

AVISO IMPORTANTE

Estimado cliente,

El pasado 23 de enero de 2025, una de nuestras unidades de transporte con producto Werfen fue robada en la zona norte del Estado de México conteniendo los productos listados en el Anexo 1.

Werfen México (IL DIAGNOSTICS) está realizando los trámites y procesos conducentes ante las autoridades correspondientes, quienes están llevando a cabo las acciones e investigaciones pertinentes. Así mismo y en cumplimiento con la regulación sanitaria se ha presentado la notificación de los hechos ante la Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS).

El presente comunicado se emite en virtud de que dicho producto podría ser distribuido por canales no oficiales, representando un riesgo para la salud de la población, ya que no se puede garantizar la calidad, seguridad y eficacia, debido a que se desconocen las condiciones de manejo y almacenamiento de estos.

Por tal motivo, es importante considere los siguientes escenarios:

- A) Podrá encontrar disponibles para uso productos de los lotes mencionados en este aviso a través de nuestros distribuidores autorizados, quienes están reconocidos por Werfen México, por lo que se tiene certidumbre de que el producto cumple con las características de calidad, seguridad y eficacia.
- B) Existe el riesgo de que producto robado pueda ser ofrecido a usted, por lo que se recomienda abstenerse de comprar productos de dudosa procedencia y adquirir dispositivos médicos con proveedores autorizados, mismos que deberán contar con aviso de funcionamiento y con evidencia documental de la legal adquisición del insumo.

Por lo anterior, nos permitimos emitir las siguientes recomendaciones:

- Siempre adquirir productos con distribuidores reconocidos y autorizados por Werfen México.
- Comprobar la legal adquisición y comercialización de los productos, incluyendo el que se cuente con las facturas correspondientes que permitan su trazabilidad.
- Si existen dudas de la originalidad de los productos, contacte a Werfen México para que esta le sea confirmada.
- Siempre adquirir productos en lugares que cumplan con la normativa vigente, es decir, que cuenten con las autorizaciones correspondientes por parte de COFEPRIS.

Para cualquier duda o reporte relacionado con los productos de Werfen, por favor comuníquese con nosotros a través de los siguientes medios:

Centro de atención Remota (CAR) Helpline: 800 831 1309

Customer Service: 55 89577257

Unidad de Tecnovigilancia: tecnovigilancia.mx@werfen.com

Nos disculpamos por cualquier inconveniente y agradecemos su comprensión.

Atentamente,
IL DIAGNOSTICS / Werfen México

Signed by Nallely Contreras Nuñez



Nallely Contreras Nuñez
Responsible Sanitario
Directora RA, Q & Sustentabilidad

I approve this document
2025-11-23 | 11:34:56 PM PST

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Firmado por Ariana González



QFB Ariana Lilian González Cadena
Responsable de Tecnología
Gerente de Asuntos Regulatorios

Apruebo este documento
2025-11-24 | 3:01:56 AM PST

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REF	Denominación Distintiva	Lote	Cantidad Robada
GXHIV-VL-CE-10	Xpert HIV-1 Viral Load	1001444825	30
00020008500	HemosIL D-Dimer	B36858	7
00020500100	HemosIL D-Dimer HS 500	B36989	12
00026330084	GEM Premier 3500 con iQM pH, pCO2, pO2, Hct	431257D	15
00024001587	GEM CVP Multipak	854	33
00018262910	Sample cups 3 mL (500 pieces)	D0165A AA	29
701125	QUANTA Flash CCP3 Reagents	244188	2
00020008610	HemosIL D-Dimer Controls	B36575	2
00020002400	HemosIL Wash-R Emulsion	N0944569	259
00026345089	GEM Premier 3500 con iQM pH, pCO2, pO2, Hct, Na+, K+, Ca++, Glucose and Lactate	434066B	4
00018167500	SeraChem HbA1c 0018167500	I1223392	16
00018167500	SeraChem HbA1c 0018167500	I0524168	6
00018168300	ReferrIL Urine Albumin	I0724200	16
701176	QUANTA Flash dsDNA Calibrators	244280	1
T3000-8204	BIO-FLASH TRIGGERS	B36864	2
T3000-8205	BIO-FLASH SYSTEM RINSE	I0424109	1
00006800000	ROTORES (REVISION 0.3)*ACL*	SSH2406	43
00029400100	CUBETAS REACCION ACL TOP	SSJ2407	27
MX015660/10	HumaClot Cubetas 500 pzas	30308F3018	8
MX015660/10	HumaClot Cubetas 500 pzas	40301J3018	6
00025000500	PAPEL TERMICO PARA GEM 4000 / 3500	NA	5
00020002950	HemosIL RecombiPlasTin 2G	N0643217	174
00020006800	HemosIL SynthASil	N0643246	89
00020003700E	HemosIL Calibration Plasma	E1035892	15
00020003210	HemosIL Low Abnormal Control Assayed	N0945761	61
00020302400	HemosIL Rinse Solution	N0944564	75
00009831700	AGENTE DE LIMPIEZA CLEAN A	N0843463	17
00009832700	AGENTE DE LIMPIEZA CLEAN B	N0843438	20
00020003110	HemosIL Normal Control Assayed	N0643230	75
00026315084	GEM Premier 3500 con iQM pH, pCO2, pO2, Hct	432043C	6
00026315089	GEM Premier 3500 con iQM pH, pCO2, pO2, Hct, Na+, K+, Ca++, Glucose and Lactate	431846C	4
00026330089	GEM Premier 3500 con iQM pH, pCO2, pO2, Hct, Na+, K+, Ca++, Glucose and Lactate	434056A	7
00026345084	GEM Premier 3500 con iQM pH, pCO2, pO2, Hct	431263D	7
00018166740	HbA1c 0018166740	I0824212	33
00018167400	ReferrIL HbA1c 0018167400	I0924256	10
00018256940	Uric Acid	I0224048	2
0018481800	Albumin 0018481800	I0724207	3
00018258440	Direct Bilirubin 0018258440	I0124005	3
00018258340	Total Bilirubin	I0624182	4
00018258940	HDL Cholesterol	I0324068	6
00018255440	Urea Nitrogen 0018255440	I0124020	7
00018259740	Alkaline Phosphatase	I0624183	1
00018167840	Urine Albumin 0018167840	I0524154	10

00018258640	Total Protein	I1023374	3
00018255640	Triglycerides	I0324065	16
00018257000	ReferrIL G	I0124022	4
00018256500	ReferrIL HDL-LDL	I0524130	3
00018257100	ReferrIL G Diluent	I1123384	6
00018162412	SeraChem Control Level 1	I0124001	2
00018162800	UriChem Control	I0524153	4
00018469100	Acid Cuvette Cleaner	I0324088	2
00018476600	False Bottom Tubes (100 pcs)	I0224080	2
MX019910/20	PUNTAS AMARILLAS (2-200 MICROLITROS)	0000009471	5
00009757600	HemosIL Factor Diluent	N0944570	6

Certificate Of Completion

Envelope Id: 9F2B0F7C-337E-4C02-999E-B4C389045096		Status: Completed
Subject: Complete with Docusign: AVISO IMPORTANTE - Robo de Producto_Nov2025.pdf		
Source Envelope:		
Document Pages: 4	Signatures: 2	Envelope Originator:
Certificate Pages: 5	Initials: 0	Nallely Contreras Nuñez
AutoNav: Enabled		180 Hartwell Road
Envelopeld Stamping: Disabled		Bedford, MA 92131
Time Zone: (UTC-08:00) Pacific Time (US & Canada)		ncontreras@werfen.com
		IP Address: 163.116.231.40

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ID: ac583481-7166-43d3-98a7-130c4964920b

Nallely Contreras Nuñez ncontreras@werfen.com Security Level: Email, Account Authentication (Required), Login with SSO	 Signature Adoption: Pre-selected Style Signature ID: 0A42746A-7C65-4DB0-86AE-C98BAE72248E Using IP Address: 163.116.231.40 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 11/23/2025 11:34:18 PM Viewed: 11/23/2025 11:34:47 PM Signed: 11/23/2025 11:35:24 PM
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Witness Events	Signature	Timestamp
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Notary Events	Signature	Timestamp
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Envelope Summary Events	Status	Timestamps
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Envelope Sent	Hashed/Encrypted	11/23/2025 11:34:18 PM
Certified Delivered	Security Checked	11/23/2025 11:34:47 PM
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Completed	Security Checked	11/24/2025 3:02:36 AM

Payment Events	Status	Timestamps
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