

LOT TOX23011A
TOX23012A
TOX23013A

 2023-01-31

Thermo
SCIENTIFIC

MAS[®] TOX CONTROL

LIQUID ASSAYED TOXICOLOGY CONTROL

IVD

INTENDED USE

MAS[®] Tox Control is intended for use as a consistent test sample of known concentration for monitoring assay conditions in the semi-quantitative measurement of Benzodiazepines and Barbiturates in human serum and plasma and Tricyclic Antidepressant drugs (TCA) in human serum, plasma and urine. Assay values are provided for specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

PRODUCT DESCRIPTION

MAS Tox Control is prepared from a bovine plasma base. Analyte levels are adjusted with Diazepam, Secobarbital and Nortriptyline. Preservatives and stabilizers are added to maintain product integrity. The packaging of this product contains dry natural rubber.

DANGER: MAS Tox Control contains $\leq 33\%$ bovine serum.

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

CAUTION: MAS Tox Control also contains small quantities of sodium azide (<0.1%) which may react with lead or copper plumbing to form metal azides. Continuous build-up of metal azides can present an explosion hazard. Upon disposal, flush drains with copious amounts of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested.

STORAGE AND STABILITY

Store **MAS Tox Control** at 2-8°C. Unopened vials are stable until the expiration date on the label. Once opened, vials of control are stable for 20 days when stored tightly capped at 2-8°C. **Do not freeze.**

Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

CONTROL RANGES

Control ranges are provided as guidelines until the laboratory has established its own statistical limits. The printed values are based upon replicate assays of representative samples by participating laboratories in accordance with established protocol and/or by direct correlation with another specific analytical system. The correlation factors used for each constituent have been derived from a comprehensive interlaboratory Quality Assurance Program. All values directly assayed have been assigned with instrument and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these assigned values.

Expected values may vary slightly with different reagent and/or methodologies used. Refer to the included table for values obtained for specific systems. Values provided are for this lot of control only and should be used to assist the laboratory in establishing its own means and ranges. Peer comparison data and QC lot specific updates are available through LabLink[®] xL Quality Assurance Program at www.maslablink.com. Refer to the Technical Assistance section for contact information.

INSTRUCTIONS FOR USE

Thoroughly mix the contents of the vial before each use by gently inverting for several minutes. Open the vial and transfer the required quantity of control into a clean sample cup. Replace the cap immediately and store the opened vial at 2-8°C. Assay controls in accordance with the reagent and/or instrument manufacturer's instructions for unknown specimens.

Dropper tips are available to help minimize exposure of control samples to air. **DO NOT** use a syringe needle to withdraw sample through the control bottle cap.

QUALITY CONTROL

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

LIMITATIONS OF PROCEDURE

Compatibility of **MAS Tox Control** has been demonstrated with methods shown in this insert. Caution should be employed when using these controls with methods for which values have not been printed. The specificity of antibodies used in immunoassay procedures may vary between lots of reagent. As with patient specimens, cross-reactivity between certain constituents in these controls may occur with some reagents. Consult reagent manufacturer's operating manual and package insert regarding possible interferences. For professional use only.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents, and good laboratory technique.

TECHNICAL ASSISTANCE

In the USA, for technical assistance, call 800-232-3342 or 510-979-5417. For insert updates and information, if your laboratory subscribes to LabLink xL, visit www.maslablink.com and select LabLink Extra. Alternatively, to subscribe to LabLink xL call 800-232-3342 or 510-979-5451.

Outside of the USA, if your laboratory subscribes to LabLink xL, visit www.maslablink.com select LabLink Extra. Alternatively, please contact your local sales office or authorized distributor.

Cat. No.
10011608
286-606

Description
MAS[®] Tox Control, Multi-Pack
Dropper Tips

Size
6 x 5 mL
Pkg. 100

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BARBITURATES														
Abbott Aeroset/Architect Systems EIA (DRI)	352	282 - 423	1608	1287 - 1930	3581	2865 - 4298	ng/mL	1.48	1.18 - 1.78	6.75	5.40 - 8.11	15.0	12.0 - 18.1	µmol/L
Beckman Coulter AU Series EIA (DRI)	396	316 - 475	1425	1140 - 1710	3562	2849 - 4274	ng/mL	1.66	1.33 - 1.99	5.99	4.79 - 7.18	15.0	12.0 - 18.0	µmol/L
Beckman Coulter Synchron/DxC Systems EIA (DRI)	389	311 - 466	1448	1159 - 1738	3540	2832 - 4248	ng/mL	1.63	1.31 - 1.96	6.08	4.87 - 7.30	14.9	11.9 - 17.8	µmol/L
Roche Cobas C Systems EIA (DRI)	480	306 - 654	1807	1301 - 2314	4127	3212 - 5042	ng/mL	2.02	1.28 - 2.75	7.59	5.47 - 9.72	17.3	13.5 - 21.2	µmol/L
Roche Hitachi/Modular Chemistry Systems EIA (DRI)	339	271 - 407	1447	1158 - 1736	3647	2918 - 4376	ng/mL	1.42	1.14 - 1.71	6.08	4.86 - 7.29	15.3	12.3 - 18.4	µmol/L
Siemens Advia Chemistry Systems EIA (DRI)	0.32	0.22 - 0.42	1.46	1.10 - 1.83	3.74	2.62 - 4.86	µg/mL	1.34	0.92 - 1.76	6.13	4.62 - 7.69	15.7	11.0 - 20.4	µmol/L
Thermo Fisher Scientific CDx90 EIA (DRI)	**		**		**		ng/mL	**		**		**		µmol/L
Thermo Fisher Scientific MGC 240 EIA (DRI)	318	213 - 423	1511	1206 - 1816	3682	2945 - 4418	ng/mL	1.34	0.90 - 1.78	6.35	5.06 - 7.63	15.5	12.4 - 18.6	µmol/L
Thermo Fisher Scientific INDIKO BASIC EIA (DRI)	379	303 - 455	1339	954 - 1724	3522	2816 - 4228	ng/mL	1.59	1.27 - 1.91	5.62	4.01 - 7.24	14.8	11.8 - 17.8	µmol/L
Thermo Fisher Scientific INDIKO PLUS EIA (DRI)	363	248 - 478	1185	948 - 1422	3336	2623 - 4048	ng/mL	1.52	1.04 - 2.01	4.98	3.98 - 5.97	14.0	11.0 - 17.0	µmol/L

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BENZODIAZEPINES														
Abbott Aeroset/Architect Systems EIA (DRI)	35.6	28.5 - 42.7	90.2	72.1 - 108	175	140 - >200	ng/mL	0.12	0.10 - 0.15	0.32	0.25 - 0.38	0.61	0.49 - >0.70	µmol/L
Abbott Aeroset/Architect Systems EIA (Multigent)	35.8	28.6 - 42.9	97.1	77.7 - >100	N/A		ng/mL	0.13	0.10 - 0.15	0.34	0.27 - >0.35	N/A		µmol/L
Beckman Coulter AU Series EIA (DRI)	33.4	26.7 - 40.1	89.2	71.4 - 107	171	135 - >200	ng/mL	0.12	0.09 - 0.14	0.31	0.25 - 0.37	0.60	0.47 - >0.70	µmol/L
Beckman Coulter Synchron/DxC Systems EIA (DRI)	35.0	28.0 - 41.9	91.2	73.0 - 109	162	129 - 194	ng/mL	0.12	0.10 - 0.15	0.32	0.26 - 0.38	0.57	0.45 - 0.68	µmol/L
Roche Cobas C Systems EIA (DRI)	35.8	28.6 - 43.0	91.9	73.5 - 110	156	115 - 198	ng/mL	0.13	0.10 - 0.15	0.32	0.26 - 0.39	0.55	0.40 - 0.69	µmol/L
Roche Hitachi/Modular Chemistry Systems EIA (DRI)	34.1	27.3 - 40.9	89.4	71.5 - 107	162	129 - 194	ng/mL	0.12	0.10 - 0.14	0.31	0.25 - 0.38	0.57	0.45 - 0.68	µmol/L
Siemens Advia Chemistry Systems EIA (DRI)	36.6	27.5 - 45.8	94.2	70.7 - 118	164	123 - >200	ng/mL	0.13	0.10 - 0.16	0.33	0.25 - 0.41	0.57	0.43 - >0.70	µmol/L
Thermo Fisher Scientific CDx90 EIA (DRI)	**		**		**		ng/mL	**		**		**		µmol/L
Thermo Fisher Scientific MGC 240 EIA (DRI)	33.5	25.7 - 41.4	110	87.9 - 132	153	123 - 184	ng/mL	0.12	0.09 - 0.14	0.38	0.31 - 0.46	0.54	0.43 - 0.64	µmol/L
Thermo Fisher Scientific INDIKO BASIC EIA (DRI)	35.5	28.4 - 42.6	91.7	73.4 - 110	175	140 - >200	ng/mL	0.12	0.10 - 0.15	0.32	0.26 - 0.39	0.61	0.49 - >0.70	µmol/L
Thermo Fisher Scientific INDIKO PLUS EIA (DRI)	34.6	26.5 - 42.7	90.9	72.7 - 109	173	138 - >200	ng/mL	0.12	0.09 - 0.15	0.32	0.25 - 0.38	0.60	0.48 - >0.70	µmol/L

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TRICYCLIC ANTIDEPRESSANTS														
Abbott Aeroset/Architect Systems EIA (DRI)	253	203 - 304	467	374 - 561	919	736 - >1000	ng/mL	0.96	0.77 - 1.16	1.77	1.42 - 2.13	3.49	2.79 - >3.80	µmol/L
Abbott Aeroset/Architect Systems EIA (Multigent)	263	210 - 316	473	378 - >500	N/A		ng/mL	1.00	0.80 - 1.20	1.80	1.44 - >1.90	N/A		µmol/L
Beckman Coulter AU Series EIA (DRI) (Int. Parameters)	232	185 - 278	445	356 - 534	893	690 - >1000	ng/mL	0.88	0.70 - 1.06	1.69	1.35 - 2.03	3.39	2.62 - >3.80	µmol/L
Beckman Coulter AU Series EIA (DRI) (U.S. Parameters)	240	192 - 288	459	367 - 550	920	688 - >1000	ng/mL	0.91	0.73 - 1.09	1.74	1.39 - 2.09	3.50	2.61 - >3.80	µmol/L
Beckman Coulter Synchron/DxC Systems EIA (DRI)	225	180 - 271	463	371 - 556	877	682 - >1000	ng/mL	0.86	0.69 - 1.03	1.76	1.41 - 2.11	3.33	2.59 - >3.80	µmol/L
Roche Cobas C Systems EIA (DRI) (Int. Parameters)	227	182 - 272	444	355 - 533	843	675 - >1000	ng/mL	0.86	0.69 - 1.03	1.69	1.35 - 2.02	3.20	2.56 - >3.80	µmol/L
Roche Cobas C Systems EIA (DRI) (U.S. Parameters)	**		**		**		ng/mL	**		**		**		µmol/L
Roche Hitachi/Modular Chemistry Systems EIA (DRI) (Int. Parameters)	**		**		**		ng/mL	**		**		**		µmol/L
Roche Hitachi/Modular Chemistry Systems EIA (DRI) (U.S. Parameters)	223	179 - 268	418	321 - 515	929	732 - >1000	ng/mL	0.85	0.68 - 1.02	1.59	1.22 - 1.96	3.53	2.78 - >3.80	µmol/L
Siemens Advia 1650/1800/2400 Chemistry Systems EIA (DRI)	242	169 - 315	485	364 - 607	975	731 - >1000	ng/mL	0.92	0.64 - 1.20	1.84	1.38 - 2.31	3.70	2.78 - >3.80	µmol/L
Thermo Fisher Scientific CDx90 EIA (DRI) (Int. Parameters)	**		**		**		ng/mL	**		**		**		µmol/L
Thermo Fisher Scientific CDx90 EIA (DRI) (U.S. Parameters)	**		**		**		ng/mL	**		**		**		µmol/L
Thermo Fisher Scientific MGC 240 EIA (DRI)	**		**		**		ng/mL	**		**		**		µmol/L
Thermo Fisher Scientific INDIKO BASIC EIA (DRI)	248	198 - 297	486	352 - 619	938	699 - >1000	ng/mL	0.94	0.75 - 1.13	1.85	1.34 - 2.35	3.56	2.66 - >3.80	µmol/L
Thermo Fisher Scientific INDIKO PLUS EIA (DRI)	245	196 - 294	466	302 - 629	958	703 - >1000	ng/mL	0.93	0.75 - 1.12	1.77	1.15 - 2.39	3.64	2.67 - >3.80	µmol/L

Advia®, Reg. TM: Siemens Healthcare Diagnostics, Tarrytown, NY
Architect®, Reg. TM: Abbott Laboratories, Inc., Abbott Park, IL
AU Series®, Reg. TM: Olympus America Inc., Allentown, PA
EMIT®, Reg. TM: Siemens Healthcare Diagnostics, Glasgow, DE
Hitachi®, **Integra**®, Reg. TM: Roche Diagnostics, Inc., Indianapolis, IN
MGC240®, Reg. TM: Microgenics Corp., Fremont, CA
Synchron®, Reg. TM: Beckman-Coulter Inc., Fullerton, CA

- ** **Data not available. If interested in participating in our value assignment process, please fax or email your contact information to our Value Assignment group at 510-771-1539, or mgc-va@thermofisher.com.**
- ** Keine Daten verfügbar. Falls Sie interessiert sind, an unserem Wertzuweisungsverfahren teilzunehmen, senden Sie bitte ein Fax oder eine E-Mail mit Ihren Kontaktdaten an unsere Abteilung „Value Assignment“ unter 510-771-1539 bzw. mgc-va@thermofisher.com.
- ** Données non disponibles. Si vous souhaitez participer à notre processus d'affectation des valeurs, veuillez nous faire parvenir vos coordonnées par fax ou par e-mail au groupe Value Assignment au 510-771-1539 ou à l'adresse mgc-va@thermofisher.com.
- ** Dati non disponibili. Per partecipare al processo di assegnazione dei valori, inviare tramite fax o e-mail le proprie informazioni di contatto al gruppo di assegnazione dei valori al numero 510-771-1539 o all'indirizzo mgc-va@thermofisher.com.
- ** Datos no disponibles. Si está interesado en participar en nuestro proceso de asignación de valores, envíe un fax o un correo electrónico con su información de contacto a nuestro grupo de asignación de valores al +1 510-771-1539 o a mgc-va@thermofisher.com.
- ** Data nejsou k dispozici. Máte-li zájem o účast v našem procesu přiřazení hodnot, pošlete skupině Value Assignment své kontaktní údaje faxem nebo e-mailem na číslo 510-771-1539, nebo mgc-va@thermofisher.com.
- ** Data er ikke tilgængelige. Hvis du er interesseret i at deltage i vores værditildelingsproces, kan du sende en fax eller en e-mail med dine kontaktoplysninger til vores værditildelingsgruppe på 510-771-1539 eller mgc-va@thermofisher.com.
- ** Geen gegevens beschikbaar. Als u geïnteresseerd bent in deelname aan ons waardetoekenningsproces, kunt u uw contactgegevens per fax of e-mail naar onze Value Assignment-groep sturen. Tel.: 510-771-1539. E-mail: mgc-va@thermofisher.com.
- ** Tietoja ei saatavilla. Jos olet kiinnostunut osallistumaan arvojen määrittämissä, faksaa tai lähetä sähköpostilla yhteystietosi Value Assignment -osastollemme numeron 510 771 1539 tai osoitteeseen mgc-va@thermofisher.com.
- ** Δεν υπάρχουν διαθέσιμα δεδομένα. Αν ενδιαφέρεστε να συμμετάσχετε στη διαδικασία καθορισμού τιμών που εφαρμόζουμε, στείλτε φάξ ή μήνυμα ηλ. ταχυδρομείου με τα στοιχεία επικοινωνίας σας στην ομάδα Καθορισμού τιμών της εταιρείας μας στον αριθμό 510-771-1539 ή στην ηλ. διεύθυνση mgc-va@thermofisher.com.
- ** Data ikke tilgjengelige. Dersom dere er interessert i å delta i verdifastsettelsesprosessen vår, kan dere sende kontaktinformasjonen deres til verdifastsettelsesgruppen vår per faks til faksnummer 510-771-1539 eller per e-post til mgc-va@thermofisher.com.
- ** Dane nie są dostępne. W razie zainteresowania udziałem w naszym procesie określenia wartości należy przysłać faksem dane kontaktowe do naszej grupy ds. określenia wartości pod numer 510-771-1539 lub pocztą elektroniczną na adres mgc-va@thermofisher.com.
- ** Informações não disponíveis. Caso esteja interessado em participar no nosso processo de atribuição de valores, por favor envie por fax ou por e-mail as suas informações de contacto para o nosso grupo de atribuição de valores pelo número 510-771-1539, ou mgc-va@thermofisher.com.
- ** Данных нет. Если вы заинтересованы в участии в нашем процессе оценки, обращайтесь в нашу группу оценки по факсу 510-771-1539 или по электронной почте mgc-va@thermofisher.com и укажите свою контактную информацию.
- ** Data ej tillgängliga. Om du är intresserad av att delta i vår process för fastställning av värden kan du skicka ett fax eller e-postmeddelande med dina kontaktuppgifter till vår avdelning för analysvärden, telefonnummer +1 510-771-1539 eller mgc-va@thermofisher.com.
- ** Mevcut değil. Değer atama sürecimize katılmaya ilgi duyarsanız, lütfen iletişim bilgilerinizi 510-771-1539 numarasındaki Değer Atama grubumuza fakslyan veya mgc-va@thermofisher.com'a veya e-posta gönderin.
- ** 无法提供数据。如果有兴趣参与我们的赋值过程，请传真或以电子邮件发送您的联系方式到我们的赋值小组。传真号码 510-771-1539，或 mgc-va@thermofisher.com。
- ** データをご利用いただけません。値付けプロセスへの参加を希望される場合は、当社へのデータ提供グループまでお客様の連絡先情報を Fax (510-771-1539) または電子メール (mgc-va@thermofisher.com) にてご連絡ください。

LOT

Lot Number / Chargennummer / Numéro de lot / Numero di lotto / Número de lote / Číslo šarže / Partinummer / Eränumero / Αριθμός παρτίδας / Lotnummer / Numer partii / Número de lote / Номер лота / Partinummer / Lot Numarası / 批号 / ロット番号

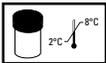


“Use By” date / Verwendbar bis / Date limite d'utilisation optimale / “Utilizzare entro” / Fecha límite de uso / Datum spotřeby / “Användes för”-dato / Houdbaarheidsdatum / “Käyt. viim.”-päivämäärä / Ημερομηνία λήξης / Utlöpsdato / Termin przydatności / Data de validade / Дата «Использовать до» / Utgångsdatum / “Son Kullanim” tarihi / 此日期前使用 / 使用期限

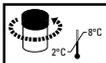


Refrigerated Temperature Limitation / Kühltemperaturbegrenzung / Limite de température de réfrigération / Limite di temperatura di refrigerazione / Limitación de la temperatura de refrigeración / Teplotní omezení chlazení / Temperaturbegrensning – nedkølet / Veperking in gekoelde toestand / Jääkaappilämpötilan rajat / Περιορισμός θερμοκρασίας ψύξης / Kjøletemperaturbegrensning / Ograniczenie temperatury chłodzenia / Limitação de Temperatura Refrigerada / Ограничение температуры заморозки / Kyltemperaturbegrensning / Soğutulmuş Sıcaklık Sınırlanması / 冷藏温度限制 / 冷藏温度限界

Unopened Vial Stability: Refrigerated Temperature / Haltbarkeit des ungeöffneten Fläschchens: Kühltemperatur / Stabilité du flacon non ouvert : température de réfrigération / Stabilità provetta non aperta: a temperatura refrigerata / Estabilidad del vial sin abrir: temperatura refrigerada / Stabilita neotevéné lahvičky: Teplota chlazení / Stabilitet i uåbnet hætteglas: Nedkølet / Stabilitet van ongeopend flesje: in gekoelde toestand / Avaamattoman ampullin stabiilius: jääkaappilämpötilassa / Σταθερότητα αφραγισμένου φιαλιδίου: θερμοκρασία ψύξης / Stabilitet i uåpnet tilstand: Kjøletemperatur / Stabiłność odczynników w nieotwartej fiołce: temperatura chłodzenia / Estabilidade no frasco fechado: Temperatura refrigerada / Стабильность нескрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kyld temperatur / Açılmamış Flakon Stabilitesi: Soğutulmuş Sıcaklık / 未开封药瓶稳定性: 冷藏温度 / 未开封的バイアル安定性: 冷藏温度



Opened Vial Stability: Refrigerated Temperature / Haltbarkeit des geöffneten Fläschchens: Kühltemperatur / Stabilité du flacon ouvert : température de réfrigération / Stabilità provetta aperta: a temperatura refrigerata / Estabilidad del vial abierto: temperatura refrigerada / Stabilita otevénen lahvičky: Teplota chlazení / Stabilitet i åbnet hætteglas: Nedkølet / Stabilitet van geopend flesje: in gekoelde toestand / Avatun ampullin stabiilius: jääkaappilämpötilassa / Σταθερότητα ανοιχμένου φιαλιδίου: θερμοκρασία ψύξης / Stabilitet i åpnet tilstand: Kjøletemperatur / Stabiłność odczynników w otwartej fiołce: temperatura chłodzenia / Estabilidade no frasco aberto: Temperatura refrigerada / Стабильность вскрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kyld temperatur / Açılmış Flakon Stabilitesi: Soğutulmuş Sıcaklık / 已开封药瓶稳定性: 冷藏温度 / 开封後的バイアル安定性: 冷藏温度

**REF**

Catalog Number / Katalognummer / Catalogue N° / Numero di catalogo / Número de catálogo / Katalogové číslo / Katalognummer / Catalogusnummer / Tuotenumero / Αριθμός καταλόγου / Katalognummer / Numer katalogowy / Referência / Номер по каталогу / Katalognummer / Katalog Numarası / 目录编号 / カタログ番号



Manufacturer / Hersteller / Fabricant / Produttore / Fabricante / Výrobce / Producent / Fabrikant / Valmistaja / Κατασκευαστής / Produzent / Producent / Fabricante / Производитель / Tillverkare / Üretici / 制造商 / メーカー



Caution / Vorsicht / Attention / Attenzione / Atención / Upozornění / Forsigtig / Let op / Varoitus / Προσοχή / Advarsel / Przestroga / Cuidado / Осторожно / Viktigt / Dikkat / 注意 / 注意



Consult instructions for use / Gebrauchsanweisung beachten / Se référer au mode d'emploi / Consultare le istruzioni per l'uso / Consultar las instrucciones de uso / Prečítate si návod k obsluze / Se brugsanvisningen / Raadpleeg de gebruiksaanwijzing / Katso käyttöohjeita / Συμβουλευτείτε τις οδηγίες χρήσης / Se i bruksanvisningen / Sprawdzić w instrukcji użytkowania / Consultar instruções de utilização / См. инструкцию по применению / Läs bruksanvisningen / Kullanim talimatlarına danışın / 参阅使用说明 / 取扱説明書を参照

EC REP

Authorized Representative / Bevollmächtigter in der Europäischen Gemeinschaft / Représentant agréé / Rappresentante autorizzato / Representante autorizado / Autorizovaný zástupce / Autoriseret repræsentant / Geautoriseerd vertegenwoordiger / Valtuutettu edustaja / Εξουσιοδοτημένος αντιπρόσωπος / Godkjent representant / Autoryzowany przedstawiciel / Representante autorizado / Авторизованный представитель / Auktoriserad representant / Yetkili Temsilci / 获授权代表 / 認定代理店

IVD

For In Vitro Diagnostic Use / In-vitro-Diagnostikum / Diagnostics in vitro / Per uso diagnostico in vitro / Para uso en diagnóstico in vitro / K diagnostickému použití in vitro / Til in vitro-diagnostisk anvendelse / Voor diagnostisch gebruik in vitro / In Vitro -diagnostiseen käyttöön / Για In Vitro διαγνωστική χρήση / For in vitro-diagnostikk / Do stosowania w diagnostyce in vitro / Para utilização em diagnóstico in vitro / Для использования в диагностике in vitro / För in vitro-diagnostisk användning / In Vitro Diagnostik Kullanım İçin / 体外诊断用 / 体外診断用



Biological risk / Biogefährdung / Matériel à risque biologique potentiel / Rischio biologico / Material potencialmente peligroso a nivel biológico / Biologické nebezpečí / Biologisk risiko / Biologisch risico / Biologinen riski / Βιολογικός κίνδυνος / Biologisk risiko / Zagrożenie biologiczne / Risco biológico / Биологическая опасность / Biologisk risk / Biyolojik risk / 生物风险 / 生物学的リスク

CE

CE Marking of Conformity / CE-Konformitätszeichen / Marquage CE de conformité / Marchio di conformità CE / Marca de conformidad CE / Označení CE / CE-mærkning / CE-conformiteitsmerk / CE-merkintä / Σήμανση συμμόρφωσης CE / CE-samsvarsmærking / Oznakowanie zgodności CE / Marca de Conformidade CE / Маркировка соответствия стандартам CE / CE-försäkran om överensstämmelse / CE Uyumluluk İşareti / CE 合格标志 / 適合のCEマーキング

X̄

Mean Value / Mittelwert / Valeur moyenne / Valore medio / Valor medio / Průměrná hodnota / Gennemsnitsværdi / Gemiddelde waarde / Keskiarvo / Μέση τιμή / Middelverdi / Wartość średnia / Valor médio / Среднее значение / Medelvärde / Ortalama Değer / 平均值 / 平均値

<R>

Expected Range / Erwarteter Bereich / Valeur attendue / Intervallo previsto / Intervallo previsto / Očekávaný rozsah / Forventet område / Verwachte bereik / Odotettu vaihteluväli / Αναμενόμενο εύρος / Forventet område / Zakres wartości oczekiwanych / Intervallo esperado / Ожидаемый интервал / Förväntat intervall / Beklenen Aralık / 预期范围 / 予測範囲

U

Units / Einheiten / Unités / Unità / Unidades / Jednotky / Enheder / Eenheden / Yksiköt / Μονάδες / Enheter / Jednostki / Unidades / Единицы / Enheter / Birimler / 单位 / 單位

CON

Conventional Units / Konventionelle Einheiten / Unités conventionnelles / Unità convenzionali / Unidades convencionales / Konvenční jednotky / Konventionelle enheder / Conventionele eenheden / Perinteiset yksiköt / Συμβατικές μονάδες / Konvensjonelle enheter / Jednostki konwencjonalne / Unidades convencionais / Условные единицы / Konventionella enheter / Konvansiyonel Birimler / 常用单位 / 慣用单位

SI

System International Units / SI-Einheiten / Système international d'unités / Unità sistema internazionale / Unidades del sistema internacional / Systém mezinárodních jednotek / SI-systemet / System International-eeenheden / Kansainväliset yksiköt / Μονάδες διεθνούς συστήματος / SI-enheter / Jednostki w układzie SI / Unidades do Sistema Internacional / Единицы СИ / SI-enheter / Sistem Uluslararası Birimleri / 国际单位 / 國際單位系

U

Constituent and Method / Bestandteil und Methode / Composant et méthode / Componente e metodo / Componente y método / Složka a metoda / Bestanddel og metode / Bestanddeel en metode / Aineosa ja menetelmä / Συστατικό και μέθοδος / Konstituent og metode / Składnik i metoda / Componentes e método / Компонент и метод / Innehåll och metod / Bileşen ve Yöntem / 成分和方法 / 成分および測定法

If you have any questions concerning this notification, in the USA please contact the Technical Support Department at 800-232-3342 or 510-979-5417. Outside the USA, please contact your local Subsidiary or Distributor.

Falls Sie Fragen zu dieser Benachrichtigung haben, wenden Sie sich in den USA an den technischen Kundendienst unter 800-232-3342 oder 510-979-5417. Außerhalb der USA wenden Sie sich bitte an die Vertriebsniederlassung in Ihrer Nähe oder an einen autorisierten Vertriebspartner.

Aux États-Unis, pour toute question concernant cet avis, contacter le Service d'assistance technique au 800-232-3342 ou au 510-979-5417. En dehors des États-Unis, contacter la filiale locale ou le distributeur local.

Per domande relative a questa notifica e vi trovate negli Stati Uniti, rivolgersi al servizio di assistenza tecnica al numero verde 800-232-3342 o al numero 510-979-5417. Al di fuori degli Stati Uniti, rivolgersi alla filiale locale o al distributore.

Para cualquier consulta acerca de esta notificación, en EE.UU. póngase en contacto con el Departamento de Asistencia técnica en los números 800-232-3342 or 510-979-5417. Fuera de EE.UU., póngase en contacto con la subsidiaria o el distribuidor local.

Máte-li nějaké otázky ohledně tohoto upozornění, v USA kontaktujte oddělení technické podpory na čísle 800-232-3342 nebo 510-979-5417. Mimo USA se prosím obraťte na místní pobočku společnosti nebo na autorizovaného distributora.

Hvis du har nogle spørgsmål til denne meddelelse, kan du kontakte den tekniske supportafdeling på 800-232-3342 eller 510-979-5417, hvis du befinder dig i USA. Uden for USA kan du kontakte det lokale datterselskab eller distributøren.

Als u vragen hebt over deze kennisgeving, kunt u contact opnemen met de afdeling Technische ondersteuning op 800-232-3342 of 510-979-5417. Buiten de VS kunt u contact opnemen met de vestiging of distributeur in uw land.

Jos sinulla on kysyttävää tästä ilmoituksesta, ota Yhdysvalloissa yhteyttä tekniseen tukeen numeroon 800 232 3342 tai 510 979 5417. Ota Yhdysvaltojen ulkopuolella yhteyttä paikalliseen tytäryhtiöön tai jälleenmyyjään.

Για οποιοδήποτε ερωτήσεις αναφορικά με την παρούσα ειδοποίηση, εντός Η.Π.Α., επικοινωνήστε με το Τμήμα τεχνικής υποστήριξης στον αριθμό 800-232-3342 ή 510-979-5417. Εκτός Η.Π.Α., επικοινωνήστε με την τοπική σας θυγατρική ή τον τοπικό διανομέα.

Dersom du befinner deg i USA og har spørsmål knyttet til denne orienteringen, kontakt avdelingen for teknisk støtte på 800-232-3342 eller 510-979-5417. Dersom du befinner deg utenfor USA, kontakte din lokale forhandler eller distributør.

W razie jakichkolwiek pytań dotyczących tego powiadomienia, należy skontaktować się z działem wsparcia technicznego pod numerem 800-232-3342 lub 510-979-5417 (na obszarze Stanów Zjednoczonych). Poza obszarem Stanów Zjednoczonych należy skontaktować się z lokalnym oddziałem firmy lub dystrybutorem.

Se tiver quaisquer questões relativas a esta notificação, nos EUA por favor contacte o departamento de assistência técnica através do número 800-232-3342 ou 510-979-5417. Fora dos EUA, por favor contacte a filial da sua área ou o distribuidor local.

Если у вас есть вопросы относительно этого уведомления, в США обращайтесь в департамент технической поддержки по телефону 800-232-3342 или 510-979-5417. За пределами США обращайтесь в местную дочернюю компанию или к дистрибьютору.

Om du har några frågor om den här informationen och befinner dig i USA kan du kontakta vår avdelning för teknisk support på telefonnummer +1 800-232-3342 eller +1 510-979-5417. Utanför USA kan du kontakta ditt lokala avdelningskontor eller en distributör.

Bu bildirime dair herhangi bir sorunuz varsa, ABD'de lütfen 800-232-3342 veya 510-979-5417 numaralı Teknik Destek Departmanı ile iletişim kurun. ABD'nin dışında, lütfen yerel Bayi veya Dağıtıcı ile iletişim kurun.

如果您有任何关于此通知的问题，在美国国内，请联系 800-232-3342 或 510-979-5417 技术支持部门。在美国以外地区，请联系您当地的分公司或经销商。

本通知に関するお問い合わせについては、米国内からはお電話にて (800-232-3342 または 510-979-5417) テクニカルサポート部門までお問い合わせください。米国外の場合は、地域の子会社または代理店までお問い合わせください。

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