test Kit		12 05 01 08	Prolactin	"Other"	N/A	DE/CA09/0170/A10/IVD/020-02
I231-4042	Incontrol® PRL EIA Test Kit		12 05 01 08	Prolactin	"Other"	N/A	DE/CA09/0170/A10/IVD/020-02
I231-4011	Foresight® Rapid HCG EIA Test Kit		12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
I231-4012	Incontrol® Rapid HCG EIA Test Kit		12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
I231-4051	Foresight® HCG EIA Test Kit	(quantitative)	12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
I231-4052	Incontrol® HCG EIA Test Kit	(quantitative)	12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
C031-021	Mission® Saliva Alcohol Test Strip		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-025	Insight® Saliva Alcohol Test Strip		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-011, C031-031	Mission® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-015, C031-035	Insight® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
L031-30121	ACON Fecal Occult Blood Rapid Test Cassette (Feces)		12 70 03 21	Fecal Occult Blood - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/090-01
L031-30111	ACON Fecal Occult Blood Rapid Test Strips (Feces)		12 70 03 21	Fecal Occult Blood - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/090-01
L031-20242	Distinct Ovulation Rapid Test Midstream		12 70 05 04	LH - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/083-01
L031-20232	Distinct LH Ovulation Rapid Test Cassette (Urine)		12 70 05 04	LH - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/083-01

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L031-20211	ACON LH Ovulation Rapid Test Strip (Urine)		12 70 05 04	LH - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/089-01
L031-20221	ACON LH Ovulation Rapid Test Cassette (Urine)		12 70 05 04	LH - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/089-01
L031-20312	Distinct Ovulation & Pregnancy Rapid Test Midstream Combo Pack		12 70 05 90	Other Fertility/Pregnancy RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/081-01
L031-20152	Distinct Pregnancy Rapid Test Cassette (Urine)		12-70-05-02	HCG - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/072-06
L031-20162	Distinct Pregnancy Rapid Test Midstream		12-70-05-02	HCG - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/072-06
L031-20111, L031-20171	ACON hCG Pregnancy Rapid Test Strip (Urine)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
L031-20121, L031-20181	ACON hCG Pregnancy Rapid Test Strip (Urine/Serum)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
L031-20141	ACON hCG Pregnancy Rapid Test Cassette (Urine/Serum)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
L031-20131	Acon hCG Pregnancy Rapid Test Cassette (Urine)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
C121-9011	Mission® 3D Hematology Reagent (Cyto-Diluent)		13 01 01 01	CBC-Reagents (Cleaning-/Diluting-/Lysing-/Sheat-fluids)	"Other"	N/A	DE/CA09/0170/A10/IVD/078-01
C121-9021	Mission® 3D Hematology Reagent (Cyto-Lyser)		13 01 01 01	CBC-Reagents (Cleaning-/Diluting-/Lysing-/Sheat-fluids)	"Other"	N/A	DE/CA09/0170/A10/IVD/078-01
C121-9031	Mission® 3D Hematology Reagent (Mi-Po Cleaner)		13 01 01 01	CBC-Reagents (Cleaning-/Diluting-/Lysing-/Sheat-fluids)	"Other"	N/A	DE/CA09/0170/A10/IVD/078-01
C121-9041	Mission® 3D Hematology Control		13 01 50 03	Blood Multilevel Controls	"Other"	N/A	DE/CA09/0170/A10/IVD/092-01
C121-3031	Mission® Hb Hemoglobin Control Strip		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-3035	Insight® Hb Hemoglobin Control Strip		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C122-3011	Mission® Plus Hb Hemoglobin Control Strip	(Optic Check)	13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C122-3021	Mission® Plus Hb Hemoglobin Control Device	(Optic Check)	13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-3091	Mission® Hb Hemoglobin Control Solution		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-6011	Mission® Ultra Hemoglobin Control Solution		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-6011	Mission® Ultra Hemoglobin Control Solution		13 01 50 04	Haemoglobin Controls	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/076-03
C131-6011	Mission Ultra Hemoglobin Test Strips	(CCS-141)	13 01 70 01	Haemoglobin (Hb)	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/075-03

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C131-3011, C131-3021	Mission® Hb Hemoglobin Test Strips		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C131-3015	Insight® Hb Hemoglobin Test Strips		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C132-3011, C132-3031	Mission® Plus Hb Hemoglobin Test Strips		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C132-3021, C132-3041	Mission® Plus Hb Hemoglobin Test Devices		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C131-6011	Mission Ultra Hemoglobin Test Strips	(CCS-141)	13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C131-4011	Mission® PT Coagulation Test Strips	(CCS-121)	13 02 70 01	Prothrombin Time RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/063-05
C132-4011	Mission® PT/INR Test Strips	(CCS-151)	13 02 70 01	Prothrombin Time RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/063-05
LMINR-0002; LMINR-0003	LUMIRATEK PT/INR Test Strips		13 02 70 01	Prothrombin Time RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/063-05
C121-4011	Mission® PT Coagulation Control Solution		13 02 70 50	Haemostasis Controls - RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/062-05
C122-4011	Mission® PT/INR Control Solution		13 02 70 50	Haemostasis Controls - RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/062-05
LMINR-0004	LUMIRATEK PT/INR Control Solution		13 02 70 50	Haemostasis Controls - RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/062-05
U031-021	Mission® UTI Urinary Tract Infection Test Strips		14 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
U031-025	Insight® UTI Urinary Tract Infection Test Strips		14 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
U031-023	ValMed UTI Urinary Tract Infection Test Strips		14 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
U031-02A	HealthyMe UTI Urinary Tract Infection Test Strips		15 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
I231-1042	Incontrol® Total Syphilis Antibody EIA Test Kit		15 01 03 03	Syphilis Antibody Assays Total	"Other"	N/A	DE/CA09/0170/A10/IVD/054-03
I231-1041	Foresight® Total Syphilis Antibody EIA Test Kit		15 01 03 03	Syphilis Antibody Assays Total	"Other"	N/A	DE/CA09/0170/A10/IVD/054-03
I231-1231	Foresight® H. pylori Antigen EIA Test Kit		15 01 04 01	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/A10/IVD/055-03
I231-1232	Incontrol® H. pylori Antigen EIA Test Kit		15 01 04 01	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/A10/IVD/055-03
I231-1241	Foresight® H. pylori IgG EIA Test Kit		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04
I231-1242	Incontrol® H. pylori IgG EIA Test Kit		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04

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L031-10611	H. pylori Antibody Rapid Test Cassette (Serum/Plasma)		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04
L031-10621	H. pylori Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04
P131-1301	Promotor™ TB Mycobacterium Tuberculosis PCR Test Kit		15 01 07 03	Mycobacteria Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/004-02
I231-1211	Foresight® HEV IgM EIA Kit		15 02 05 06	HEV Antibody IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/044-03
I231-1212	Incontrol® HEV IgM EIA Kit		15 02 05 06	HEV Antibody IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/044-03
I231-1112	Incontrol® Rubella IgG EIA Test Kit		15 04 01 05	Rubella Virus IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/038-06
I231-1111	Foresight® Rubella IgG EIA Test Kit		15 04 01 05	Rubella Virus IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/038-06
I231-1121	Foresight® Rubella IgM EIA Test Kit		15 04 01 06	Rubella Virus IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/039-06
I231-1122	Incontrol® Rubella IgM EIA Test Kit		15 04 01 06	Rubella Virus IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/039-06
I231-1132	Incontrol® CMV IgG EIA Test Kit		15 04 02 05	CMV IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/036-06
I231-1131	Foresight® CMV IgG EIA Test Kit		15 04 02 05	CMV IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/036-06
I231-1141	Foresight® CMV IgM EIA Test Kit		15 04 02 06	CMV IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/037-06
I231-1142	Incontrol® CMV IgM EIA Test Kit		15 04 02 06	CMV IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/037-06
I231-1192	Incontrol® HSV 1/2 IgG EIA Test Kit		15 04 03 05	HSV 1+2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/053-03
I231-1191	Foresight® HSV 1/2 IgG EIA Test Kit		15 04 03 05	HSV 1+2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/053-03
I231-1202	Incontrol® HSV 1/2 IgM EIA Test Kit		15 04 03 06	HSV 1+2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/050-03
I231-1201	Foresight® HSV 1/2 IgM EIA Test Kit		15 04 03 06	HSV 1+2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/050-03
I231-1152	Incontrol® HSV 1 IgG EIA Test Kit		15 04 03 08	HSV 1 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/052-03
I231-1151	Foresight® HSV 1 IgG EIA Test Kit		15 04 03 08	HSV 1 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/052-03
I231-1162	Incontrol® HSV 1 IgM EIA Test Kit		15 04 03 09	HSV 1 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/010-03
I231-1161	Foresight® HSV 1 IgM EIA Test Kit		15 04 03 09	HSV 1 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/010-03
I231-1172	Incontrol® HSV 2 IgG Test Kit		15 04 03 11	HSV 2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/051-03
I231-1171	Foresight® HSV 2 IgG Test Kit		15 04 03 11	HSV 2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/051-03
I231-1182	Incontrol® HSV 2 IgM EIA Test Kit		15 04 03 12	HSV 2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/049-03
I231-1181	Foresight® HSV 2 IgM EIA Test Kit		15 04 03 12	HSV 2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/049-03
P131-1121	Promotor™ PCR-Fluorescence Detection Kit for Human Papillomavirus Genotype 16/18 DNA		15 04 08 41	Partial Genotyping High-Risk HPV - NA reagents	"Other"	N/A	DE/CA09/0170/A10/IVD/093
P131-1481	Promotor™ HPV Human Papillomavirus Genotyping PCR-RDB Test Kit		15 04 08 42	Full Genotyping High-Risk + Low-Risk HPV - NA reagents	"Other"	N/A	DE/CA09/0170/A10/IVD/005-02
P131-1501	Promotor™ HPV 15 High-risk with 16/18 Genotyping PCR Test Kit		15 04 08 42	Full Genotyping High-Risk + Low-Risk HPV - NA reagents	"Other"	N/A	DE/CA09/0170/A10/IVD/005-02
P131-1591	Promotor® SARS-CoV-2 RT-PCR Test Kit		15 04 40 19	Coronavirus - NA Reagents (PCR test)	"Other"	N/A	DE/CA09/0170/A10/IVD/097-01

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
I231-1321	Foresight® SARS-CoV-2 IgG EIA Test Kit		15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/A10/IVD/099
I231-1331	Foresight® SARS-CoV-2 IgM EIA Test Kit		15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/A10/IVD/099
I231-1091	Foresight® Toxoplasma IgG EIA Test Kit		15 05 01 05	Toxoplasma Antibody IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/040-06
I231-1092	Incontrol® Toxoplasma IgG EIA Test Kit		15 05 01 05	Toxoplasma Antibody IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/040-06
I231-1101	Foresight® Toxoplasma IgM EIA Test Kit		15 05 01 06	Toxoplasma Antibody IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/041-06
I231-1102	Incontrol® Toxoplasma IgM EIA Test Kit		15 05 01 06	Toxoplasma Antibody IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/041-06
L031-10711	ACON H. pylori Antigen Rapid Test Cassette (Feces)		15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/085-02
L031-10411	ACON Syphilis Rapid Test Strip (Serum/Plasma)		15 70 01 05	Syphilis - RT &POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10421	ACON Syphilis Rapid Test Strip (Serum/Plasma/Whole Blood)		15 70 01 05	Syphilis - RT &POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10431	ACON Syphilis Rapid Test Cassette (Serum/Plasma)		15 70 01 05	Syphilis - RT &POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10441	ACON Syphilis Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 01 05	Syphilis - RT &POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-11011	Malaria P.f/P.v Antigen Rapid Test Cassette (Whole Blood)		15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/091-01
L031-10911	Malaria P.f/Pan Antigen Rapid Test Cassette (Whole Blood)		15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/091-01
L031-11815	Flowflex® SARS-CoV-2 Antigen Rapid Test		15 70 90 08	Coronavirus – RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/100
P121-1101	Promotor™ Nucleic Acid (DNA) Extraction Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-03
P121-1121; P121-1221	Promotor™ Nucleic Acid (RNA) Extraction Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-03
P121-1111	Promotor™ Whole Blood Genomic DNA Extraction Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-03
P121-1301	Promotor® Nucleic Acid Extraction Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-03
P121-1051	Promotor Viral Nucleic Acid Isolation Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-03
P121-1291	Promotor Viral DNA/ RNA Isolation Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-03

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

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L031-11211	ACON® Dengue NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11311	ACON® Dengue IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11511	ACON® Dengue NS1 Ag & IgG/IgM Combo Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11711	ACON® SARS-CoV-2 IgG/IgM Rapid Test		15 70 90 90	Other Other Virology - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/095
C111-1011	Mission® C 100 Dry Chemistry Analyzer		21 01 10 01	CH Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/023-02
C121-1011	Mission® Optical Check Strips		21 01 10 01	CH Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/023-02
C121-1031	Mission® C 100 Data Transfer Kit		21 01 10 01	CH Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/023-02
G114-106, G114-116, G114-126, G114-136	On Call® Chosen Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-102	On Call® Vivid Blood Glucose Monitoring System	(OGM-101)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-112, G115-122, G115-132	On Call® Vivid Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-109	D-ONE Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-105, G115-115, G115-125, G115-135	On Call® Sharp Blood Glucose Monitoring System	(OGM-121)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-107, G115-117, G115-127, G115-137	On Call® Vivid Pal Blood Glucose Monitoring System	(OGM-102)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G113-10C, G113-11C, G113-12C	On Call® Plus II Blood Glucose Monitoring System	(OGM-171)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
GK114-13B	On Call® GK Dual Blood Glucose & Ketone Monitoring System	(OGM-161)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-10H	On Call® Extra Blood Glucose Monitoring System	(OGM- 191)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11H, G115-12H, G115-13H	On Call® Extra Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G115-10T	On Call® Extra Mobile Blood Glucose Monitoring System	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11T, G115-12T, G115-13T	On Call® Extra Mobile Blood Glucose Meter	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
GU114-11D	On Call® GU Dual Blood Glucose & Uric Acid Meter	(OGM-201)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-10W	On Call® Sure Sync Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11W, G115-12W, G115-13W	On Call® Sure Sync Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-10U	On Call® Sure Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11U, G115-12U, G115-13U	On Call® Sure Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G117-107	On Call® Extra Voice Blood Glucose Monitoring System	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G117-117, G117-127, G117-137	On Call® Extra Voice Blood Glucose Meter	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
24110, 24111	GIMA Blood Glucose Monitoring System	(OGM-211)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
24114	GIMA Bluetooth® Blood Glucose Monitoring System	(OGM-212)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07

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24108	GIMA Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/026-07**
GK114-90BA	Go-Keto Blood & Ketone Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/026-07**
G113-111, G113-112	On Call® Plus Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/060-08**
G113-211, G113-214, G113-215, G113-216	On Call® Plus Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/060-08**
G114-101, G114-111, G114-121, G114-131	On Call®Advanced Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/060-08**
G113-171, G113-271, G113-274	On Call® Redi Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/060-08**
G113-151, G113-251, G113-152, G113-251, G113-254	On Call® EZ II Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/060-08**
G114-102, G114-112, G114-122, G114-132	On Call® Platinum Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	**DE/CA09/0170/A10/IVD/060-08**
G115-10T	On Call® Extra Mobile Blood Glucose Monitoring System	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	**DE/CA09/0170/A10/IVD/084-05**
G115-11T, G115-12T, G115-13T	On Call® Extra Mobile Blood Glucose Meter	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	**DE/CA09/0170/A10/IVD/084-05**
GU114-11D	On Call® GU Dual Blood Glucose & Uric Acid Meter	(OGM-201)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	**DE/CA09/0170/A10/IVD/084-05**
G115-10W	On Call® Sure Sync Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	**DE/CA09/0170/A10/IVD/084-05**
G115-11W, G115-12W, G115-13W	On Call® Sure Sync Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	**DE/CA09/0170/A10/IVD/084-05**
G115-10U	On Call® Sure Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	**DE/CA09/0170/A10/IVD/084-05**

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G115-11U, G115-12U, G115-13U	On Call® Sure Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G117-107	On Call® Extra Voice Blood Glucose Monitoring System	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G117-117, G117-127, G117-137	On Call® Extra Voice Blood Glucose Meter	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
24110, 24111	GIMA Blood Glucose Monitoring System	(OGM-211)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
24114	GIMA Bluetooth® Blood Glucose Monitoring System	(OGM-212)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
24108	GIMA Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
GK114-13B	On Call® GK Dual Blood Glucose & Ketone Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
GK114-90BA	Go-Keto Blood & Ketone Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-10H	On Call® Extra Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-11H, G115-12H, G115-13H	On Call® Extra Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-102	On Call® Vivid Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-112, G115-122, G115-132	On Call® Vivid Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05

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G113-111, G113-112	On Call® Plus Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G113-211, G113-214, G113-215, G113-216	On Call® Plus Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
U111-101, U111-111	Mission® U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U221-111	Mission® Urine Analyzer Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U121-131	Mission® U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U121-101	Mission® Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U111-105, U111-115	Insight® U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U221-115	Insight® Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U121-135	Insight® U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U121-105	Insight® Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U113-101, U113-111	Mission® Expert U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U223-111	Mission® Expert Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07

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REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
U123-131	Misson® Expert U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U113- 105, U113-115	Insight® Expert U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U223-115	Insight® Expert Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U123-135	Insight® Expert U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U211-101, U211-111	Mission® U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U221-131	Mission® U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U211-105, U211-115	Insight® U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U221-135	Insight® U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U213-101, U213-111	Mission® Expert U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U223-131	Mission® Expert U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
U213-105, U213-115	Insight® Expert U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U223-135	Insight® Expert U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U114-101, U114-111	Mission® U120 Ultra Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U124-111	Mission® Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U124-131	Mission® U120 Ultra Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U114-105, U114-115	Insight® U120 Ultra Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U124-115	Insight® Urine Analyzer Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U124-135	Insight® U120 Ultra Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
5004001, 5004001BCR	Urispin U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
U211-1X3	Urispin U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
5004002	Urispin U500 Urine Analyzer (SPINREACT)		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U221-113	Urispin Urine Analyzer Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U111-1X3	Uri-Plus 1A Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U211-1X3	Uri-Plus 5A Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U121-103	Urispin Pinter Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
C111-5011	Mission® Ultra Cholesterol Monitoring System		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
C111-2011	Mission® Cholesterol Monitoring System	(CCM-111)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
C111-2021	Mission® Cholesterol Meter	(CCM-111)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
C111-2041	Mission® Cholesterol Meter	(CCM-111) 5 extra lancets	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
C111-2023	LipidScan Lipid Profile Analyzer	(CCM-111)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
G116-111	On Call® A1c HbA1c Analyzer	(OGM-141)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U118-101, U118-111	Mission® Expert U120 Smart Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U128-131	Mission® Expert U120 Smart Urine Analyzer Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U118-105, U118-115	Insight® Expert U120 Smart Urine Analyser		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U128-135	Insight® Expert U120 Smart Urine Analyser Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U117-101, U117-111	Mission® U120 Smart Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U127-131	Mission® U120 Smart Urine Analyzer Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U117-105, U117-115	Insight® U120 Smart Urine Analyser		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U127-135	Insight® U120 Smart Urine Analyser Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U123-101	Mission® Expert Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U123-105	Insight® U120 Expert Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
5004003	Urispin U120 Smart Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
U114-103	SURESIGN® U120 Ultra Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
5040007	Exacto® U120 Ultra		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**
BU121-103	Exacto® Printer Paper Rolls (Thermal)		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	**DE/CA09/0170/A10/IVD/001-07**

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Annex A: 2020-10-26
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REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
BU124-113	Exacto® BarCode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
C111-2011	Mission® Cholesterol Monitoring System	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-2021	Mission® Cholesterol Meter	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-2041	Mission® Cholesterol Meter	(CCM-111) 5 extra lancets	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-5011	Mission® Ultra Cholesterol Monitoring System	(CCM-101)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-2023	LipidScan Lipid Profile Analyzer	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
G116-112, G116-122	On Call® MultiPro Analyzer	OGM-221	21 07 10 09	RT_CI Hardware + dedicated accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/096
C111-9011	Mission® HA-360 3-Diff Automatic Hematology Analyzer		23 01 10 01	CC Hardware + accessories + consumables +software	"Other"	N/A	DE/CA09/0170/A10/IVD/079-01
C111-3021, C111-3031	Mission® Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
C111-3015, C111-3025, C111-3035	Insight® Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
C112-3011, C112-3021, C112-3031	Mission® Plus Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
C121-3021	Mission® Hb Data Transfer Kit		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
C111-6011	Mission Ultra Hemoglobin Testing System	(CCM-141)	23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
C111-6011	Mission Ultra Hemoglobin Testing System	(CCM-141)	23 07 10 00	RT_HHC Hardware + dedicated accessories or software	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/074-03
C111-4011	Mission® PT Coagulation Monitoring System	(CCM-121)	23 07 10 02	RT_Coagulation Hardware +accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/064-05
C112-4021	Mission® PT/INR Monitoring System	(model CCM-151)	23 07 10 02	RT_Coagulation Hardware +accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/064-05
LMINR-0001	LUMIRATEK PT/INR Monitoring System		23 07 10 02	RT_Coagulation Hardware +accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/064-05
P111-1011	Promotor™ NES-32 Nucleic Acid Extraction System		26 02 10 01	NA Extraction Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/006-02

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REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G123-191	Testamed Diabetes Care Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3041	Mission® Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-191	Testamed Diabetes Care Soft Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-7B1 C121-3061	On Call Safety Lancets I	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3061	Mission® Safety Lancets I	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
N/A (kit component)	D-One Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G124-10A	On Call Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-191	Testamed Diabetes Care Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-191	Testamed Diabetes Care Soft Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-7B2	On Call® Safety Lancets III	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3101	Mission® Safety Lancets III	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G124-90AA	Swiss Point of Care Lancets	10	UMDNS 10-440	Lancets, Blood	IIa	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3081	Mission® Capillary Transfer Tubes	10	UMDNS 15-192	Tube, Capillary	I	N/A	DE/CA09/0170/A10/001-02
C121-3085	Insight® Capillary Transfer Tubes	10	UMDNS 15-192	Tube, Capillary	I	N/A	DE/CA09/0170/A10/001-02
G123-291	Testamed Diabetes Care Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
C121-3051	Mission® Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
N/A (kit component)	D-One Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
G124-11A	On Call Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
G124-17A	On Call GenTouch Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
G124-91AA	Swiss Point of Care Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive, #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Flowflex® SARS-CoV-2 Antigen Rapid Test (L031-11815)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 13 day of October, 2020
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Flowflex™ SARS-CoV-2 Antigen Rapid Test

Evaluation Report

November 2020

Flow*flex* SARS-CoV-2 Antigen Rapid Test Evaluation Report

The Flow*flex* SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The Flow*flex* SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results from patients with more than seven days post symptom onset should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The Flow*flex* SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

1. **Purpose:** To evaluate the performance of the Flow*flex* SARS-CoV-2 Antigen Rapid Test

2. **Material:**

Materials	Lot		
SARS-CoV-2 Antigen Rapid Test	202009101	202009001	202009201
Extraction Buffer	202008001	202008002	202008003

3. **Study procedure and results**

3.1 Imprecision/reproducibility Study

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 Antigen Negative Sample Lot#: COVAG200904N
- SARS-CoV-2 Antigen Low Positive Sample P3 Lot#: COVAG200904P3
- SARS-CoV-2 Antigen Middle Positive Sample P2 Lot#: COVAG200904P2
- SARS-CoV-2 Antigen High Positive Sample P1 Lot#: COVAG200904P1

Procedure:

3 Lots of SARS-CoV-2 Antigen Rapid Test were tested according to the package insert by 3 operators. Each operator performed 2 tests on each control for 5 days in 2 sites in China. Total 180 tests were performed per each control: 2 replicates X 5 days X 3 lots X 3 operators X 2 sites = 180 tests.

Test results:

SARS-CoV-2 Samples	Lot 1	Lot 2	Lot 3
High Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Mid Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Low Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Neg	- / 60 replicates	- / 60 replicates	- / 60 replicates

Conclusions:

All three lots identified the samples 100% correctly as negative or positive.

3.2 Limit of Detection (LOD)

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 viral culture

Procedure:

1. Sample Application Method: Apply 4~5 drops (approximately 100~125 ul) of sample to the sample well on the test cassette, then start the timer, read the result at 15-20 minutes.
2. Dilute the high concentration SARS-CoV-2 viral culture with the Extraction Buffer.
3. Use 3 lots of SARS-CoV-2 antigen rapid test to test the samples, and every sample is tested in 10 replicates. Calculate the detectable rate for each sample.
4. The minimum concentration with ≥95% detectable rate is defined as the minimum detectability (LOD).

Test results:

Culture sample:

Concentration	Lot	Test Result	Detectable rate
2.56×10^3 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
1.28×10^3 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	

6.4×10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
3.2×10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
1.6×10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	96.7% (29/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ 9 replicates / - 1 replicate	
8 x 10 $TCID_{50}$/mL	**Lot 1**	- / 10 replicates	0% (0/30)
	Lot 2	- / 10 replicates	
	Lot 3	- / 10 replicates	

Conclusion:

According to the test result, the LOD is 1.6×10^2 TCID50/mL

3.3 **Clinical study – nasal swabs**

A multi-site clinical study was conducted to evaluate the performance of the SARS-CoV-2 Antigen Rapid Test, and the results are shown below.

Site 1 Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Comparison method: RT-PCR, Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), manufactured by Sansure BioTech Inc.
- Extraction Buffer, Lot1#:202008001
- Nasal swab samples from infected patients and non-infected patients

Site 1 Procedure:

1. Study was conducted in Hangzhou, China
    - 304 clinical nasal swabs were collected from patients who were suspected of COVID-19 (within 7 days of onset). All the samples were confirmed with RT-PCR.
    - 34 positive clinical nasal swabs collected from patients. 29 samples with Ct counts <33, 5 samples with Ct counts ≥33.

2. Following product package insert, performed the test and read the result at 15-20 minutes.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive*	Total
Flow*flex* Test Results	Negative	269	1	270
	Positive	1	33	34
	Total	270	34	304

Site 2 Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Comparison method: TaqPath COVID-19 Combo Kit, FDA authorized RT-PCR test for emergency use, manufactured by Thermo Fisher Scientific, Inc.
- Nasal swab samples from infected patients and non-infected patients

Site 2 Procedure:

1. Study is being conducted in multiple U.S. sites in California and Florida, and it is ongoing. So far, 125 clinical nasal swabs were collected from patients who were suspected of COVID-19 (within 7 days of onset). All the samples were confirmed with RT-PCR method.
2. Following product package insert, performed the test and read the result at 15-20 minutes.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	32	3*	35
	Positive	1	89	90
	Total	33	92	125

***3 samples with PCR CT value 33.97 – 33.99**

Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	301	4	305
	Positive	2	122	124
	Total	303	126	429

Conclusions:

The sensitivity, specificity, and accuracy are meeting MHRA acceptable requirement, which has sensitivity greater than 80% and specificity greater than 95%.

	Performance	95% CI
Sensitivity	96.8% (122/126)	92.1%-99.1%
Specificity	99.3% (301/303)	97.6%-99.9%
Accuracy	98.6% (423/429)	97.0% -99.5%

3.4 Endogenous Interfering Substances

To determine if the substances that naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity interfere with Flow*flex* SARS-CoV-2 Antigen Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot# 102820
- Pooled human negative clinical matrix

Procedure 1: Test the endogenous substances in the absence of heat inactivated SARS-Cov-2 virus.

The samples were prepared by spiking each substance into the human negative clinical matrix to the target concentration listed in the table below. Each sample was tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Test according to the package insert.

Test Results:

No cross-reactivity was observed with the endogenous interfering substances when tested at the concentration presented in the table below.

Procedure 2: Test the endogenous substances in the presence of heat inactivated SARS-CoV-2 virus.

The samples were prepared by spiking each substance and heat inactivated SARS-Cov-2 virus into the human negative clinical matrix to the target concentration in the presence of heat inactivated SARS-CoV-2 virus at 9.71 x 10^2 TCID50/mL. Each sample was tested in triplicate according to the package insert.

Test Results:

No interference was observed.

Endogenous Interference Substances Study Results

Interfering Substances	Active Ingredient	Concentration	Cross-Reactive Results			Interference Results		
Endogenous	Mucin	0.5% w/v	-	-	-	+	+	+
	Whole Blood	4% v/v	-	-	-	+	+	+
Afrin Original Nasal Spray	Oxymetazoline	15% v/v	-	-	-	+	+	+
ALKALOL Allergy Relief Nasal Spray	Homeopathic	1:10 Dilution	-	-	-	+	+	+
Chloraseptic Max Sore Throat Lozenges	Menthol, Benzocaine	1.5 mg/mL	-	-	-	+	+	+
CVS Health Fluticasone Propionate Nasal Spray	Fluticasone propionate	5% v/v	-	-	-	+	+	+
Equate Fast-Acting Nasal Spray	Phenylephrine	15% v/v	-	-	-	+	+	+
Equate Sore Throat Phenol Oral Anesthetic Spray	Phenol	15% v/v	-	-	-	+	+	+
Original Extra Strong Menthol Cough Lozenges	Menthol	1.5 mg/mL	-	-	-	+	+	+
NasalCrom Nasal Spray	Cromolyn	15% v/v	-	-	-	+	+	+
NeilMed NasoGel for Dry Noses	Sodium Hyaluronate	5% v/v	-	-	-	+	+	+
Throat Lozenge	Dyclonine Hydrochloride	1.5mg/mL	-	-	-	+	+	+
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	-	-	-	+	+	+
Antibiotic	Mupirocin	10 mg/mL	-	-	-	+	+	+
Tamiflu	Oseltamivir Phosphate	5 mg/mL	-	-	-	+	+	+
Antibiotic	Tobramycin	4 ug/mL	-	-	-	+	+	+

Conclusion:

Based on the data generated by this study, the endogenous interfering substances tested do not cross-react or interfere with Flow*flex* SARS-CoV-2 Antigen test.

3.5 Cross Reactivity (Analytical Specificity)

To demonstrate the related pathogens and organisms that are reasonably likely to be present in the nasal cavity do not interfere with test performance of Flow*flex* SARS-Cov-2 Antigen Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#2:202009001
- Extraction Buffer, Lot#102820
- Pooled human negative clinical matrix

Procedure: Cross-Reactivity Wet Testing

Samples were prepared by spiking each stock inactivated viruses and bacteria into the pooled human negative clinical matrix. Each organism and virus were tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Test.

Test Results:

No cross-reactivity was observed with the following bacteria and viruses when tested at the concentration presented in the table below.

Potential Cross -Reactant		Test Concentration	Cross-Reactive Results		
Virus	Adenovirus	1.14×10^6 TCID50/mL	-	-	-
	Enterovirus	9.50×10^5 TCID50/mL	-	-	-
	Human coronavirus 229E	1.04×10^5 TCID50/mL	-	-	-
	Human coronavirus OC43	2.63×10^5 TCID50/mL	-	-	-
	Human coronavirus NL63	1.0×10^5 TCID50/mL	-	-	-
	Human Metapneumovirus	1.25×10^5 TCID50/mL	-	-	-
	MERS-coronavirus	7.90×10^5 TCID50/mL	-	-	-

	Influenza A	1.04×10^5 TCID50/mL	-	-	-
	Influenza B	1.04×10^5 TCID50/mL	-	-	-
	Parainfluenza virus 1	1.25×10^5 TCID50/mL	-	-	-
	Parainfluenza virus 2	3.78×10^5 TCID50/mL	-	-	-
	Parainfluenza virus 3	1.0×10^5 TCID50/mL	-	-	-
	Parainfluenza virus 4	2.88×10^6 TCID50/mL	-	-	-
	Respiratory syncytial virus	3.15×10^5 TCID50/mL	-	-	-
	Rhinovirus	3.15×10^5 TCID50/mL	-	-	-
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	-	-	-
	Chlamydia trachomatis	3.13×10^8 CFU/mL	-	-	-
	Haemophilus influenza	1.36×10^8 CFU/mL	-	-	-
	Legionella pneumophila	4.08×10^9 CFU/mL	-	-	-
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	-	-	-
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	-	-	-
	Staphylococcus epidermidis	2.32×10^9 CFU/mL	-	-	-
	Streptococcus pneumoniae	1.04×10^8 CFU/mL	-	-	-
	Streptococcus pyogenes	4.10×10^6 CFU/mL	-	-	-
	Pneumocystis jirovecii-S. cerevisiae	8.63×10^7 CFU/mL	-	-	-
	Pseudomonas aeruginosa	1.87×10^8 CFU/mL	-	-	-
	Pooled human nasal wash	N/A	-	-	-
Yeast	Candida albicans	1.57×10^8 CFU/mL	-	-	-

3.6 Microbial Interference Studies

To demonstrate that false negatives will not occur with Flow*flex* SARS-Cov-2 Antigen Test when SARS-CoV-2 is present in a specimen with other microorganisms.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot#102820
- Pooled human negative clinical matrix

Procedure:

The samples were prepared by spiking each inactivated viruses and bacterial cells and heat inactivated SARS-CoV-2 virus into the pooled human negative clinical matrix. Each organism and virus in the presence of heat inactivated SARS-CoV-2 virus at 9.71 x 10^2 TCID50/mL were tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Test.

Test Results:

No interference was observed in the presence of heat inactivated SARS-CoV-2 virus with the following bacteria and viruses when tested at the concentration presented in the table below.

Potential Cross -Reactant		Test Concentration	Interference Results		
Virus	Adenovirus	1.14 x 10^6 TCID50/mL	+	+	+
	Enterovirus	9.50 x 10^5 TCID50/mL	+	+	+
	Human coronavirus 229E	1.04 x 10^5 TCID50/mL	+	+	+
	Human coronavirus OC43	2.63 x 10^5 TCID50/mL	+	+	+
	Human coronavirus NL63	1.0 x 10^5 TCID50/mL	+	+	+
	Human Metapneumovirus	1.25 x 10^5 TCID50/mL	+	+	+
	MERS-coronavirus	7.90 x 10^5 TCID50/mL	+	+	+

	Influenza A	1.04×10^5 TCID50/mL	+	+	+
	Influenza B	1.04×10^5 TCID50/mL	+	+	+
	Parainfluenza virus 1	1.25×10^5 TCID50/mL	+	+	+
	Parainfluenza virus 2	3.78×10^5 TCID50/mL	+	+	+
	Parainfluenza virus 3	1.0×10^5 TCID50/mL	+	+	+
	Parainfluenza virus 4	2.88×10^6 TCID50/mL	+	+	+
	Respiratory syncytial virus	3.15×10^5 TCID50/mL	+	+	+
	Rhinovirus	3.15×10^5 TCID50/mL	+	+	+
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	+	+	+
	Chlamydia trachomatis	3.13×10^8 CFU/mL	+	+	+
	Haemophilus influenza	1.36×10^8 CFU/mL	+	+	+
	Legionella pneumophila	4.08×10^9 CFU/mL	+	+	+
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	+	+	+
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	+	+	+
	Staphylococcus epidermidis	2.32×10^9 CFU/mL	+	+	+
	Streptococcus pneumoniae	1.04×10^8 CFU/mL	+	+	+
	Streptococcus pyogenes	4.10×10^6 CFU/mL	+	+	+
	Pneumocystis jirovecii-S. cerevisiae	8.63×10^7 CFU/mL	+	+	+
	Pseudomonas aeruginosa	1.87×10^8 CFU/mL	+	+	+
	Pooled human nasal wash	N/A	+	+	+
Yeast	Candida albicans	1.57×10^8 CFU/mL	+	+	+

Conclusion:

Based on the data generated by this study, the organisms or viruses tested do not cross-react or interfere with Flow*flex* SARS-CoV-2 Antigen test.

3.7 Hook effect

To evaluate if the false negative result can be observed when test very high levels of heat inactivated SARS-CoV-2 virus with Flow*flex* SARS-Cov-2 Antigen Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot#102820
- Pooled human negative clinical matrix

Procedure:

Samples were prepared by adding heat inactivated SARS CoV-2 virus into the human negative nasal matrix pool for preparing the highest concentration 7.5 x 10^5 TCID50/mL of heat inactivated SARS-CoV-2 available in the human negative nasal matrix. Contrived nasal swab samples were prepared by absorbing 50 uL of the virus at 7.5 x 10^5 TCID50/mL onto the swab. The contrived swab samples were tested in triplicate according to the package insert.

Conclusion:

No high dose hook effect was observed when tested with up to a concentration of 7.5 x 10^5 TCID50/mL of heat inactivated SARS-CoV-2 virus with Flow*flex* SARS-CoV-2 Antigen Test.

3.8 Read Time Flex

To demonstrate that the test result is stable when read within the recommended time window.

Material:

SARS-CoV-2 Antigen Rapid Test, Lot#1:COV0110005
Buffer, Lot#:TDE20110009
SARS-CoV-2 Antigen Negative Sample Lot#: 20201104
SARS-CoV-2 Antigen Low Positive Control Lot#: COVAG200930L
SARS-CoV-2 Antigen Middle Positive Control Lot#: COVAG200930M
ACON Rapid Flow Test Color Card, Lot#20200112

Procedure:

SARS-CoV-2 Antigen negative, high, middle and low positive sample are tested with SARS-CoV-2 Antigen Rapid Test according to package insert. Each test was performed in triplicate. The test results were recorded at 5, 10, 15, 20 and 30 mins.

Test results:

SARS-CoV-2 Samples	5 min	10 min	15 min	20 min	30 min
Neg	- / 3 replicates	- / 3 replicates	- / 3 replicates	- / 3 replicates	- / 3 replicates
Low Pos	- / 3 replicates	+/ 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates
Mid Pos	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates
High Pos	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates

Conclusion:

The results are stable when read between 10 minutes to 30 minutes.

3.9 Stability Study

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 Antigen Negative Sample Lot#: COVAG200904N
- SARS-CoV-2 Antigen Low Positive Sample P3 Lot#: COVAG200904P3
- SARS-CoV-2 Antigen Middle Positive Sample P2 Lot#: COVAG200904P2
- SARS-CoV-2 Antigen High Positive Sample P1 Lot#: COVAG200904P1
- SARS-CoV-2 Antigen positive control swab, Lot#1: 202009003P-1, Lot#2: 202009003P-2, Lot#3: 202009003P-3
- SARS-CoV-2 Antigen negative control swab, Lot#1: 202009003N-1, Lot#2: 202009003N-2, Lot#3: 202009003N-3

3.9.1 Accelerated stability

Estimate the shelf life for SARS-CoV-2 Antigen Rapid Test, Extraction Buffer and Control Swabs basing on the accelerate stability study.

Procedure:

Accelerated stability study for three lots (including tests in individual pouches, control swabs in individual pouches, extraction buffer in tube) will be stored at 55°C/65°C to estimate product stability. Tests will be assayed according to package insert at designated time points. For each device lot, run 3 replicates per sample at each time points. Read the results according to package insert.

Test results:

Result of SARS-CoV-2 Antigen Rapid Test

55°C

SARS-CoV-2 Samples	0 day	7 days	14 days
Neg	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots
Low Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Mid Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
High Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots

65°C

SARS-CoV-2 Samples	0 day	7 days	14 days
Neg	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots
Low Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Mid Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
High Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots

Result of SARS-CoV-2 Antigen Control swab:

55°C

Samples	0 day	7 days	14 days
Positive Control Swab	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Negative Control Swab	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots

65°C

Samples	0 day	7 days	14 days
Positive Control Swab	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Negative Control Swab	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots

Conclusion:

SARS-CoV-2 Antigen Rapid Test, extraction buffer and SARS-CoV-2 Antigen Control Swabs are stable at 65°C for 14 days, so the shelf life can be estimated at least 24 months.

3.9.2 Real time stability

Estimate the shelf life for SARS-CoV-2 Antigen Rapid Test, Extraction Buffer and Control Swabs basing on the real time stability study.

Procedure:

Real time stability study for three lots (including tests in individual pouches, control swabs in individual pouches, extraction buffer in tube) will be stored at 2-8°C/30°C to estimate product stability. Tests will be assayed according to package insert at designated time points every 3 months until the timepoints that performance does not meet the acceptance criteria. For each device lot, negative and different levels of positive samples will be tested, run 3 replicates per sample at each time points. Read the results according to package insert.

Acceptance criteria:

Negative sample will generate negative result

Low positive, medium positive and high positive sample will generate positive results

Test results:

Result of SARS-CoV-2 Antigen Rapid Test:

2-8°C

SARS-CoV-2 Samples	Neg	Low Pos	Mid Pos	High Pos
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months				
6 months				
9 months				
12 months				

30°C

SARS-CoV-2 Samples	Neg	Low Pos	Mid Pos	High Pos
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months				

6 months				
9 months				
12 months				

Result of SARS-CoV-2 Antigen Control swab:

2-8°C

SARS-CoV-2 Samples	Neg control swab	Pos control swab
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months		
6 months		
9 months		
12 months		

30°C

SARS-CoV-2 Samples	Neg control swab	Pos control swab
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months		
6 months		
9 months		
12 months		

Conclusion:

The real time stability of SARS-CoV-2 Antigen Rapid Test, extraction buffer and SARS-CoV-2 Antigen Control Swab are still in process. It is scheduled to finish in December 2022.

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Test rápido de antígenos para el SARS-CoV-2
Prospecto

REF L031-11815	Español

Un test rápido para realizar una detección cualitativa de antígenos de la nucleocápside del SARS-CoV-2 en muestras obtenidas mediante hisopos nasales.

Solo para uso profesional de diagnóstico in vitro.

USO PREVISTO

El test rápido de antígenos para el SARS-CoV-2 es un inmunoanálisis cromatográfico de flujo lateral destinado a la detección cualitativa del antígeno de la proteína nucleocápside del SARS-CoV-2 en muestras obtenidas mediante hisopos nasales directamente de personas cuyo proveedor de asistencia sanitaria sospeche que pueden sufrir COVID-19 durante los primeros siete días de la aparición de síntomas. El test rápido de antígenos para el SARS-CoV-2 no diferencia entre el SARS-CoV y el SARS-CoV-2.

Los resultados tienen el objetivo de identificar el antígeno de la nucleocápside del SARS-CoV-2. Este antígeno generalmente puede detectarse en las muestras obtenidas de las vías respiratorias superiores durante la fase aguda de la infección. Un resultado positivo indica la presencia de antígenos víricos, pero es necesario realizar una correlación clínica con el historial del paciente y otros datos diagnósticos para determinar el estado de infección. Un resultado positivo no descarta las infecciones bacterianas ni las coinfecciones con otros virus. El virus detectado podría no ser la causa final de la enfermedad.

Un resultado negativo en pacientes con síntomas transcurridos siete días debería tratarse como indicio y confirmarse con un análisis molecular, si fuera necesario, para poder tratar al paciente. Un resultado negativo no descarta el contagio del SARS-CoV-2 y no debe emplearse como base única para las decisiones relativas al tratamiento o la gestión de los pacientes, incluidas las decisiones relativas al control de la infección. Los resultados negativos deben entenderse en el contexto de las exposiciones recientes del paciente, su historial y la presencia de signos y síntomas correspondientes a la COVID-19.

El test rápido de antígenos para el SARS-CoV-2 deben usarlo profesionales de laboratorios clínicos formados y personas formadas en instalaciones de atención médica.

RESUMEN

Los nuevos coronavirus pertenecen al género β.[1] La COVID-19 es una enfermedad respiratoria infecciosa y aguda. Todas las personas presentan una predisposición general hacia ella. Actualmente, los pacientes contagiados con el nuevo coronavirus representan la principal fuente de infección; las personas contagiadas y asintomáticas también pueden ser una fuente de infección. De acuerdo con las investigaciones epidemiológicas actuales, el periodo de incubación dura entre 1 y 14 días; generalmente entre 3 y 7 días. Los principales síntomas son la fiebre, el cansancio y la tos seca. También puede observarse en algunos casos congestión nasal, mucosidad nasal, dolor de garganta, mialgia y diarrea.

PRINCIPIO

El test rápido de antígenos para el SARS-CoV-2 es un inmunoanálisis cromatográfico cualitativo basado en membranas destinado a la detección cualitativa del antígeno de la nucleocápside del SARS-CoV-2 en muestras humanas obtenidas mediante hisopos nasales.

Al procesar las muestras e incorporarlas al casete de la prueba, los antígenos del SARS-CoV-2, de haberlos en la muestra, reaccionarán con las partículas impregnadas de anticuerpos frente al SARS-CoV-2, que se habrán impregnado previamente en la tira reactiva. A continuación, la mezcla se desplaza hacia arriba por la membrana mediante acción capilar. Los complejos conjugados con el antígeno se desplazan por la tira reactiva hacia la zona de reacción y una línea de fijación mediante anticuerpos los captura sobre la membrana. Los resultados de la prueba pueden observarse a simple vista en 15 minutos en función de la presencia o ausencia de líneas de color.

Para contar con un control del procedimiento, siempre aparecerá una línea de color en la región de la línea de control para indicar que se haya incorporado el volumen de muestra adecuado y que la membrana haya absorbido la sustancia.

REACTIVOS

El casete de la prueba contiene partículas impregnadas con anticuerpos frente al SARS-CoV-2 sobre la membrana. El hisopo de control positivo contiene antígenos recombinantes del SARS-CoV-2 previamente impregnados en el hisopo.

PRECAUCIONES

- Solo para uso profesional de diagnóstico in vitro. No usar tras la fecha de caducidad.
- No comer, beber ni fumar en la zona en la que se manipulen las muestras y los kits.
- No usar el test si la bolsa está dañada.
- Manipular las muestras como si contuvieran agentes infecciosos. Seguir las precauciones en vigor contra los riesgos biológicos mediante la realización de pruebas y cumplir los procedimientos estándar para desechar las muestras de manera adecuada.
- Usar ropa de protección como batas de laboratorio, guantes desechables y gafas protectoras al someter las muestras a prueba.
- Las pruebas utilizadas deben desecharse de acuerdo con las normativas locales. Las pruebas utilizadas deben considerarse potencialmente infecciosas y deben desecharse de acuerdo con las normativas locales.
- La humedad y la temperatura pueden influir de forma negativa en los resultados.
- Este prospecto debe leerse por completo antes de realizar la prueba. Si no se siguen las instrucciones del prospecto, podrían producirse resultados imprecisos en las pruebas.

ALMACENAMIENTO Y ESTABILIDAD

- El kit puede almacenarse a temperaturas de entre 2 y 30 °C.
- La prueba mantiene su estabilidad hasta la fecha de caducidad que figura en la bolsa sellada.
- La prueba debe conservarse en la bolsa sellada hasta su uso.
- NO CONGELAR.
- No usar tras la fecha de caducidad.

MATERIALES

Materiales suministrados

- Casetes de prueba
- Hisopo de control positivo
- Hisopos nasales estériles*
- Tubos del tampón de extracción
- Hisopo de control negativo
- Prospecto

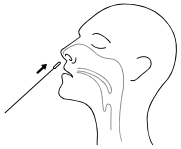
* *Los hisopos nasales estériles los produce otro fabricante.*

Materiales necesarios y no suministrados

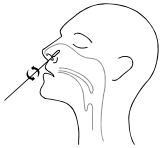
- Equipo de protección personal
- Temporizador

EXTRACCIÓN DE MUESTRAS Y PREPARACIÓN

- El test rápido de antígenos para el SARS-CoV-2 puede realizarse usando muestras obtenidas mediante hisopos nasales.
- La prueba debe realizarse de inmediato tras la extracción de la muestra o en un plazo máximo de una (1) hora desde dicha extracción.
- Para extraer una muestra mediante hisopo nasal:
  1. Introduzca con cuidado un hisopo nasal estéril, **que se suministra en el kit**, en un orificio nasal. Mediante una suave rotación, empuje el hisopo unos 2,5 cm desde el borde del orificio nasal.



  2. Gire el hisopo cinco veces tocando la mucosa del interior del orificio nasal para garantizar que se extraiga una muestra suficiente.



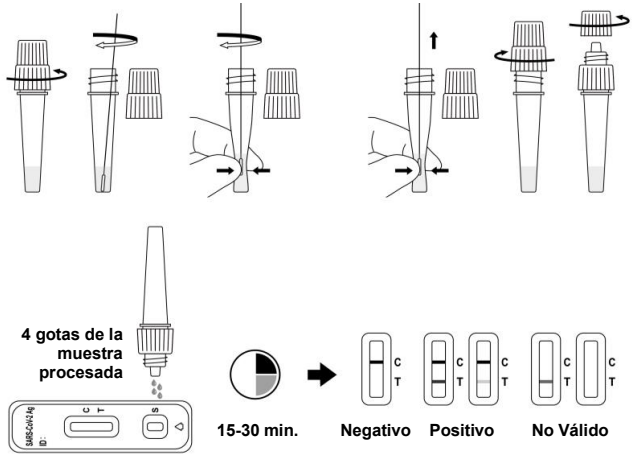
  3. Con el mismo hisopo, repita este proceso en el otro orificio nasal para asegurarse de extraer una cantidad adecuada de muestra de ambas cavidades nasales.

  4. Retire el hisopo de la cavidad nasal. La muestra ya está lista para su preparación con los tubos del tampón de extracción.

INSTRUCCIONES DE USO

Deje que la prueba y el tampón de extracción alcancen la temperatura ambiente (15-30 °C) antes de proceder con la prueba.

1. Use un tubo del tampón de extracción para cada muestra que deba someterse a prueba y etiquete cada tubo de manera adecuada.
2. Desenrosque la tapa del gotero del tubo de la disolución amortiguadora de extracción sin apretar.
3. Introduzca el hisopo en el tubo y remuévalo durante al menos 30 segundos. A continuación, gírelo al menos cinco veces mientras ejerce presión en los laterales del tubo. Tenga cuidado de no verter el contenido del tubo.
4. Saque el hisopo mientras presiona los laterales del tubo para extraerle el líquido.
5. Enrosque firmemente la tapa del gotero en el tubo de tampón de extracción que contiene la muestra. Mezcle bien la muestra removiendo o agitando la parte inferior del tubo.
6. Saque el casete de la prueba de la bolsa de aluminio y úselo lo antes posible. Los mejores resultados se obtendrán si el análisis se lleva a cabo lo antes posible tras la extracción de la muestra y **en un plazo máximo de una hora** desde dicha extracción.
7. Coloque el casete de la prueba sobre una superficie plana y limpia.
8. Vierta la muestra en el pocillo del casete de la prueba
   a. Desenrosque la pequeña tapa de la punta del gotero.
   b. Invierta el tubo del tampón de extracción con el tapón de goteo hacia abajo y sujételo en vertical (a aproximadamente unos 2,5 cm del pocillo de la muestra).
   c. Apriete el tubo con suavidad y vierta 4 gotas de la muestra procesada en el pocillo de la muestra.
9. Espere a que aparezca(n) la(s) línea(s) de color. El resultado deberá verse en 15 - 30 minutos. **No lea al resultado una vez transcurridos 30 minutos.**



INTERPRETACIÓN DE LOS RESULTADOS

(Consulte la ilustración anterior)

NEGATIVO: solo aparece una línea de color en la región de control (C). No aparecen líneas de color aparentes en la región de la línea de la prueba (T). Esto indica que no se han detectado antígenos del SARS-CoV-2.

POSITIVO:* Aparecen dos líneas de color diferentes. Una línea en la región de la línea de control (C) y otra en la región de la línea de la prueba (T). Esto indica que se ha detectado la presencia de antígenos del SARS-CoV-2.

*** NOTA:** La intensidad del color de la línea de la prueba (T) puede variar en función del nivel de antígenos del SARS-CoV-2 presentes en la muestra. Por lo tanto, cualquier tonalidad de color en la región de la línea de la prueba (T) debe considerarse como un resultado positivo.

NO VÁLIDO: no aparece la línea de control. Un volumen insuficiente de la muestra o un procedimiento incorrecto son los motivos más probables para que no aparezca la línea de control. Revise el procedimiento y repita la prueba con un casete de prueba nuevo. Si el problema persiste, deje de usar el kit de prueba de inmediato y póngase en contacto con su distribuidor local.

CONTROL DE CALIDAD

En la prueba se incluyen controles de procedimientos internos. La línea de color que aparece en la región de la línea de control (C) es un control de procedimientos interno. Esta confirma un nivel de muestra suficiente y que se haya usado la técnica de uso correcta.

Los hisopos de control negativo y positivo se suministran con cada kit. Estos hisopos de control deben usarse para garantizar que el casete de la prueba y el procedimiento de la prueba se empleen de manera adecuada. Siga las indicaciones de la sección «**INSTRUCCIONES DE USO**» para realizar la prueba de control.

LIMITACIONES

1. El test rápido de antígenos para el SARS-CoV-2 está destinado exclusivamente a un uso diagnóstico *in vitro*. Esta prueba solo debe usarse para la detección de antígenos del SARS-CoV-2 en muestras obtenidas mediante hisopos nasales. La intensidad de la línea de la prueba no guarda necesariamente una relación con la concentración vírica del SARS-CoV-2 en la muestra.
2. Las muestras deben someterse a la prueba tan pronto como sea posible tras su extracción, y siempre en un plazo máximo de una hora tras esta extracción.
3. El uso de medios de transporte vírico puede conllevar una reducción de la sensibilidad de la prueba.
4. Puede producirse un resultado falso negativo si el nivel de antígenos de la muestra se encuentra por debajo del límite de detección de la prueba o si la extracción se realizó de forma incorrecta.
5. Los resultados de la prueba deben combinarse con otros datos clínicos de los que disponga el personal médico.
6. Un resultado positivo no descarta coinfecciones con otros patógenos.
7. Un resultado positivo no diferencia entre el SARS-CoV y el SARS-CoV-2.
8. Un resultado negativo no puede descartar otras infecciones bacterianas o víricas.
9. Un resultado negativo en pacientes cuyos síntomas aparezcan después de siete días debería tratarse como indicio y confirmarse con un análisis molecular, si fuera necesario, para poder realizar la gestión clínica.

   (Si es necesario establecer una diferenciación entre los distintos virus y cepas específicos del SARS, deberán realizarse otras pruebas.)

CARACTERÍSTICAS DE RENDIMIENTO

Precisión, sensibilidad y especificidad clínicas

El rendimiento del test rápido de antígenos para el SARS-CoV-2 se estableció con 304 hisopos nasales extraídos de pacientes independientes sintomáticos (en un plazo de siete días desde la aparición de los síntomas) de los que se sospechaba que pudieran estar contagiados con la COVID-19. Los resultados mostraron que la sensibilidad relativa y la especificidad relativa son las siguientes:

Rendimiento clínico del test rápido de antígenos para el SARS-CoV-2

Método		RT-PCR		Resultados totales
Test rápido de antígenos para el SARS-CoV-2	Resultados	Negativo	Positivo	
	Negativo	269	1	270
	Positivo	1	33	34
Resultados totales		270	34	304

Sensibilidad relativa: 97,1 % (83,8 % - 99,9 %)*
Especificidad relativa: 99,6 % (97,7 % - 99,9 %)*
Precisión: 99,3 % (97,5 % - 99,9 %)*
*** 95% Intervalos de confianza**

Límite de detección

El límite de detección del test rápido de antígenos para el SARS-CoV-2 se estableció usando diluciones restrictivas de una muestra vírica inactiva mediante irradiación gamma. La muestra vírica se enriqueció con una agrupación de muestras nasales humanas negativas en distintas concentraciones. Cada nivel se sometió a pruebas relativas a 30 réplicas. Los resultados mostraron que el límite de detección es de $1,6 \times 10^2$ $TCID_{50}$/mL.

Concentración del SARS-CoV-2 en muestra	% Positivo (Pruebas)
$1,28*10^3$ $TCID_{50}$/mL	100% (30/30)
$6,4*10^2$ $TCID_{50}$/mL	100% (30/30)
$3,2*10^2$ $TCID_{50}$/mL	100% (30/30)
$1,6*10^2$ $TCID_{50}$/mL	96,7% (29/30)
8*10 $TCID_{50}$/mL	0% (0/30)

Interferencia y reactividad cruzada

No se observó reactividad cruzada con las muestras de pacientes contagiados con coronavirus-229E, coronavirus-NL63, coronavirus-OC43, coronavirus-HKU1[1, 2], tipo de virus de la parainfluenza (tipo 1, tipo 2, tipo 3 y tipo 4), gripe por virus A/B, rinovirus humano, bocavirus humano, virus sincitial respiratorio humano, metapneumovirus humano, adenovirus humano, enterovirus, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Candida albicans, coronavirus del síndrome respiratorio de Oriente Medio o Pneumocystis jirovecii.

El test rápido de antígenos para el SARS-CoV-2 no diferencia entre el SARS-CoV y el SARS-CoV-2.

Las sustancias que interfieren (sangre, aerosol de clorhidrato de oxymetazolina de dafenlina, aerosol nasal de furoato de mometasona, propionato de fluticasona o limpiador nasal fisiológico de agua marina) con una determinada concentración no interfieren en la prueba del test rápido de antígenos para el SARS-CoV-2.

PRECISIÓN

Intraanalítica

La precisión dentro de una misma serie se determinó usando 10 réplicas de muestras: controles positivos de antígenos del SARS-CoV-2 y control negativo. Las muestras se identificaron correctamente en más del 99 % de las ocasiones.

Interanalítica

La precisión entre distintas series se determinó usando 10 análisis independientes de la misma muestra: muestra positiva de antígenos del SARS-CoV-2 y muestra negativa. Se probaron tres lotes diferentes de tests rápidos de antígenos para el SARS-CoV-2 con estas muestras. Las muestras se identificaron correctamente en más del 99 % de las ocasiones.

BIBLIOGRAFÍA

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502.
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164.

Índice de símbolos

	Fabricante		Contiene suficiente para <*n*> pruebas
IVD	Diagnóstico *in vitro* dispositivo médico		Fecha de caducidad
	Consultar instrucciones antes de usar	LOT	Código del lote
	Límite de temperatura		No reutilizar
REF	Número del catálogo		Fecha de fabricación
EC REP	Representante autorizado en la Comunidad Europea		

Tabela de Conteúdos

SARS-CoV-2 Antigen	Antígeno del SARS-CoV-2
Negative Control Swab	Hisopo de control negativo
Positive Control Swab	Tubo del tampón de extracción
Extraction Buffer Tubes	Tubos del tampón de extracción
Disposable Swabs	Hisopos nasales estériles
SARS-CoV-2 Antigen Rapid Test	Test rápido de antígenos para el SARS-CoV-2

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