RECIPE® Clinical Diagnostic Chemicals & Instrument

RECIPE® 临床诊断化学品和仪器

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Esensing Analytical Technology Co., LTD (仪真分析仪器有限公司)

RECIPE

RECIPE公司在1982年成立于德国慕尼黑，是一家目前在HPLC和LC-MS/MS诊断领域处于领先地位的企业。过去30年的企业宗旨是以客户为导向，贯彻实施严格的质量方针。所有诊断产品的开发和生产均在本国最先进的制造工厂完成。

RECIPE所有的公司业务流程均通过了ISO 13485 和 ISO 9001质量管理控制体系的认证。目前我们的客户分布在全球超过60个的国家和地区。

产品目录

HPLC 方法完整试剂盒

ClinRep® 临床诊断

ClinRep® 治疗药物监测

ClinTox® 人体生物监测

LC-MS/MS方法

ClinMass® 完整试剂盒

ClinMass® 应用方法包

ClinMass® 优化混合物及内标物

Quality Assurance配套试剂

ClinTest® 测试溶液

ClinCal® 标准品

ClinChek® 质控品

HPLC 仪器

ClinLab® 仪器

Clarity™ 色谱软件

HPLC 附件

ClinRep® 色谱试剂

ClinLab®色谱附件

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HPLC 完整试剂盒

- ClinRep®
  Diagnostics
- ClinRep®
  Therapeutic Drug Monitoring
- ClinTox®
  Human Biomonitoring

ClinRep® HPLC完整试剂盒，用于临床、毒理和法医实验室内的诊断和治疗药物检测。ClinTox® HPLC完整试剂盒专门设计用于职业医学实验室内进行的人体生物监测。

我们的试剂盒可用于任何传统的HPLC系统。一个完整的试剂盒包含分析所需的所有组件，如缓冲溶液、样品制备试剂、标准品以及基质内的校准品等。此外还可提供起始配件(预柱、萃取柱和分析柱)、基质控品以及其他附件。

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临床，毒理和法医分析

ClinRep® Diagnostics

for clinical, toxicological and forensic analysis

I. 酗酒，药物滥用

血清中的缺糖转铁蛋白

- 手动样品制备
- 在线分析
- 自动在线分析

TOX.I.S.(在线分析)

- 尿液中的碱性药物
- 血浆中的药物
- 尿液中的药物

II. 生物胺

血浆中的儿茶酚胺

尿液中的儿茶酚胺

- 手动样品制备
- 使用Gilson Aspec XL
- 使用HTA, HT400E
- 在线分析

尿液中的甲氧基肾上腺素

- 手动样品制备
- 使用Gilson Aspec XL
- 使用HTA, HT400E

血浆中的血清素

尿液中的血清素

尿液中的香草扁桃酸，高香草酸和5-羟基吲哚乙酸

- 手动样品制备
- 使用Gilson Aspec XL
- 使用HTA, HT400E

III. 糖尿病，血红蛋白测试

全血中的血红蛋白变异体

全血中的 β-地中海贫血筛查

IV. 代谢疾病

尿液中的5-氨基乙酰丙酸和胆色素原

血浆中的同型半胱氨酸

尿液中的羟脯氨酸

尿液中的卟啉的区分

V. 氧化应激

全血/血浆/血清中的辅酶Q10

血浆/血清中的丙二醛

血浆中的维生素C

VI. 维生素状态

血浆中的维生素A和E

全血中的维生素B1

全血中的维生素B2

血浆/全血中的维生素B6

血浆/血清中的25-羟基维生素D2/D3

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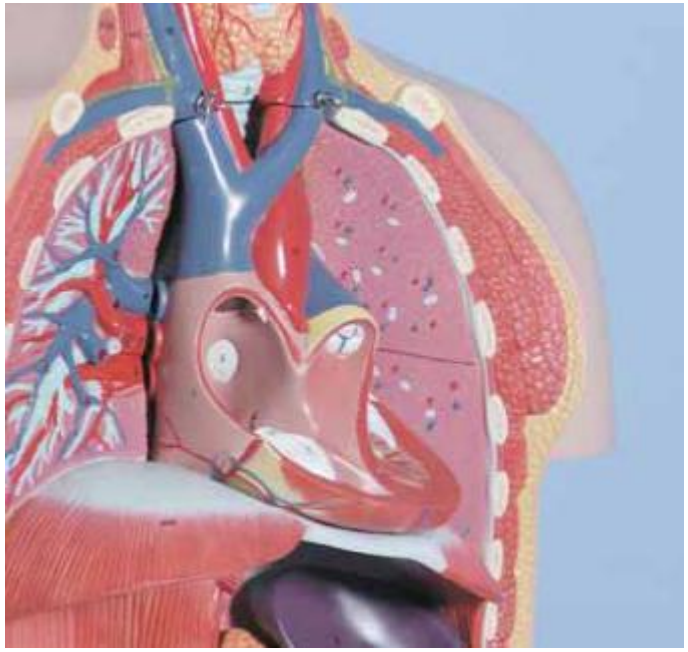
血清中的缺糖转铁蛋白

CDT (Carbohydrate-Deficient Transferrin) in Serum



酗酒，药物滥用
Alcoholism, Drug Abuse

CDT(碳水化合物缺乏转铁蛋白)是对长期酗酒症状进行检测的具体参数。

RECIPE的分析方法符合国际临床化学和实验室医学联合会(IFCC-CDT-WG)的候选参考方法标准，并且为转铁蛋白异构体的分离提供了可靠保证。

相对于手工样品制备方法，RECIPE为在线分析提供了ClinRep®完全试剂盒。可对所有转铁蛋白异构体进行定量检测，并可实现遗传变异体的安全性识别。

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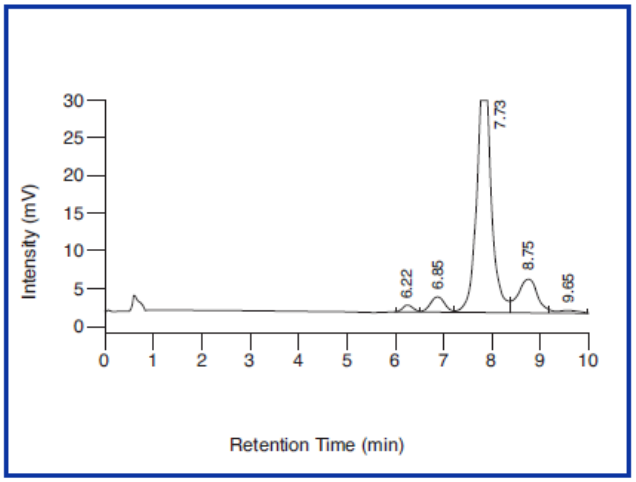
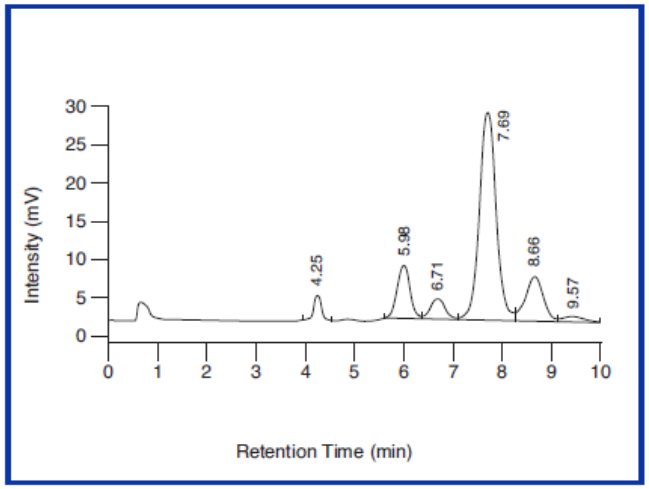
CDT in Serum

Native sample, normal range



Disialotransferrin: 6.22 min, Trisialotransferrin: 6.85 min,
Tetrasialotransferrin: 7.73 min, Pentasialotransferrin: 8.75 min,
Hexasialotransferrin: 9.65 min

Native sample, pathological range



Asialotransferrin: 4.25 min, Disialotransferrin: 5.98 min,
Trisialotransferrin: 6.71 min, Tetrasialotransferrin: 7.69 min,
Pentasialotransferrin: 8.66 min, Hexasialotransferrin: 9.57 min

Test Data

Lower detection limit:	0.1 %*
Lower determination limit:	0.3 %*
Intraassay precision:	4.2 %
Interassay precision:	4.3 %

*depends on the amount on total transferrin

HPLC Parameters

Pump:	ternary gradient pump, flow rates: 1.2, 2.0 ml/min
Injection volume:	400 - 500 µl
Injection interval:	20 min
UV/VIS-Detector:	460 nm
HPLC-Thermostat:	40 °C

Sample Preparation

Stabilisation/Precipitation:

稳定化/沉淀

150 µl serum	30 µl Stabilising Reagent S	10 µl mixture of Precipitants P1+P2

1. incubate (30 min, 4 °C) ↓ 2. centrifuge

Dilution:

稀释

100 µl supernatant	1.0 ml Diluting Solution D

HPLC Analysis:

HPLC分析

Inject 400 - 500 µl

上海仪真分析/孙韬

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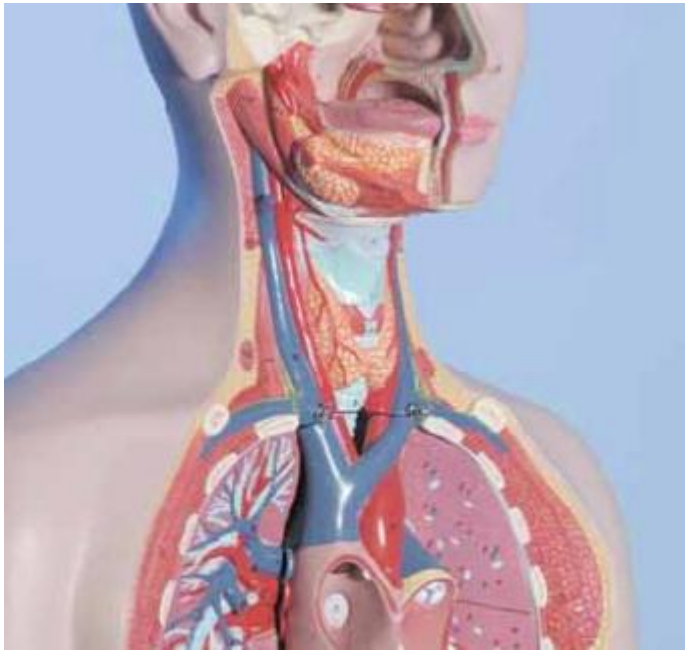
血清中的缺糖转铁蛋白-在线分析

CDT (Carbohydrate-Deficient Transferrin) in Serum - On-line Analysis



酗酒，药物滥用
Alcoholism, Drug Abuse

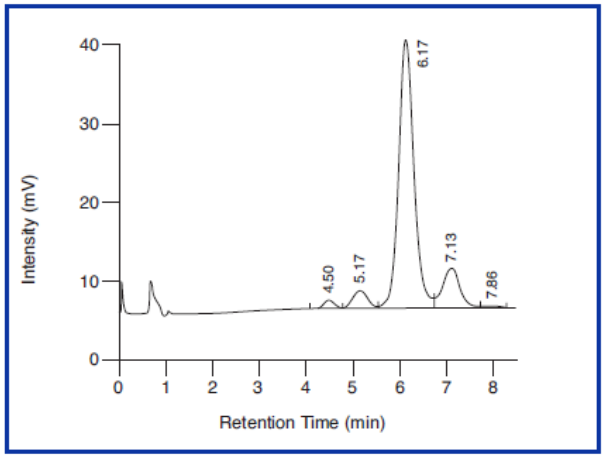
ClinRep®完整试剂盒提供了一种对CDT原始样本进行病理范围分析的进样间隔仅为9.5分钟的在线HPLC方法。

该试剂盒无需手工样品制备步骤，而是通过使用一个特殊的HPLC预柱，将分析物从血清基质中分离出来。进样之前，样品将被稀释和培养(即样品预处理)。

该分析方法符合国际临床化学和实验室医学联合会(IFCC-CDT-WG)的候选参考方法标准，并为所有临床相关转铁蛋白异构体(a-, mono-, di-, ..., hexasialotransferrin)的分离提供了可靠的保证。

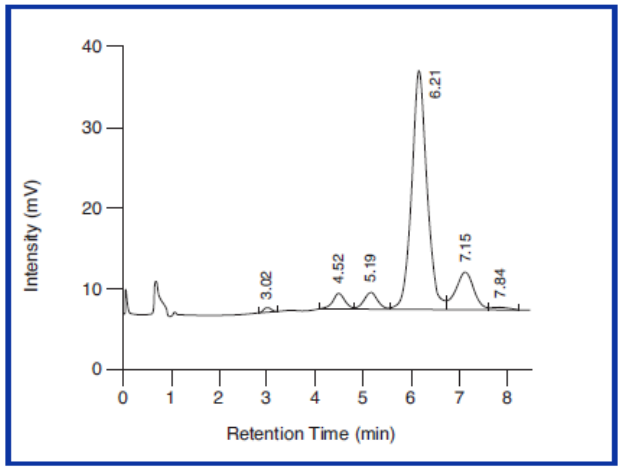
CDT in Serum - On-line Analysis

Native sample, normal range



Disialotransferrin: 4.50 min, Trisialotransferrin: 5.17 min,
Tetrasialotransferrin: 6.17 min, Pentasialotransferrin: 7.13 min,
Hexasialotransferrin: 7.86 min

Native sample, pathological range



Asialotransferrin: 3.02 min, Disialotransferrin: 4.52 min,
Trisialotransferrin: 5.19 min, Tetrasialotransferrin: 6.21 min,
Pentasialotransferrin: 7.15 min, Hexasialotransferrin: 7.84 min

Test Data

Lower detection limit:	0.1 %*
Lower determination limit:	0.3 %*
Intraassay precision:	4.5 %
Interassay precision:	3.9 %

*depends on the amount on total transferrin

HPLC Parameters

Pump 1:	binary gradient pump, flow rate: 1.4 ml/min
Pump 2:	isocratic pump, flow rate: 0.4 ml/min
Injection volume:	400 - 500 µl
Injection interval:	9.5 min
UV/VIS-Detector:	460 nm
HPLC-Thermostat:	40 °C

Sample Pretreatment

Dilution:

稀释

Pipette 100 µl serum into a pretreatment vial
(contains 1 ml diluting solution)

1. incubate (30 min, 4 °C) ↓ 2. centrifuge

HPLC Analysis:

HPLC分析

Inject 400 - 500 µl

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血清中的缺糖转铁蛋白-自动在线分析

CDT (Carbohydrate-Deficient Transferrin) in Serum - Automated On-line Analysis

酗酒，药物滥用
Alcoholism, Drug Abuse

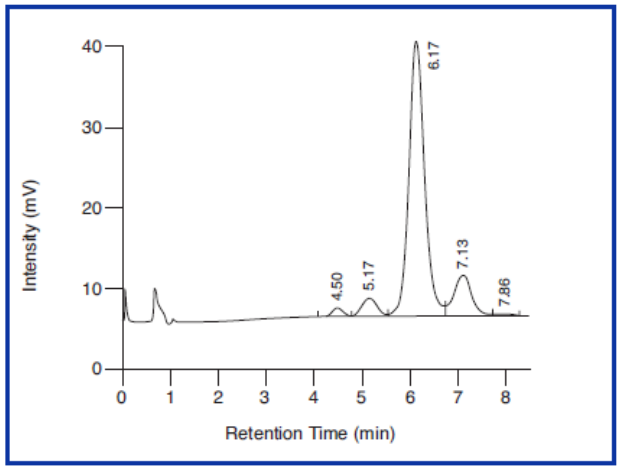
ClinRep®完整试剂盒提供了一种完全自动化的CDT分析方法。类似于上一种检测试剂盒，该分析使用进样间隔仅9.5分钟的。

该试剂盒无需手工样品制备步骤，而是通过使用一个特殊的HPLC预柱，将分析物从血清基质中分离出来。进样之前，通过使用96/500 uL 深孔板对样品自动进行稀释和培养(即样品预处理)。

该检测试剂盒为所有临床相关转铁蛋白异构体(a-, mono-, di-, ..., hexasialotransferrin)的稳定分离提供了有效保证，并符合国际临床化学和实验室医学联合会(IFCC-CDT-WG)的候选参考方法标准。

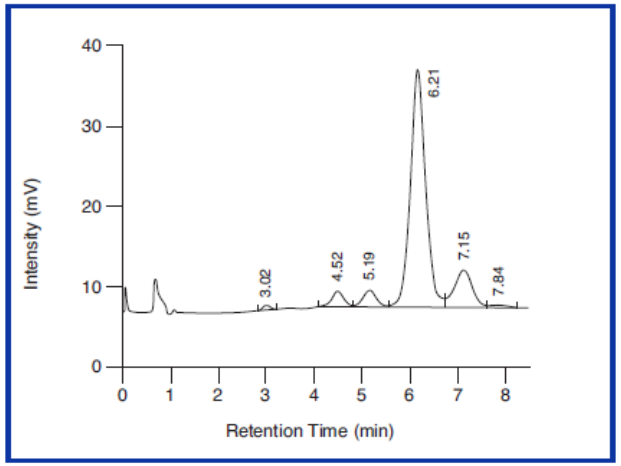
CDT in Serum - Automated On-line Analysis

Native sample, normal range



Disialotransferrin: 4.50 min, Trisialotransferrin: 5.17 min,
Tetrasialotransferrin: 6.17 min, Pentasialotransferrin: 7.13 min,
Hexasialotransferrin: 7.86 min

Native sample, pathological range



Asialotransferrin: 3.02 min, Disialotransferrin: 4.52 min,
Trisialotransferrin: 5.19 min, Tetrasialotransferrin: 6.21 min,
Pentasialotransferrin: 7.15 min, Hexasialotransferrin: 7.84 min

Test Data

Lower detection limit:	0.1 %*
Lower determination limit:	0.3 %*
Intraassay precision:	2.8 %
Interassay precision:	2.5 %

*depending on the amount of total transferrin and on detector sensitivity

HPLC Parameters

Pump 1:	binary gradient pump, flow rate: 1.4 ml/min
Pump 2:	isocratic pump, flow rate: 0.4 ml/min
Injection volume:	400 µl
Injection interval:	9.5 min
UV/VIS-Detector:	460 nm
HPLC-Thermostat:	40 °C

Sample Pretreatment (Automated)

Dilution:

稀释

500 µl Diluting Solution D	50 µl serum

1. incubate (30 min, 4 °C) ↓ 2. centrifuge

HPLC Analysis:

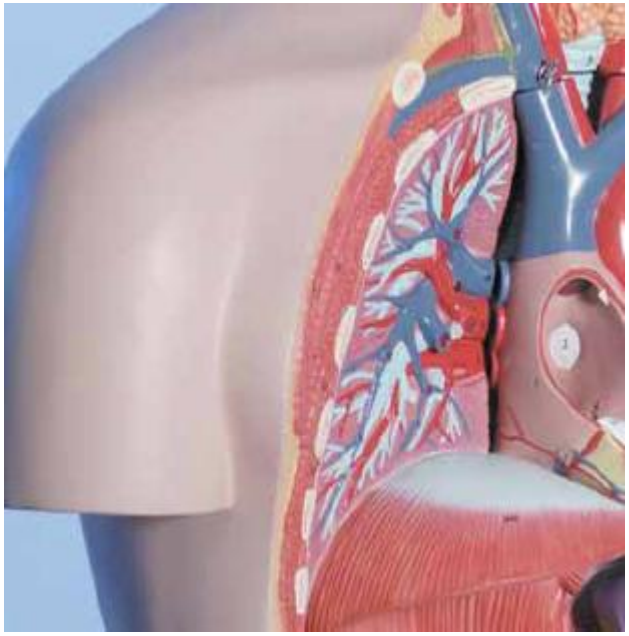
HPLC分析

Inject 400 µl

RECIPE®

尿液中的碱性药物-TOX.I.S.在线分析

Basic Drugs in Urine - On-Line Analysis with TOX.I.S.™



酗酒，药物滥用
Alcoholism, Drug Abuse

ClinRep®试剂盒应用于岛津 TOX.I.S.在线HPLC系统，被用来实现自动药物筛选(在线分析)。该分析方法可对300多种违禁药物进行可靠的筛选，例如吗啡、美沙酮和安非他命等。

RECIPE和岛津联合提供了一种从尿液中筛选违禁药物的完整解决方案。岛津公司的TOX.I.S.系统是一款在线HPLC联接光电二级管阵列检测器系统。它被设计用来对急性中毒、药物滥用以及兴奋剂进行定性或者半定量筛检。

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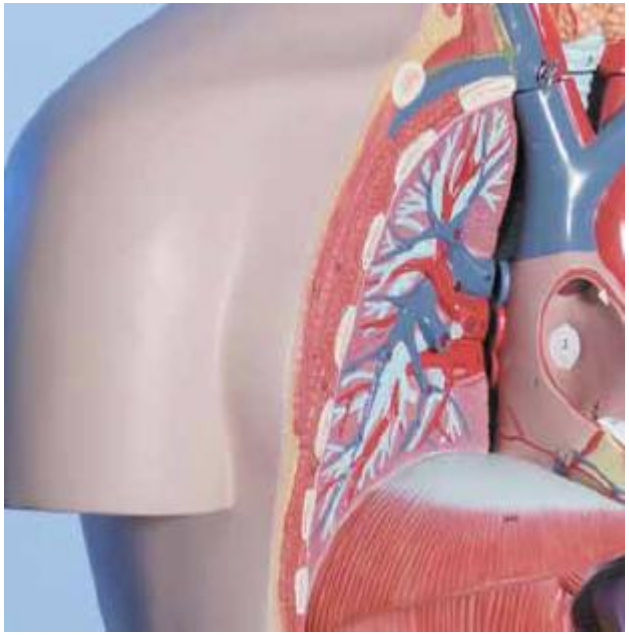
尿液中的碱性药物-TOX.I.S.在线分析

Basic Drugs in Urine - On-Line Analysis with TOX.I.S.™



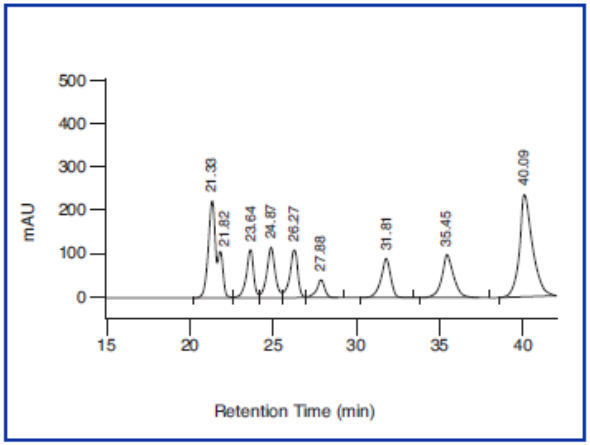
酗酒，药物滥用
Alcoholism, Drug Abuse

RECIPE 试剂盒包含了缓冲溶剂、内标物和一种检测溶液，为岛津TOX.I.S.系统实现可靠的标准化HPLC分析提供了保证。此外，也可提供色谱柱和其他附件。

岛津的分析方法允许对300多种碱性滥用药物进行自动筛检。分析物的鉴定依据对不同保留时间和紫外吸收光谱的比较。为此目的，该系统的评估软件同时提供了一款广泛的紫外吸收光谱库。

RECIPE® Basic Drugs in Urine - On-Line Analysis with TOX.I.S.™

Chromatogram of the ClinTest® Test Solution



MDA: 21.33 min, Amphetamine: 21.82 min,
6-Acetylmorphine: 23.64 min, Methadone: 24.87 min,
Morphine: 26.27 min, Tilidine: 27.88 min,
Codeine: 31.81 min, EDDP: 35.45 min, IS: 40.09 min

Ordering Information

Order No.	Description	Quantity
60000	ClinRep® Reagent Kit for the TOX.I.S.™ System from Shimadzu for 100 assays	1 pce.
	Kit Components (order no. 60000):	
60007	Mobile Phase A	2500 ml
60008	Mobile Phase B	5000 ml
60009	SPE-Buffer	2500 ml
60012	IS Internal Standard	50 ml
60014	Test Solution	2 x 60014 (2 x 15 ml)
60021	SPE-Washing Solution	2 x 60021 (2 x 2500 ml)
	Additional Components:	
60006	Mobile Phase AB	2500 ml
	Start Accessories:	
60030	Analytical Column with test chromatogram	1 pce.
60031	SPE-Column Holder incl. 1 SPE-Column	1 pce.
60032	SPE-Column	1 pce.
60033	Guard Column Holder incl. 1 Guard Column	1 pce.
60034	Guard Columns	10 pcs.

RECIPE®

血浆或尿液中的药物-在线分析

Pharmaceuticals in Plasma or Urine- On-Line Analysis with TOX.I.S.™

酗酒，药物滥用
Alcoholism, Drug Abuse

ClinRep®试剂盒应用于岛津 TOX.I.S.在线HPLC系统，被用来实现血浆或尿液中的药物筛选。该分析方法可对超过500种潜在的被滥用药物进行可靠的筛选(包含除非法碱性药物外的酸性、中性和弱碱性药物化合物)。

RECIPE和岛津联合提供了一种从血浆或尿液中筛选药物的完整解决方案。岛津公司的TOX.I.S.系统是一款在线HPLC联接光电二级管阵列检测器系统。它被设计用来对急性中毒、药物滥用以及兴奋剂进行定性或者半定量筛检。

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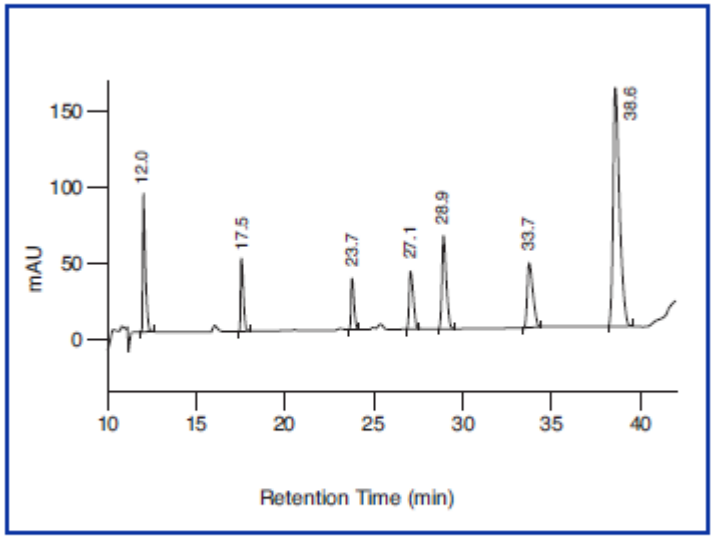
血浆或尿液中的药物-在线分析

Pharmaceuticals in Plasma

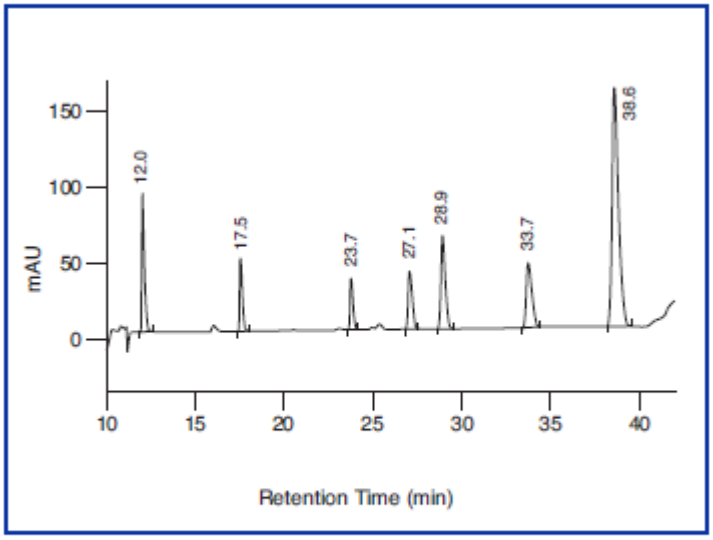
Chromatogram of the ClinTest® Test Solution



Doxylamine: 12.0 min, Desmethylclozapine: 17.5 min,
Doxepine: 23.7 min, Carbamazepine: 27.1 min,
Oxazepam: 28.9 min, Temazepam: 33.7, IS: 38.6 min

Pharmaceuticals in Urine

Chromatogram of the ClinTest® Test Solution



Doxylamine: 12.0 min, Desmethylclozapine: 17.5 min,
Doxepine: 23.7 min, Carbamazepine: 27.1 min,
Oxazepam: 28.9 min, Temazepam: 33.7, IS: 38.6 min

RECIPE®

血浆中的儿茶酚胺

Catecholamines in Plasma

生物胺
Biogenic Amines

肾上腺素(Epinephrine, E),去甲肾上腺素(norepinephrine, NE)和多巴胺(dopamine, D)被统称为儿茶酚胺(Catecholamines)。儿茶酚胺类药物的测定主要用于帮助检查和排除患者的嗜铬细胞瘤症状，例如患者的持续性高血压。 该方法也可用于帮助监测并病人体内的嗜铬细胞瘤发现并切除后的复发情况。故此ClinRep® 完整工具包允许对儿茶酚胺进行快速安全的量化检测。该工具包易于使用并具有非常良好的检测下限。

Catecholamines in Plasma

Test Data

Linearity:	10 - 2500 ng/l
Recovery:	70 - 90 %
Lower detection limit:	5 ng/l
Lower determination limit:	10 ng/l
Intraassay precision:	6.7 % (NE), 7.6 % (E), 6.1 % (D)
Interassay precision:	5.3 % (NE), 4.2 % (E), 3.9 % (D)

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	40 µl
Injection interval:	15 min
EC-Detector:	potential: 500 mV, sensitivity: 10 nA
Temperature:	25 °C (or ambient)

Sample Preparation

Extraction:

萃取

Apply 1 ml plasma and 50 µl Internal Standard IS to a sample preparation column

↓ wash (3 x 1 ml Washing Solution W)

Elution:

洗脱

Elute with 120 µl Eluting Reagent E

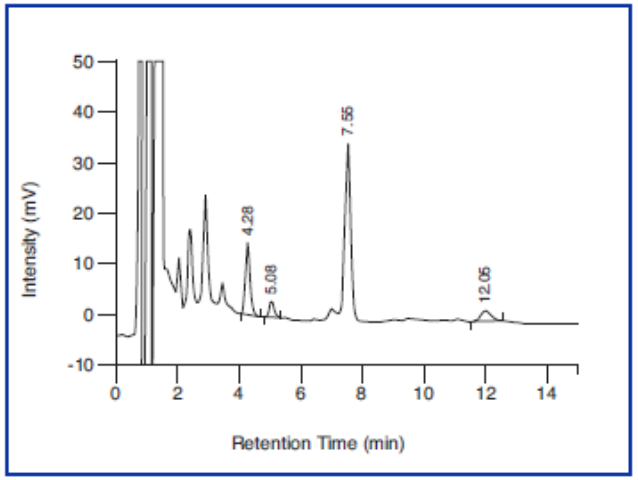
↓ collect the eluate

HPLC Analysis:

HPLC分析

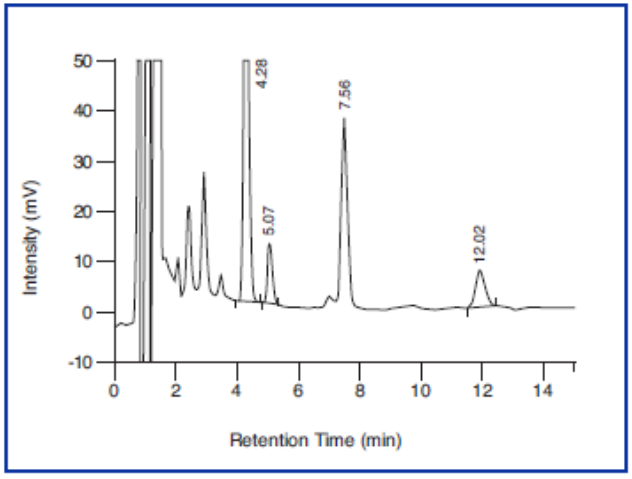
Inject 40 µl

ClinChek® Plasma Control, Level I



Norepinephrine: 4.28 min, Epinephrine: 5.08 min,
IS: 7.55 min, Dopamine: 12.05 min

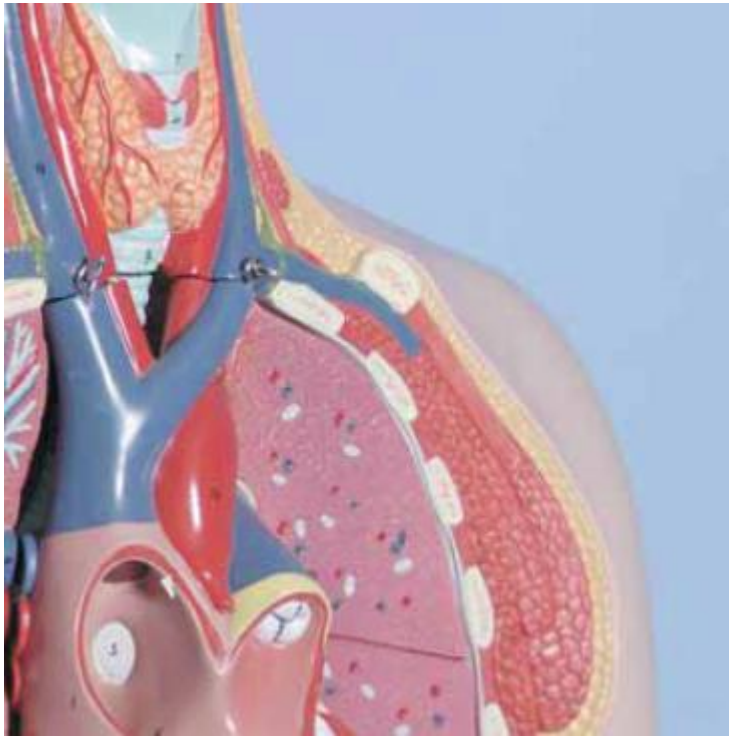
ClinChek® Plasma Control, Level II



Norepinephrine: 4.28 min, Epinephrine: 5.07 min,
IS: 7.56 min, Dopamine: 12.02 min

尿液中的儿茶酚胺

Catecholamines in Urine

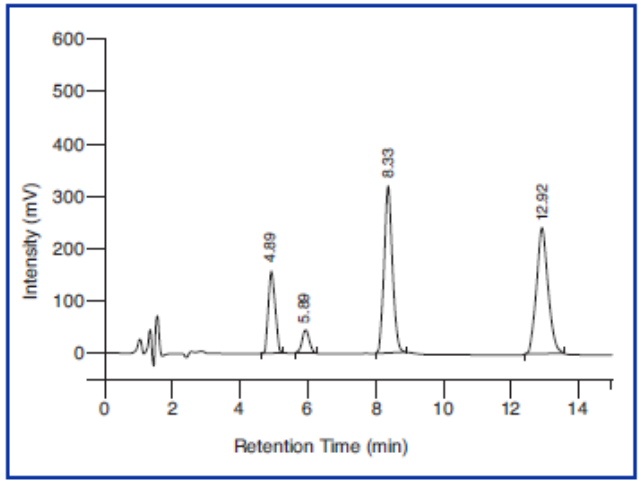


生物胺
Biogenic Amines

使用此完整工具包可测定尿液中的肾上腺素(Epinephrine, E),去甲肾上腺素(norepinephrine, NE)和多巴胺(dopamine, D)。用户可轻松实现实验室常规样品制备。在提取样品之前，用户可使用一种特殊的含显色指示剂的稳定试剂对样品的pH值进行安全方便的检查。不同的显色指示剂确保设置适当的pH范围(pH 2-5)。此外，此方法中进行手动样品制备时，RECIPE提供的ClinRep®完整工具包可与Gilson®和HTA自动移液系统一同使用。

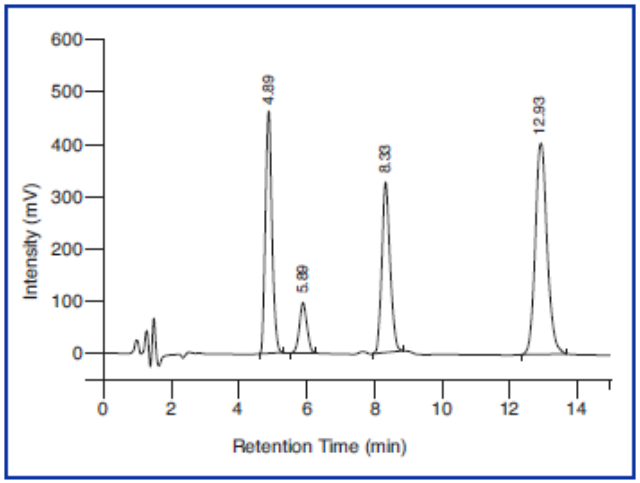
RECIPE® Catecholamines in Urine

ClinChek® Urine Control, Level I



Norepinephrine: 4.89 min, Epinephrine: 5.89 min,
IS: 8.33 min, Dopamine: 12.92 min

ClinChek® Urine Control, Level II



Norepinephrine: 4.89 min, Epinephrine: 5.89 min,
IS: 8.33 min, Dopamine: 12.93 min

Test Data

Linearity:	2 - 1000 µg/l
Recovery:	70 - 85 %
Lower det. / determ. limit:	1 µg/l / 2 µg/l
Precision	
Intraassay:	0.8 % (NE), 1.4 % (E), 1.7 % (D)
Interassay:	2.0 % (NE), 2.3 % (E), 3.1 % (D)

HPLC Parameters

Isocratic Pump:	flow rate: 1.0 ml/min
Injection vol. / int.:	20 µl / 15 min
EC-Detector:	pot.: 500 mV, sen.: 10 nA
HPLC-Thermostat:	30 °C

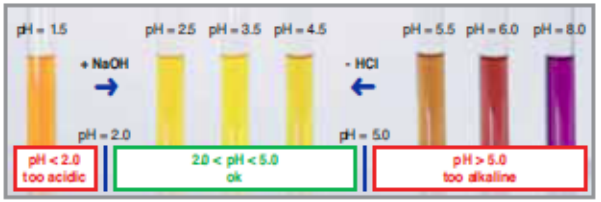
Sample Preparation

Addition of IS / pH adjustment:

加入内标/调整pH

3 ml urine	5 ml Stab. Reagent S (contains colour indic.)	30 µl Internal Standard IS

adjust with 1 M NaOH, until the indicator switches to yellow



Extraction:

萃取

Apply the whole sample on the sample preparation column

Elution: wash (HPLC water)

洗脱

Apply 6 ml Eluting Reagent E

HPLC Analysis:

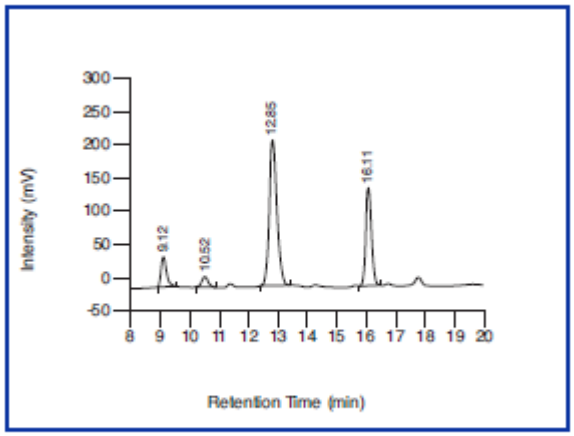
HPLC分析

Inject 20 µl

RECIPE®

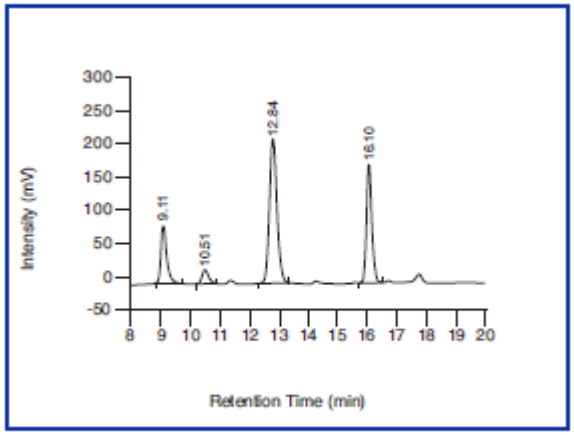
Catecholamines in Urine – On-Line Analysis

ClinChek® Urine Control, Level I (+ 20 µl IS/ml urine)



Norepinephrine: 9.12 min, Epinephrine: 10.52 min,
IS: 12.85 min, Dopamine: 16.11 min

ClinChek® Urine Control, Level II (+ 20 µl IS/ml urine)



Norepinephrine: 9.11 min, Epinephrine: 10.51 min,
IS: 12.84 min, Dopamine: 16.10 min

Test Data

Linearity:	3 - 1500 µg/l
Recovery:	95 - 100 %
Lower detection limit:	1 µg/l
Lower determination limit:	3 µg/l
Intraassay precision:	3.0 % (NE), 4.5 % (E), 0.8 % (D)
Interassay precision:	3.6 % (NE), 6.4 % (E), 2.4 % (D)

HPLC Parameters

Pump 1 (SPE buffer):	isocratic pump, flow rates: 0.5, 2.0 ml/min
Pump 2 (mobile phase):	isocratic pump, flow rate: 1.2 ml/min
Switching valve:	6-port/3-channel switching valve (order no. FK1102)
Injection volume:	50 µl
Injection interval:	20 min
Fluorescence detector:	275 nm (exc.), 330 nm (em.)
HPLC-Thermostat:	30 °C

Sample Pretreatment

无需手动样品制备

Addition of IS:

加入内标

Add 20 µl Internal Standard IS/ml urine

centrifuge

HPLC Analysis:

HPLC分析

Inject 50 µl

RECIPE®

尿液中的甲氧基肾上腺素

Metanephrines in Urine

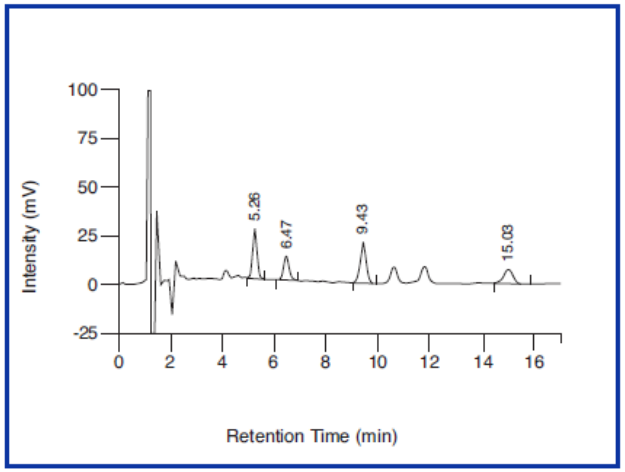
生物胺
Biogenic Amines

甲氧基肾上腺素(Metanephrines)例如甲肾上腺素(metanephrine, M)，异丙肾上腺素(normetanephrine, NM)和3-甲氧酪胺(3-methoxytyramine, MT)是儿茶酚胺(Catecholamines)的初级代谢物。类似于儿茶酚胺，甲氧基肾上腺素的测定被用来检查或者排除交感肾上腺系统的肿瘤。为此目的，这款检测试剂盒可以让用户轻松实现实验室常规样品制备。一种特殊的含显色指示剂的稀释液可被安全方便的用来在提取样品之前对pH值进行检查。不同的显色指示剂可确保分析物的提取在适当的pH条件下进行(pH>6)。

RECIPE®

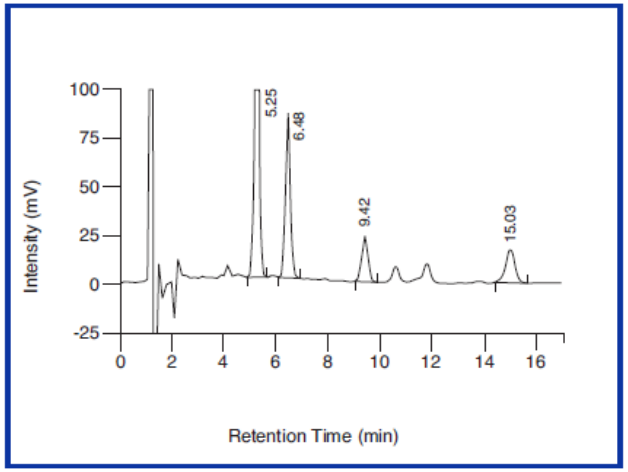
Metanephrines in Urine

ClinChek® Urine Control, Level I



Normetanephrine: 5.26 min, Metanephrine: 6.47 min,
IS: 9.43 min, 3-Methoxytyramine: 15.03 min

ClinChek® Urine Control, Level II



Normetanephrine: 5.25 min, Metanephrine: 6.48 min,
IS: 9.42 min, 3-Methoxytyramine: 15.03 min

Test Data

Linearity:	8 - 10000 µg/l
Recovery:	60 %
Lower det. / determ. limit:	5 µg/l / 8 µg/l
Precision	
Intraassay:	1.7 % (NM), 3.0 % (M), 2.5 % (MT)
Interassay:	1.8 % (NM), 2.9 % (M), 1.9 % (MT)

HPLC Parameters

Isocratic Pump:	flow rate: 1.0 ml/min
Injection vol. / int.:	20 µl / 17 min
EC-Detector:	pot.: 650 mV, sen.: 50 nA
HPLC-Thermostat:	30 °C

Sample Preparation

Hydrolysis:

水解

1 ml urine | 20 µl Internal Standard IS

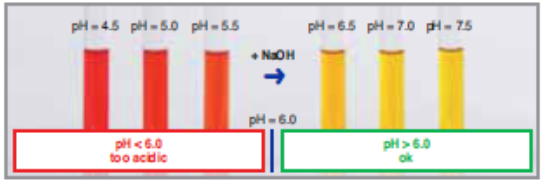
1. adjust pH to 0.5 - 1.0 ↓ 2. incubate (30 min, 90 - 100 °C

pH adjustment:

调整pH

Add 4 ml Diluting Solution D (contains colour indicator)

check, if the sample is yellow (pH > 6) ↓ if necessary, add 1 M NaOH dropwise



Extraction:

萃取

Apply the whole sample on the sample preparation column

Elution:

洗脱

wash (HPLC water and Washing Solution W)

Elute with 5 ml Eluting Reagent E
(receiver vial: 1 ml Stabilising Reagent S)

HPLC Analysis:

色谱分析

collect the eluate

Inject 20 µl

仪真分析/孙韬

RECIPE®

血浆中的血清素

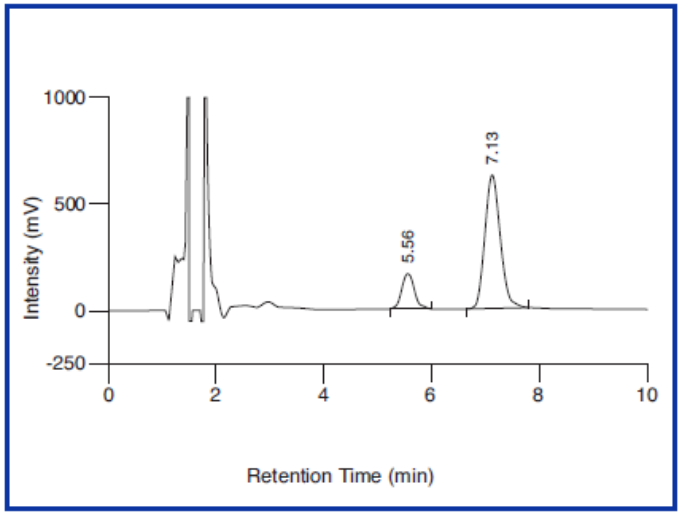
Serotonin in Plasma

血清素是中枢神经系统内的一种神经递质。人体内的血清素缺乏将导致神经紊乱疾病如抑郁症，精神分裂症和帕金森氏病。此外，类癌将产生过量的血清素。这里，血清素及其代谢物5-HIAA的测定可用于确定或排除肿瘤的发生。RECIPE检测试剂盒可以快速灵敏的测定血清素在富血小板血浆，贫血小板血浆以及血清中的含量。

生物胺
Biogenic Amines

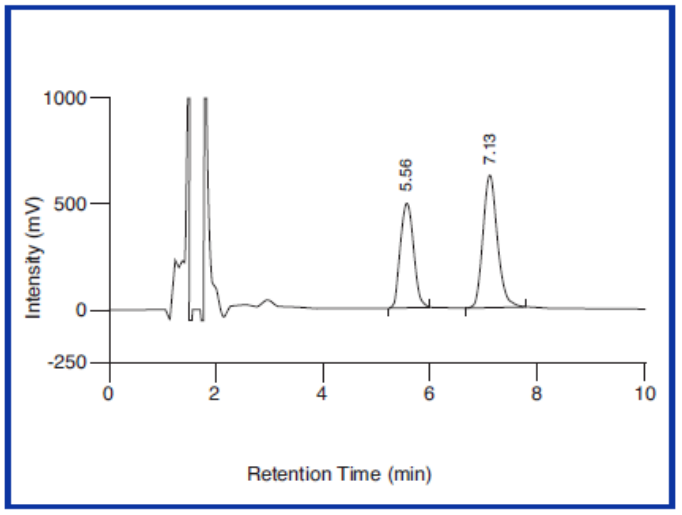
Serotonin in Plasma

ClinChek® Plasma Control, Level I



Serotonin: 5.56 min, IS: 7.13 min

ClinChek® Plasma Control, Level II



Serotonin: 5.56 min, IS: 7.13 min

Test Data

Linearity:	1 - 1000 µg/l
Recovery:	80 - 90 %
Lower detection limit:	0.5 µg/l
Lower determination limit:	1 µg/l
Intraassay precision:	3 %
Interassay precision:	4 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	20 µl
Injection interval:	10 min
EC-Detector:	potential: 450 mV, sensitivity: 20 nA
HPLC-Thermostat:	30 °C

Sample Preparation

Precipitation:

沉淀

200 µl plasma	10 µl Internal Standard IS

1. add 200 µl Precipitant P ↓ 2. centrifuge

HPLC Analysis:

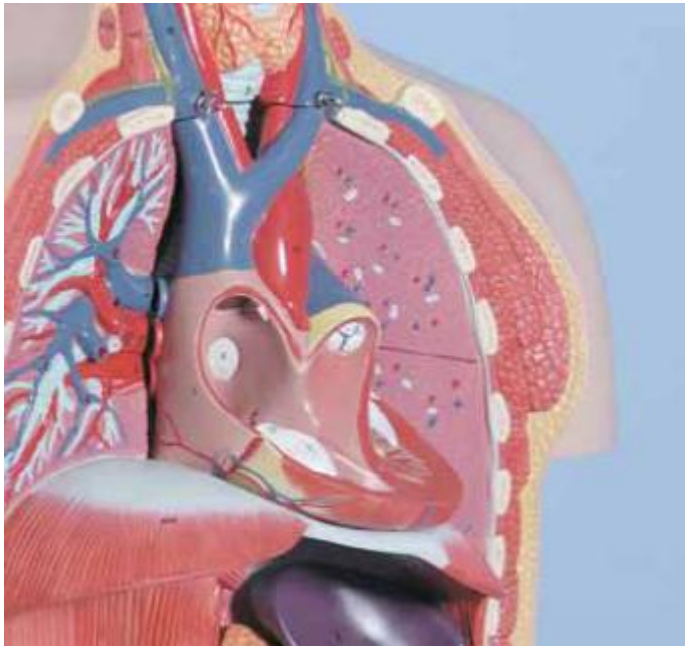
色谱分析

Inject 20 µl

RECIPE®

尿液中的血清素

Serotonin in Urine

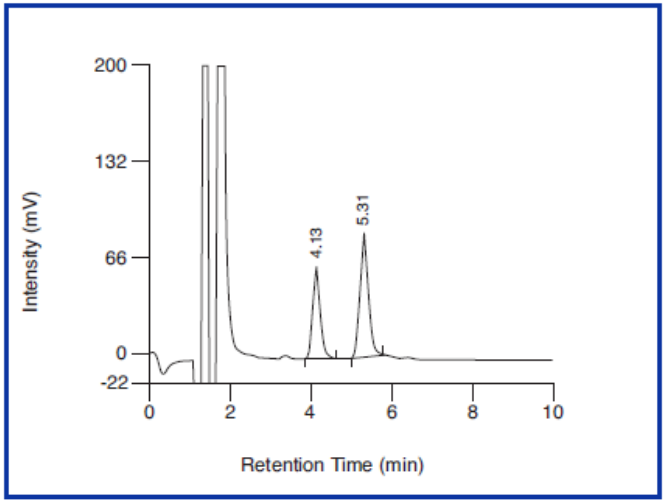


生物胺
Biogenic Amines

血清素是一种重要的神经递质，其主要代谢物为尿液排泄物5-羟基吲哚乙酸(5-HIAA)。类癌患者通常表现出血浆和尿液中血清素水平升高以及5-羟基吲哚乙酸在尿液中水平的升高。由于某些肿瘤的产生会降低血清素代谢(例如肿瘤AADC缺陷)，故低水平5-羟基吲哚乙酸的出现必须通过血清素测定的验证。RECIPE检测试剂盒提供了一种具有高度选择性的样品制备方法，确保可靠的色谱分离方法。

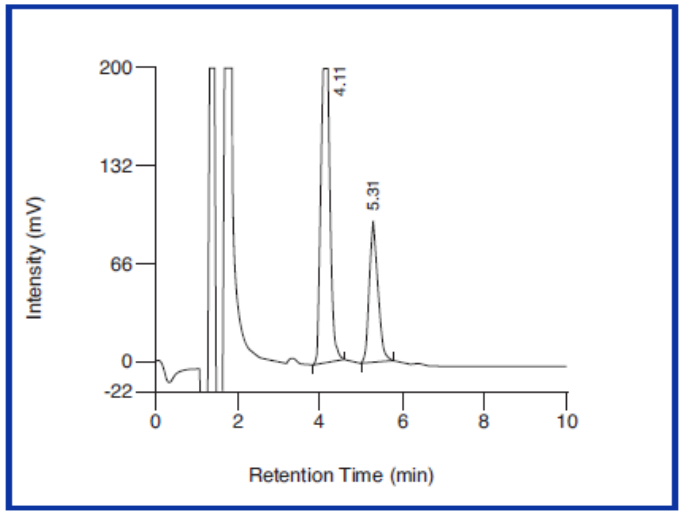
Serotonin in Urine

ClinChek® Urine Control, Level I



Serotonin: 4.13 min, IS: 5.31 min

ClinChek® Urine Control, Level II



Serotonin: 4.11 min, IS: 5.31 min

稀释

萃取

洗脱

色谱分析

Test Data

Linearity:	5 - 1000 µg/l
Recovery:	70 - 85 %
Lower detection limit:	3 µg/l
Lower determination limit:	5 µg/l
Intraassay precision:	3 %
Interassay precision:	4 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	20 µl
Injection interval:	10 min
EC-Detector:	potential: 450 mV, sensitivity: 50 nA
HPLC-Thermostat:	30 °C

Sample Preparation

Dilution:

2 ml urine	4 ml Stabilising Reagent S	50 µl Internal Standard IS

↓ adjust pH to 4.5 - 6.5

Extraction:

Apply the whole sample on the sample preparation column

↓ wash (HPLC water and Washing Solution W)

Elution:

Apply 5 ml Eluting Reagent E

↓ collect the eluate

HPLC Analysis:

Inject 20 µl

RECIPE®

尿液中的香草扁桃酸，高香草酸和5-羟基吲哚乙酸

VMA, HVA and 5-HIAA in Urine

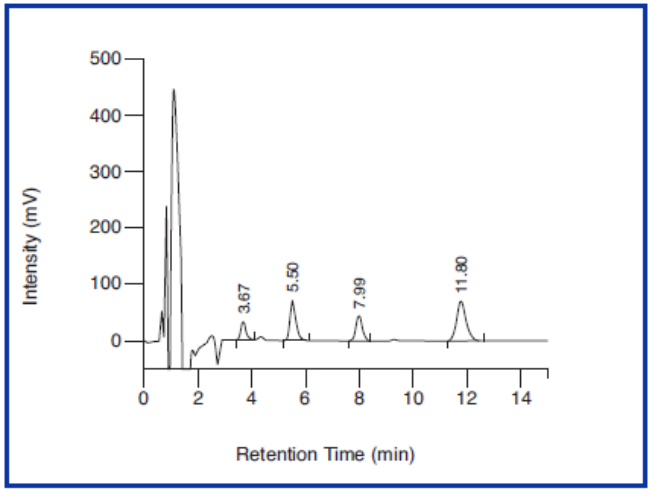
生物胺
Biogenic Amines

香草扁桃酸(Vanillylmandelic acid, VMA)和高香草酸(homovanillic acid, HVA)是儿茶酚胺的代谢最终产物。测定尿液中的VMA和HVA的含量水平被用于婴幼儿期最常见的实体肿瘤神经母细胞瘤的筛选试验。5-HIAA作为血清素的代谢物被用于诊断类癌肿瘤。RECIPE生产的ClinRep®完整试剂盒是一种可靠的能在15分钟内测定尿液中VMA,HVA和5-HIAA水平含量的分析方法。

上海仪真分析/孙韬

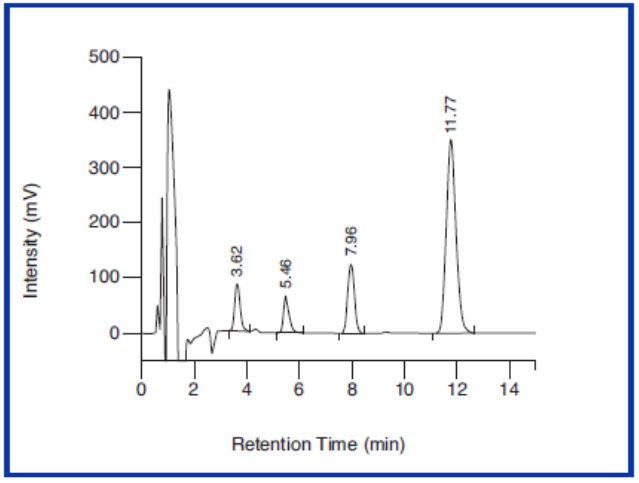
RECIPE® VMA, HVA and 5-HIAA in Urine

ClinChek® Urine Control, Level I



VMA: 3.67 min, IS: 5.50 min, HVA: 7.99 min,
5-HIAA: 11.80 min

ClinChek® Urine Control, Level II



VMA: 3.62 min, IS: 5.46 min, HVA: 7.96 min,
5-HIAA: 11.77 min

Test Data

Linearity:	VMA: 0.6 - 100 mg/l
	HVA: 0.3 - 100 mg/l
	5-HIAA: 0.2 - 50 mg/l
Recovery:	75 - 90 %
Lower detection limit:	VMA: 0.2 mg/l
	HVA: 0.1 mg/l
	5-HIAA: 0.1 mg/l
Lower determination limit:	VMA: 0.6 mg/l
	HVA: 0.3 mg/l
	5-HIAA: 0.2 mg/l

Precision

Intraassay:	2.6 % (VMA), 2.5 % (HVA), 3.0 % (5-HIAA)
Interassay:	3.7 % (VMA), 3.8 % (HVA), 3.6 % (5-HIAA)

HPLC Parameters

Isocratic Pump:	flow rate: 0.9 ml/min
Injection vol. / int.:	20 µl / 15 min
EC-Detector:	pot.: 800 mV, sen.: 50 nA
HPLC-Thermostat:	30 °C

Sample Preparation

Addition of IS:

50 µl urine | 1 ml Internal Standard IS

内标

Extraction:

Apply the whole sample on the sample preparation column

萃取

1. wash with 1 ml Ammonia Solution A → 2. fill up with Boric Acid B

Elution:

Apply 2 ml Eluting Reagent E

洗脱

HPLC Analysis: collect the eluate

Inject 20 µl

色谱分析

RECIPE®

全血中的血红蛋白变异体和 β-地中海贫血筛查

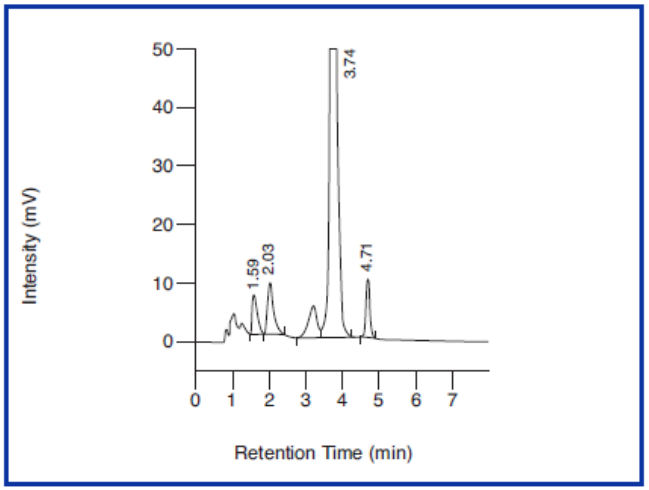
Hemoglobin Variants and β-Thalassemia Screening in Whole Blood

糖尿病，血红蛋白测试
Diabetes, Hemoglobin Testing

人体内负责血红蛋白分子合成的基因缺陷将导致一组遗传性疾病的产生，被称为“血红蛋白病”。根据分子的缺陷，血红蛋白病可分为“结构性血红蛋白变异体”和“地中海贫血”。该检测试剂盒为日常和临床上显著的血红蛋白变异体的分离和检测提供了一种可靠的途径。对于 β-地中海贫血筛查，该试剂盒可确保对HbF和HbA2的准确定量。一种测试溶液(含HbA1c, HbF, HbA0, HbE, HbA2, HbD, HbS, HbC)，一种溶血校准品(含HbF, HbA2)以及两种浓度级别的溶血质控品可用于质量保证。

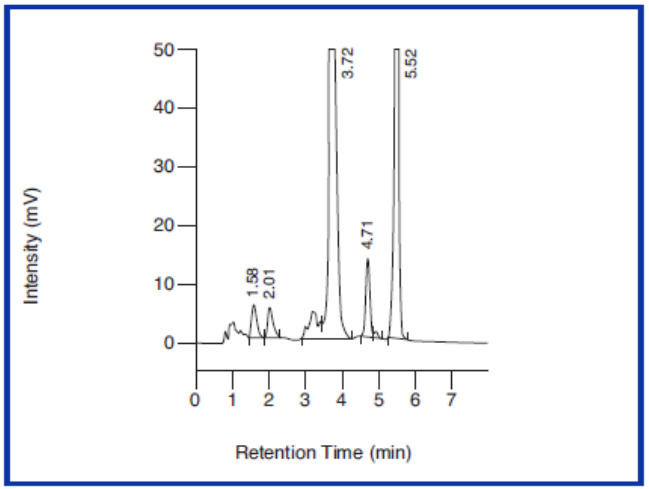
RECIPE® Hemoglobin Variants and β-Thalassemia Screening in Whole Blood

ClinCal® Hemolysate Calibrator (HbF/A2)



HbA1c: 1.59 min, HbF: 2.03 min, HbA0: 3.74 min, HbA2: 4.71 min

ClinCheck® Hemolysate Control (HbF/A2/S), Level I



HbA1c: 1.58 min, HbF: 2.01 min, HbA0: 3.72 min, HbA2: 4.71, HbS: 5.52 min

Test Data

Intraassay precision:	1.0 - 3.3 % (HbF)
	0.6 - 3.6 % (HbA2)
Interassay precision:	2.1 - 2.8 % (HbF)
	0.7 - 2.4 (HbA2)

Dependence on total hemoglobin:

The HbF and HbA2 values are independent on the amount of total hemoglobin in a range from 6 - 24 g/dl total hemoglobin.

HPLC Parameters

Pump:	binary gradient pump
Flow rate:	1.2 ml/min
Injection volume:	20 µl
Injection interval:	8 min
UV/VIS-Detector:	415 nm
HPLC-Thermostat:	23 °C

Sample Preparation

Hemolysis:

溶血

5 µl venous blood	1 ml Hemolysis Reagent H

↓ incubate (10 min, ambient temp.)

HPLC Analysis:

色谱分析

Inject 20 µl

RECIPE®

尿液中的5-氨基乙酰丙酸和胆色素原

5-Aminolevulinic Acid/Porphobilinogen in Urine

代谢疾病
Metabolic Diseases

5-氨基乙酰丙酸(5-ALA)和胆色素原(PBG)是血红素和血红蛋白生物合成的中间体。在某些疾病中，卟啉症的产生是由于血红素生成异常导致5-ALA和PBG的积累。卟啉症可由遗传导致(遗传性卟啉症)，或者也可由不同的外部因素例如铅中毒引起。

RECIPE®

5-ALA/PBG in Urine

Test Data

Linearity:	0.8 - 80 mg/l
Recovery:	> 90 %
Lower detection limit:	0.6 mg/l
Lower determination limit:	0.8 mg/l
Intraassay precision:	5-ALA: 3.4 %
	PBG: 5.2 %
Interassay precision:	5-ALA: 4.6 %
	PBG: 6.4 %

Sample Preparation

Extraction:

Apply 0.5 ml urine to a conditioned 5-ALA / PBG double column

萃取

↓ wash (3 x 10 ml HPLC water)

Separate the double column
Colourless column: ➜ A: Sample Preparation for 5-ALA
Blue column: ➜ B: Sample Preparation for PBG

A: Sample Preparation for 5-ALA

Elution:

Elute with 7.0 ml Reagent A (receiver tube: 500 µl Reagent B)

洗脱

↓ collect the eluate

Derivatisation:

1. Incubate at 100 °C (water bath, 10 min)
2. Add 7.0 ml Ehrlich's Reagent
3. Incubate at room temperature (15 min)

衍生化

↓

Analysis:

Photometric measurement

光度测量

B: Sample Preparation for PBG

Elution:

Elute with 4.0 ml Reagent D

洗脱

↓ collect the eluate

Derivatisation:

1. Add 4.0 ml Ehrlich's Reagent
2. Incubate at room temperature (15 min)

衍生化

↓

Analysis:

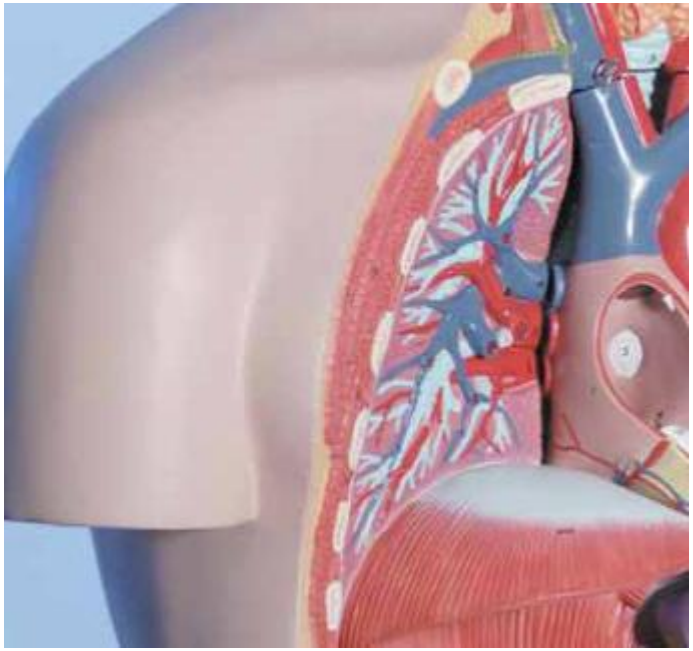
Photometric measurement

光度测量

RECIPE®

血浆中的同型半胱氨酸

Homocysteine in Plasma

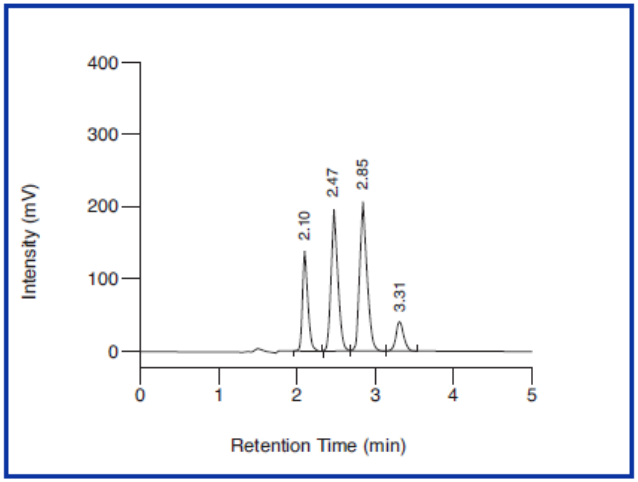


代谢疾病
Metabolic Diseases

同型半胱氨酸是一种对动脉粥样硬化及冠心病风险评估的已知标记物。无论是由营养不足还是遗传缺陷引起的血浆中同型半胱氨酸水平的升高(高同型半胱氨酸血症)，均可通过服用叶酸，维生素B6和B12得到降低。因此，同型半胱氨酸的测定不仅为动脉粥样硬化提供风险评估，也可保证实行营养补充疗法所需的适当剂量组合。RECIPE生产的检测试剂盒可同时分析同型半胱氨酸(tHcys)和总半胱氨酸(tCys)。

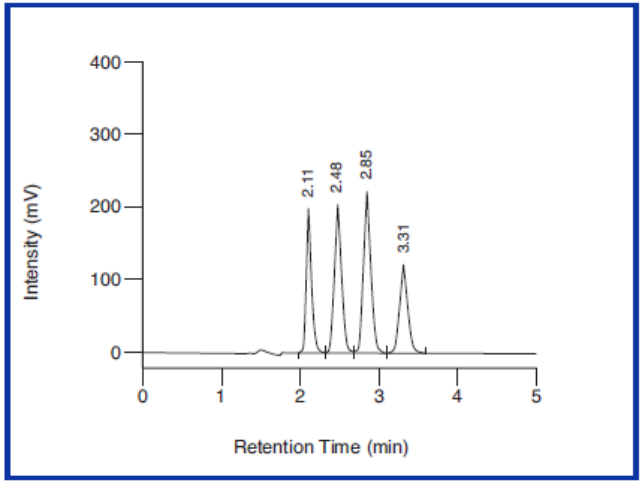
Homocysteine in Plasma

ClinChek® Plasma Control, Level I



Cysteine: 2.10 min, IS: 2.47 min, Cysteinylglycine: 2.85 min, Homocysteine: 3.31 min

ClinChek® Plasma Control, Level II



Cysteine: 2.11 min, IS: 2.48 min, Cysteinylglycine: 2.85 min, Homocysteine: 3.31 min

Test Data

Linearity:	1 - 100 µmol/l
Recovery:	95 - 105 %
Lower detection limit:	0.5 µmol/l
Lower determination limit:	1 µmol/l
Intraassay precision:	3.9 %
Interassay precision:	5.8 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	20 µl
Injection interval:	5 min
Fluorescence detector:	385 nm (exc.), 515 nm (em.)
HPLC-Thermostat:	30 °C

Sample Preparation

Reduction:

还原

100 µl plasma	25 µl Internal Standard IS	25 µl Reagent A

Precipitation:

沉淀

150 µl reduced sample	100 µl Reagent B

centrifuge

Derivatisation:

衍生化

50 µl supernatant	100 µl Reagent C	50 µl Reagent D

incubate (60 min, 60 °C)

HPLC Analysis:

色谱分析

Inject 20 µl

RECIPE®

尿液中的羟脯氨酸

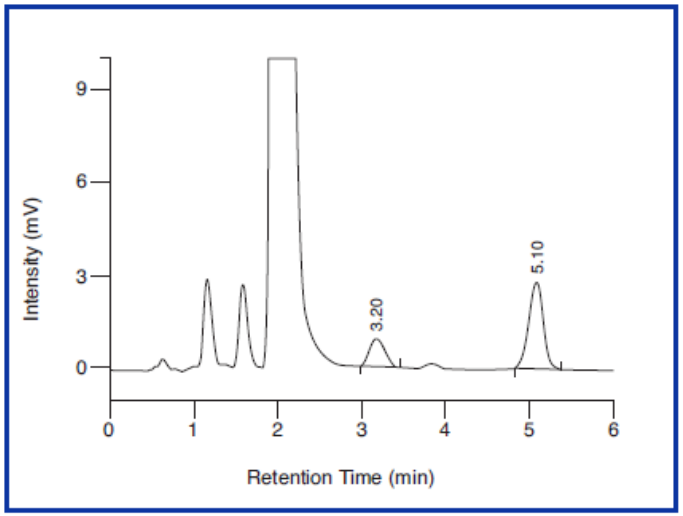
Hydroxyproline in Urine

代谢疾病
Metabolic Diseases

骨质疏松症是一种骨代谢疾病，骨质密度低于正常水平因此增加了骨折的风险。伴随而来的骨质退化会导致氨基酸中的羟基脯氨酸形成增加，并被释放入血液循环随尿液排出体外。RECIPE检测试剂盒确保对羟基脯氨酸的准确测量。经特殊样品制备过程，羟基脯氨酸变为衍生物，从而在不被其他氨基酸干扰的情况下获得准确测量。

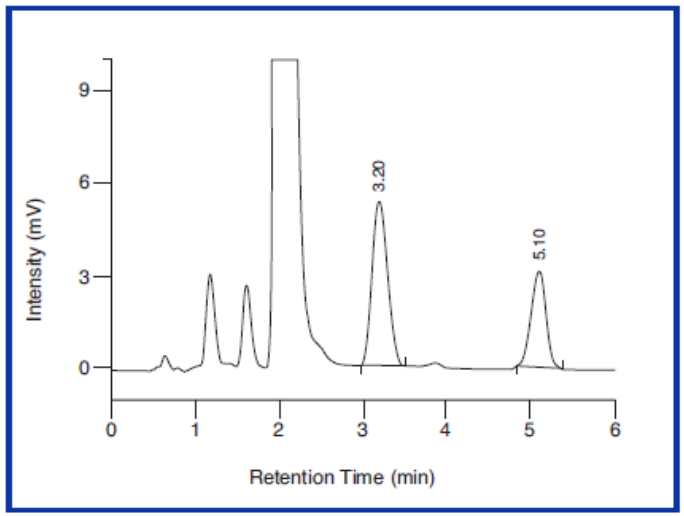
RECIPE® Hydroxyproline in Urine

ClinChek® Urine Control, Level I



Hydroxyproline: 3.20 min, IS: 5.10 min

ClinChek® Urine Control, Level II



Hydroxyproline: 3.20 min, IS: 5.10 min

水解

衍生化

稀释

色谱分析

Test Data

Linearity:	5 - 170 mg/l
Recovery:	90 - 100 %
Lower detection limit:	3 mg/l
Lower determination limit:	5 mg/l
Intraassay precision:	3.5 %
Interassay precision:	4.5 %

HPLC Parameters

Pump:	binary gradient pump, flow rates: 1.2, 1.4 ml/min
Injection volume:	20 µl
Injection interval:	8 min
UV/VIS-Detector:	471 nm
HPLC-Thermostat:	60 °C

Sample Preparation

Hydrolysis:

1 ml urine	100 µl Internal Standard IS	1 ml HCl

↓ incubate (16 h, 95 °C)

Derivatisation:

1. 100 µl sample + 300 µl Reagent A + 800 µl Reagent B / C
2. 500 µl sample + 200 µl Reagent D
3. 150 µl sample + 200 µl Reagent E

↓ incubate (10 min, 70 °C)

Dilution:

Complete sample	500 µl Mobile Phase A

↓

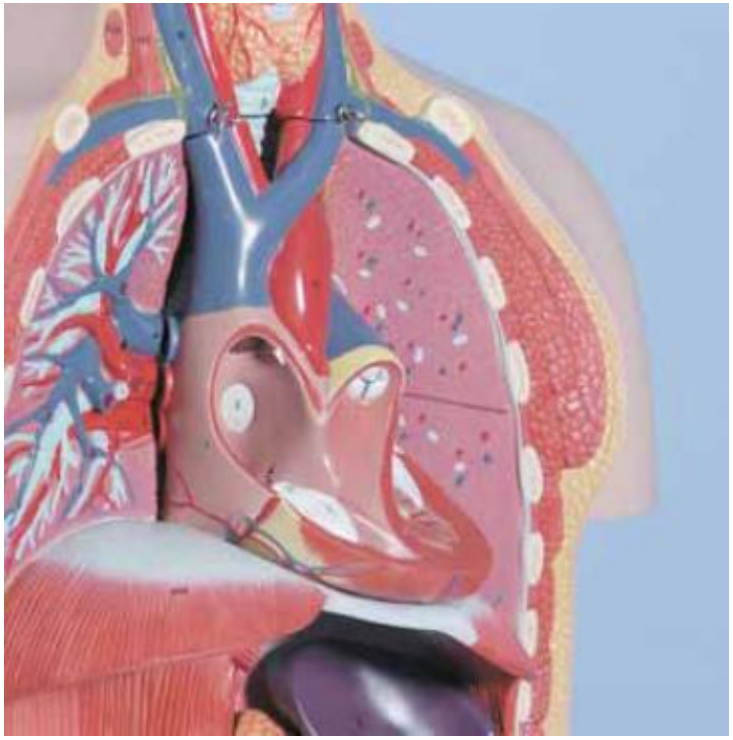
HPLC Analysis:

Inject 20 µl

RECIPE®

尿液中的卟啉的区分

Porphyrins Differentiated in Urine

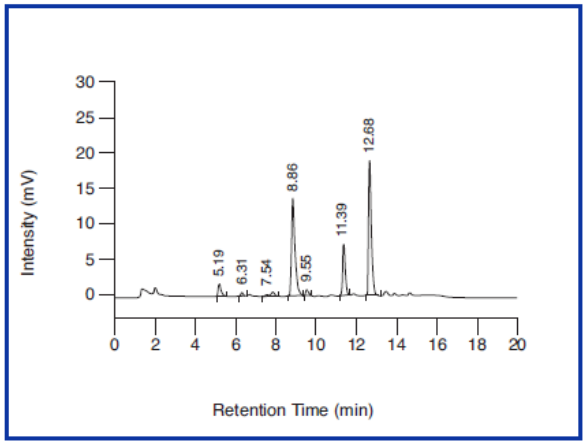


代谢疾病
Metabolic Diseases

卟啉排泄检测用于卟啉症的诊断。该ClinRep®完整试剂盒可实现高分辨率的尿卟啉分离(不同的卟啉异构体)并确保精确的定量测定。在前处理阶段，样品需加入一种内标并进行离心。筛选卟啉的“快速测试”包括一个总卟啉柱测试和一个5-氨基乙酰酸和胆色素原的柱测试。

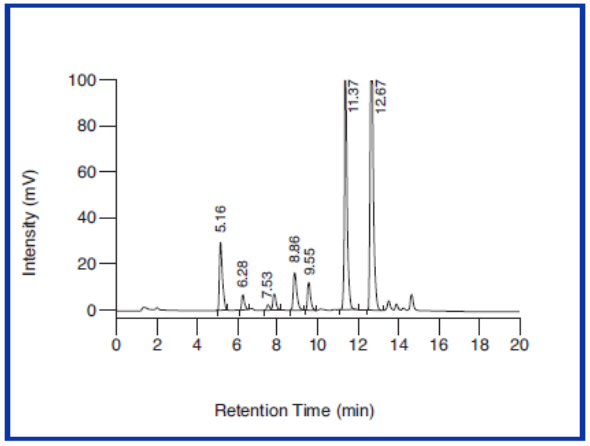
Porphyrins Differentiated in Urine

ClinChek® Urine Control, Level I



Uroporphyrin I: 5.19 min, Heptacarboxyporphyrin I: 6.31 min,
Hexacarboxyporphyrins (Iac and Iab Isomer): 7.54 min,
Internal Standard IS: 8.86 min, Pentacarboxyporphyrin I: 9.55 min,
Coproporphyrin I: 11.39 min, Coproporphyrin III: 12.68 min

ClinChek® Urine Control, Level II



Uroporphyrin I: 5.16 min, Heptacarboxyporphyrin I: 6.28 min,
Hexacarboxyporphyrins (Iac and Iab Isomer): 7.53 min,
Internal Standard IS: 8.86 min, Pentacarboxyporphyrin I: 9.55 min,
Coproporphyrin I: 11.37 min, Coproporphyrin III: 12.67 min

Test Data

Linearity:	1 - 5000 µg/l
Lower detection limit:	0.5 µg/l
Lower determination limit:	1 µg/l
Intraassay precision:	2.3 %
Interassay precision:	2.6 %

HPLC Parameters

Pump:	binary gradient pump, flow rate: 0.7 ml/min
Injection volume:	20 µl
Injection interval:	20 min
Fluorescence detector:	394 nm (exc.), 624 nm (em.)
HPLC-Thermostat:	30 °C

Sample Pretreatment

Addition of IS:

内标加入

500 µl urine (calibrator, control, patient)	50 µl Internal Standard IS

↓ centrifuge

HPLC Analysis:

色谱分析

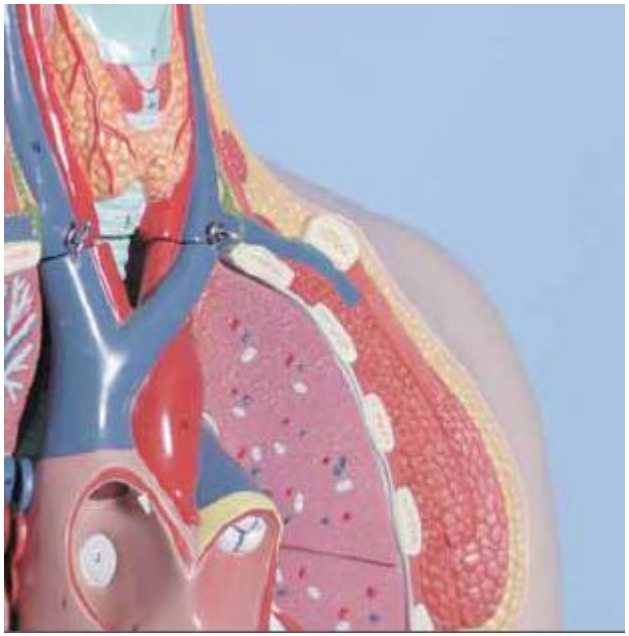
Inject 20 µl of the supernatant

上海仪真分析/孙韬

RECIPE®

全血/血浆/血清中的辅酶Q10

Coenzyme Q10 in Whole Blood/Plasma/Serum

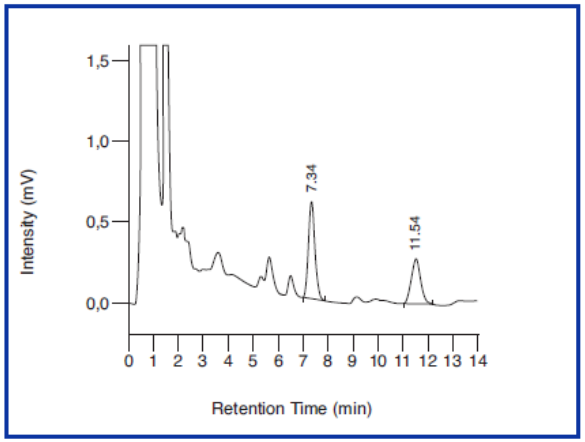


氧化应激
Oxidative Stress

辅酶Q10(CoQ10)在细胞新陈代谢中的能量产生起到了重要作用。同时，辅酶Q10也是重要的抗氧化剂，为细胞免受自由基氧化(氧化应激)提供保护。某些疾病主要包括心血管疾病会降低血液中的辅酶Q10浓度。RECIPE的ClinRep®完整试剂盒能够对全血/血浆/血清中的辅酶Q10进行可靠的检测。经快速样品制备，分析色谱法将通过等度HPLC和紫外检测器实现分离检测。对于质量保证，参考物质(ClinTest® Test Solution, ClinCal® Plasma Calibrator and ClinChek® Plasma Controls)具有优良的稳定性。

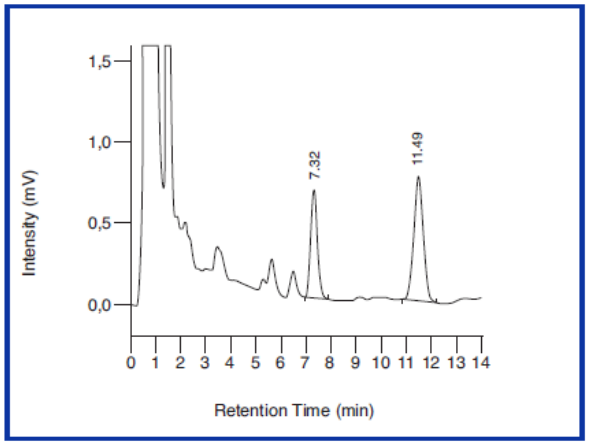
Coenzyme Q10 in Whole Blood/Plasma/Serum

ClinChek® Plasma Control, Level I



IS: 7.34 min, CoQ10: 11.54 min

ClinChek® Plasma Control, Level II



IS: 7.32 min, CoQ10: 11.49 min

Test Data

Linearity:	38.9 - 20000 µg/l
Recovery:	94 - 108 %
Lower detection limit:	19.5 µg/l
Lower determination limit:	38.9 µg/l
Intraassay precision:	3.4 %
Interassay precision:	5.0 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.4 ml/min
Injection volume:	30 µl
Injection interval:	14 min
UV-Detector:	275 nm
HPLC-Thermostat:	30 °C

Sample Preparation

Precipitation:

沉淀

500 µl Precipitant P

↓

1. Add 400 µl sample
2. Add 50 µl Oxidation Reagent O

↓ mix

Add 400 µl Internal Standard IS

↓ mix, centrifuge

HPLC Analysis:

色谱分析

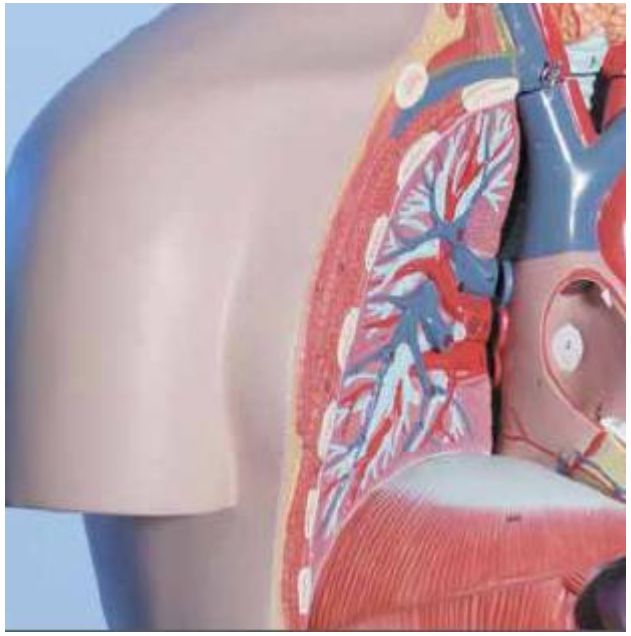
Inject 30 µl of the supernatant

上海仪真分析/孙韬

RECIPE®

血浆/血清中的丙二醛

Malondialdehyde in Plasma/Serum

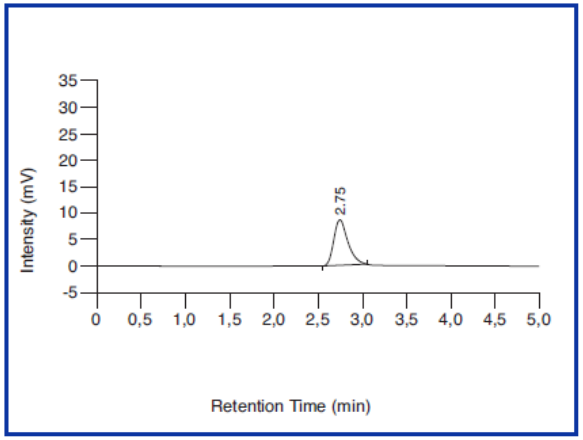


氧化应激
Oxidative Stress

丙二醛由自由基介导的脂质经过氧化反应(氧化应激)形成，并通过进一步与DNA反应产生诱变和细胞毒素的影响。由于此原因，丙二醛被认为是一种合适的测定氧化应激反应的生物标记物。RECIPE的ClinRep®完整试剂盒可为定量测定血浆/血清中的丙二醛提供可靠的方法。对于质量保证，两种浓度级别的ClinCal® Plasma Calibrator和ClinChek®Plasma Controls 可被使用。

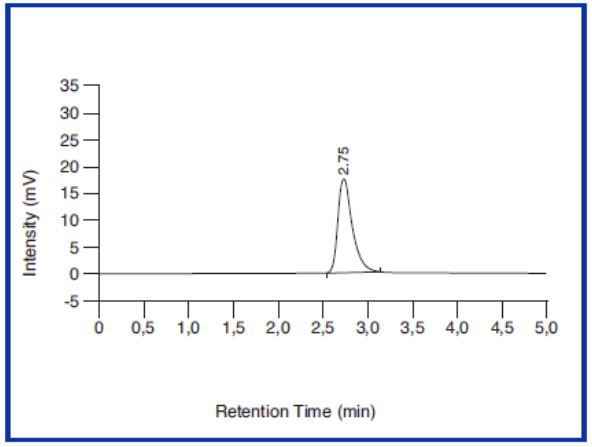
Malondialdehyde in Plasma/Serum

ClinChek® Plasma Control, Level I



Malondialdehyde: 2.75 min

ClinChek® Plasma Control, Level II



Malondialdehyde: 2.75 min

Test Data

Linearity:	0.04 - 20 µmol/l
Recovery:	100 %
Lower detection limit:	0.02 µmol/l
Lower determination limit:	0.04 µmol/l
Intraassay precision:	3.7 %
Interassay precision:	7.4 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 0.8 ml/min
Injection volume:	20 µl
Injection interval:	5 min
Fluorescence detector:	515 nm (exc.), 553 nm (em.)
HPLC-Thermostat:	30 °C

Sample Preparation

Derivatisation:

衍生化

100 µl plasma / serum	700 µl Reagent A	200 µl Reagent B

↓ incubate (60 min, 100 °C)

Neutralisation / Precipitation:

中和/沉淀

200 µl sample	200 µl Reagent C

↓ centrifuge

HPLC Analysis:

色谱分析

Inject 20 µl of the supernatant

RECIPE®

血浆中的维生素C

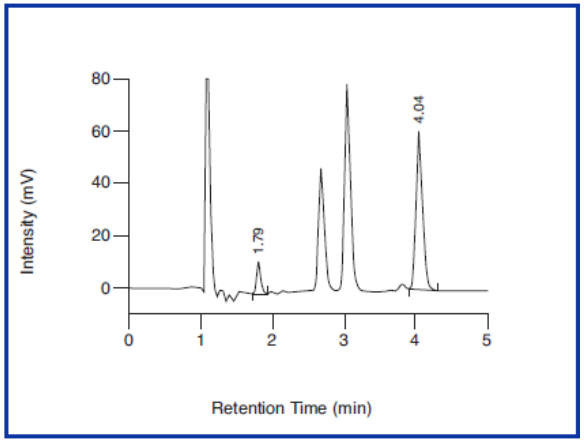
Vitamin C in Plasma

氧化应激
Oxidative Stress

维生素C(抗坏血素)是一种自由基和氧化剂的潜在清除剂。这些物质的暴露被称为“氧化应激”。氧化应激被认为对各种慢性病如心血管疾病、糖尿病和癌症的发展产生了助推作用。维生素C不足的状况通常在营养不良、吸烟、酗酒、慢性中毒和压力等情况下被观察到。此外，哺乳期妇女和老人也处于低维生素C的危险之中。 RECIPE检测试剂盒具有分析时间短(样品制备简单，运行时间短)的特点，并且确保了结果的可靠性。

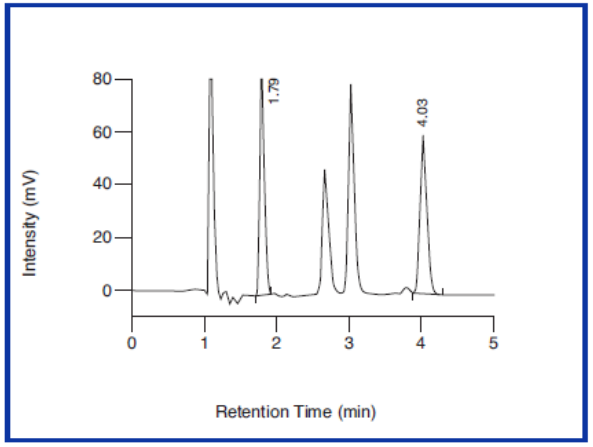
Vitamin C in Plasma

ClinChek® Serum Control, Level I



Vitamin C: 1.79 min, IS: 4.04 min

ClinChek® Serum Control, Level II



Vitamin C: 1.79 min, IS: 4.03 min

Test Data

Linearity:	0.5 - 300 mg/l
Recovery:	95 - 100 %
Lower detection limit:	0.1 mg/l
Lower determination limit:	0.5 mg/l
Intraassay precision:	5.9 %
Interassay precision:	6.9 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.3 ml/min
Injection volume:	20 µl
Injection interval:	5 min
UV-Detector:	243 nm
HPLC-Thermostat:	30 °C

Sample Preparation

Precipitation:

沉淀

100 µl plasma	100 µl Precipitant P (contains Internal Standard IS)

1. incubate (10 min, + 4°C) ↓ 2. centrifuge

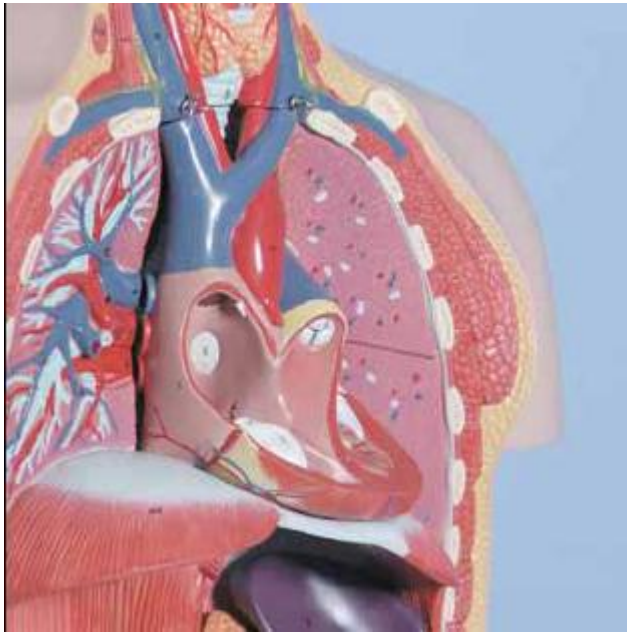
HPLC Analysis:

色谱分析

Inject 20 µl of the supernatant

血浆中的维生素A和E

Vitamin A and E in Plasma

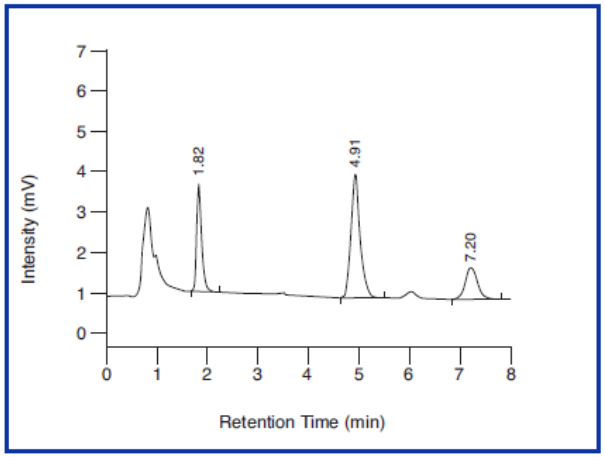


维生素状态
Vitamin Status

维生素A(视黄醇)和维生素E(α-生育酚)属于脂溶性维生素类。与此相反的水溶性维生素，过度给药可能会导致维生素过多症。 维生素A缺乏症是导致可预防性儿童失明的重要原因，同时会增加引发感染性疾病和死亡的风险。维生素E是一种重要的抗氧化剂，被认为通过抑制低密度脂蛋白(LDL)的氧化从而预防动脉粥样硬化。RECIPE的ClinRep®完整试剂盒可在8分钟内同时分析上述两种维生素。对于质量保证，参考物质具有优良的稳定性。

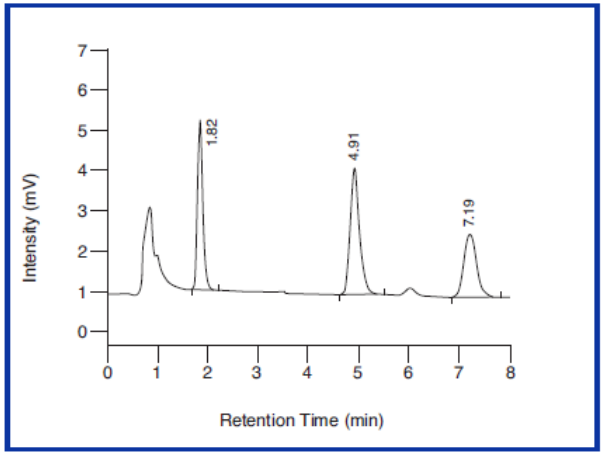
Vitamin A and E in Plasma

ClinChek® Serum Control, Level I



Vitamin A: 1.82 min, IS: 4.91 min, Vitamin E: 7.20 min

ClinChek® Serum Control, Level II



Vitamin A: 1.82 min, IS: 4.91 min, Vitamin E: 7.19 min

Test Data

Linearity:	Vitamin A: 0.02 - 5.0 mg/l, Vitamin E: 0.40 - 50 mg/l
Recovery:	92 - 98 %
Lower detection limit:	Vitamin A: 0.01 mg/l, Vitamin E: 0.30 mg/l
Lower determination limit:	Vitamin A: 0.02 mg/l, Vitamin E: 0.40 mg/l
Intraassay precision:	Vitamin A: 1.4 %, Vitamin E: 1.4 %
Interassay precision:	Vitamin A: 5.0 %, Vitamin E: 3.2 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.5 ml/min
Injection volume:	50 µl
Injection interval:	8 min
UV-Detector:	325 / 295 nm
HPLC-Thermostat:	30 °C

Sample Preparation

Extraction:

萃取

150 µl plasma / serum	150 µl Precipitant P (contains Internal Standard IS)

↓ centrifuge

Stabilisation:

稳定化

100 µl supernatant	100 µl Stabilising Reagent S

↓ centrifuge

HPLC Analysis:

色谱分析

Inject 50 µl of the supernatant

RECIPE®

全血中的维生素B1

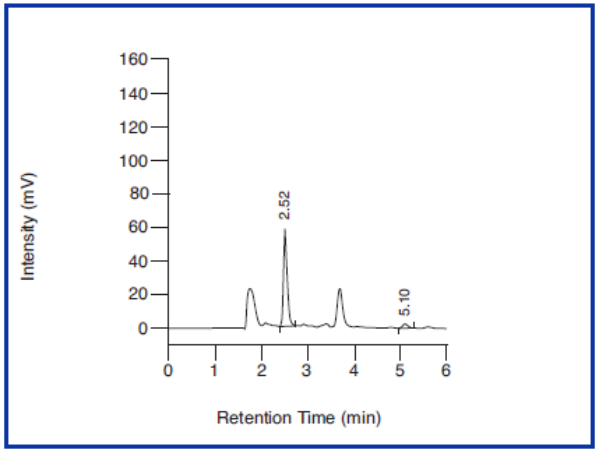
Vitamin B1 in Whole Blood

维生素状态
Vitamin Status

维生素B1(硫胺，硫胺素焦磷酸(TTP))作为辅酶在碳水化合物代谢以及有机体的正常运作中是必不可少的的。其缺乏症主要发生于营养不良者、酗酒者或者特殊的临床情况(例如血液透析)。一种完全的缺陷综合症被称作“脚气病”。使用RECIPE检测试剂盒，TPP可用来测定维生素B1。该试剂盒可与维生素B2和B6检测试剂盒方便的结合使用。

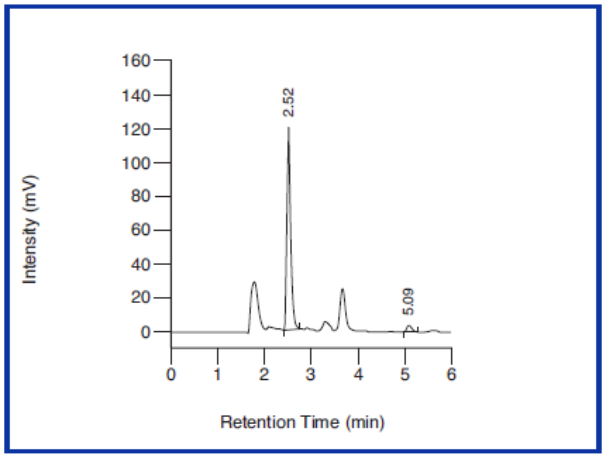
Vitamin B1 in Whole Blood

ClinChek® Whole Blood Control, Level I



TPP: 2.52 min, Thiamine: 5.10 min

ClinChek® Whole Blood Control, Level II



TPP: 2.52 min, Thiamine: 5.09 min

Test Data

Determination as TPP

Linearity:	1 - 200 µg/l
Recovery:	95 - 100 %
Lower detection limit:	0.5 µg/l
Lower determination limit:	1 µg/l
Intraassay precision:	2.7 %
Interassay precision:	4.2 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Pump (Reagent N):	flow rate: 0.1 ml/min
Injection volume:	50 µl
Injection interval:	4 min
Fluorescence detector:	376 nm (exc.), 435 nm (em.)
HPLC-Thermostat:	35 °C

Sample Preparation

萃取

Extraction:

300 µl whole blood | 500 µl Reagent A

1. centrifuge ↓ 2. take off 400 µl supernatant

稳定化

Stabilisation:

Add 50 µl Reagent S

氧化

Oxidation:

450 µl sample | 50 µl Reagent C | 100 µl Reagent D

add 100 µl Reagent E

色谱分析

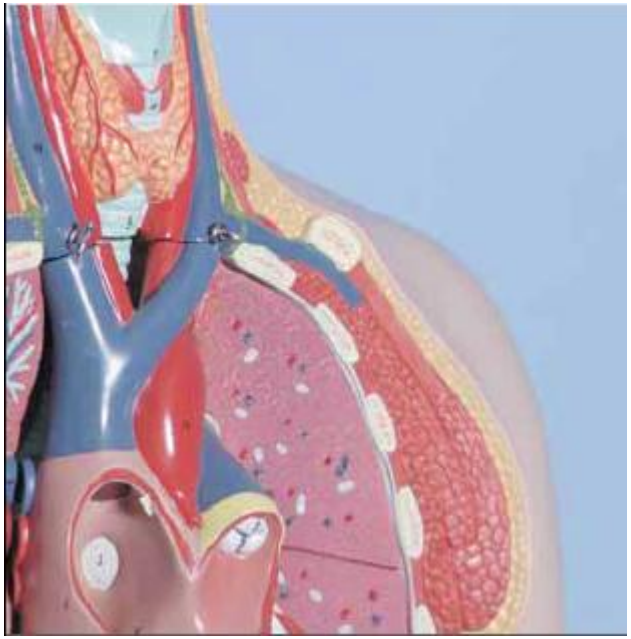
HPLC Analysis:

Inject 50 µl of the supernatant

RECIPE®

全血中的维生素B2

Vitamin B2 in Whole Blood

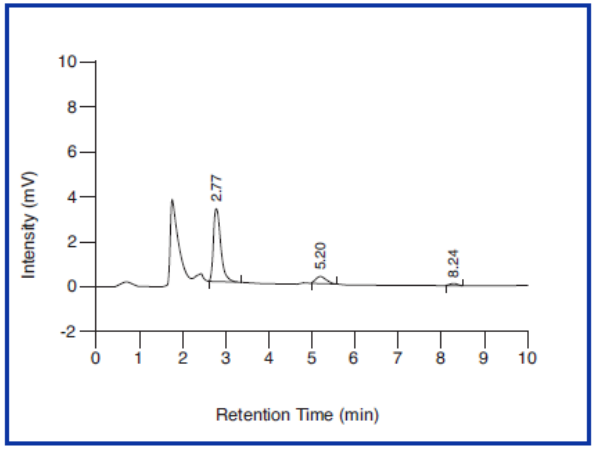


维生素状态
Vitamin Status

术语维生素B2包括三种同效维生素：核黄素(riboflavin)，黄素单核苷酸(FMN)和黄素腺嘌呤二核苷酸(FAD)。FMN和FAD是维生素B2的有效形式，通过体内核黄素磷酸化合成而来。维生素B2对于能量产生，酶功能以及脂肪酸和氨基酸的合成极为重要。维生素B2供给不足主要是由于营养不良。它常见于具有酗酒问题，高龄和极端饮食习惯等危险因素的人群。该RECIPE检测试剂盒具有分析时间短(样品制备简单，运行时间短)和易与维生素B1和B6检测试剂盒相结合的特点。

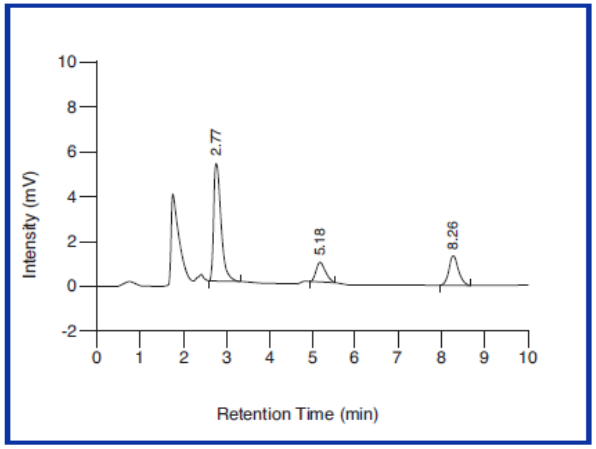
Vitamin B2 in Whole Blood

ClinChek® Whole Blood Control, Level I



Flavin adenine dinucleotide: 2.77 min,
Flavin mononucleotide: 5.20 min,
Riboflavin: 8.24 min

ClinChek® Whole Blood Control, Level II



Flavin adenine dinucleotide: 2.77 min,
Flavin mononucleotide: 5.18 min,
Riboflavin: 8.26 min

Test Data

Determination as FAD

Linearity:	20 - 500 µg/l
Recovery:	95 - 100 %
Lower detection limit:	10 µg/l
Lower determination limit:	20 µg/l
Intraassay precision:	3.8 %
Interassay precision:	4.0 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	50 µl
Injection interval:	10 min
Fluorescence detector:	450 nm (exc.), 530 nm (em.)
HPLC-Thermostat:	40 °C

Sample Preparation

Extraction:

萃取

200 µl whole blood	300 µl Precipitation Reagent P

1. add 500 µl Stabilising Reagent S → 2. centrifuge

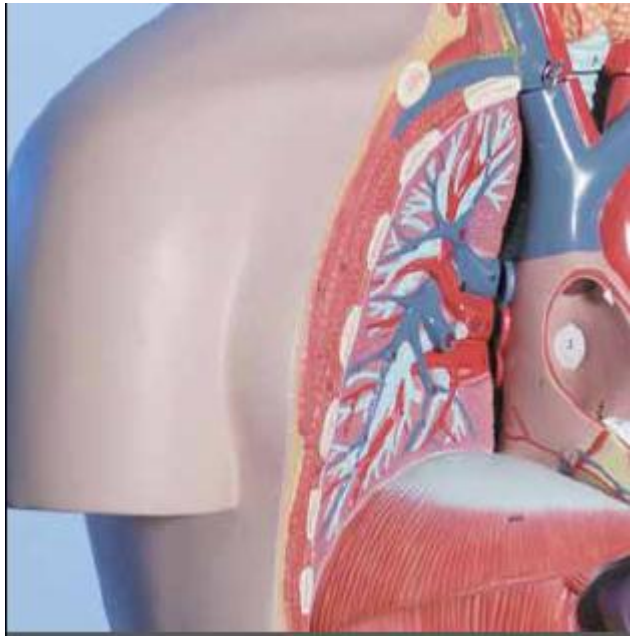
HPLC Analysis:

色谱分析

Inject 50 µl of the supernatant

血浆/全血中的维生素B6

Vitamin B6 in Plasma and Whole Blood

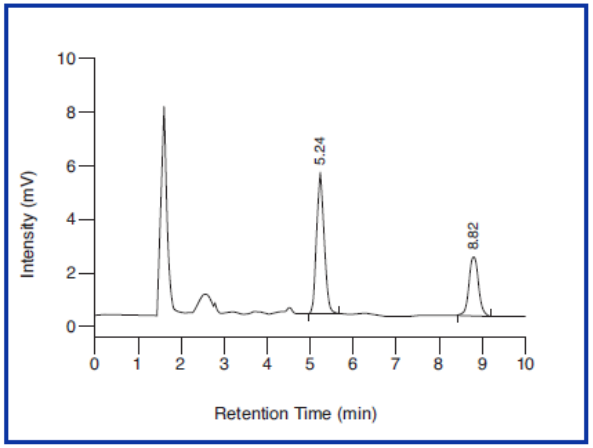


维生素状态
Vitamin Status

维生素B6由三种同效维生素组成：吡哆醇、吡哆醛和吡哆胺。维生素B6的代谢活性辅酶形式是吡哆醛-5`-磷酸(PLP)。维生素B6缺乏症的临床症状主要表现在皮肤改变、神经逻辑紊乱和贫血。此外，低浓度维生素状态会导致血浆中同型半胱氨酸水平升高(超高同型半胱氨酸血症)。 RECIPE的ClinRep®完整试剂盒能够测定血浆和全血中的维生素B6形态物吡哆醛和PLP。该检测手段具有较高的分析测试灵敏度，并且可以很容易的结合维生素B1和B2检测试剂盒。

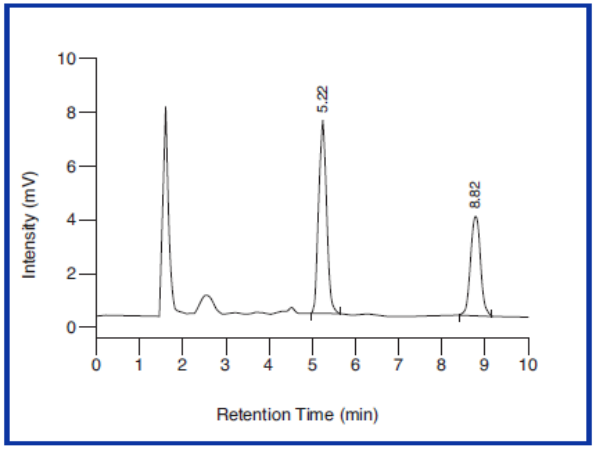
Vitamin B6 in Plasma and Whole Blood

ClinChek® Whole Blood Control, Level I



Pyridoxal-5'-phosphate: 5.24 min, Pyridoxal: 8.82 min

ClinChek® Whole Blood Control, Level II



Pyridoxal-5'-phosphate: 5.22 min, Pyridoxal: 8.82 min

Test Data

Determination from plasma / *from whole blood*

Linearity:	Pyridoxal: 0.6 - 800 µg/l / *0.6 - 1200 µg/l* Pyridoxal-5'-phosphate: 0.6 - 800 µg/l / *0.6 - 1500 µg/l*
Recovery:	95 - 100 % / *95 - 100 %*
Lower detection limit:	0.4 µg/l for both analytes and both matrizes
Lower determination limit:	0.6 µg/l for both analytes and both matrizes
Intraassay precision:	Pyridoxal: 5.1 % / *8.4 %* Pyridoxal-5'-phosphate: 2.5 % / *2.3 %*
Interassay precision:	Pyridoxal: 6.9 % / *9.2 %* Pyridoxal-5'-phosphate: 3.1 % / *2.9 %*

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Pump (Reagent N):	flow rate: 0.2 ml/min
Injection volume:	50 µl
Injection interval:	10 min
Fluorescence detector:	370 nm (exc.), 470 nm (em.)
Temperature:	25 °C (or ambient)

Sample Preparation

Extraction:

100 µl plasma / whole blood	100 µl Precipitant P

↓ centrifuge

HPLC Analysis:

Inject 50 µl of the supernatant

萃取

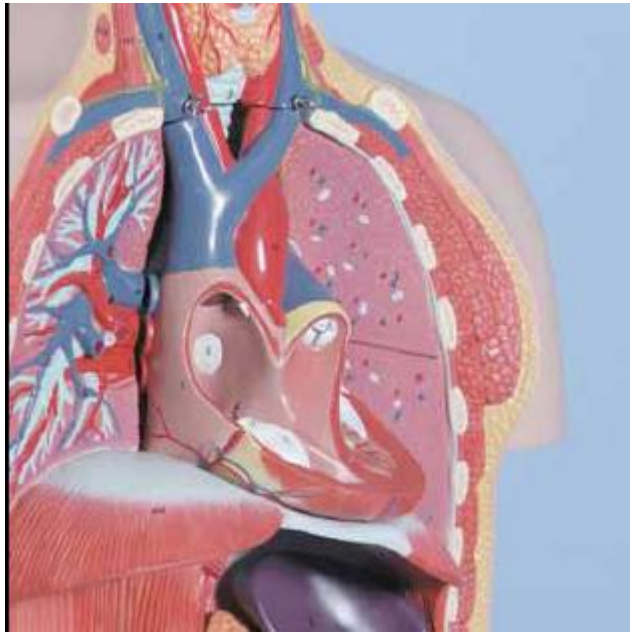
色谱分析

上海仪真分析/孙韬

RECIPE®

血浆/血清中的25-羟基维生素D2/D3

25-OH Vitamin D2/D3 in Plasma and Serum

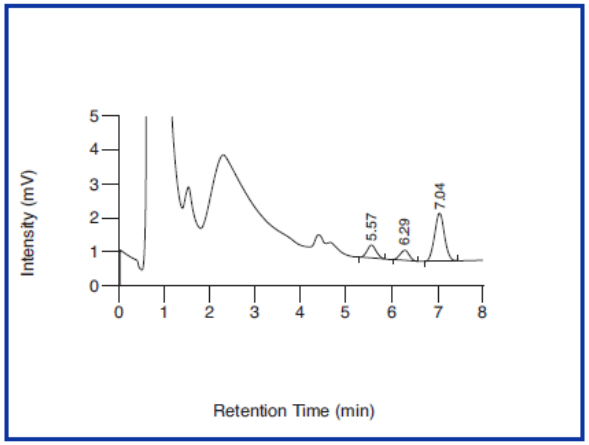


维生素状态
Vitamin Status

测定25-羟基维生素D(如D2, D3)可用于评估维生素D的状态。维生素D在骨质矿化，肌肉收缩，神经传导和一般细胞功能过程中起到了重要作用。因此维生素D不足会与许多慢性疾病和延迟疾病的发生产生联系，严重的缺乏会导致儿童佝偻病和成人骨软化症。RECIPE完整试剂盒能够实现对血浆和血清中的分析物进行快速可靠的检测。样品制备包含了一个简单的沉淀步骤，之后样品可被注射进HPLC系统。对于校准和内部质量控制，可使用不同浓度范围的ClinCal® Serum Calibrator和ClinChek® Serum Controls。

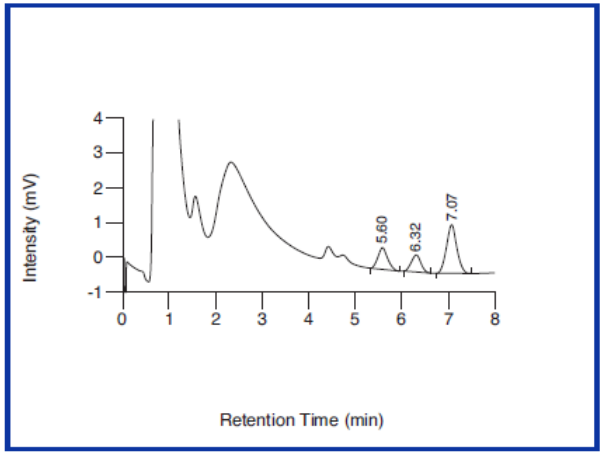
25-OH Vitamin D2/D3 in Plasma and Serum

ClinChek® Serum Control, Level I



25-OH Vitamin D3: 5.57 min, 25-OH Vitamin D2: 6.29 min,
IS: 7.04 min

ClinChek® Serum Control, Level II



25-OH Vitamin D3: 5.60 min, 25-OH Vitamin D2: 6.32 min,
IS: 7.07 min

Test Data

Linearity:	3.0 - 500 µg/l (D2)
	2.6 - 500 µg/l (D3)
Recovery:	99 - 104 %
Lower detection limit:	1.1 µg/l (D2)
	1.0 µg/l (D3)
Lower determination limit:	3.0 µg/l (D2)
	2.6 µg/l (D3)
Intraassay precision:	2.7 % (D2)
	2.5 % (D3)
Interassay precision:	3.7 % (D2)
	3.7 % (D3)

HPLC Parameters

Pump:	isocratic pump,
	flow rate: 1.0 ml/min
Injection volume:	50 µl
Injection interval:	10 min
UV-Detector:	264 nm
HPLC-Thermostat:	40 °C

Sample Preparation

Precipitation:

沉淀

500 µl Precipitant P

↓

1. Add 400 µl sample
2. Add 400 µl Internal Standard IS

↓ mix, centrifuge

HPLC Analysis:

色谱分析

Inject 50 µl of the supernatant

RECIPE®

UPLC法处理血浆/血清中的25-羟基维生素D2/D3

25-OH Vitamin D2/D3 in Plasma and Serum with UPLC

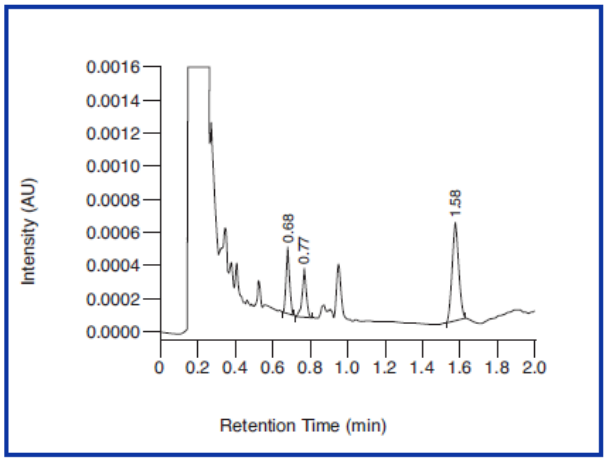
维生素状态
Vitamin Status

25-羟基维生素D(如D2, D3)是评估维生素D状态的一个重要参数。除了RECIPE的HPLC完整试剂盒外，用户还可使用一个可用于Waters ACQUITY UPLC®系统的ClinRep® Complete Kit完整试剂盒。该试剂盒方法色谱持续时间仅为2分钟，故具有显著提高样品通量并减少缓冲液消耗的特点。对于系统检查，校准和内部质量控制，我们提供了一种ClinTest® Test Solution测试解决方案, 一种ClinCal®Serum Calibrator血清校准品和一种ClinChek® Serum Controls血清控制品。ClinCal®Serum Calibrator可溯源至一种认证的参考物质(NIST 标准 SRM972)。

上海仪真分析/孙韬

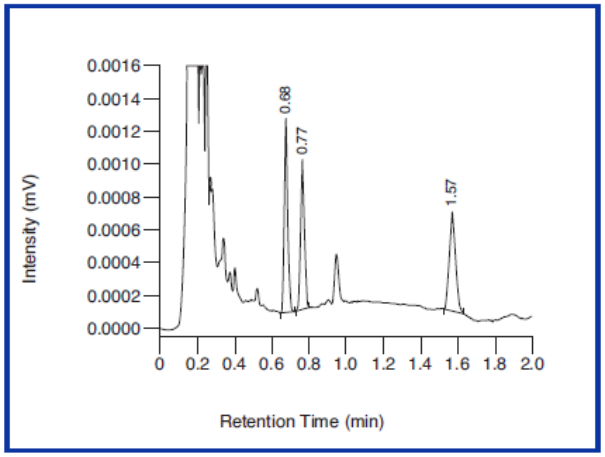
25-OH Vitamin D2/D3 in Plasma and Serum with UPLC

ClinChek® Serum Control, Level I



25-OH-Vitamin D3: 0.68 min, 25-OH-Vitamin D2: 0.77 min, IS: 1.58 min

ClinChek® Serum Control, Level II



25-OH Vitamin D3: 0.68 min, 25-OH Vitamin D2: 0.77 min, IS: 1.57 min

Test Data

Linearity:	4.6 - 500 µg/l (D2)
	3.7 - 500 µg/l (D3)
Recovery:	99 - 104 %
Lower detection limit:	2.8 µg/l (D2)
	2.2 µg/l (D3)
Lower determination limit:	4.6 µg/l (D2)
	3.7 µg/l (D3)
Intraassay precision:	4.3 % (D2)
	4.6 % (D3)
Interassay precision:	5.9 % (D2)
	3.9 % (D3)

UPLC Parameters

Pump:	isocratic pump, flow rate: 0.75 ml/min
Injection volume:	10 µl
Injection interval:	2 min
UV-Detector:	264 nm
HPLC-Thermostat:	40 °C

Sample Preparation

Precipitation:

沉淀

500 µl Precipitant P

↓

1. Add 400 µl sample
2. Add 400 µl Internal Standard IS

↓ mix, centrifuge

Dilution:

稀释

Pipette 200 µl of the supernatant into a Diluting Vial and add 200 µl Diluting Solution D

↓ mix, incubate (20 min, 4° C), centrifuge

UPLC® Analysis:

UPLC分析

Inject 10 µl of the supernatant

RECIPE®

HPLC 完整试剂盒

治疗药物监测

ClinRep® TDM
for Therapeutic Drug Monitoring

抗心律失常药物

血浆中的胺碘酮

平喘药物

血浆中的茶碱、可可碱和咖啡因

抗癫痫药物

血清中的抗癫痫药

血浆中的拉莫三嗪和硫塞嗪

免疫抑制剂

血浆中的霉酚酸

精神药品

血浆/血清中的非典型抗精神药

RECIPE®

血浆中的胺碘酮

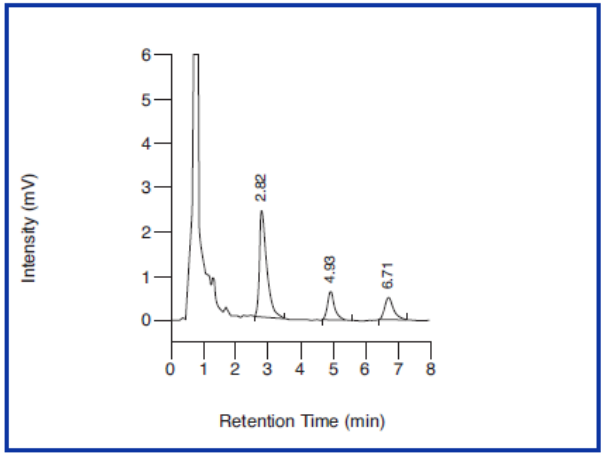
Amiodarone in Plasma

抗心律失常药物
Antiarrhythmics

心律失常是全世界发病率和死亡率的主要原因。心律失常可通过几种药物进行控制，如抗心律失常药物胺碘酮可帮助稳定心脏的正常节律。胺碘酮的吸收率和生物利用度低而且变化极大。因此使用该药物需对药物剂量的调整进行密切监测。RECIPE ClinRep®Complete Kit完整试剂盒可快速、灵敏和可靠的对胺碘酮及其主要代谢物脱乙基乙胺碘呋酮进行检测， 同时样品制备包含了一个简单的沉淀步骤。

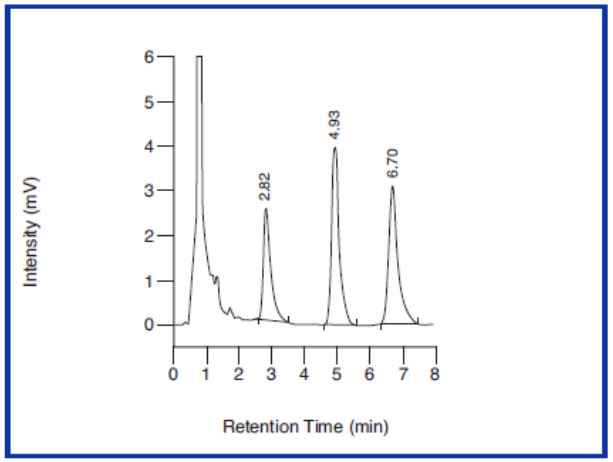
Amiodarone in Plasma

ClinChek® Serum Control, Level I



IS: 2.82 min, Desethylamiodarone: 4.93 min,
Amiodarone: 6.71 min

ClinChek® Serum Control, Level II



IS: 2.82 min, Desethylamiodarone: 4.93 min,
Amiodarone: 6.70 min

Test Data

Linearity:	0.1 - 10 µg/ml
Recovery:	95 - 105 %
Lower detection limit:	0.07 µg/ml
Lower determination limit:	0.1 µg/ml
Intraassay precision:	Amiodarone: 2.1 %, Desethylamiod.: 2.5 %
Interassay precision:	Amiodarone: 4.0 %, Desethylamiod.: 4.2 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 0.8 ml/min
Injection volume:	20 µl
Injection interval:	8 min
UV/VIS-Detector:	255 nm
HPLC-Thermostat:	30 °C

Sample Preparation

Extraction:

萃取

100 µl sample	150 µl Precipitant P (contains Internal Standard IS)

centrifuge

HPLC Analysis:

HPLC分析

Inject 20 µl of the supernatant

RECIPE®

血浆中的茶碱、可可碱和咖啡因

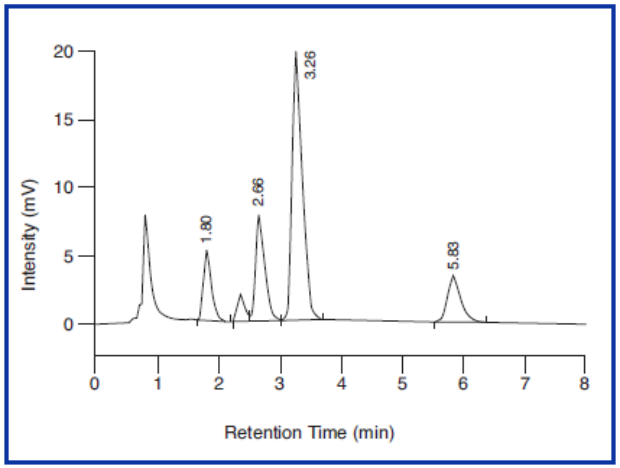
Theophylline, Theobromine and Caffeine in Plasma

平喘药物
Antiasthmatics

茶碱、可可碱和咖啡因被统称为甲基黄嘌呤类药物，被用于控制支气管哮喘疾病。甲基黄嘌呤可对支气管平滑肌产生松弛作用，从而帮助开通狭窄的气道(支气管扩张剂)。药物的吸收和代谢可能受多种因素的影响，包括与其他药物共同作用(几种抗癫痫药物AEDs). 因此，血浆水平的监测对于确保治疗中药物剂量应用没有毒性显得尤为重要。 RECIPE ClinRep® Complete Kit完整试剂盒具有样品制备简单快速，分析成本低以及检测结果可靠的特点。

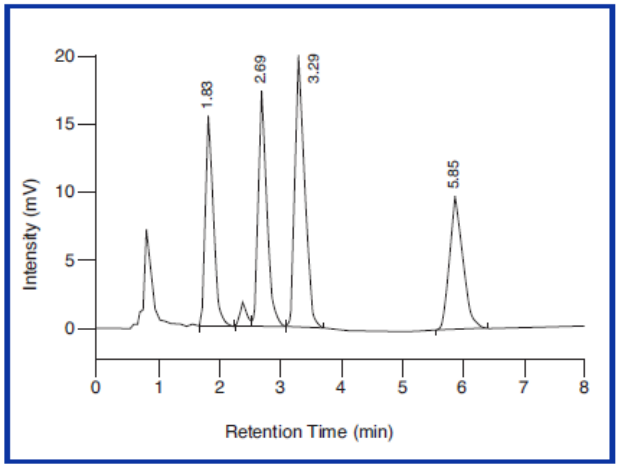
Theophylline, Theobromine and Caffeine in Plasma

ClinChek® Plasma Control, Level I



Theobromine: 1.80 min, Theophylline: 2.66 min,
IS: 3.26 min, Caffeine: 5.83 min

ClinChek® Plasma Control, Level II



Theobromine: 1.83 min, Theophylline: 2.69 min,
IS: 3.29 min, Caffeine: 5.85 min

Test Data

Linearity:	1.3 - 50 mg/l
Recovery:	approx. 70 %
Lower detection limit:	Theophylline: 0.8 mg/l
	Theobromine: 0.6 mg/l
	Caffeine: 0.6 mg/l
Lower determination limit:	Theophylline: 1.7 mg/l
	Theobromine: 1.3 mg/l
	Caffeine: 1.4 mg/l
Intraassay precision:	2.5 %
Interassay precision:	1.7 %

HPLC Parameters

Pump:	isocratic pump,
	flow rate: 1.5 ml/min
Injection volume:	20 µl
Injection interval:	8 min
UV/VIS-Detector:	273 nm
HPLC-Thermostat:	37 °C

Sample Preparation

Extraction:

萃取

100 µl plasma	150 µl Precipitant P (contains Internal Standard IS)

↓ centrifuge

Dilution:

稀释

50 µl supernatant	250 µl Diluting Solution D

↓

HPLC Analysis:

HPLC分析

Inject 20 µl of the diluted supernatant

RECIPE®

血清中的抗癫痫药

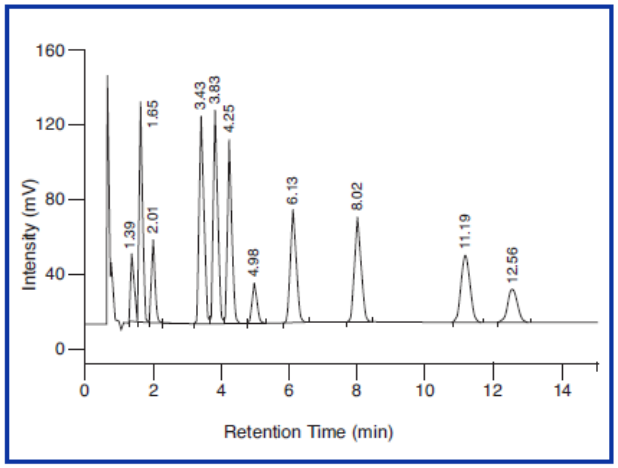
Antiepileptics in Serum

抗癫痫药物
Antiepileptic Drugs

抗癫痫药物(AED)是癫痫治疗前后的中流砥柱。通过药物治疗可使患者在日常生活中无癫痫发作。根据不同类型的癫痫，具有不同活性机理的抗癫痫药物可被用于控制该疾病。对于监测血浆中的AED， ClinRep® Complete Kit完整试剂盒可在15分钟内同时分析监测12种目标物。由于使用了一种有效地样品净化手段(样品小瓶填充了一种特殊的盐混合物以获得最佳分析物萃取效果)，为色谱法提供了高纯度的洗脱物质。

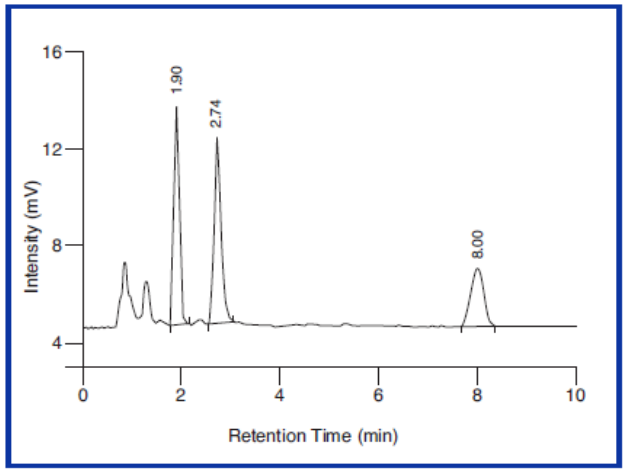
Antiepileptics in Serum

ClinChek® Serum Control, Level II, recorded at 205 nm:



PEMA: 1.39 min, Ethosuximide: 1.65 min, Primidone: 2.01 min, 10-Hydroxy-carbamazepine: 3.43 min, Phenobarbital: 3.83 min, N-Desmethylmethsuximide: 4.25 min, Carbamazepine-epoxide: 4.98 min, Oxcarbazepine: 6.13 min, IS: 8.02 min, Phenytoin: 11.19 min, Carbamazepine: 12.56 min

ClinChek® Serum Control, Level II, recorded at 265 nm:



Sulthiame: 1.90 min, Lamotrigine: 2.74 min, IS: 8.00 min

Test Data

Linearity:	Lamotrig., Sulthiame: 0.5 - 50 µg/ml Other Antiepileptics: 0.3 - 300 µg/ml
Recovery:	95 - 105 %
Lower detection limit:	Lamotrig., Sulthiame: 0.2 µg/ml Other Antiepileptics: 0.1 µg/ml
Lower determination limit:	Lamotrig., Sulthiame: 0.5 µg/ml Other Antiepileptics: 0.3 µg/ml
Intraassay precision:	2.3 %
Interassay precision:	2.8 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	10 µl
Injection interval:	15 min
UV/VIS-Detector:	Lamotrig., Sulthiame: 265 nm Other Antiepileptics: 205 nm
HPLC-Thermostat:	55 °C

Sample Preparation

萃取

Extraction:

100 µl sample	150 µl Precipitant P (contains Internal Standard IS)

↓ centrifuge

稀释

Dilution:

100 µl supernatant	100 µl Diluting Solution D

↓

HPLC分析

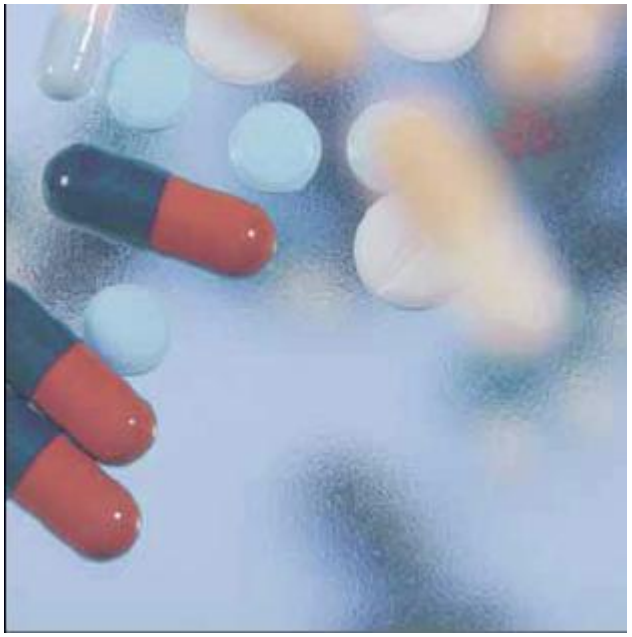
HPLC Analysis:

Inject 10 µl of the diluted supernatant

RECIPE®

血清中的拉莫三嗪和硫塞嗪

Lamotrigine and Sulthiame in Plasma

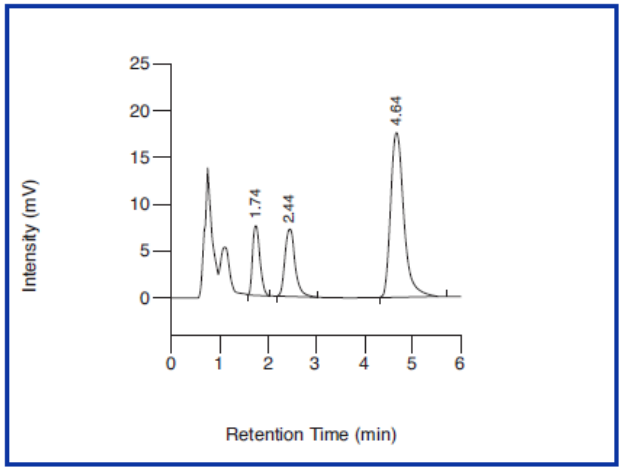


抗癫痫药物
Antiepileptic Drugs

拉莫三嗪和硫塞嗪是可控制多种类型癫痫病况的抗癫痫药物。 该ClinRep® Complete Kit完整试剂盒被特殊设计用来检测血浆中的拉莫三嗪和硫塞嗪。它具有很短的分析时间(7分钟)和优异的测试精度。

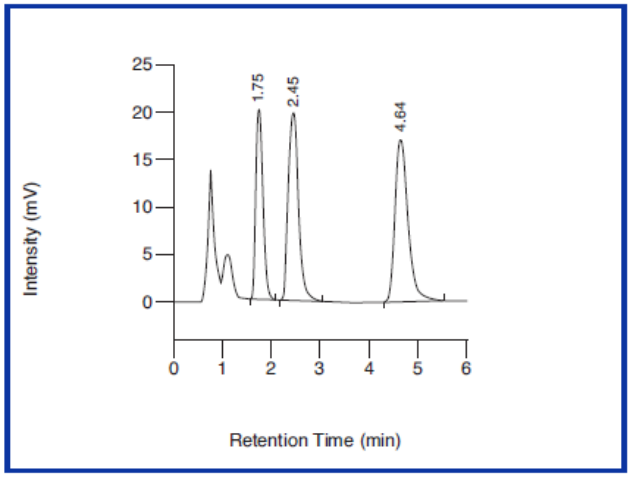
Lamotrigine and Sulthiame in Plasma

ClinChek® Plasma Control, Level I:



Sulthiame: 1.74 min, Lamotrigine: 2.44 min, IS: 4.64 min

ClinChek® Plasma Control, Level II:



Sulthiame: 1.75 min, Lamotrigine: 2.45 min, IS: 4.64 min

Test Data

Linearity:	0.5 - 50 µg/ml
Recovery:	95 - 105 %
Lower detection limit:	0.2 µg/ml
Lower determination limit:	0.5 µg/ml
Intraassay precision:	2.4 %
Interassay precision:	2.6 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	20 µl
Injection interval:	7 min*
UV/VIS-Detector:	265 nm
HPLC-Thermostat:	55 °C

* In case the sample contains carbamazepine, the run time must be extended to 15 min.

Sample Preparation

Extraction:

萃取

100 µl plasma	150 µl Precipitant P (contains Internal Standard IS)

↓ centrifuge

Dilution:

稀释

100 µl supernatant	100 µl Diluting Solution D

HPLC Analysis:

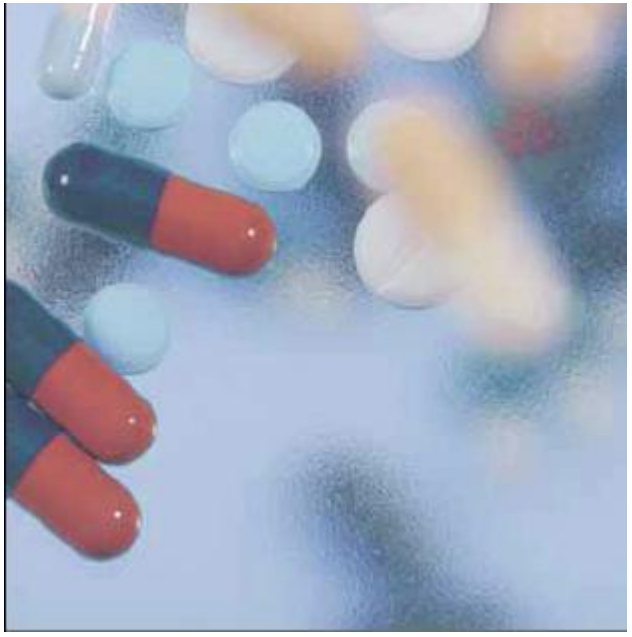
HPLC分析

Inject 20 µl of the diluted supernatant

RECIPE®

血浆中的霉酚酸

Mycophenolic Acid in Plasma

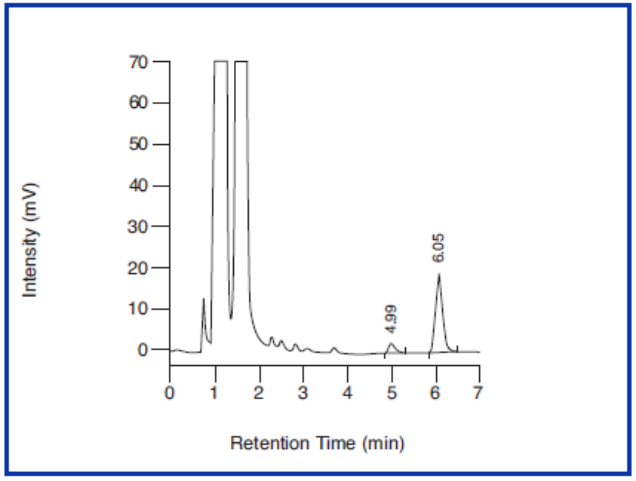


免疫抑制剂
Immunosuppressants

霉酚酸酯(MMF)属于新的免疫抑制药物，常与环孢素A和他克莫司共同使用。作为一个前体药物，MMF在人体内被迅速水解成为其活性成分霉酚酸(MPA)。为达到最佳疗效，如提高药物效率同时降低其毒性，对MMF的使用需要在随后的剂量调整时监测MPA的浓度。为此目的， ClinRep® HPLC Complete Kit完整试剂盒提供了方便快捷的样品制备和欠打可靠的分析方法。对于质量保证，厂方同样提供了校准品和控制品。

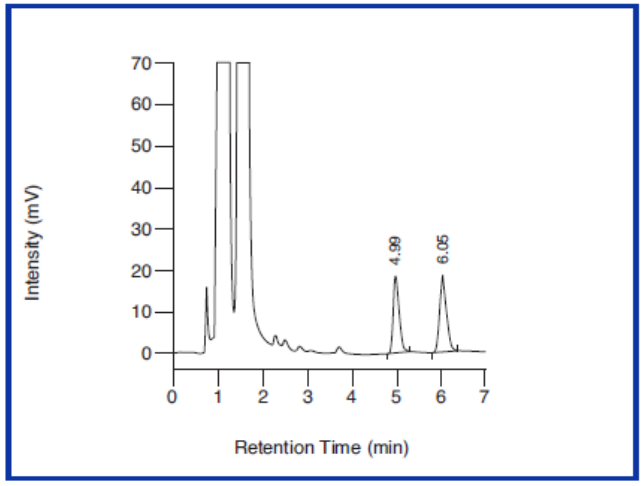
Mycophenolic Acid in Plasma

ClinChek® Plasma Control, Level I:



Mycophenolic acid: 4.99 min, IS: 6.05 min

ClinChek® Plasma Control, Level II:



Mycophenolic acid: 4.99 min, IS: 6.05 min

Test Data

Linearity:	0.1 - 40 mg/l
Recovery:	95 - 105 %
Lower detection limit:	0.06 mg/l
Lower determination limit:	0.1 mg/l
Intraassay precision:	3.3 %
Interassay precision:	4.0 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.2 ml/min
Injection volume:	50 µl
Injection interval:	7 min
UV/VIS-Detector:	215 nm
HPLC-Thermostat:	30 °C

Sample Preparation

Precipitation:

沉淀

100 µl plasma	20 µl Internal Standard IS	200 µl Precipitant P

centrifuge

HPLC Analysis:

HPLC分析

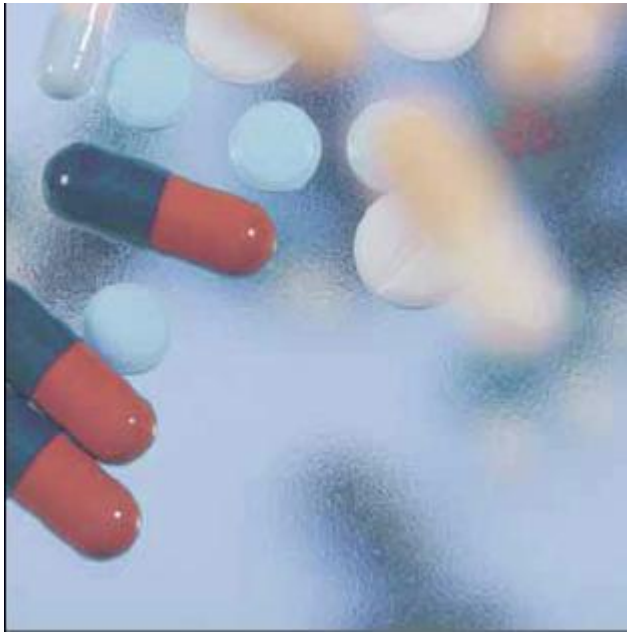
Inject 50 µl of the supernatant

上海仪真分析/孙韬

RECIPE®

血浆/血清中的非典型抗精神药-在线分析

Atypical Neuroleptics in Plasma/Serum – Online Analysis

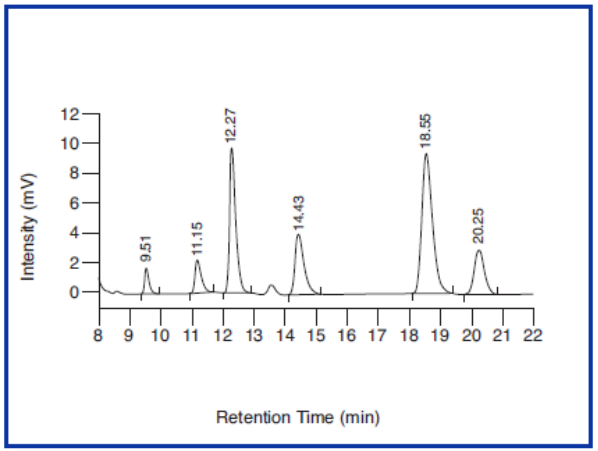


精神药品
Psychoactive Drugs

药物奥氮平， 氯氮平，奎硫平，利培酮和帕利哌酮(=9-OH-利培酮)均属于非典型性“抗精神病药”，并用于治疗精神分裂症。联合用药，吸烟，咖啡因和食物是广泛影响其新陈代谢的因素，并会导致不同及相同个体之间血液药物浓度的大幅变化。为避免过量和严重的副作用，确保最佳的治疗效果，治疗药物监测(TDM)是必需的。
RECIPE完整试剂盒是一套完全自动化的，功能强大的子在线技术，可以实现HPLC 系统直接进样。

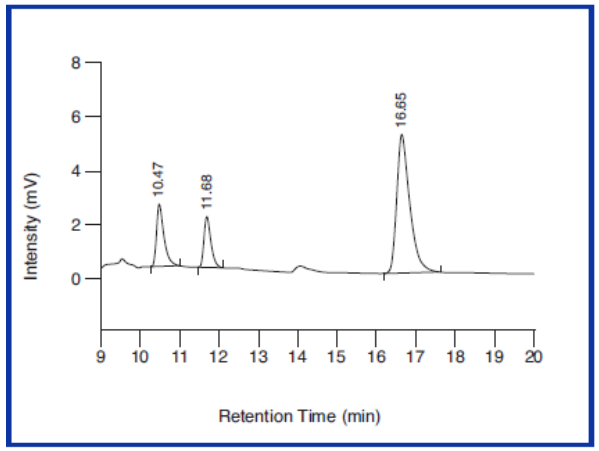
Atypical Neuroleptics in Plasma/Serum – Online Analysis

Chromatogram of the plasma calibrator, order no. 40013
(+ 20 µl Internal Standard IS per ml sample, order no. 40012)



Desmethylolanzapine (D-Olz): 9.51 min, Olanzapine (Olz): 11.15 min, Desmethylclozapine (D-Clz): 12.27 min, Internal Standard IS: 14.43 min, Clozapine (Clz): 18.55 min, Quetiapine (Qtp): 20.25 min

Chromatogram of the plasma calibrator, order no. 40113
(+ 10 µl Internal Standard IS per ml sample, order no. 40012)



Paliperidone (Plp): 10.47 min, Risperidone (Rsp): 11.68 min, Internal Standard IS: 16.65 min

Test Data

Linearity:	Olz / *D-Olz*:
	5 / *10* - 1000 µg/l
	Clz / *D-Clz*:
	6 / *5* - 5000 µg/l
	Qtp: 10 - 2000 µg/l
	Plp, Rsp: 1 - 200 µg/l
Recovery:	100 %
Lower detection limit:	2 µg/l (Olz, Clz, D-Clz),
	4 µg/l (D-Olz, Qtp)
	0.4 µg/l (Plp, Rsp)
Lower determination limit:	5 µg/l (Olz), 6 µg/l (Clz),
	10 µg/l (D-Olz, Qtp),
	4 µg/l (D-Clz)
	1 µg/l (Plp, Rsp)
Intraassay precision:	0.2 - 2 %
Interassay precision:	1 - 6 %

HPLC Parameters

A: Determination of Olz, D-Olz, Clz, D-Clz, Qtp
B: Determination of Plp, Rsp

Isocratic pump 1	
(SPE buffer):	flow rates: 0.5 / 1.0 ml/min
Isocratic pump 2	
(mobile phase):	flow rate: **A:** 1.3 ml/min
	B: 1.0 ml/min
Switching valve:	6-port/3-channel
	(order no. FK1102)
Injection volume:	**A:** 250 µl, **B:** 750 µl
Injection interval:	**A:** 22 min, **B:** 20 min
UV-detector:	**A:** 254 nm, **B:** 280 nm
HPLC-thermostat:	30 °C

Sample Pretreatment

Addition of IS:

加入内标

A: Add 20 µl Internal Standard IS/ml sample
B: Add 10 µl Internal Standard IS/ml sample

centrifuge

HPLC Analysis:

HPLC分析

A: Inject 250 µl
B: Inject 750 µl

HPLC 完整试剂盒

人体生物监测

ClinTox® HBM
for Human Biomonitoring

苯及苯的衍生物

尿液中的邻-甲酚和苯酚

尿液中的马尿酸和甲基马尿酸

尿液中的t,t-己二烯二酸

多环芳烃

尿液中的1-羟基芘

RECIPE®

尿液中的邻-甲酚和苯酚

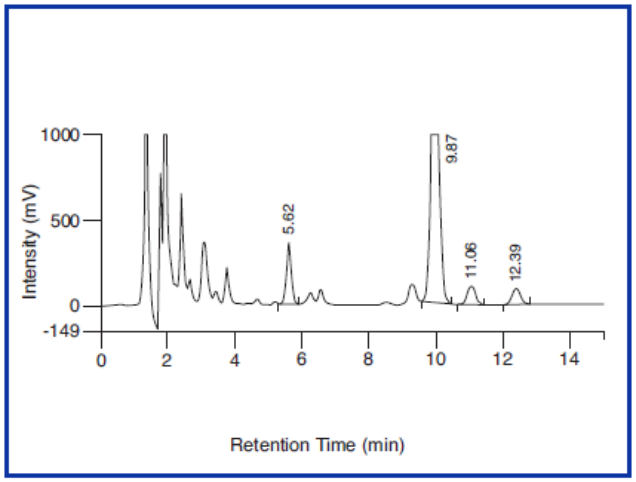
Ortho-Cresol and Phenol in Urine

苯及苯的衍生物
Benzene/Benzene-Derivatives

邻甲酚是甲苯的次要代谢物，常被用于评估甲苯在常用溶剂如胶水，涂料和稀释剂中的暴露程度。相对于甲苯的主要代谢物马尿酸，邻甲酚不是尿液的生理成分，因此反映了污染物的内部暴露。苯酚是苯的主要代谢物，并用于苯及苯酚自身的暴露评估。RECIPE ClinTOX®完整试剂盒提供了很好的分析灵敏度，并确保对所有分析物的生物监测可靠稳定。本试剂盒样品的净化通过固相萃取法实现。

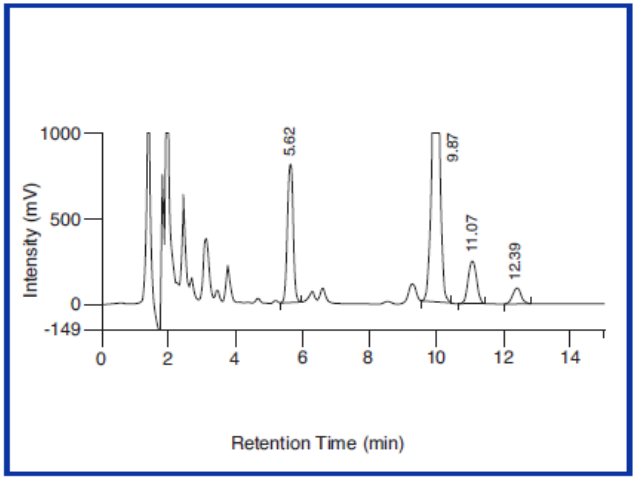
Ortho-Cresol and Phenol in Urine

ClinChek® Urine Control, Level I:



Phenol: 5.62 min, p-Cresol: 9.87 min, o-Cresol: 11.06 min, IS: 12.39 min

ClinChek® Urine Control, Level II:



Phenol: 5.62 min, p-Cresol: 9.87 min, o-Cresol: 11.07 min, IS: 12.39 min

Test Data

Linearity:	o-Cresol: 0.05 - 50 mg/l, Phenol: 0.2 - 50 mg/l
Recovery:	85 - 95 %
Lower detection limit:	o-Cresol: 0.03 mg/l, Phenol: 0.1 mg/l
Lower determination limit:	o-Cresol: 0.05 mg/l, Phenol: 0.2 mg/l
Intraassay precision:	o-Cresol: 2.4 %, Phenol: 3.2 %
Interassay precision:	o-Cresol: 2.8 %, Phenol: 4.8 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	10 - 20 µl
Injection interval:	15 min
Fluorescence detector:	277 nm (exc.), 300 nm (em.)
HPLC-Thermostat:	30 °C

Sample Preparation

Enzymatic treatment:

酶处理

250 µl urine	250 µl Reagent C	50 µl Internal Standard IS	50 µl Reagent D

↓ incubate (37 °C, 2 - 24 h)

Extraction:

萃取

Transfer the whole sample to a conditioned sample preparation column

↓ wash (2 x 2 ml Reagent B)

Elution:

洗脱

Elute with 2 ml Reagent A

↓ collect the eluate

HPLC Analysis:

HPLC分析

Inject 10 - 20 µl

RECIPE®

尿液中的马尿酸和甲基马尿酸

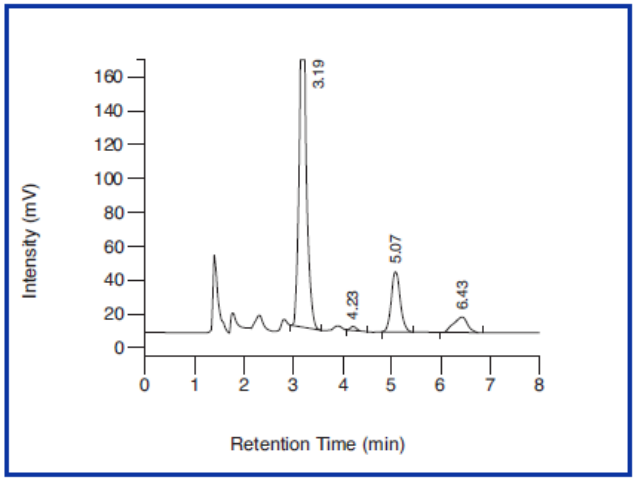
Hippuric Acid and Methylhippuric Acids in Urine

苯及苯的衍生物
Benzene/Benzene-Derivatives

ClinTOX®完整试剂盒专为马尿酸和甲基马尿酸的可靠的生物监测而设计。这些化合物作为甲苯和相应的二甲苯在尿液中的代谢物，可对普染污的暴露水平进行反映。该工具包中的样品制备柱和分析色谱柱也可用于测定尿液中的邻甲酚和苯酚。

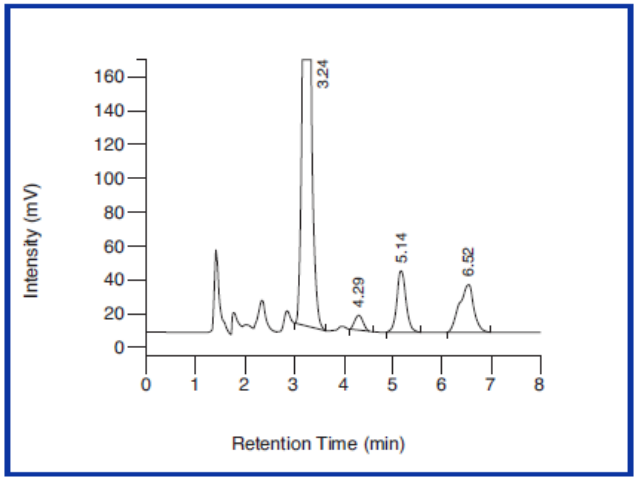
Hippuric Acid and Methylhippuric Acids in Urine

ClinChek® Urine Control, Level I:



Hippuric acid: 3.19 min, o-Methylhippuric acid: 4.23 min,
IS: 5.07 min, m-/p-Methylhippuric acid: 6.43 min

ClinChek® Urine Control, Level II:



Hippuric acid: 3.24 min, o-Methylhippuric acid: 4.29 min,
IS: 5.14 min, m-/p-Methylhippuric acid: 6.52 min

Test Data

Linearity:	Hippuric Acid: 50 - 10000 mg/l, Methylhippuric Acids: 5 - 5000 mg/l
Recovery:	85 - 95 %
Lower detection limit:	Hippuric Acid: 30 mg/l, Methylhip. Acids: 2 mg/l
Lower determination limit:	Hippuric Acid: 50 mg/l, Methylhip. Acids: 4 mg/l
Intraassay precision:	Hippuric Acid: 2.0 %, Methylhip. Acids: 2.1 %
Interassay precision:	Hippuric Acid: 2.3 %, Methylhip. Acids: 3.2 %

HPLC Parameters

Pump:	isocratic pump, flow rate: 1.0 ml/min
Injection volume:	20 µl
Injection interval:	8 min
UV-Detector:	230 nm
HPLC-Thermostat:	30 °C

Sample Preparation

稀释 **Dilution:**

100 µl urine	100 µl Internal Standard IS	2 ml Reagent B

↓

萃取 **Extraction:**

Transfer the whole sample to a conditioned sample preparation column

↓ wash (2 x 2 ml Reagent B)

洗脱 **Elution:**

Elute with 2 ml Reagent A

↓ collect the eluate

HPLC分析 **HPLC Analysis:**

Inject 20 µl

RECIPE®

尿液中的t,t-己二烯二酸

t,t-Muconic Acid in Urine

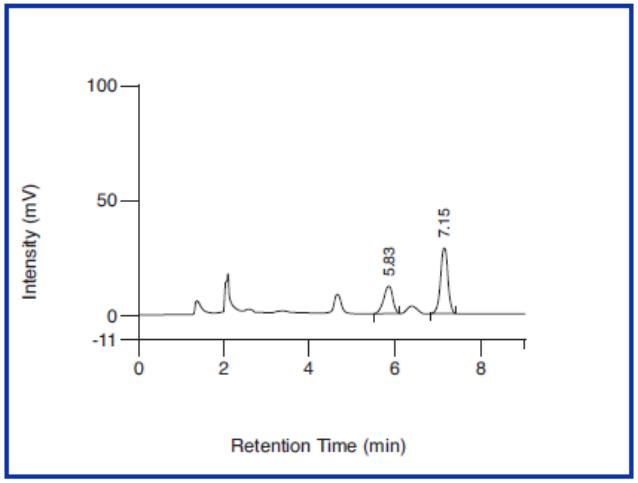
苯及苯的衍生物
Benzene/Benzene-Derivatives

t,t-己二烯二酸是一种苯的次要代谢物，可用于评估职业苯暴露的水平。与苯酚不同， t,t-己二烯二酸不是尿液的生理成分，因此可提供更高的诊断特异性。 ClinTOX®完整试剂盒具有高效灵敏的特点，该法包含高选择性样品制备步骤，等度洗脱分离以及紫外检测。

RECIPE®

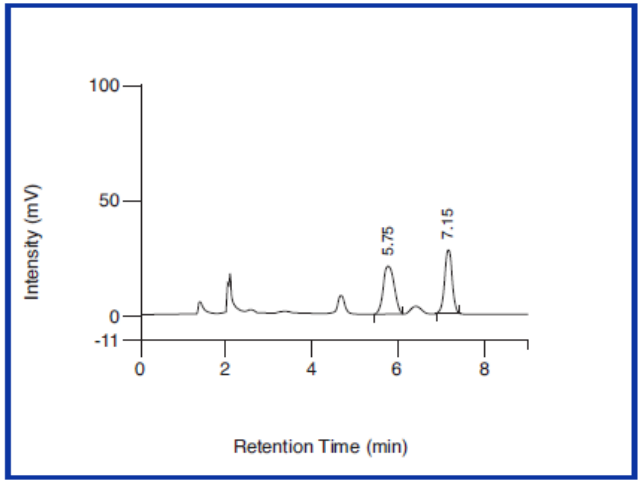
t,t-Muconic Acid in Urine

ClinChek® Urine Control, Level I:



t,t-Muconic acid: 5.83 min, IS: 7.15 min

ClinChek® Urine Control, Level II:



t,t-Muconic acid: 5.75 min, IS: 7.15 min

Test Data

Linearity:	0.24 - 20 mg/l
Recovery:	75 - 80 %
Lower detection limit:	0.07 mg/l
Lower determination limit:	0.24 mg/l
Intraassay precision:	5.9 %
Interassay precision:	5.5 %

HPLC Parameters

Pump:	gradient pump, flow rate: 1.0 ml/min
Injection volume:	50 µl
Injection interval:	18 min
UV-Detector:	264 nm
HPLC-Thermostat:	35 °C

Sample Preparation

稀释

Dilution:

1 ml urine	150 µl Internal Standard IS	1 ml Reagent B

萃取

Extraction:

Transfer the whole sample to a conditioned sample preparation column

洗脱

Elution: wash (2 x 1.5 ml Reagent C)

Elute with 2 x 1.5 ml Reagent D

HPLC分析

HPLC Analysis: collect the eluates

Inject 50 µl

上海仪真分析/孙韬

尿液中1-羟基芘 - 在线分析

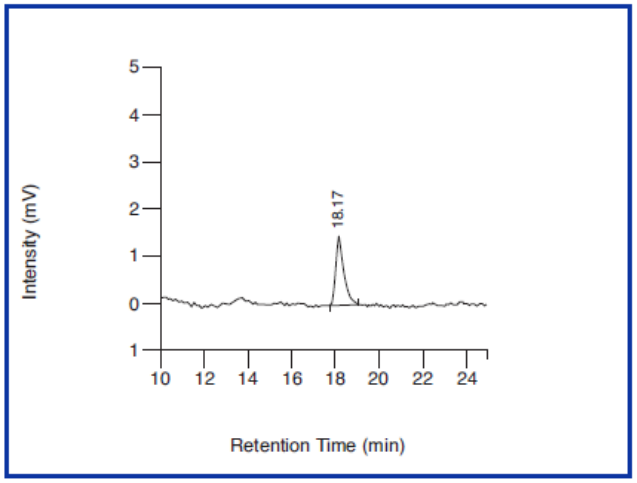
1-Hydroxypyrene in Urine – Online Analysis

多环芳烃
PAH Polycyclic Aromatic Hydrocarbons

尿液中的1-羟基芘可作为一种评估多换环芳香烃(PAH)暴露程度的生物指示剂。多种PAH均为遗传毒性致癌物，通过化石燃料的不完全燃烧形成。RECIPE的ClinTOX®完整试剂盒可用于自动检测尿液中的1-羟基芘，用以评估环境和职业相关的PAH暴露。样品制备过程通过一种具有高选择性SPE柱的在线柱切换设备完成(SPE:在线固相萃取)。

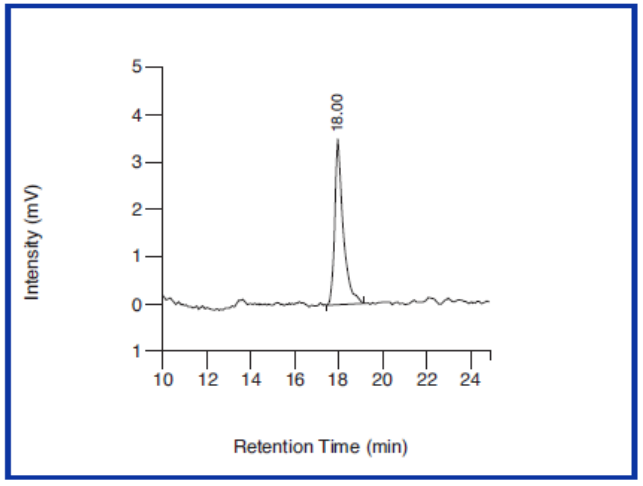
1-Hydroxypyrene in Urine – Online Analysis

ClinChek® Urine Control, Level I:



1-Hydroxypyrene: 18.17 min

ClinChek® Urine Control, Level II:



1-Hydroxypyrene: 18.00 min

Test Data

Linearity:	100 - 24000 ng/l
Recovery:	100 %
Lower detection limit:	20 ng/l
Lower determination limit:	100 ng/l
Intraassay precision:	2.6 %
Interassay precision:	2.9 %

HPLC Parameters

Pump 1:	gradient pump, flow rates: 1.0, 1.5 ml/min
Pump 2:	isocratic pump: 1.0 ml/min
Switching valve:	6-port/3-channel (order no. FK1103)
Injection volume:	250 µl
Injection interval:	36 min
Fluorescence detector:	242 nm (exc.), 388 nm (em.)
HPLC-Thermostat:	30 °C

Sample Pretreatment

Enzymatic hydrolysis:

酶法水解

2 ml urine	1 ml Stabilising Reagent S	10 µl Enzyme Solution

1. incubate (37 °C, 2 - 36 h) ↓ 2. centrifuge

HPLC Analysis:

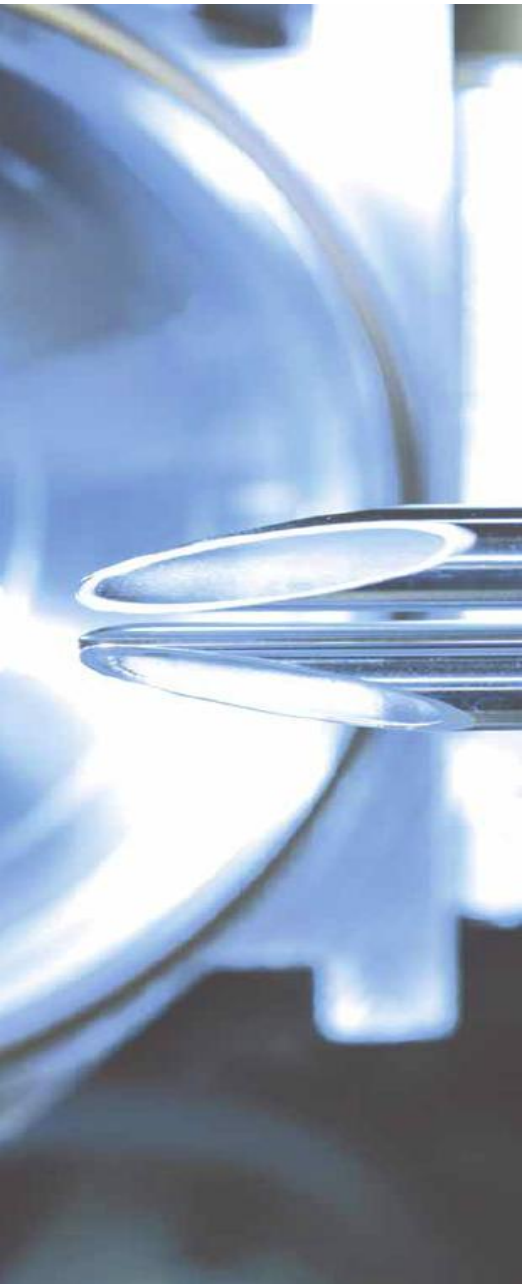
HPLC分析

Inject 250 µl

上海仪真分析/孙韬

RECIPE®

LC-MS/MS方法



- **ClinMass® Complete Kits**
- **ClinMass® Applications**
- **ClinMass® Optimisation Mixes and Internal Standards**

- ClinMass ®LC-MS/MS完整试剂盒可用于与串联质谱联合使 用的可靠标准化分析。与我们的HPLC完整试剂盒类似，所有进行分析所需的组建均包含在内(除初始配件、优化混合物、配件以及基质控品)。除完整试剂盒外， RECIPE也为LC-MS/MS方法提供了ClinMass ®Application Notes应用指南。对于分析测量和质量保证，欧盟CE标志的标准品，基质校准品以及控品也同时可被提供。
- ClinMass ®Optimisation Mixes用于优化质谱参数，以及随后的分析系统检查。
- ClinMass ®Internal Standards用于LC-MS/MS分析内部标准化。

RECIPE®

LC-MS/MS方法

完整试剂盒

ClinMass® Complete Kits

酗酒

尿液中乙基葡萄糖醛酸酐和硫酸乙酯

免疫抑制剂

全血中的环孢霉素A, 他克莫司, 西罗莫司和依维莫司 – 在线分析

精神药品

血清中的苯二氮卓类药物 – 在线分析

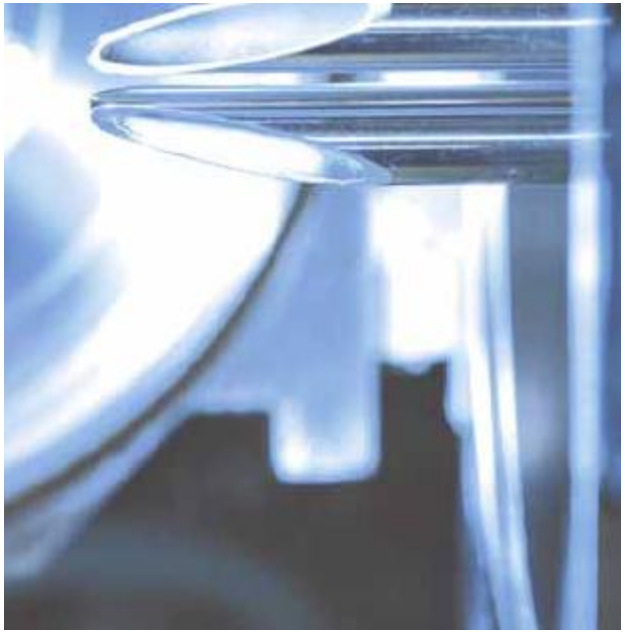
维生素状态

血清/血浆/尿液中的甲基丙二酸

RECIPE®

尿液中的乙基葡萄糖醛酸酐和硫酸乙酯

Ethylglucuronide and Ethylsulfate in Urine

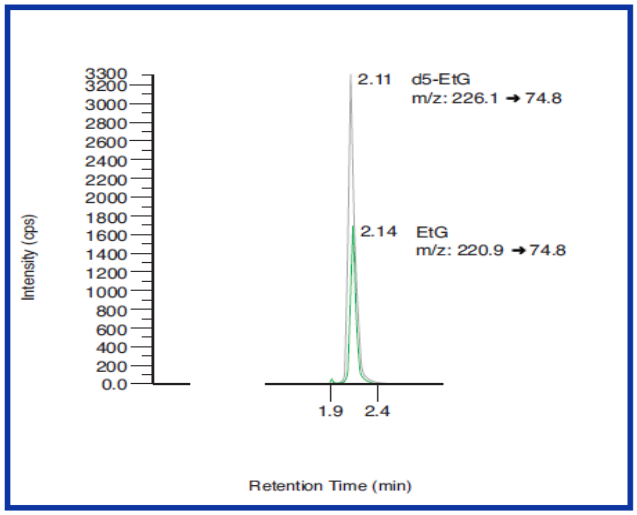


酗酒
Alcoholism

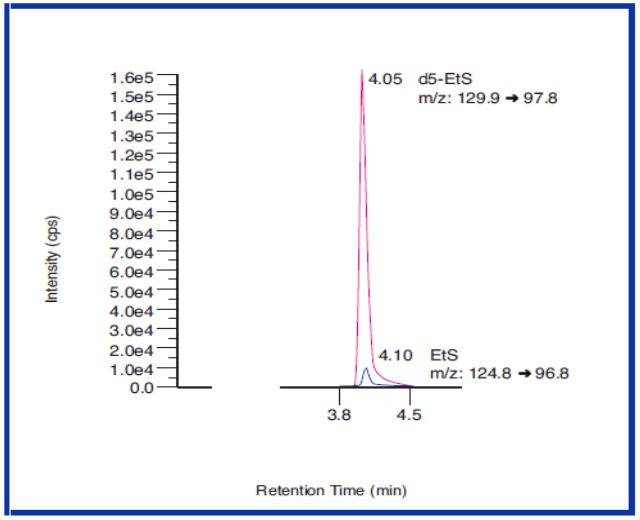
乙基葡萄糖醛酸酐和硫酸乙酯被认为是相对较新的评估究竟消耗的具体参数。在德国，它们被特别用作司机资质的心里医疗诊断的节制工具。RECIPE的ClinMass ®完整试剂盒提供了现今第一个LC-MS/MS系统的商用CE/IVD检测试剂盒。在临床相关领域，同时提供定量分析的多级校准品，同位素标记的内标以及尿液控品。对MS/MS系统可提供优化混合物。符合德国GTFCh准则的ClinMass ®完整试剂盒方法验证可为法医毒理分析提供质量保证。

Ethylglucuronide and Ethylsulfate in Urine

Chromatogram of the ClinChek® Urine Control, Level II (order no. MS8081):



Chromatogram of the ClinChek® Urine Control, Level II (order no. MS8081):



Test Data

Linearity:	EtG: 76.2 - 10000 µg/l
	EtS: 21.8 - 76356 µg/l
Lower detection limit:	EtG: 45.7 µg/l
	EtS: 13.1 µg/l
Lower determination limit:	EtG: 76.2 µg/l
	EtS: 21.8 µg/l
Intraassay precision:	EtG: 5.3 %
	EtS: 4.6 %
Interassay precision:	EtG: 5.4 %
	EtS: 4.9 %

LC-MS/MS Parameters

LC-Parameters

HPLC pump:	isocratic, flow rates: 0.2 ml/min, 0.5 ml/min
Injection volume:	10 µl
Injection interval:	5 min
Column heater:	40 °C

MS-Parameters

Ion sourc:	ESI negative
MS/MS-Mode:	MRM

Sample Preparation

Dilution:

1000 µl Internal Standard IS	50 µl urine (calibrator, control, patient)

稀释

LC-MS/MS Analysis:

Inject 10 µl

LC-MS/MS分析

RECIPE®

全血中的环孢霉素A, 他克莫司, 西罗莫司和依维莫司 – 在线分析

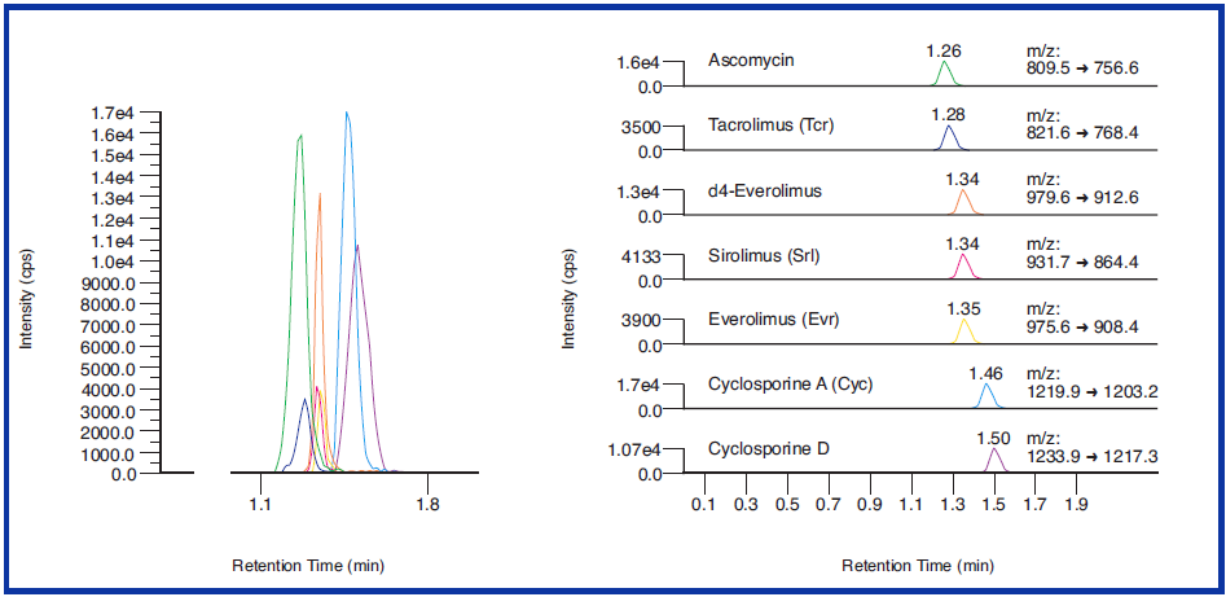
Cyclosporine A, Tacrolimus, Sirolimus and Everolimus in Whole Blood – Online Analysis

免疫抑制剂
Immunosuppressants

ClinMass ®完整试剂盒专为治疗药物检测环孢素A、他克莫司、西罗莫斯和依维莫司而设计。样品制备过程包含一个简单的前处理步骤和一个完全自动化的在线样品分析。在2分钟的样品注射间隔内同时进行样品检测。2种优化混合物被用于MS/MS系统参数优化和分析系统测试运行。一个4级和7级的 ClinCal®全血校准品系列可用于精确的校准与测量。3种不同级别的ClinChek ®全血控品可用于质量控制。2中额外级别控品可用于C-2级别环孢素A的监测。

Cyclosporine A, Tacrolimus, Sirolimus and Everolimus in Whole Blood – Online Analysis

Chromatogram (left) and mass traces (right) of the ClinCal® Whole Blood Calibrator for Immunosuppressants, Level 4, order no. 9933



LC-MS/MS Parameters

LC-Parameters

Pump 1: SPE-Buffer (0.1 / 2.5 ml/min)

Pump 2: Mobile Phase (0.5 / 1.0 ml/min)

Injection volume: 50 µl

Injection interval: 2 min

Switching valve: 6-port/3-channel (order no. FK1102)

Column heater: 60 °C

MS-Parameters

Ion-Source: ESI positive

MS/MS-Mode: MRM

Sample Pretreatment

Precipitation:

200 µl Precipitant P	20 µl Internal Standard IS	100 µl whole blood (calibrator, control, patient)

↓ 1. mix and incubate (ambient temperature)
2. mix and centrifuge

沉淀

On-Line Analysis:

Inject 50 µl of the supernatant

在线分析

Test Data

Linearity (up to):
2000 µg/l (Cyc), 80 µg/l (Tcr, Srl, Evr)

Lower detection limit:
0.011 µg/l (Cyc), 0.004 µg/l (Tcr),
0.073 µg/l (Srl), 0.126 µg/l (Evr)

Lower determination limit:
0.037 µg/l (Cyc), 0.014 µg/l (Tcr),
0.244 µg/l (Srl), 0.420 µg/l (Evr)

Intraassay precision:
2.3 % (Cyc), 4.8 % (Tcr), 4.8 % (Srl), 5.0 % (Evr)

Interassay precision:
7.7 % (Cyc), 3.6 % (Tcr), 4.4 % (Srl), 4.1 % (Evr)

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血清中的苯二氮卓类药物 – 在线分析

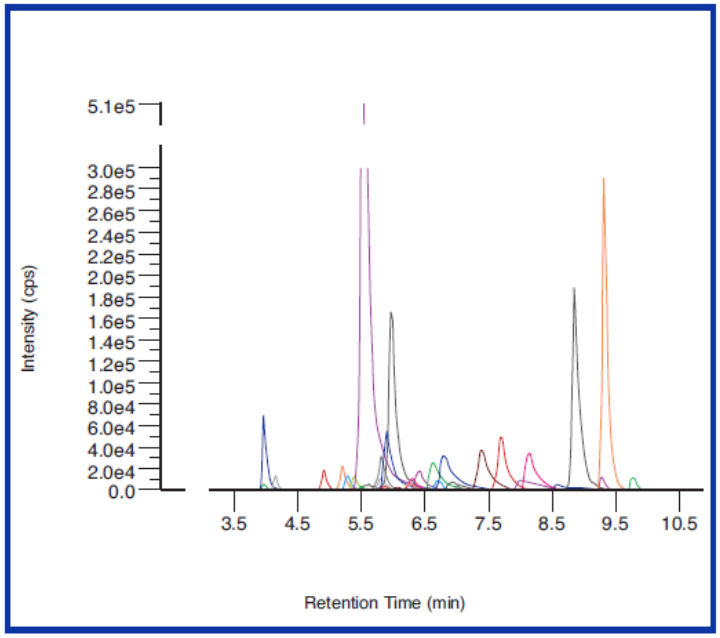
Benzodiazepines in Serum – Online Analysis

精神药品
Psychoactive Drugs

苯二氮卓类药物是一类精神药品，广泛用于焦虑和失眠的处方治疗。长期服用苯二氮卓类药物可额能需要治疗药物检测。因此， ClinMass ®完整试剂盒为33种不同的苯二氮卓类药物及其代谢物提供了常规分析手段。该过程无需手动样品制备，血清样品可直接注射；内标通过自动进样器注射程序添加，同时样品制备通过在线固相萃取实现。整个运行时间为11分钟，包括样品进化，LC-MS/MS分析和柱再生，以上均通过自动柱切换功能实现。

Benzodiazepines in Serum – Online Analysis

Chromatogram of the ClinCal® Serum Calibrator, Level 1 (order no. MS6013)



7-Aminoclonazepam	3.96	Alprazolam	6.21
7-Aminonitrazepam	3.96	Oxazepam	6.23
7-Aminoflunitrazepam	4.13	Desalkylflurazepam	6.54
Zaleplon	4.86	Zolpidem	6.56
Demoxepam	5.12	Temazepam	6.64
Bromazepam	5.27	α-OH-Midazolam	6.81
Desmethylflunitrazepam	5.27	Lormetazepam	6.84
Norclobazam	5.43	Chlordiazepoxide	7.21
α-OH-Triazolam	5.44	Nordiazepam	7.51
Clonazepam	5.59	Midazolam	7.93
Flunitrazepam	5.64	Diazepam	7.98
Nitrazepam	5.66	Flurazepam	8.55
α-OH-Alprazolam	5.75	Trazodone	8.74
Estazolam	5.81	Tetrazepam	9.19
Clobazam	5.86	Prazepam	9.23
Triazolam	6.01	Medazepam	9.67
Lorazepam	6.13		

Test Data

Test data are available on request.

LC-MS/MS Parameters

LC-Parameters

Isocratic HPLC pump:	SPE Buffer (0.1 / 1.5 / 5.0 ml/min)
Binary HPLC pump:	Mobile Phases A/B (0.7 ml/min)
Injection volume:	20 µl
Injection interval:	11 min
Switching valve:	6-port/3-channel (order no. FK1103)
Column heater:	30 °C

MS-Parameters

Ion-Source:	Heated Nebulizer (APcI), positive
MS/MS mode:	MRM

On-Line Analysis

Injection of 10 µl sample +
10 µl Internal Standard IS*

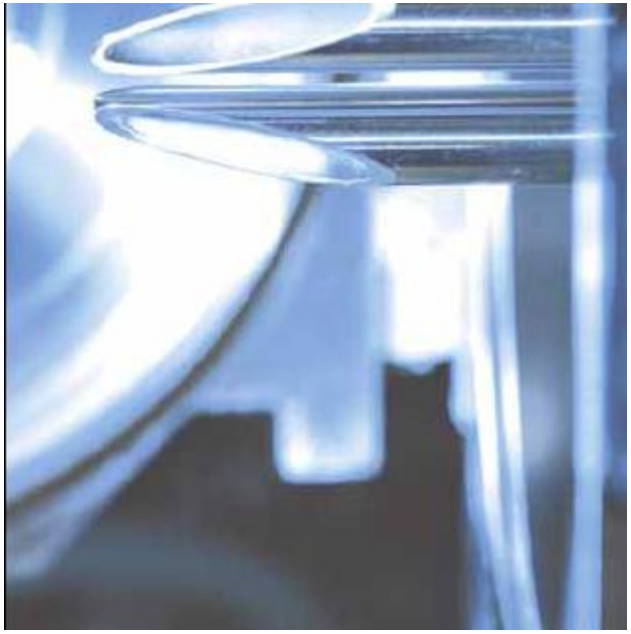
*contains 20 isotope labeled compounds

上海仪真分析/孙韬

RECIPE®

血清/血浆/尿液中的甲基丙二酸

Methylmalonic Acid in Serum/Plasma/Urine

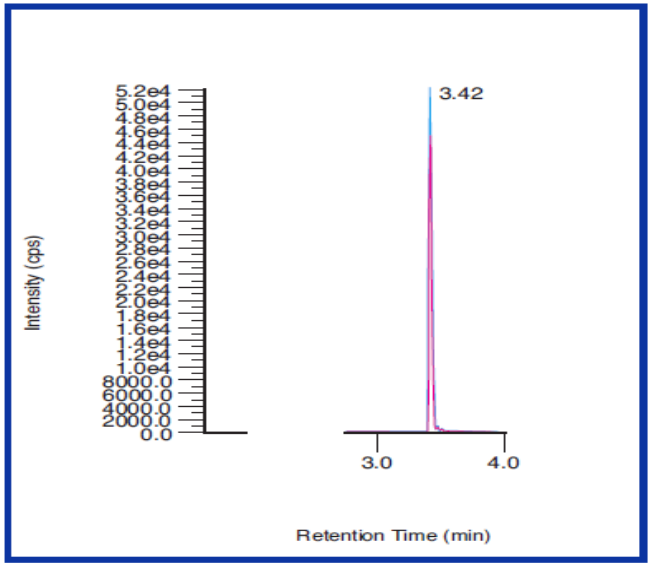


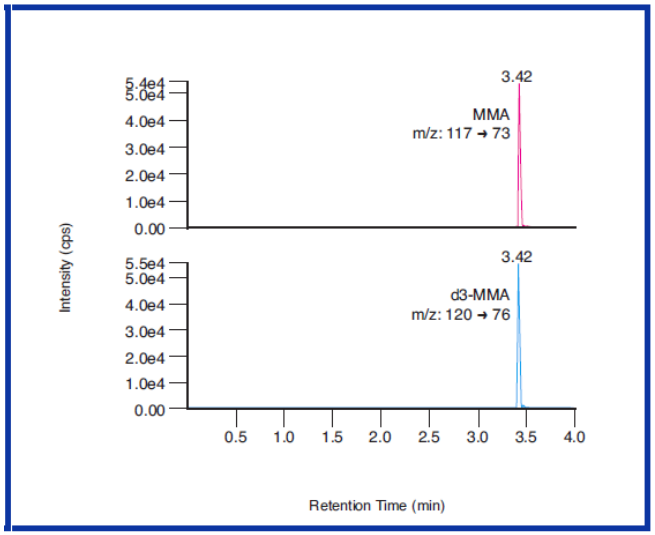
维生素状态
Vitamin Status

甲基丙二酸(MMA)是一种用于功能性维生素B12缺乏症诊断的灵敏生物标志物。MMA的检测通常使用血清，除了对肾功能不全者使用尿液检测。根据样品可用性情况，血浆有时可作为血清的替代品进行样品分析。对于常规分析， ClinMass ® 完整试剂盒在4分钟的样品注射间隔内提供了一种可靠快速的MMA分析手段。样品制备过程需要一步简单的基质沉淀。 ClinMass ®优化混合物可用于串联质谱的优化以及分析系统的测试运行。ClinCal®4级血清校准品系列和ClinChek®血清控品可放表有效的用于所有三种样品基质的校准和质量控制。

Methylmalonic Acid in Serum/Plasma/Urine

Chromatogram of the ClinCal® Serum Calibrator, Level 2





Test Data

Linearity (up to):	Serum, Plasma: 3388 nmol/l
	Urine: 71148 nmol/l
Lower detection limit:	Serum, Plasma: 9.30 nmol/l
	Urine: 95.3 nmol/l
Lower determination limit:	Serum, Plasma: 33.9 nmol/l
	Urine: 711 nmol/l
Intraassay precision:	2.9 %
Interassay precision:	3.1 %

LC-MS/MS Parameters

LC-Parameters

Gradient pump:	Mobile Phase A / B (0.1 - 1.4 ml/min)
Injection volume:	10 µl
Injection interval:	4 min
Column heater:	30 °C

MS-Parameters

Ion-Source:	ESI negative
MS/MS-Mode:	MRM

Sample Preparation

Precipitation / Addition of IS:

400 µl P Precipitant (contains internal standard)	100 µl sample* (calibrator, control, patient)

沉淀/加入内标

LC-MS/MS Analysis: ↓ mix and centrifuge

LC-MS/MS分析

Inject 10 µl of the supernatant

*Urines are diluted (50 µl urine + 1000 µl Diluting Solution D)

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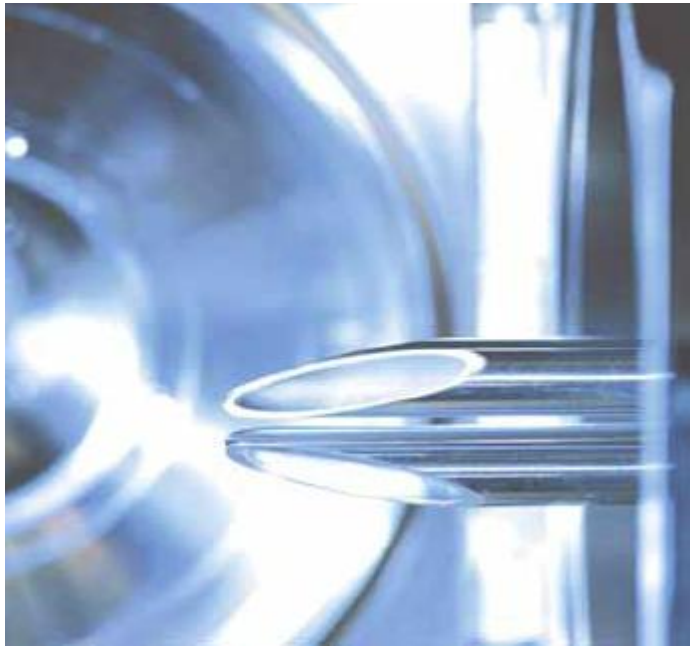
LC-MS/MS方法



方法应用

ClinMass® Applications

代谢疾病

血浆中的同型半胱氨酸

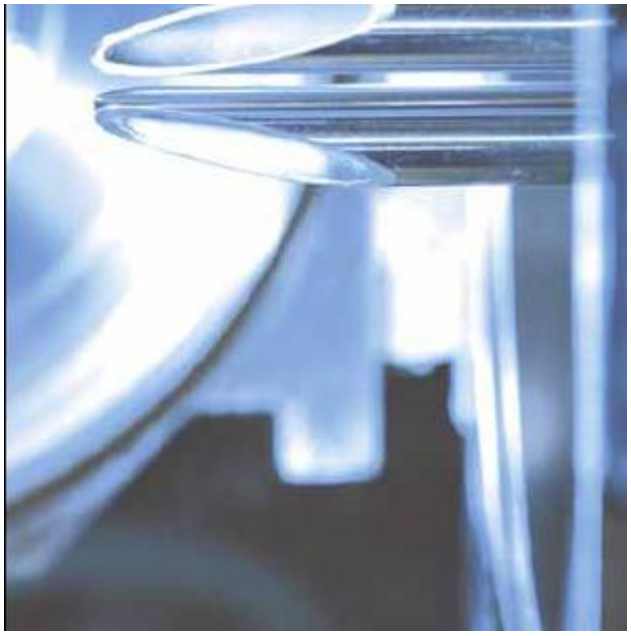
尼古丁和代谢物

尿液中的尼古丁和代谢物

RECIPE®

血浆中的同型半胱氨酸

Homocycsteine in Plasma

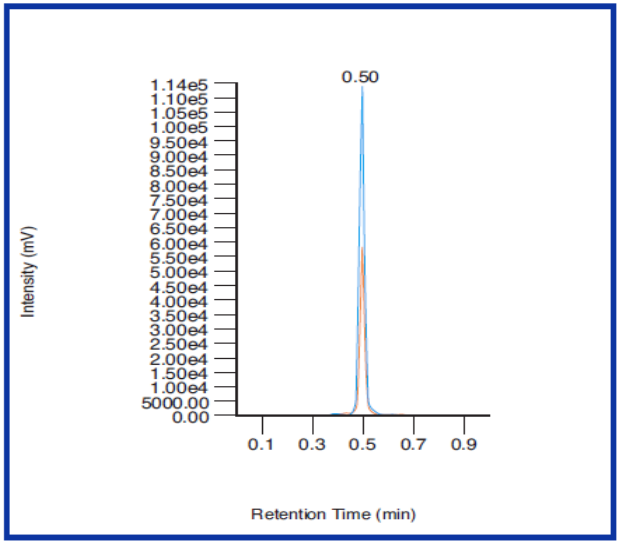


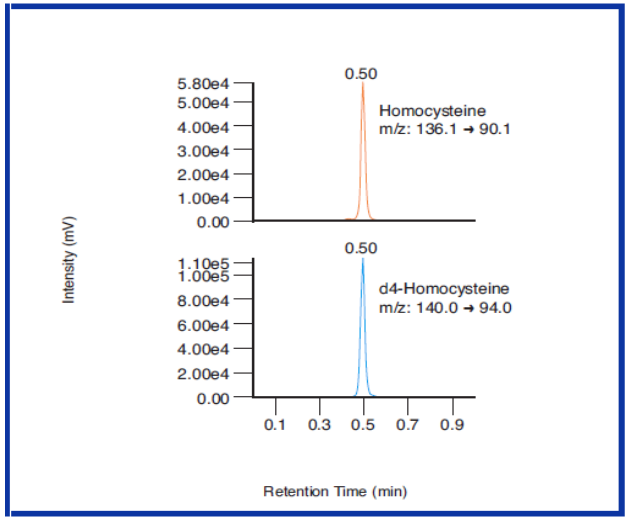
代谢疾病
Metabolic Diseases

同型半光氨酸是导致血管疾病的一个重要风险因素。同型半光氨酸水平的升高已被证明与增加冠状动脉心脏疾病的风险和中风的可能性有很大关系。 ClinMass ®应用方法是一种使用LC-MS/MS系统对总血浆中的同型半光氨酸进行定量的有效方法。经过一个方便快捷的两步样品制备过程(还原，以及蛋白质基质沉淀)，样品可在2分钟的注射间隔内，通过LC-MS/MS系统被快速分析。对于校准和测量，RECIPE提供了一个4级校准品系列和同位素标定的内标。对于质量控制，厂方提供了两种不同水平的血浆控品。

Homocycsteine in Plasma

Chromatogram of the ClinChek® Plasma Control for Homocysteine, Level I





Test Data

Linearity:	0.6 - 92 µmol/l
Lower detection limit:	0.2 µmol/l
Lower determination limit:	0.6 µmol/l
Intraassay precision:	4.2 %
Interassay precision:	4.4 %

LC-MS/MS Parameters

LC-Parameters

Pump:	HPLC, flow rate 0.7 ml/min, acetonitrile / water
Injection volume:	1 µl
Injection interval:	2 min
Analytical column:	Supelcosil LC-CN

MS-Parameters

MS/MS-System:	Applied Biosystems API 3000
Ion-Source:	ESI positive

Sample Preparation

Reduction:

还原

20 µl plasma (+ 20 µl internal standard)	20 µl reduction reagent*

Precipitation: ↓ incubate (RT, 15 min)

沉淀

100 µl precipitation reagent**

↓ 1. incubate (4 °C, 10 min) 2. centrifuge

HPLC Analysis:

HPLC分析

Inject 1 µl of the supernatant

* reduction reagent: 1,4-dithiothreitol

** precipitation reagent: acetonitrile

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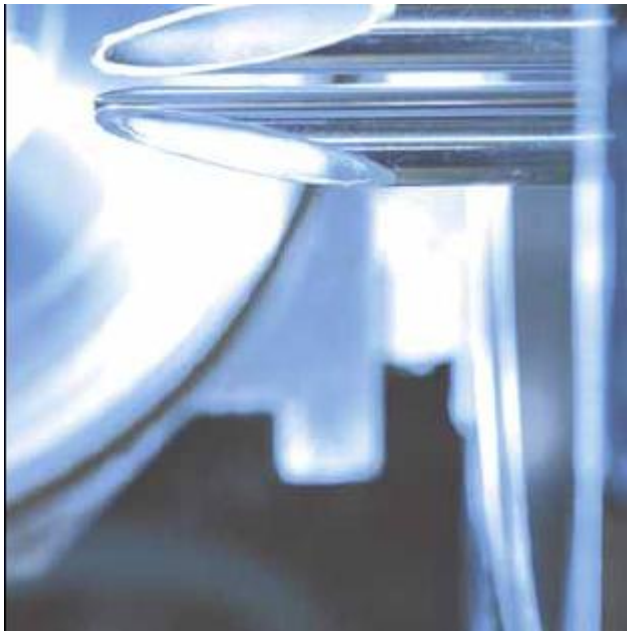
尿液中的尼古丁和代谢物

Nicotine and –Metabolites in Urine

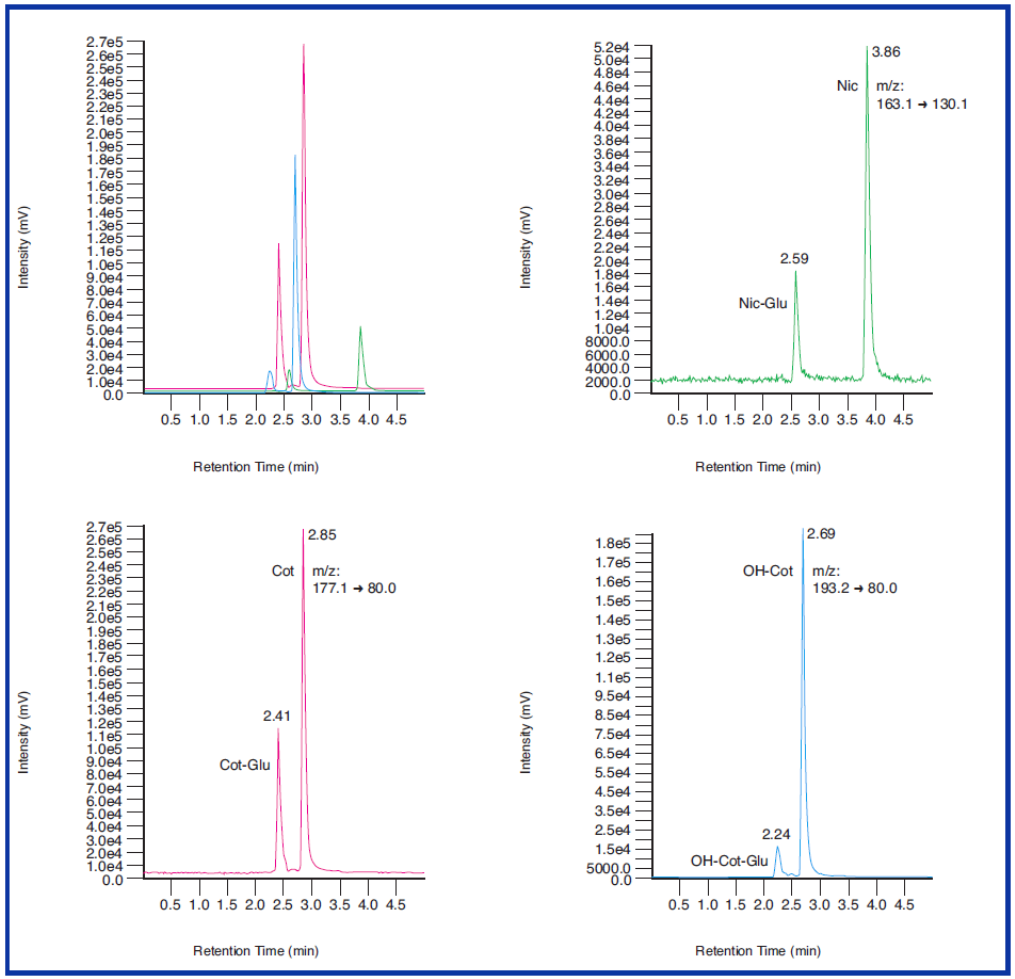


尼古丁和代谢物
Nicotine and –Metabolites

吸烟是一个公认的产生呼吸道癌症和心脑血管疾病的风险因素。对尿液中的尼古丁及其嗲写产物的生物监测可被用来评估或者控制环境中的烟草烟雾的暴露。因此，ClinMass ®应用方法使用串联质谱对尿液中的尼古丁及五个主要代谢产物进行有效地定量检测。对于校准和测量，RECIPE提供了一个7级尿液校准品系列以及同位素标记的内标。对于质量控制，厂方提供了三种不同水平的尿液控品。

Nicotine and –Metabolites in Urine

Chromatogram and mass traces of the ClinCal® Urine Calibrator for Nicotine and -Metabolites, Level 4, order no. MS3013



Test Data

Linearity:	up to 61.6 µmol/l (all analytes)
Lower detection limit (µmol/l):	0.11 (Nic), 0.02 (Cot), 0.01 (OH-Cot), 0.17 (Nic-Glu), 0.03 (Cot-Glu, OH-Cot-Glu)
Lower determination limit (µmol/l):	0.19 (Nic), 0.04 (Cot), 0.01 (OH-Cot), 0.28 (Nic-Glu), 0.04 (Cot-Glu), 0.05 (OH-Cot-Glu)
Intraassay precision:	1 - 9 %
Interassay precision:	3 - 9 %

Abbreviations:
Nic: Nicotine, Cot: Cotinine, Nic-Glu: Nicotine glucuronide, Cot-Glu: Cotinine glucuronide, OH-Cot: OH-Cotinine, OH-Cot-Glu: OH-Cotinine glucuronide

LC-MS/MS Parameters

LC-Parameters

Isocratic HPLC pump 1:	HPLC, flow rate 0.5 ml/min, ammonia acetate / water / methanol
Isocratic HPLC pump 2:	HPLC, flow rate 0.5 ml/min, methanol
Injection volume:	1 µl
Injection interval:	6 min
Analytical column:	ReproSil-Pur Basic C18

MS-Parameters

MS/MS-System:	Applied Biosystems API 3000
Ion-Source:	Heated Nebulizer, APCI positive

Sample Preparation

Addition of IS:

100 µl urine	25 µl Internal Standard IS

加入内标

mix and centrifuge

HPLC Analysis:

Inject 1 µl of the supernatant

HPLC分析

上海仪真分析/孙韬

RECIPE®

Esensing

Thank you for your attention!

Questions?

欢迎提问,请多指正.