

LOT DAT24031 DAT24034
DAT24032 DAT24035
DAT24033 DAT24036

2024-03-31

thermo
scientific

MAS[®] DOA TOTAL

LIQUID ASSAYED DRUGS OF ABUSE CONTROL

IVD

INTENDED USE

THERMO SCIENTIFIC MAS[®] DOA TOTAL is intended for use as an assayed control for monitoring assay conditions in semi-quantitative and qualitative analysis of patient urine specimens for drugs and drug metabolites. These controls are human urine based and are composed of d-methamphetamine, secobarbital, nitrazepam, oxazepam, buprenorphine, benzoylcegonine, cotinine, ethyl glucuronide, ethanol, LSD, methadone, EDDP, methaqualone, morphine, oxycodone, phencyclidine, propoxyphene, nortriptyline, and L-Δ-9-THC-COOH.

DOA TOTAL provides an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects.

PRODUCT DESCRIPTION

DOA TOTAL is prepared from certified drug free human urine pools. Analyte levels are adjusted with purified drugs or drug metabolites. Preservatives and stabilizers are added to maintain product integrity.

DOA TOTAL offers levels of controls, at concentrations 25% below and 25% above the screening cutoff levels used by the United States Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA); for Amphetamines, PCP (Phencyclidine), Opiates, Cocaine and Marijuana (Cannabinoid)¹.

Please refer to the latest SAMHSA guidelines and the enclosed **DOA TOTAL** target data to confirm the required levels of quality control to use, if applicable.

CAUTION: DOA TOTAL is prepared from human urine pools. Each pool has been tested using FDA accepted methods and found to be non-reactive for Hepatitis B surface antigen (HBsAg), Hepatitis C Antibody (HCV), and HIV-1 and HIV-2 antibody. However, no test method can offer complete assurance that products derived from human source material are free of infectious agents. This control must be handled in accordance with recommendations from Centers for Disease Control/National Institutes of Health manual, *"Biosafety in Microbiological and Biomedical Laboratories,"* 2009.

DANGER: DOA TOTAL control contains ≤2% bovine serum albumin (BSA).
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.

DOA TOTAL contains less than 0.1% of sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

STORAGE AND STABILITY

Store **DOA TOTAL** at 2-8°C. Unopened vials are stable until the expiration date on the label. Once opened, vials of control are stable for 30 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

The lot specific GC/MS confirmation values are based upon replicate assays of representative samples by participating laboratories in accordance with established protocol. Subsequent instrument or reagent modifications may invalidate these assigned values.

Expected values may vary slightly with different reagent and/or methodologies used. Values provided are for this lot of control only and should be used to assist the laboratory in establishing its own target values. 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.

Recovered values are dependent upon the method used, standardization, method interferences and/or cross reactivities and antibody specificity. Refer to reagent kit manufacturer's recovery claims as an aid in establishing values for specific methods used.

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. Include **DOA TOTAL** in the test run following the same procedures used for patient samples.

QUALITY CONTROL

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

LIMITATIONS OF PROCEDURE

It has been reported that certain types of plastic and glass laboratory ware will bind the Methaqualone and Cannabinoid metabolite present in these controls. Use new pipettes and sample cups for each patient sample, calibrator and control. Assay samples without delay. The concentration of certain constituents in these controls may exceed the assay range of some analytical methods. If this occurs dilute, as necessary, with **DOA TOTAL Level 1 (Negative)**. Results obtained must be corrected for dilution.

Variability in antibody specificity with different reagent lots may affect values obtained with immunological procedures. Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. This product is intended for use as an assayed control for quantitative assays of listed constituents in human urine. This product is not intended for use as a calibrator. For professional use only.

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 Thermo Scientific distributor.

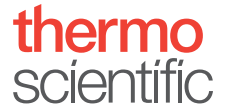
BIBLIOGRAPHY

1. United States Department of Health and Human Services Substance Abuse and Mental Health Services Administration, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Federal Register, June 9, 1994, 59 FR, 29916.

Cat. No.	Description	Size
DOAT-1	Level 1, MAS DOA TOTAL (Negative)	6 x 18 mL
DOAT-2	Level 2, MAS DOA TOTAL	6 x 18 mL
DOAT-3	Level 3, MAS DOA TOTAL	6 x 18 mL
DOAT-4	Level 4, MAS DOA TOTAL (SAMHSA -25%)	6 x 18 mL
DOAT-5	Level 5, MAS DOA TOTAL (SAMHSA +25%)	6 x 18 mL
DOAT-6	Level 6, MAS DOA TOTAL (Elevated High Positive)	6 x 18 mL
DOAT-MP	Multi-Pack, MAS DOA TOTAL	6 x 18 mL

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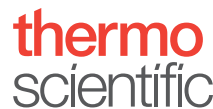
IVD

RV

QUAL										
U	CON									U
	LVL 1 DAT24031A	LVL 2 DAT24032A	(-) ↓ (+)	LVL 3 DAT24033A	LVL 4 DAT24034A	(-) ↓ (+)	LVL 5 DAT24035A	LVL 6 DAT24036A		
Amphetamine										
(d-methamphetamine)	Negative	750	1000	1250	375	500	625	2000	ng/mL	
Barbiturates (Secobarbital)	Negative	225	300	375	150	200	250	1000	ng/mL	
Benzodiazepine (Nitrazepam)	Negative	225	300	375	-	-	-	-	ng/mL	
Benzodiazepine (Oxazepam)	Negative	-	-	-	150	200	250	1000	ng/mL	
Buprenorphine	Negative	-	-	-	15	20	25	60	ng/mL	
Cannabinoid										
(11-nor-9-COOH-Δ-9-THC)	Negative	19 ^(a)	25	31 ^(a)	38 ^(a)	50	62 ^(a)	150 ^(a)	ng/mL	
Cocaine (Benzoyllecgonine)	Negative	225	300	375	112	150	188	500	ng/mL	
Cotinine	Negative	375	500	625	-	-	-	-	ng/mL	
Ethanol	Negative	15	20	25	40	50	70	300	mg/dL	
Ethyl Glucuronide	Negative	375	500	625	750	1000	1250	-	ng/mL	
LSD	Negative	0.3	0.5	0.7	0.3	0.5	0.7	2.5	ng/mL	
Methadone	Negative	225	300	375	225	300	375	750	ng/mL	
Methadone Metabolite (EDDP)	Negative	75	100	125	750	1000	1250	1500	ng/mL	
Methaqualone	Negative	225	300	375	225	300	375	750	ng/mL	
Opiates (Morphine, free)	Negative	225	300	375	1500	2000	2500	750	ng/mL	
Oxycodone	Negative	75	100	125	225	300	375	750	ng/mL	
PCP (Phencyclidine)	Negative	19	25	31	19	25	31	100	ng/mL	
Propoxyphene	Negative	225	300	375	225	300	375	750	ng/mL	
Tricyclics (Nortriptyline)	Negative	185	300	415	750	1000	1250	-	ng/mL	

QUAL										
U	SI									U
	LVL 1 DAT24031A	LVL 2 DAT24032A	(-) ↓ (+)	LVL 3 DAT24033A	LVL 4 DAT24034A	(-) ↓ (+)	LVL 5 DAT24035A	LVL 6 DAT24036A		
Amphetamine										
(d-methamphetamine)	Negative	5027	6702	8378	2513	3351	4189	13405	nmol/L	
Barbiturates (Secobarbital)	Negative	944	1259	1574	629	839	1049	4196	nmol/L	
Benzodiazepine (Nitrazepam)	Negative	800	1066	1333	-	-	-	-	nmol/L	
Benzodiazepine (Oxazepam)	Negative	-	-	-	523	698	872	3488	nmol/L	
Buprenorphine	Negative	-	-	-	32.1	42.8	53.5	128.3	nmol/L	
Cannabinoid										
(11-nor-9-COOH-Δ-9-THC)	Negative	55 ^(a)	73	90 ^(a)	110 ^(a)	145	180 ^(a)	435 ^(a)	nmol/L	
Cocaine (Benzoyllecgonine)	Negative	778	1037	1296	387	518	650	1728	nmol/L	
Cotinine	Negative	2128	2838	3547	-	-	-	-	nmol/L	
Ethanol	Negative	3.3	4.3	5.4	8.7	10.8	15.2	65.1	mmol/L	
Ethyl Glucuronide	Negative	1688	2250	2813	3375	4500	5626	-	nmol/L	
LSD	Negative	0.93	1.55	2.16	0.93	1.55	2.16	7.73	nmol/L	
Methadone	Negative	727	969	1212	727	969	1212	2423	nmol/L	
Methadone Metabolite (EDDP)	Negative	270	360	451	2704	3605	4506	5407	nmol/L	
Methaqualone	Negative	899	1199	1498	899	1199	1498	2996	nmol/L	
Opiates (Morphine, free)	Negative	789	1052	1314	5258	7010	8763	2629	nmol/L	
Oxycodone	Negative	238	317	396	713	951	1189	2378	nmol/L	
PCP (Phencyclidine)	Negative	78	103	127	78	103	127	411	nmol/L	
Propoxyphene	Negative	663	884	1105	663	884	1105	2209	nmol/L	
Tricyclics (Nortriptyline)	Negative	702	1139	1576	2847	3797	4746	-	nmol/L	

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IVD

GCMS +									
U	LVL 1	LVL 2	(-) (+)	CON	LVL 4	(-) (+)	LVL 5	LVL 6	U
	DAT24031A	DAT24032A		DAT24033A	DAT24034A		DAT24035A	DAT24036A	
Amphetamine (d-methamphetamine)	Negative	643 - 786	1000	1057 - 1292	324 - 396	500	554 - 677	1765 - 2157	ng/mL
Barbiturates (Secobarbital)	Negative	194 - 237	300	328 - 401	128 - 157	200	217 - 265	844 - 1031	ng/mL
Benzodiazepine (Nitrazepam)	Negative	188 - 229	300	320 - 391	-	-	-	-	ng/mL
Benzodiazepine (Oxazepam)	Negative	-	-	-	135 - 165	200	229 - 280	854 - 1044	ng/mL
Buprenorphine	Negative	-	-	-	13 - 16	20	22 - 27	52 - 63	ng/mL
Cannabinoid (11-nor-9-COOH-Δ-9-THC)	Negative	17 - 21	25	27 - 33	34 - 42	50	56 - 68	127 - 156	ng/mL
Cocaine (Benzoyllecgonine)	Negative	198 - 241	300	348 - 425	99 - 121	150	167 - 204	432 - 528	ng/mL
Cotinine	Negative	327 - 400	500	534 - 653	-	-	-	-	ng/mL
Methadone	Negative	191 - 234	300	341 - 417	191 - 233	300	338 - 413	653 - 798	ng/mL
Methadone Metabolite (EDDP)	Negative	71 - 87	100	113 - 138	662 - 809	1000	1091 - 1334	1327 - 1622	ng/mL
Methaqualone	Negative	177 - 216	300	300 - 359	181 - 221	300	300 - 361	596 - 729	ng/mL
Opiates (Morphine, free)	Negative	200 - 245	300	331 - 405	1302 - 1592	2000	2247 - 2746	662 - 809	ng/mL
Oxycodone	Negative	63 - 78	100	111 - 135	187 - 229	300	329 - 402	623 - 761	ng/mL
PCP (Phencyclidine)	Negative	17 - 20	25	26 - 32	16 - 20	25	26 - 32	84 - 103	ng/mL
Propoxyphene	Negative	180 - 219	300	322 - 394	186 - 228	300	325 - 398	653 - 798	ng/mL

GCMS +									
U	LVL 1	LVL 2	(-) (+)	SI	LVL 4	(-) (+)	LVL 5	LVL 6	U
	DAT24031A	DAT24032A		DAT24033A	DAT24034A		DAT24035A	DAT24036A	
Amphetamine (d-methamphetamine)	Negative	4308 - 5266	6702	7086 - 8660	2173 - 2656	3351	3713 - 4538	11829 - 14458	nmol/L
Barbiturates (Secobarbital)	Negative	812 - 992	1259	1377 - 1683	539 - 659	839	911 - 1114	3540 - 4326	nmol/L
Benzodiazepine (Nitrazepam)	Negative	667 - 815	1066	1139 - 1392	-	-	-	-	nmol/L
Benzodiazepine (Oxazepam)	Negative	-	-	-	471 - 576	698	799 - 976	2979 - 3641	nmol/L
Buprenorphine	Negative	-	-	-	27.3 - 33.4	42.8	47.0 - 57.4	111.0 - 135.6	nmol/L
Cannabinoid (11-nor-9-COOH-Δ-9-THC)	Negative	49 - 60	73	77 - 95	99 - 121	145	162 - 198	370 - 452	nmol/L
Cocaine (Benzoyllecgonine)	Negative	683 - 835	1037	1202 - 1470	341 - 417	518	578 - 706	1494 - 1826	nmol/L
Cotinine	Negative	1856 - 2269	2838	3031 - 3704	-	-	-	-	nmol/L
Methadone	Negative	618 - 755	969	1103 - 1348	616 - 753	969	1091 - 1333	2110 - 2579	nmol/L
Methadone Metabolite (EDDP)	Negative	256 - 313	360	408 - 499	2385 - 2915	3605	3935 - 4809	4783 - 5845	nmol/L
Methaqualone	Negative	706 - 862	1199	1199 - 1435	723 - 884	1199	1199 - 1443	2383 - 2912	nmol/L
Opiates (Morphine, free)	Negative	703 - 859	1052	1160 - 1418	4564 - 5579	7010	7876 - 9626	2321 - 2837	nmol/L
Oxycodone	Negative	201 - 246	317	351 - 429	594 - 725	951	1042 - 1274	1974 - 2413	nmol/L
PCP (Phencyclidine)	Negative	68 - 83	103	107 - 131	68 - 83	103	109 - 133	345 - 422	nmol/L
Propoxyphene	Negative	529 - 646	884	948 - 1159	549 - 671	884	959 - 1172	1922 - 2349	nmol/L

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IVD

LCMS +									
U	LVL 1 DAT24031A	LVL 2 DAT24032A	(-) (+)	LVL 3 DAT24033A	LVL 4 DAT24034A	(-) (+)	LVL 5 DAT24035A	LVL 6 DAT24036A	U
Ethyl Glucuronide	Negative	356 - 435	500	659 - 805	684 - 836	1000	1226 - 1499	-	ng/mL
LSD	Negative	0.23 - 0.28	0.5	0.55 - 0.67	0.23 - 0.28	0.5	0.55 - 0.67	1.92 - 2.34	ng/mL
Tricyclics (Nortriptyline)	Negative	137 - 168	300	331 - 404	602 - 736	1000	1009 - 1233	-	ng/mL
IA +									
Ethanol ^(b)	Negative	14 - 17	20	23 - 28	36 - 44	50	64 - 78	275 - 336	mg/dL

LCMS +									
U	LVL 1 DAT24031A	LVL 2 DAT24032A	(-) (+)	LVL 3 DAT24033A	LVL 4 DAT24034A	(-) (+)	LVL 5 DAT24035A	LVL 6 DAT24036A	U
Ethyl Glucuronide	Negative	1601 - 1957	2250	2965 - 3624	3079 - 3764	4500	5519 - 6745	-	nmol/L
LSD	Negative	0.70 - 0.85	1.55	1.69 - 2.07	0.72 - 0.88	1.55	1.71 - 2.08	5.93 - 7.25	nmol/L
Tricyclics (Nortriptyline)	Negative	521 - 637	1139	1255 - 1534	2285 - 2793	3797	3831 - 4683	-	nmol/L
IA +									
Ethanol ^(b)	Negative	2.9 - 3.6	4.3	5.0 - 6.1	7.9 - 9.6	10.8	13.8 - 16.9	59.6 - 72.8	mmol/L

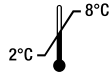
- (a) **Weighed-in amounts are not relevant due to inherent process loss.**
- (a) Eingewogene Mengen sind infolge inhärenter Prozessverluste nicht relevant.
- (a) Les quantités pesées ne sont pas pertinentes en raison de la perte inhérente au processus.
- (a) Le quantità pesate non sono rilevanti a causa della perdita intrinseca dovuta al processo.
- (a) Las cantidades ponderadas no son relevantes debido a la pérdida inherente al proceso.
- (a) Indvejede mængder er ikke relevante på grund af iboende processtab.
- (a) Gewogen hoeveelheden zijn niet relevant vanwege het inherente gewichtsverlies tijdens het proces.
- (a) Punnitut määrität eivät ole olennaisia luontaisen prosessihävikin vuoksi.
- (a) Οι σταθμισμένες ποσότητες δεν είναι σχετικές λόγω εγγενούς απώλειας της διαδικασίας.
- (a) Innveide mengder er ikke relevante på grunn av naturlig prosesstap.
- (a) Odważone ilości są nieistotne z powodu strat związanych z przetwarzaniem.
- (a) As quantidades ponderadas não são relevantes devido a perdas inerentes no processo.
- (a) Взвешенные количества не применимы из-за потерь, присущих процедуре.
- (a) Viktade mängder är inte relevanta på grund av inbyggd processförlust.
- (a) Yapısal işlem kaybı nedeniyle tartılan miktarlar ilgili değildir.
- (a) 由于存在固有的过程性损失，称取的量不影响检测结果。
- (a) 秤量値は、固有のプロセス損失により関連性はありません。
- (a) Izvagane količine nisu relevantne zbog gubitka svojstvenog procesu.
- (a) 由於存在固有的過程性損失，與所稱的量無關。
- (b) **No GC/MS method available for Ethanol quantitation. Confirmation values for Ethanol obtained using Thermo Scientific DRI Ethyl Alcohol assay.**
- (b) Keine GC/MS-Methode zur Quantifizierung von Ethanol verfügbar. Bestätigungswerte für Ethanol wurden mittels Thermo Scientific DRI Ethanol-Assay ermittelt.
- (b) Aucune méthode GC/MS n'est disponible pour la quantification de l'éthanol. Valeurs de confirmation pour l'éthanol obtenues en utilisant le dosage Thermo Scientific DRI Ethyl Alcohol.
- (b) Nessun metodo GC/MS disponibile per la quantificazione dell'etanolo. Valori di conferma per l'etanolo ottenuti mediante il saggio Thermo Scientific DRI Ethyl Alcohol.
- (b) No se dispone de método GC-MS para la cuantificación de etanol. Los valores de confirmación para el etanol se han obtenido mediante ensayo para alcohol etílico Thermo Scientific DRI.
- (b) Ingen GC/MS-metode tilgjengelig til ethanolquantifisering. Bekræftelsesverdier for ethanol opnået ved hjælp af Thermo Scientific DRI Ethyl Alcohol-analyse.
- (b) Voor Ethanol-kwantificering is geen GC/MS-methode beschikbaar. Bevestigingswaarden voor Ethanol zijn verkregen uit de Thermo Scientific DRI-ethylalcoholanalyse.
- (b) GC-/MS-menetelmä ei ole käytettävissä etanolin kvantitointiin. Etanolin vahvistusarvot saatiin käyttämällä Thermo Scientificin DRI-etyylialkoholimääritystä.
- (b) Δεν υπάρχει διαθέσιμη μέθοδος GC/MS για την ποσοτικοποίηση της Αιθανόλης. Οι τιμές επιβεβαίωσης για την Αιθανόλη λήφθηκαν μέσω του DRI Ethyl Alcohol assay της Thermo Scientific.
- (b) Det finnes ingen tilgjengelige GC-/MS-metoder for etanolkvantitering. Bekreftelsesverdier for etanol er fastsatt med Thermo Scientific DRI etylalkoholanalyse.
- (b) Nie ma metody ilościowego oznaczenia etanolu opartej na chromatografii gazowej/spektrometrii masowej. Wartości potwierdzenia dla etanolu uzyskano za pomocą oznaczenia DRI Ethyl Alcohol firmy Thermo Scientific.
- (b) Nenhum método GC/MS disponível para a quantificação de etanol. Valores de confirmação para etanol obtidos através do Thermo Scientific DRI Ethyl Alcohol Assay.
- (b) Для количественного определения этанола нет методов ГХ/МС. Подтверждение значений этанола проводилось с помощью теста Thermo Scientific DRI Ethyl Alcohol для этилового спирта.
- (b) Ingen GC/MS-metod finns tillgänglig för etanolkvantifiering. Bekräftelsevärden för etanol erhållna med Thermo Scientific DRI etylalkoholanalys.
- (b) Etanol miktar tayini için hiçbir GC/MS yöntemi mevcut değildir. Thermo Scientific DRI Ethyl Alcohol Assay kullanılarak elde edilen Etanol için onay değerleri.
- (b) 酒精定量尚无适用的GC/MS方法。使用Thermo Scientific DRI酒精检测法确定获得的酒精值。
- (b) エタノール定量にGC/MS法は使用できません。Thermo Scientific DRIエチルアルコールアッセイを使用して得られたエタノールの確認値。
- (b) Za kvantifikaciju etanola nije dostupna metoda GC/MS. Potvrđne vrijednosti za etanol dobivene su testom Thermo Scientific DRI Ethyl Alcohol.
- (b) 無適用於乙醇定量的GC/MS方法。透過Thermo Scientific DRI Ethyl Alcohol assay取得的乙醇確認值。

LOT

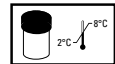
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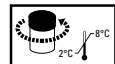
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Refrigerated Temperature Limitation / Kühltemperaturbegrenzung / Limite de température de réfrigération / Limite di temperatura di refrigerazione / Limitación de la temperatura de refrigeración / Temperaturbegrensning – nedkølet / Bepierking in gekoelde 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 / 冷藏温度界限 / Ogranicenje temperature za čuvanje u hladnjaku / 冷藏温度限制



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 / Stabilitet i uåbnet hætteglas: Nedkølet / Stabilitet van ongeopend flesje: in gekoelde toestand / Avaamattoman ampullin stabiilius: jääkaappilämpötilassa / Σταθερότητα σφραγισμένου φιαλιδίου: θερμοκρασία ψύξης / Stabilitet i uåbnet tilstand: Kjøletemperatur / Stabilność odczynników w nieotwartej fiole: temperatura chłodzenia / Estabilidade no frasco fechado: Temperatura refrigerada / Стабильность не вскрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kylt temperatur / Açılmıř 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 / Stabilitet neotvorene pruvete: temperatura za čuvanje u hladnjaku / 未开封瓶稳定性: 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 / 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 / Stabilność odczynników w otwartej fiole: temperatura chłodzenia / Estabilidade no frasco aberto: Temperatura refrigerada / Стабильность вскрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kylt temperatur / Açılmıř Flakon Stabilitesi: Soğutulmuş Sıcaklık / 已开封药瓶稳定性: 冷藏温度 / 开封后的バイアル安定性: 冷藏温度 / Stabilitet otvorene pruvete: temperatura za čuvanje u hladnjaku / 已开封瓶稳定性: 冷藏温度

REF

Catalog Number / Katalognummer / Catalogue N° / Numero di catalogo / Número de catálogo / Katalognummer / Katalognummer / Tuotenumero / Αριθμός καταλόγου / Katalognummer / Numer katalogowy / Referência / Номер по каталогу / Katalognummer / Katalog Numarası / 目录编号 / Каталог番号 / Kataloški broj / 料號



Manufacturer / Hersteller / Fabricant / Produttore / Fabricante / Producent / Fabrikant / Valmistaja / Κατασκευαστής / Produzent / Producent / Fabricante / Производител / Tillverkare / Üretici / 制造商 / メーカー / Proizvođač / 製造商



Caution / Vorsicht / Attention / Attenzione / Atención / Forsigtig / Let op / Varoitus / Προσοχή / Advarsel / Przestroga / Cuidado / Осторожно / Viktigt / Dikkat / 注意 / 注意 / Oppez / 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 / 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 / Kullanım talimatlarına başvurun / 参阅使用说明 / 取扱説明書を参照 / Pogledajte upute za upotrebu / 查閱使用指示

EC REP

Authorized Representative / Bevollmächtigter in der Europäischen Gemeinschaft / Représentant agréé / Rappresentante autorizzato / Representante autorizado / 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 / Ovlašteni predstavnik / 授權代表

IVD

For In Vitro Diagnostic Use / In-vitro-Diagnostikum / Diagnostics in vitro / Per uso diagnostico in vitro / Para uso en diagnóstico 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 / 体外診斷用 / Za in vitro dijagnosticku upotrebu / 供體外診斷使用

CE

CE Marking of Conformity / CE-Konformitätszeichen / Marquage CE de conformité / Marchio di conformità CE / Marca de conformidate 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 / 適合的 CE マーキング / CE oznaka sukladnosti / CE 符合性標記

U

Units / Einheiten / Unités / Unità / Unidades / Enheder / Eenheden / Yksiköt / Μονάδες / Enheter / Jednostki / Unidades / Единици / Enheter / Birimler / 單位 / 單位 / Jedinice / 單位

CON

Conventional Units / Konventionelle Einheiten / Unités conventionnelles / Unità convenzionali / Unidades convencionales / Konventionelle enheder / Conventionele eenheden / Perinteiset yksiköt / Συμβατικές μονάδες / Konvensjonelle enheter / Jednostki konwencjonalne / Unidades convencionais / Условные единицы / Konventionella enheter / Konvansiyonel Birimler / 常用單位 / 慣用單位 / Konventionálne jedinice / 常規單位

SI

System International Units / SI-Einheiten / Système international d'unités / Unità sistema internazionale / Unidades del sistema internacional / SI-systemet / System International-eenheden / Kansainväliset yksiköt / Μονάδες διεθνούς ουστήματος / SI-enheter / Jednostki w układzie SI / Unidades do Sistema Internacional / Единици СИ / SI-enheter / Sistem Uluslararası Birimleri / 国际单位 / 國際單位系 / Sustav međunarodnih jedinica / 系統國際單位

U

Constituent and Method / Bestandteil und Methode / Composant et méthode / Componente e metodo / Komponente y método / Bestanddel og metode / Bestanddeel en methode / Aineosa ja menetelmä / Συστατικό και μέθοδος / Konstituent og metode / Skladnik i metoda / Componentes e método / Komponent och metod / Innehåll och metod / Bileşen ve Yöntem / 成分和方法 / 成分および測定法 / Sastojak i metoda / 成分與方法

RV

Reference Values / Referenzwerte / Valeurs de référence / Valori di riferimento / Valores de referencia / Referençeværdier / Referentiewaarden / Viitearvot / Τιμές αναφοράς / Referanseverdier / Wartości referencyjne / Valores de Referência / Справочные значения / Referensvärden / Referans Değerler / 參考值 / 參照值 / Referentne vrijednosti / 參考值

QUAL

Qualitative Reference / Qualitative Referenz / Référence qualitative / Riferimento qualitativo / Referencia cualitativa / Kvalitativ reference / Kvalitative referentie / Kvalitativinen viite / Ποιοτική αναφορά / Kvalitativ referanse / Jakościowa wartość referencyjna / Referência Qualitativa / Количественная справочная информация / Kvalitativ referens / Nitelksel Referans / 定性参考 / 定性的基準 / Kvalitative referentne vrijednosti / 定性參考

X̄

Mean Value / Mittelwert / Valeur moyenne / Valore medio / Valor medio / Gennemsnitsværdi / Gemiddelde waarde / Keskiarvo / Μέση τιμή / Middelværdi / Wartość średnia / Valor médio / Среднее значение / Medelvärde / Ortalama Değer / 平均值 / Srednja vrijednost / 平均值

<R>

Expected Range / Erwarteter Bereich / Valeur attendue / Intervallo previsto / Intervalo previsto / Forventet område / Verwachte bereik / Odotettu vaihteluväli / Αγορευόμενο εύρος / Forventet område / Zakes wartości oczekiwanych / Intervallo esperado / Ожидаемый интервал / Förväntat intervall / Beklenen Aralık / 预期范围 / 予測範囲 / Očekivani raspon / 预期範圍

GCMS +

GCMS Confirmation / Bestätigung durch GCMS / Confirmation GCMS / Conferma GCMS / Confirmación GCMS / GCMS-bekræftelse / GCMS-bevestiging / GCMS-vahvistus / Επιβεβαίωση GCMS / GCMS-bekræftelse / Potwierdzenie chromatografii gazowej / spektrometrii masowej / Confirmação por Cromatografia Gasosa / Espectrometria de Massa / Подтверждение GCMS / GCMS-bekræftelse / GCMS Onayı / GCMS 确认 / GCMS 確認 / GCMS potvrda / GCMS 確認

LCMS +

LCMS Confirmation / Bestätigung durch LC-MS / Confirmation LCMS / Conferma LCMS / Confirmación mediante LCMS / LCMS-bekræftelse / Bevestiging door middel van LCMS / LCMS-vahvistus / Επιβεβαίωση LCMS / LCMS-bekræftelse / Potwierdzenie chromatografii cieczowej / spektrometrii masowej / Confirmação de LCMS / Подтверждение методом LC-MS / LCMS-bekræftelse / LCMS Onayı / LCMS 确认 / LCMS 確認 / LCMS potvrda / LCMS 確認

IA +

Immunoassay Confirmation / Bestätigung durch Immunoassay / Confirmation de dosage immunologique / Conferma immunodosaggio / Confirmación de inmunoenayo / Bekræftelse af immunanalyse / Immuoassaybevestiging / Immunomäärityksen vahvistus / Επιβεβαίωση ανοσοπροσδιορισμού / Bekræftelse av immunitetsprøve / Wykorzystano techniki immunologiczne / Confirmação por Imunoensaio / Подтверждение иммуноанализа / Bekræftelse med immunanalyse / İmmün Testi Onayı / 免疫分析确认 / イムノアッセイ確認 / Potvrda imunotesta / 免疫檢定確認

(-) ; (+)

Cutoff Value / Cutoff-Wert / Valeur de seuil / Valore di cutoff / Valor de corte / Cutoff-værdi / Grenswaarde / Raja-arvo / Τιμή διαχωρισμού / Grenseverdi / Wartość odcięcia / Valor de Corte / Значение отсечки / Gränsvärde / Hassasiyet Değeri / 截止值 / Каттออฟ-вал / Granična vrijednost / 臨界濃度值

LVL 1

Level 1 / Stufe 1 / Niveau 1 / Livello 1 / Nivel 1 / Niveau 1 / Niveau 1 / Taso 1 / Επίπεδο 1 / Nivå 1 / Poziom 1 / Nivel 1 / Уровень 1 / Nivå 1 / Düzey 1 / 浓度 1 / レベル 1 / Razina 1 / 濃度 1

LVL 2

Level 2 / Stufe 2 / Niveau 2 / Livello 2 / Nivel 2 / Niveau 2 / Niveau 2 / Taso 2 / Επίπεδο 1 / Nivå 2 / Poziom 2 / Nivel 2 / Уровень 2 / Nivå 2 / Düzey 2 / 浓度 2 / レベル 2 / Razina 2 / 濃度 2

LVL 3

Level 3 / Stufe 3 / Niveau 3 / Livello 3 / Nivel 3 / Niveau 3 / Niveau 3 / Taso 3 / Επίπεδο 3 / Nivå 3 / Poziom 3 / Nivel 3 / Уровень 3 / Nivå 3 / Düzey 3 / 浓度 3 / レベル 3 / Razina 3 / 濃度 3

LVL 4

Level 4 / Stufe 4 / Niveau 4 / Livello 4 / Nivel 4 / Niveau 4 / Niveau 4 / Taso 4 / Επίπεδο 4 / Nivå 4 / Poziom 4 / Nivel 4 / Уровень 4 / Nivå 4 / Düzey 4 / 浓度 4 / レベル 4 / Razina 4 / 濃度 4

LVL 5

Level 5 / Stufe 5 / Niveau 5 / Livello 5 / Nivel 5 / Niveau 5 / Niveau 5 / Taso 5 / Επίπεδο 5 / Nivå 5 / Poziom 5 / Nivel 5 / Уровень 5 / Nivå 5 / Düzey 5 / 浓度 5 / レベル 5 / Razina 5 / 濃度 5

LVL 6

Level 6 / Stufe 6 / Niveau 6 / Livello 6 / Nivel 6 / Niveau 6 / Niveau 6 / Taso 6 / Επίπεδο 6 / Nivå 6 / Poziom 6 / Nivel 6 / Уровень 6 / Nivå 6 / Düzey 6 / 浓度 6 / レベル 6 / Razina 6 / 濃度 6

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.

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 ερωτήσες 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 bildirimde 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。

Ako imate pitanja o ovoj obavijesti, u SAD-u nazovite odjel za tehničku podršku na broj 800-232-3342 ili 510-979-5417. Ako ste izvan SAD-a, obratite se lokalnoj podružnici ili distributeru.

若您對於此通知書有任何疑問，請致電 800-232-3342 或 510-979-5417 聯繫技術支援部門 (美國)。在美國以外地區，請聯繫您當地的子公司或是經銷商。

USA
☎ 800-232-3342
sales.diagnostics.fmt@thermofisher.com

China
☎ +86 800-810-5118
cdx.cn.info@thermofisher.com

New Zealand
☎ 0800 933 966
auiinfo@thermofisher.com

Switzerland & Austria
☎ +41 26 663 86 70
cdx.ch.info@thermofisher.com

Asia Pacific
☎ +61 1800 333 110
cdd.asia.info@thermofisher.com

France
☎ +33 1 40 86 65 20
cdx.fr.info@thermofisher.com

Nordic
☎ +47 2 325 0433
info.nordic.cdd@thermofisher.com

United Kingdom & Ireland
☎ +44 1442 868 940
cdx.uk.info@thermofisher.com

Australia
☎ +61 1800 333 110
auiinfo@thermofisher.com

Germany
☎ +49 0800-40 40 771
cdx.de.info@thermofisher.com

South Africa
☎ +27117926790
support-za.idd@thermofisher.com

Canada
☎ 800-282-4075
info.cddcanada@thermofisher.com

Japan
☎ +81 (0)120-147-075
JPYOK-CDD.QC@thermofisher.com

Spain, Portugal & Italy
☎ +34 93589 8338
cdx.es.info@thermofisher.com

For countries not listed:
distributor.cdd@thermofisher.com



Microgenics Corporation
46500 Kato Road
Fremont, CA 94538 USA
ISO 13485 Certified Company
www.thermofisher.com/diagnostics



EC REP

B-R-A-H-M-S GmbH
Neuendorfstrasse 25
16761 Hennigsdorf, Germany
Tel: +49 (0) 800 404 077 12
Fax: +49 (0) 800 404 077 13

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