



2010/2011 Clinical HPLC and Toxicology

BIO-RAD

Bio-Rad
Laboratories

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Clinical
Diagnostics Group

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BIO-RAD

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At Bio-Rad, it is a priority to provide laboratorians with the appropriate resources for speciality testing, so that assays can be completed with the greatest accuracy and efficiency.

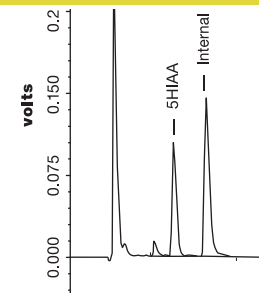
Bio-Rad offers the convenience of ready-to-use kits for the analysis of biogenic amines, homocysteine, vitamins, bone markers and alcohol abuse markers as well as for therapeutic drug monitoring and drug screening. These high performance liquid chromatography kits couple convenience with specificity, sensitivity and reliability for routine operation in the clinical laboratory.





Clinical HPLC

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Biogenic Amines

URINARY CATECHOLAMINES BY HPLC (REVERSED PHASE)

Manual method and automated method on Gilson ASPEC™

This HPLC test is designed for the quantitative determination of free catecholamines (epinephrine, norepinephrine, dopamine) in urine, for the diagnosis of pheochromocytoma. In addition, this application is easily compatible with Bio-Rad's Urinary Metanephrines by HPLC assay due to use of the same analytical column and mobile phase.

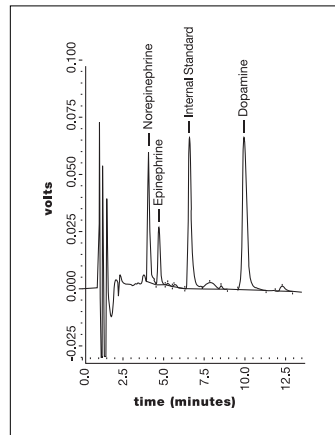
- Use of specimen preparation columns eliminates interfering substances
- Quick and easy specimen preparation (no pH adjustment)
- Automated application on Gilson ASPEC™ XL or GX-271 available
 - Reduced hands-on time
 - Overnight processing option
 - High specimen throughput



Urinary Catecholamines by HPLC

Test characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 14 minutes
- Sample volume: 1 ml urine (manual method)
250 µL urine (automated method)
- Flow rate: 0.5 ml/min
- Electrochemical detection: 550 mV



Chromatogram of the Urinary Catecholamines Test Mix

HPLC Automation

Bio-Rad has developed automated protocols for many of our HPLC kits by making use of the Gilson ASPEC™ XL or GX-271. Each protocol is validated so you can have confidence in the results. These methods help reduce laboratory costs by dramatically decreasing labor hours. Contact your local Bio-Rad representative for more information about the Gilson ASPEC™ methods.

Ordering Information • CE Marked

Reagent Kit

195-5841N	Urinary Catecholamines by HPLC Reagent Kit	100 tests
195-5700	Urinary Catecholamines by HPLC Reagent Kit, Automated Method	300 tests

Additionally Required Items

195-6088	Analytical Cartridge (incl. 2 Micro-Guard™ Cartridges)	500 injections
195-5925	Analytical Cartridge Holder	1 unit
195-5030	Micro-Guard™ Cartridge Holder	1 unit
195-4088	Capillary Connection Set	1 unit
195-5976	Application CD ROM for Biogenic Amines on ASPEC™	1 unit

Separately Available Items

195-5843	Disposable Columns	50 columns
195-5852	Disposable Columns, Automated Method	100 columns
195-5844	Test Mix	1 x 1 mL
195-5846	Urine Calibrator (mono-level)	1 x 25 mL
195-6090	Mobile Phase	1 x 2400 mL
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package
376/377	Lyphochek® Quantitative Urine Control	12 x 10 mL

PLASMA CATECHOLAMINES BY HPLC (REVERSED PHASE)

This kit offers an optimized assay for the quantitative determination of catecholamines in human plasma for the diagnosis of pheochromocytoma.

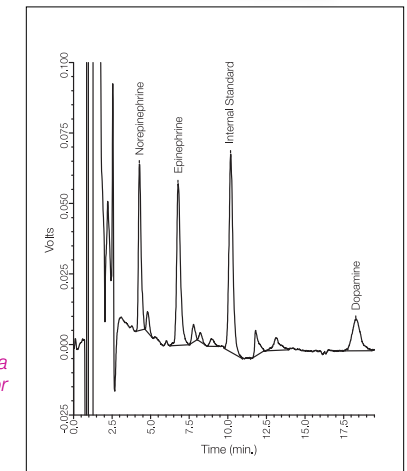
- Simplified sample preparation
- Ready-to-use reagents

Test characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 19 minutes
- Sample volume: 1 mL plasma
- Flow rate: 0.7 mL/min.
- Electrochemical detection: 550 mV



Plasma Catecholamines by HPLC



Chromatogram of the Plasma Catecholamines Calibrator

Ordering Information • CE Marked

Reagent Kit

195-5880	Plasma Catecholamines by HPLC Reagent Kit	100 tests
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Additionally Required Items

195-5886	Analytical Cartridge (includes 2 Micro-Guard™ cartridges)	500 injections
195-5925	Analytical Cartridge Holder	1 unit
195-5030	Micro-Guard™ Cartridge Holder	1 unit
195-4088	Capillary Connecting Set	1 unit

Separately Available Items

195-5884	Disposable Columns	100 columns
195-5885	Mobile Phase	1 x 2500 mL
195-6066M	Calibrator Set (mono-level)	2 x 10 mL
195-5844	Test Mix	1 x 1 mL
195-5889	Elution Vials	100 vials
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package
535	Lyphochek® Endocrine Controls	2 x 6 x 10 mL

URINARY METANEPHRINES BY HPLC (REVERSED PHASE)

Manual method and automated method on Gilson ASPEC™

This HPLC test is designed for the quantitative determination of metanephrine and normetanephrine in urine. These analytes are used in the diagnosis of pheochromocytoma and related neurogenic tumors. In addition, this application is easily compatible with Bio-Rad's Urinary Catecholamines by HPLC assay due to the same analytical column and mobile phase used.

- No manual pH check of sample necessary
- Automated application on Gilson ASPEC™ XL or GX-271 available:
 - Reduced hands-on time
 - Overnight processing option
 - High specimen throughput

Test characteristics:

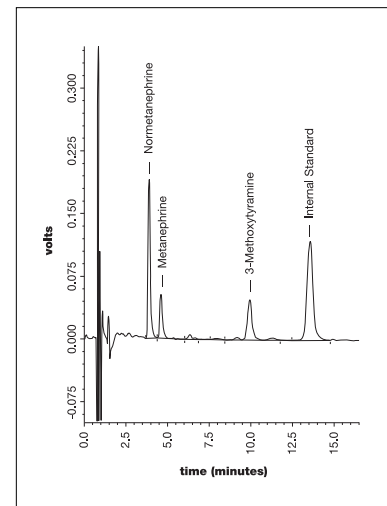
- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 16 minutes
- Sample volume: 2 mL urine (manual method), 500 µL urine (automated method)
- Flow rate: 0.7 mL/min
- Electrochemical detection: 650 mV



Urinary Metanephrines by HPLC

HPLC Automation

Bio-Rad has developed automated protocols for many of our HPLC kits by making use of the Gilson ASPEC™ XL or GX-271. Each protocol is validated so you can have confidence in the results. These methods help reduce laboratory costs by dramatically decreasing labor hours. Contact your local Bio-Rad representative for more information about the Gilson ASPEC™ methods.



Chromatogram of the Metanephrines Urine Calibrator

Ordering Information • CE Marked

Reagent Kit

195-5935	Urinary Metanephrines by HPLC Reagent Kit	100 tests
195-6087	Urinary Metanephrines by HPLC Reagent Kit, Automated Method	300 tests

Additionally Required Items

195-6088	Analytical Cartridge (includes 2 Micro-Guard™ Cartridges).....	500 injections
195-5925	Analytical Cartridge Holder	1 unit
195-5030	Micro-Guard™ Cartridge Holder.....	1 unit
195-5976	Application CD ROM for Biogenic Amines on ASPEC™.....	1 unit

Separately Available Items

195-6103	Disposable Columns 1	50 columns
195-6104	Disposable Columns 2	50 columns
195-5852	Disposable Columns 1, Automated Method.....	100 columns
195-6089	Disposable Columns 2, Automated Method.....	100 columns
195-5846	Urine Calibrator (mono-level)	1 x 25 mL
195-6090	Mobile Phase	1 x 2400 mL
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package
376/377	Lyphochek® Quantitative Urine Control	12 x 10 mL

VMA/HVA/5-HIAA BY HPLC (REVERSED PHASE)

Improved Application for VMA only by HPLC

Manual method and automated method on Gilson ASPEC™

This assay permits either simultaneous quantitative determination of vanillylmandelic acid (VMA), homovanillic acid (HVA) and 5-hydroxyindoleacetic acid (5-HIAA) or the quantitative determination of vanillylmandelic acid (VMA) only in urine by HPLC for diagnosis of pheochromocytoma, neuroblastoma, and carcinoid syndrome.

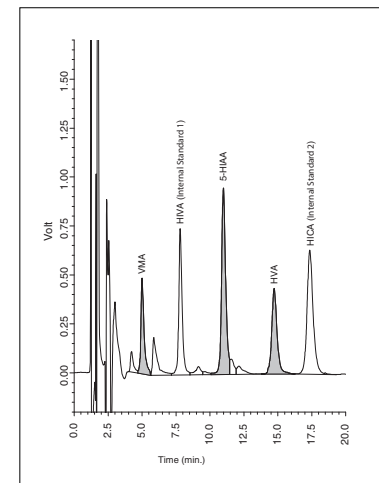
- Simultaneous determination of VMA, HVA and 5-HIAA in a single run or determination of VMA only
- Isocratic HPLC method (Reversed Phase) with electrochemical (EC) detection
- Fast, easy specimen preparation
- Specific, precise HPLC separation
- Automated application on Gilson ASPEC™ XL or GX-271 available
 - Reduced hands-on time
 - Overnight processing option
 - High specimen throughput



VMA/HVA/5-HIAA by HPLC

Test characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 19 minutes (for VMA, HVA and 5-HIAA) or 10 minutes (for VMA only)
- Sample volume: 50 µL urine
- Flow rate: 1.1 mL/min.
- Electrochemical detection: 750 mV



Chromatogram of the VMA/HVA/5-HIAA Calibrator (VHH method)

HPLC Automation

Bio-Rad has developed automated protocols for many of our HPLC kits by making use of the Gilson ASPEC™ XL or GX-271. Each protocol is validated so you can have confidence in the results. These methods help reduce laboratory costs by dramatically decreasing labor hours. Contact your local Bio-Rad representative for more information about the Gilson ASPEC™ methods.

Ordering Information • CE Marked

Reagent Kit

195-4129	VMA/HVA/5-HIAA by HPLC Reagent Kit	100 tests
195-4135	VMA/HVA/5-HIAA by HPLC Reagent Kit, Automated Method	300 tests

Additionally Required Items

195-5961	Analytical Column (includes Micro-Guard™ Cartridge).....	500 injections
195-5030	Micro-Guard™ Cartridge Holder	1 unit
195-4088	Cappillary Connection Set.....	1 unit
195-5976	Application CD ROM for Biogenic Amines on ASPEC™	1 unit

Separately Available Items

195-6586	Disposable Columns.....	100 columns
195-6584	Disposable Columns for Automated Method	1 x 100
195-5969	Test Mix	1 x 1 mL
195-5970	Urine Calibrator Set (mono-level).....	2 x 5 mL
195-6583	Mobile Phase.....	2 x 1500 mL
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package
376/377	Lyphochek® Quantitative Urine Control.....	12 x 10 mL



Serotonin by HPLC

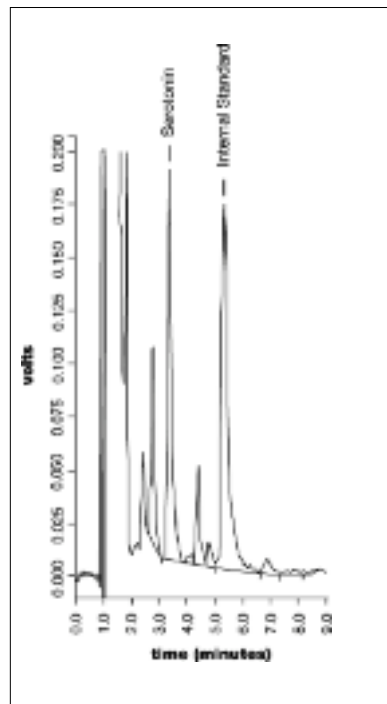
SEROTONIN BY HPLC (REVERSED PHASE)

This assay provides quantitative determination of serotonin in urine or serum by specific and precise HPLC separation for the diagnosis of carcinoid syndrome.

- Analysis of urine or serum specimen using one kit
- Ready-to-use reagents

Test characteristics:

- Principle: Isocratic HPLC Method (Reversed Phase)
- Duration of chromatography: 7.5 minutes
- Sample volume: 500 µL serum or 1 mL urine
- Flow rate: 1.0 mL/min.
- Electrochemical detection: 600 mV



Chromatogram of the Serotonin Urine Standard

Ordering Information • CE Marked

Reagent Kit

195-5854	Serotonin by HPLC Reagent Kit	100 tests
	Consisting of:	
	195-5854R Reagent Set	1 unit
	195-5859 Calibrator Set	1 unit

Additionally Required Items

195-5855	Analytical Column (includes Micro-Guard™ cartridges).....	500 injections
195-5030	Micro-Guard™ Cartridge Holder	1 unit
195-4088	Capillary Connection Set	1 unit

Separately Available Items

195-5857	Disposable Columns	2 x 50 columns
195-5859	Urine Calibrator Set (mono-level).....	2 x 10 mL
195-5866	Serum Calibrator (mono-level).....	1 x 1 mL
195-5862	Mobile Phase	1 x 2000 mL
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package
580	Lyphocheck® Tumor Marker Serum Control	6 x 2 mL

Homocysteine Assay for Risk Assessment Testing

The presence of elevated total homocysteine levels in plasma or serum has been connected to the increased risk of thrombosis, neural tube defects and atherosclerotic vascular disease. With the steadily growing demand for testing, laboratories require a fast, reliable determination that is cost-effective to process. Bio-Rad's expertise in HPLC technologies assures you of quality results and efficient workflow.

HOMOCYSTEINE BY HPLC (REVERSED PHASE)

This application provides a rapid and cost-effective method for quantitative homocysteine analysis in serum or plasma.

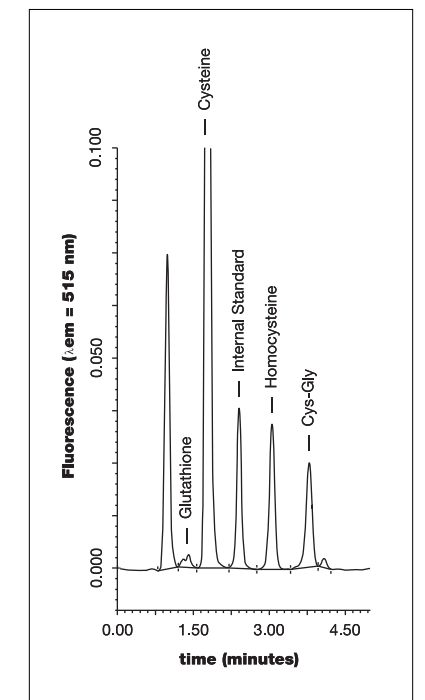
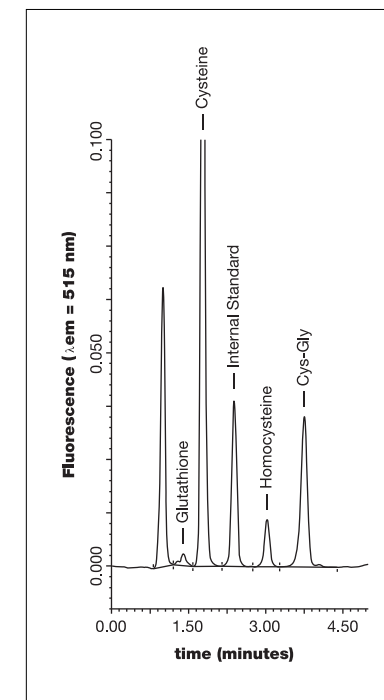
- One-step derivatization and reduction
- Five minutes incubation
- Unique internal standard
- Fluorescence labeling performed with thiol-specific dye

Test Characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 5 minutes
- Sample volume: 50 µL plasma or serum
- Flow rate: 0.7 mL/min.
- Fluorescence Detection: excitation : 385 nm, emission: 515 nm

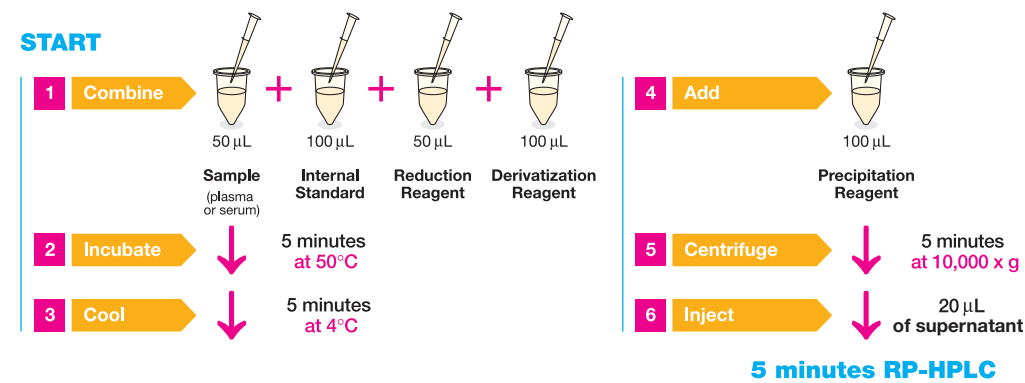


Homocysteine by HPLC



Chromatograms of a normal and an elevated patient sample

Homocysteine by HPLC Assay Protocol
From sample to results in 20 minutes



Ordering Information • CE Marked

Reagent Kit

195-4075 Homocysteine by HPLC.....100 tests

Additionally Required Items

195-4076 Analytical Cartridge (includes 2 Micro-Guard™ Cartridges)500 injections
 195-5023 Analytical Cartridge Holder.....1 unit
 195-5030 Micro-Guard™ Cartridge Holder.....1 unit
 195-4088 Capillary Connection Set.....1 unit

Separately Available Items

195-4089 Test Mix.....1 x 2 mL
 195-4082 Serum Calibrator Set2 x 1 mL
 195-4077 Mobile Phase.....1 x 700 mL
 195-6003 Micro-Guard™ Cartridges (250 injections each).....2 per package
 195-4085 Homocysteine Control Set (bi-levels)2 x 2 x 1 mL

Bone and Mineral Testing

HYDROXYPROLINE BY HPLC (REVERSED PHASE)

Hydroxyproline is a frequently used marker for bone density. A high secretion of hydroxyproline is of clinical importance and a signal of destructive processes in the skeletal system.

Measurement of hydroxyproline allows early diagnosis and control of progression of bone metastases of malignant diseases as well as control of progression or therapy of osteoporosis, acromegaly, rheumatoid arthritis, or Morbus Paget and diagnosis of hyperparathyroidism.

This assay is intended for the quantitative determination of hydroxyproline in urine.

- Only an 18-hour collagen-free diet required
- Only a 2-hour urine collection is necessary

Test Characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 6 minutes
- Sample volume: 1 mL urine
- Flow rate: 1.5 mL/min
- UV Detection: 471 nm



Hydroxyproline by HPLC

Ordering Information • CE Marked

Reagent Kit

195-9501 Hydroxyproline by HPLC Reagent Kit.....100 tests
 Consisting of
 195-9501R Reagent Set1 unit
 195-9515 Mobile Phase.....2 x 2000 mL
 195-9509 Hydrolysis glass tubes100 tubes

Additionally Required Items

195-9520 Analytical Column (includes 2 Micro-Guard™ Cartridges)500 injections
 195-5030 Micro-Guard™ Cartridge Holder1 unit
 195-4088 Capillary Connection Set1 unit

Separately Available Items

195-9502 Test Mix.....1 x 5 mL
 195-9504 Urine Calibrator1 x 15 mL
 195-9515 Mobile Phase.....2 x 2000 mL
 195-6003 Micro-Guard™ Cartridges (250 injections).....2 per package
 376/377 Lyphochek® Quantitative Urine Control.....12 x 10 mL
 195-9509 Hydrolysis glass tubes100 tubes

PYRIDINIUM CROSSLINKS BY HPLC (REVERSED PHASE)

Manual method and automated method on Gilson ASPEC™

The pyridinium derivatives, pyridinoline (PYD) and deoxypyridinoline (DPD), are considered to be the most specific markers of bone resorption. Measurement of these biochemical markers of bone metabolism provides information concerning the dynamics of bone transformation and the related loss of bone mass and allows control of progression or therapy of osteoporosis, for example.

This assay is intended for the quantitative determination of pyridinoline (PYD) and deoxypyridinoline (DPD) in urine.

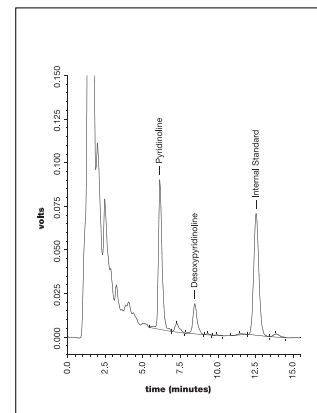
- No dietary restrictions required
- Easy specimen preparation eliminates interfering substances
- Unique internal standard
- Calibration traceable to CDC* reference material
- Automated application on Gilson ASPEC™ XL available:
 - Reduced hands-on time
 - Overnight processing option
 - High specimen throughput

Test Characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 16 minutes
- Sample volume: 150 µL urine
- Flow rate: 0.7 mL/min
- Fluorescence Detection:
 - excitation : 295 nm
 - emission : 400 nm



Pyridinium Crosslinks by HPLC



Chromatogram of the Pyridinium-Crosslinks Test Mix

HPLC Automation

Bio-Rad has developed automated protocols for many of our HPLC kits by making use of the Gilson ASPEC XL. Each protocol is validated so you can have confidence in the results. These methods help reduce laboratory costs by dramatically decreasing labor hours. Contact your local Bio-Rad representative for more information about the Gilson ASPEC methods.

Ordering Information • CE Marked

Reagent Kit

195-6576	Pyridinium-Crosslinks by HPLC Reagent Kit.....	100 tests
<i>Consisting of:</i>		
	195-6576R Reagent Set	1 unit
	195-6579 Calibrator Set.....	1 unit
195-6596	Pyridinium-Crosslinks by HPLC Reagent Kit.....	100 tests
<i>Consisting of:</i>		
	195-6596R Reagent Set	1 unit
	195-6579 Calibrator Set.....	1 unit
	195-9509 Hydrolysis glass tubes	100 tubes
195-5930	Pyridinium-Crosslinks by HPLC Reagent Kit, Automated Method.....	300 tests
<i>Consisting of:</i>		
	195-5930R Reagent Set	1 unit
	195-6579 Calibrator Set.....	1 unit

Additionally Required Items

195-5929	Analytical Cartridge (includes two Micro-Guard™ Cartridges).....	500 injections
195-5925	Analytical Cartridge Holder	1 unit
195-5030	Micro-Guard™ Cartridge Holder	1 unit
195-9530	Valve-device for Gilson ASPEC™, Automated Method	1 unit
195-5954	Application Disk for ASPEC™ V 2.0, Automated Method	1 unit

Separately Available Items

195-6577	Disposable Columns.....	100 columns
195-6575	Disposable Columns, Automated Method	100 columns
195-5915	Test Mix	1 x 2.5 mL
195-6579	Urine Calibrator Set (mono-level).....	2 x 3 mL
195-6570	Mobile Phase	1 x 1700 mL
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package
195-5959	Pyridinium-Crosslinks by HPLC Control Set (bi-level)	2 x 2 x 5 mL
195-9509	Hydrolysis glass tubes	100 tubes

Vitamin Assays

VITAMIN D₃/D₂ BY HPLC (REVERSED PHASE)

Improved Application for simultaneous measurement of D₃ & D₂

Vitamin D is an essential bioregulator of calcium metabolism and thus significant for bone mineralization. Vitamin D deficiency is recognized to be a cause of secondary hyperparathyroidism, increased bone turnover and bone loss (osteopenia) in the elderly people. Therefore Vitamin D testing is essential in the management of patients with various disorders of calcium metabolism.

Recent studies have suggested that Vitamin D may play a role in protecting against cancer¹ and in regulating normal immune function. Deficiency has been linked with autoimmune conditions such as type 1 diabetes², multiple sclerosis and rheumatoid arthritis.

Vitamin D supplementation to prevent and treat deficiency can be provided in the form of 25-OH Vitamin D₃ or 25-OH Vitamin D₂. Serum concentration of 25-OH Vitamin D has been accepted as the clinical indicator of a patient's Vitamin D status. In order to identify and correct the deficiency of these 25-OH metabolites it becomes more and more essential to measure them accurately.

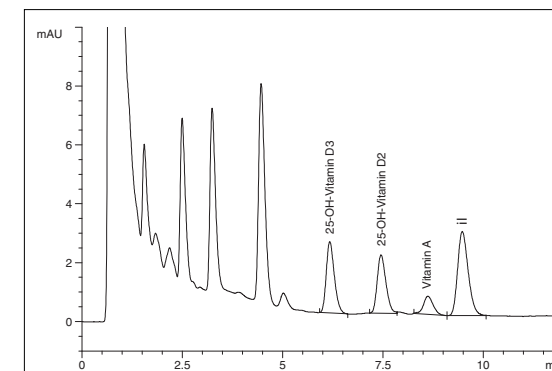
When an accurate 25-OH Vitamin D level is critical for a diagnosis or a clinical decision, the Bio-Rad 25-OH Vitamin D₃/D₂ by HPLC assay provides precise and accurate test results for circulating 25-OH Vitamin D₃ and 25-OH Vitamin D₂ levels.

- Discrete values of 25-OH Vitamin D₃ and 25-OH Vitamin D₂
- HPLC method for daily routine analysis
- Precise monitoring of response to therapy in patients

Test Characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of chromatography: 12 minutes
- Sample volume: 500 µL serum or plasma
- Flow rate: 1.1 mL/min
- UV Detection: 265 nm

¹ American Journal of Clinical Nutrition 2007;85:158-1591, ² Medical Journal of Australia 2007;187:59-60



Chromatogram of the 25-OH Vitamin D₃/D₂ Calibrator

Ordering Information • CE Marked

Reagent Kit

195-6529	25-OH-Vitamin D ₃ /D ₂ by HPLC Reagent Kit.....	100 tests
<i>Consisting of:</i>		
	195-6529R Reagent Set	1 unit
	195-6527 Serum Calibrator Set.....	1 unit
	195-6545 Internal Standard Set	1 unit

Additionally Required Items

195-6528	Analytical Cartridge (includes two Micro-Guard™ Cartridges)	500 injections
195-5925	Analytical Cartridge Holder	1 x 1
195-5030	Micro-Guard™ Cartridge Holder	1 x 1
195-4088	Capillary Connection Set	1 x 1

Separately Available Items

195-6537G	Mobile Phase	1 x 2400 mL
195-6527	Serum Calibrator Set (mono-level)	4 x 3 mL
195-6548	Serum Control Set (bi-level)	2 x 2 x 3 mL
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package

*Center of Disease Control and Prevention, Atlanta, USA

VITAMIN A/E (REVERSED PHASE)

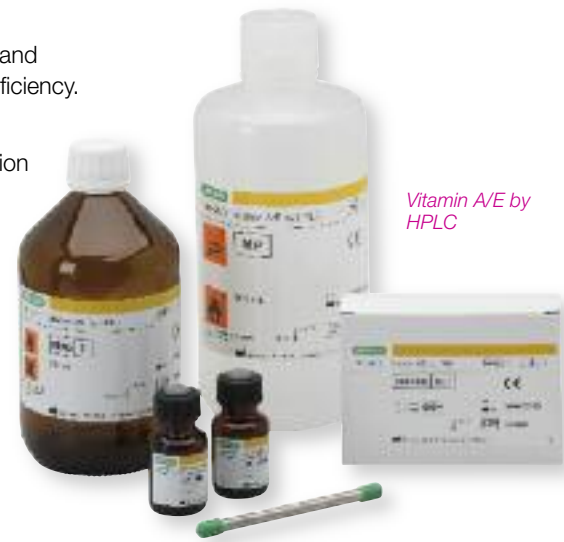
Improved Application

This assay provides quantitative determination of Vitamin A (Retinol) and Vitamin E (Tocopherol) in serum by HPLC for diagnosis of vitamin deficiency.

- Simultaneous determination of Vitamins A and E in a single run
- Sample preparation eliminates interfering substances by precipitation
- Serum control set available

Test characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of the chromatography: 7 min
- Sample volume: 200 µL serum or plasma
- Flow rate: 0.6 mL/min
- UV Detection: 340 nm (Vitamin A)
295 nm (Vitamin E)

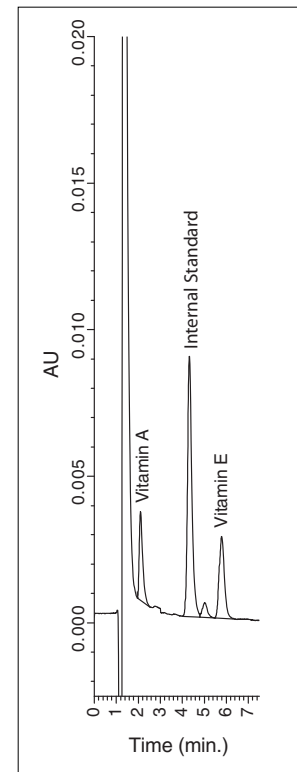


Vitamin A/E by HPLC



Toxicology

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TOX/See™ Rapid Urine Drug Screen Test	24



Chromatogram of Vitamin A/E Serum Calibrator

Ordering Information • CE Marked

Reagent Kit

195-5869	Vitamin A/E by HPLC Reagent Kit100 tests
<i>Consisting of:</i>		
	195-5869R Reagent Set1 unit
	195-5878 Calibrator Set1 unit

Additionally Required Items

195-5870C	Analytical Cartridge500 injections
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Separately Available Items

195-5874G	Mobile Phase1 x 900 mL
195-5878	Calibrator Set (mono-level)5 x 1 mL
195-5879	Vitamin A/E Serum Control Set (bi-level)2 x 1 x 1 mL



Alcohol Abuse Monitoring

%CDT BY HPLC

NEW: Fast Method available

Currently CDT (carbohydrate deficient transferrin) is the most specific biochemical marker for detection of alcohol abuse and for monitoring abstinence during treatment. Daily consumption on 50 - 80 grams ethanol for one week or longer results in elevated levels of %CDT. The %CDT by HPLC kit measures the relative amounts of single transferrin isoforms (e.g. disialotransferrin) to total transferrin.

The Bio-Rad %CDT by HPLC kit is designed for reliable, fast and easy determination of %CDT in human serum.

To assist laboratories in the standardization of their assay, Bio-Rad CDT testing calibrator material can now be provided.

New: When time and/or throughput matters, customers using modular HPLC equipment can now choose the „fast“ method.

- For routine screening and confirmatory testing
- Detection of genetic transferrin variants
- Rapid and convenient sample preparation
- **New:** Sample throughput per hour can be more than doubled
- Two level calibrator set available
- Two level control set available
- Excellent correlation with a HPLC reference method¹

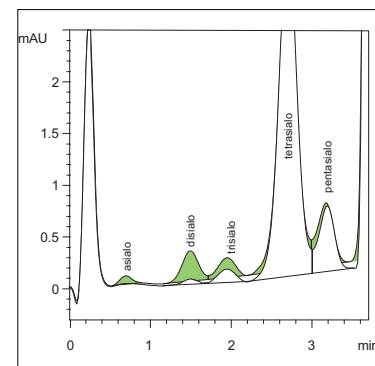


%CDT by HPLC

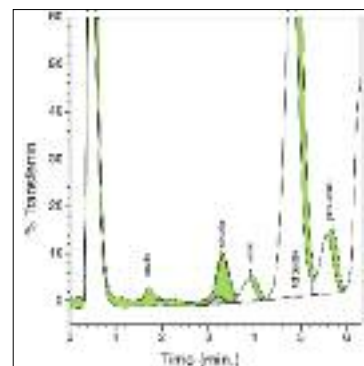
Test characteristics:

- Principle: Gradient HPLC method (Anion-exchange)
- Duration of the chromatography: 10 min (Standard method) / 4.5 min (Fast method)
- Sample volume: 150 µL serum or plasma
- Flow rate: 1.4 mL/min (Standard method) / 2.8 mL/min (Fast method)
- UV Detection: 460 nm

¹ Helander A, Husa, Jeppson JO. Improved HPLC Method for Carbohydrate-Deficient Transferrin in Serum. Clin. Chem. 2003; 49:11, 1881-1890.

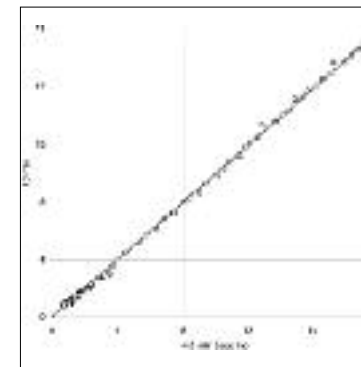


4.5 min method

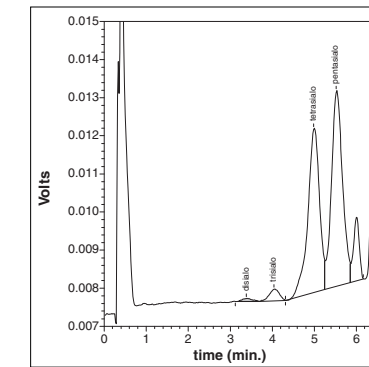


10 min method

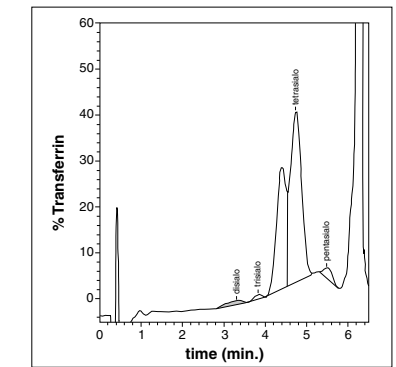
Sample from a light drinker (white) compared to a heavy drinker (green)



Correlation 4.5 / 10 min method



Chromatogram of a patient with a BC variant



Chromatogram of a patient with a CD variant

Ordering Information • CE Marked

Reagent Kit

195-6660 %CDT by HPLC Reagent Kit100 tests

Additionally Required Items

195-6662 Analytical Cartridge600 injections
 195-6663 Holder for Analytical and Guard Cartridge.....1 unit

Separately Available Items

195-6650 Calibrator Set (bi-level).....2 x 1 mL
 195-6654 Wash.....1 x 1900 mL
 195-6665 Test Mix.....1 x 1 mL
 195-6669 Control Set (bi-level)2 x 2 x 1 mL

Bio-Rad offers several options for a convenient automated sample preparation, a time-saving walk-away operation, and a solution for high-throughput customers (up to 100 samples per run).

For more information please contact your local Bio-Rad office.

Therapeutic Drug Monitoring

Therapeutic drug monitoring (TDM) is the measurement of drugs at various intervals of treatment in order to maintain a relatively constant concentration of the medication in the bloodstream.

TDM is an established procedure for cardiac drugs, antidepressants, antipsychotics, or immunosuppressives for example. Drugs that are monitored tend to have a narrow “therapeutic range” – the quantity required to be effective is not far removed from the quantity that causes significant side effects and/or signs of toxicity. Maintaining this steady state is not as simple as giving a standard dose of medication. Each person will absorb, metabolize, utilize, and eliminate drugs at a different rate based upon their age, general state of health, genetic makeup, and the interference of other medications that they are taking. Therapeutic drug monitoring is a valid tool to optimize pharmacotherapy. It identifies patient noncompliance, effects of drug interactions, and helps to tailor dosages to fit the current needs of the specific patient.

AMIODARONE BY HPLC (REVERSED PHASE)

The Bio-Rad Amiodarone by HPLC Reagent Kit permits therapeutic drug monitoring of amiodarone and its metabolite desethylamiodarone in serum.

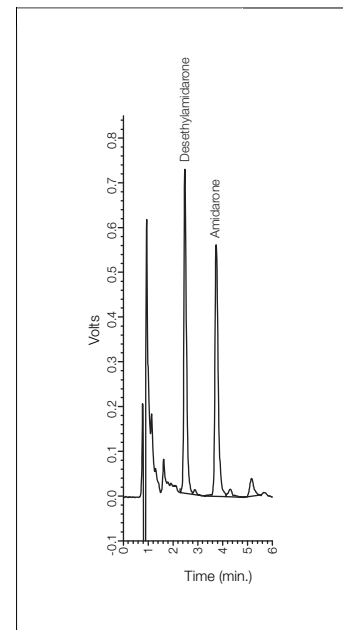
- Easy specimen preparation
- Ready-to-use reagents

Test characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of the chromatography: 6 min
- Sample volume: 200 µL serum or plasma
- Flow rate: 0.7 mL/min
- UV Detection: 242 nm



Amiodarone by HPLC



Chromatogram of Serum Calibrator

Ordering Information • CE Marked

Reagent Kit

195-5917	Amiodarone by HPLC Reagent Kit.....	100 Tests
Consisting of:		
195-5917R	Reagent Set	1 unit
195-5921	Calibrator Set.....	1 unit

Additionally Required Items

195-5918	Analytical HPLC Cartridge (includes two Micro-Guard™ cartridges)	500 injections
195-5023	Analytical Cartridge Holder	1 unit
195-5030	Micro-Guard™ Cartridge Holder	1 unit

Separately Available Items

195-5921	Serum Calibrator Set (mono-level).....	3 x 1 mL
195-5923	Mobile Phase	1 x 1000 mL
195-6003	Micro-Guard™ Cartridges (250 injections each)	2 per package



Antiepileptics by HPLC

Ordering Information • CE Marked

Reagent Kit

195-6210	Antiepileptics by HPLC Reagent Kit, Manual Method.....	100 tests
Consisting of:		
195-6210R	Reagent Set	1 unit
195-6205	Calibrator A Set.....	1 unit
195-6220	Antiepileptics by HPLC Reagent Kit, Online Method	200 tests
Consisting of:		
195-6220R	Reagent Set	1 unit
195-6205	Calibrator A Set.....	1 unit
195-6209	Mobile Phase 2	1 unit

Additionally Required Items

195-6206	Analytical Column (includes one Micro-Guard™ Cartridge)	500 injections
195-6219	Extraction Cartridge, Online Method	1 unit
270-0613	Extraction Cartridge Holder.....	1 unit
195-5030	Micro-Guard™ Cartridge Holder, Online Method	1 unit
195-6682	Prefilter Holder, Online Method	1 unit
270-0338	Prefilter Holder	1 unit

Separately Available Items

195-5898	Test Mix	1 x 2 mL
195-6205	Calibrator Set A (mono-level)	2 x 1 mL
195-5896	Calibrator Set B (mono-level)	2 x 1 mL
195-6208	Calibrator Set C (mono-level)	2 x 1 mL
195-6215	Control A Set (bi-level)	2 x 1 mL
195-6500	Control B Set (bi-level)	2 x 1 mL
195-6218	Control C Set (bi-level)	2 x 1 mL
195-6203G	Mobile Phase 1	1 x 800 mL
195-6209	Mobile Phase 2	1 x 800 mL
195-6003	Micro-Guard™ Cartridge (250 injections each)	2 per package
195-6636	HPLC Prefilter	2 per package

ANTIEPILEPTICS BY HPLC (REVERSED PHASE)

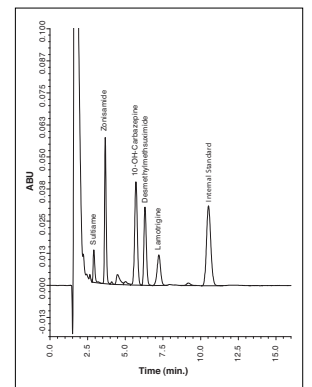
Manual method and new automated online method

This assay is suitable for reliable, fast and easy quantitative determination of a broad range of first and second generation antiepileptic drugs in plasma and serum. The panel consists of 11 antiepileptics and/or their active metabolites. The analytes can be extracted and separated with a fully automatable method by online column switching between an extraction cartridge and an analytical column.

- Time-saving and convenient sample preparation with protein precipitation (manual method)
- Allows efficient therapeutic drug monitoring in cases of multi-drug treatment
- Bi-level control sets available
- Fully automatable online application available:
 - Reduced hands-on time
 - Overnight processing option
 - High specimen throughput
- **(NEW):** 200 tests per kit
- **– NEW:** Reduced consumption of mobile phase

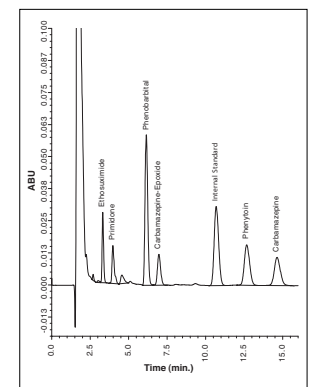
Test characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of the chromatography: 16.5 minutes
- Sample volume: 100 µL serum or plasma
- Flow rate: 0.8 mL/min.
- UV Detection: 210 nm



Chromatogram of the Antiepileptics Calibrator A

- 10-OH-Carbamazepine
- Desmethylmethsuximide
- Lamotrigine
- Sultiame
- Zonisamide



Chromatogram of the Antiepileptics Calibrator B

- Carbamazepine
- Carbamazepine-Epoxide
- Ethosuximide
- Phenobarbital
- Phenytoin
- Primidone

RAPsyD BY HPLC (REVERSED PHASE)*Improved online application*

Bio-Rad's application for Rapid Analysis of Psychiatric Drugs (RAPsyD) is suitable for reliable, fast and easy simultaneous quantitative measurement of clozapine, olanzapine, quetiapine, risperidone, and their pharmacologically active metabolites. The antipsychotics are extracted and separated with an HPLC method that involves online column switching between an extraction cartridge and an analytical column. With its fully automated HPLC method, the RAPsyD assay allows for time-saving and convenient measurement of the prescribed drugs. RAPsyD by HPLC gives physicians an efficient tool for initial determination of dosage and for subsequent therapeutic drug monitoring.

NEW: Application easily compatible with Bio-Rad's new Benzo/TCA by HPLC assay due to use of the same analytical column, extraction cartridge and mobile phases.

Test characteristics:

- Principle: Isocratic HPLC Method
- Duration of the chromatography: 25 min.
- Sample volume: 100 µL serum or plasma
- Flow rate: 1.3 mL/min (clozapine, olanzapine, quetiapine); 0.8 mL/min (risperidone)
- UV Detection: 254 nm (clozapine, olanzapine, quetiapine); 278 nm (risperidone)



- Online sample preparation
- No manual pipetting steps
- Fast and efficient therapeutic drug monitoring

Ordering Information • CE Marked**Reagent Kit**

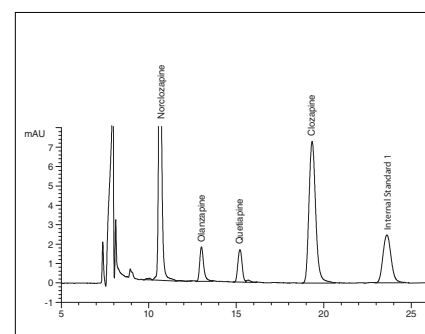
195-6600	RAPsyD by HPLC Reagent Kit	200 tests
Consisting of:		
195-6686	Mobile Phase 1 Set	1 unit
195-6687	Mobile Phase 2 Set	1 unit
195-6634	Standard Extraction Set.....	1 unit

Additionally Required Items

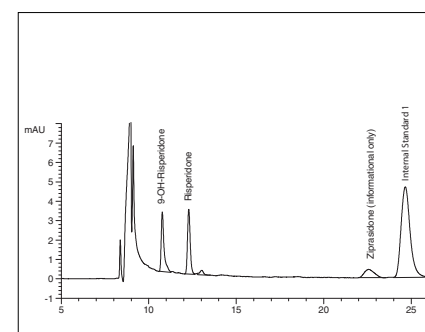
195-6684	Analytical Column (includes 2 Micro-Guard™ cartridges)	600 injections
195-6685	Extraction Cartridges (inkl. 2 prefilters).....	100 injections
195-5030	Micro-Guard™ Cartridge Holder	1 unit
270-0613	Holder for Extraction Cartridge.....	1 unit
195-6682	Holder for Prefilter	1 unit

Separately Available Items

195-6686	Mobile Phase 1 Set.....	1 x 4 L
195-6687	Mobile Phase 2 Set.....	1 x 4 L
195-6685	Extraction Cartridge (inkl. 2 prefilters)	100 injections
195-6607	Calibrator A (mono-level).....	1 x 5 mL
195-6606	Calibrator C (mono-level).....	1 x 5 mL
195-6677	Control A Set (bi-level)	2 x 5 mL
195-6678	Control C Set (bi-level)	2 x 5 mL



Chromatogram of Calibrator A, contains clozapine, norclozapine, olanzapine and quetiapine



Chromatogram of Calibrator C, contains risperidone and 9-OH risperidone

BENZODIAZEPINES AND TRICYCLICS BY HPLC (REVERSED PHASE)*Improved online application available soon*

The Benzodiazepines and Tricyclics Reagent Kit provides a reliable, fast and easy-to-use method for the analysis of 23 antidepressants, benzodiazepines, selective serotonin re-uptake inhibitors (SSRIs), and their pharmacologically active metabolites.

NEW: The analytes are extracted and separated by online column switching between an extraction cartridge and an analytical column. With its fully automated HPLC method, this assay allows for time-saving and convenient measurement of the prescribed drugs.

This application is easily compatible with Bio-Rad's RAPsyD by HPLC assay due to the same analytical column, extraction cartridge and mobile phases used.

- No manual pipetting steps
- Fast & efficient therapeutic drug monitoring
- Online application available:
 - Reduced hands-on time
 - Overnight processing option
 - High specimen throughput

Test characteristics:

- Principle: Isocratic HPLC method (Reversed Phase)
- Duration of the chromatography: 35 min. (Analyte panel A) / 25 min. (Analyte panel B, C & D)
- Sample volume: 100 µL serum or plasma
- Flow rate: 1.3 mL/min.
- UV Detection: 233 nm (Analyte panel A & C) / 250 nm (Analyte panel B & D)

Ordering Information • CE Marked**Reagent Kit**

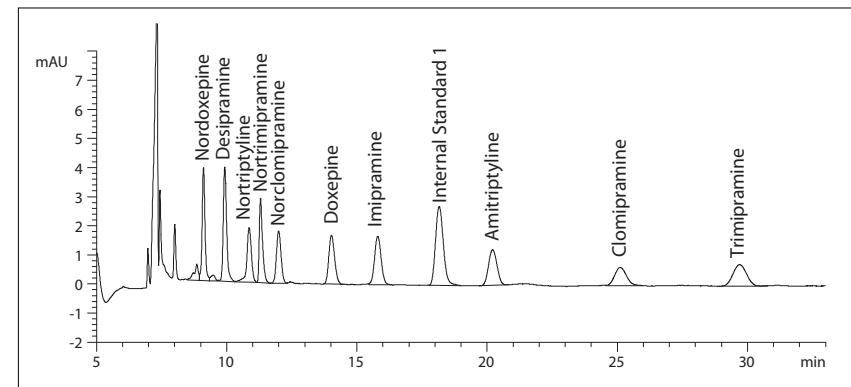
195-6550	Benzodiazepines and Tricyclics Reagent Kit	200 tests
Consisting of:		
195-6686	Mobile Phase 1 Set	1 unit
195-6687	Mobile Phase 2 Set	1 unit
195-6556	Standard Extraction Set.....	1 unit

Additionally Required Items

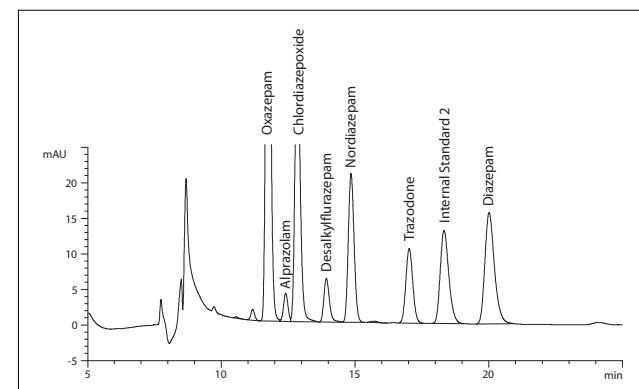
195-6684	Analytical Column (includes two Micro-Guard™ cartridges)	600 injections
195-6685	Extraction Cartridge (inkl. 2 prefilters)	100 injections
195-5030	Micro-Guard™ Cartridge Holder	1 unit
195-6682	Holder for Prefilter	1 unit
270-0613	Holder for Extraction Cartridge.....	1 unit

Separately Available Items

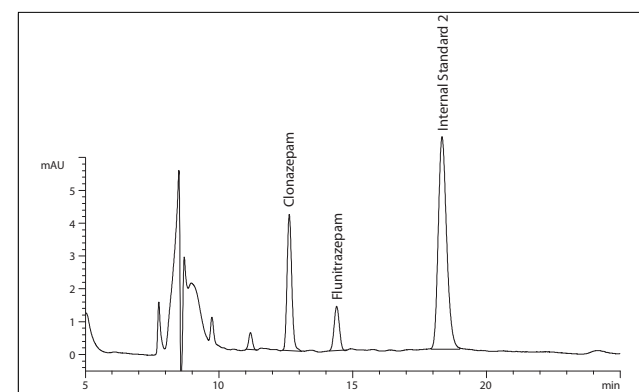
195-6552	Calibrator A (mono-level)	1 x 5 mL
195-6553	Calibrator B (mono-level).....	1 x 5 mL
195-6554	Calibrator C (mono-level).....	1 x 5 mL
195-6555	Calibrator D (mono-level).....	1 x 5 mL
195-6559	Control A Set (bi-level).....	2 x 2 x 5 mL
195-6562	Control B Set (bi-level).....	2 x 2 x 5 mL
195-6565	Control C Set (bi-level)	2 x 2 x 5 mL
195-6568	Control D Set (bi-level).....	2 x 2 x 5 mL
195-6686	Mobile Phase 1 Set	1 x 4 L
195-6687	Mobile Phase 2 Set	1 x 4 L



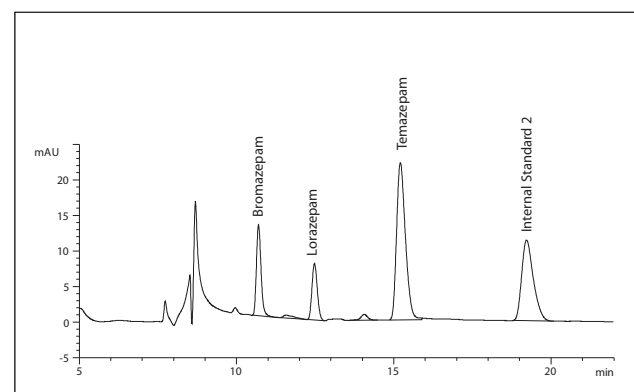
Chromatogram of Tricyclic Antidepressants from Calibrator A



Chromatogram of Benzodiazepines from Calibrator B



Chromatogram of Benzodiazepines from Calibrator C



Chromatogram of Benzodiazepines from Calibrator D

Bio-Rad's Benzodiazepines and Tricyclics Reagent Kit identifies Antidepressants (Analyte panel A)

- amitriptyline
- clomipramine
- desipramine
- doxepin
- imipramine
- norclomipramine
- nordoxepin
- nortriptyline
- nortrimipramine
- trimipramine

Selective Serotonin Re-uptake Inhibitors (SSRIs) (Analyte panel B)

- trazodone

Benzodiazepines (Analyte panel B)

- alprazolam
- chlordiazepoxide
- desalkylflurazepam
- diazepam
- nordiazepam
- oxazepam

Benzodiazepines (Analyte panel C)

- clonazepam
- flunitrazepam

Benzodiazepines (Analyte panel D)

- bromazepam
- lorazepam
- temazepam

Additional analytes*

- bupropion
- citalopram
- escitalopram
- duloxetine
- fluoxetine
- fluvoxamine
- mirtazepine
- norfluoxetine
- paroxetine
- reboxetine
- sertraline
- venlafaxine

Drug screening

MICROPLATE DRUGS-OF-ABUSE ASSAYS

PYXIS™ 24 ELISAs are non-isotopic immunoassays possessing high sensitivity and specificity. These assays are used for drug screening with urine, serum, hair, blood, tissue samples and other forensic specimens. Sample preparation is not necessary for analysis of body fluids. The tests are intended to run with serum or oral fluid, but they are matrix independent and therefore all-purpose applications.

The assays can be run on semi- or fully-automated microplate systems.



PYXIS 24 Drugs-of-Abuse-Assays auf Mikrotiterplatten

Ordering Information

194-5161	Amphetamine Specific Serum EIA.....	192 tests
194-4501	Amphetamine Specific Serum EIA.....	480 tests
194-5144	Amphetamine Specific Intercept EIA*.....	480 tests
194-5162	Methamphetamine Serum EIA (Reacts with Ecstasy).....	192 tests
194-4503	Methamphetamine Serum EIA (Reacts with Ecstasy).....	480 tests
194-5145	Methamphetamine Intercept EIA (Reacts with Ecstasy)*.....	480 tests
194-5262	Barbiturates Intercept EIA*.....	192 tests
194-5142	Barbiturates Intercept EIA*.....	480 tests
194-5260	Benzodiazepines Intercept EIA*.....	192 tests
194-5143	Benzodiazepines Intercept EIA*.....	480 tests
194-5251	Buprenorphine EIA.....	.96 tests
194-5263	Cannabinoids (THC) Intercept EIA*.....	192 tests
194-5138	Cannabinoids (THC) Intercept EIA*.....	480 tests
194-5254	Cocaine Metabolite Intercept EIA*.....	192 tests
194-5139	Cocaine Metabolite Intercept EIA*.....	480 tests
194-5167	Cotinine Saliva EIA*.....	480 tests
194-5163	Fentanyl Serum EIA**.....	192 tests
194-5252	LSD EIA.....	.96 tests
194-5258	Methadone Intercept EIA*.....	192 tests
194-5146	Methadone Intercept EIA*.....	480 tests
194-5164	Morphine Specific Serum EIA.....	192 tests
194-4521	Morphine Specific Serum EIA.....	480 test
194-5165	Opiates Serum EIA.....	192 tests
194-4523	Opiates Serum EIA.....	480 test
194-5144	Opiates Intercept EIA*.....	480 tests
194-5253	TCA EIA.....	.96 tests
194-52535	TCA EIA*.....	480 tests

* Oral Fluid ** For Forensic Use only

*Available late 2010

TOX/SEE™ RAPID URINE DRUG SCREEN TESTS

TOX/See™ is a one-step, hand-held, point-of-care test device for the qualitative detection of 14 drugs or drug metabolites in human urine. The TOX/See™ product portfolio includes specific tests for emerging drugs of abuse, such as Buprenorphine, Ecstasy, Oxycodone, and Propoxyphene to meet today's customers' demands and features a variety of combinations of the drugs listed below. The straightforward test protocol is designed for use in hospitals, emergency departments, correctional facilities, juvenile facilities, police departments, workplaces, and recovery and rehabilitation programs.

- Differentiates between Amphetamine, Methamphetamine and Ecstasy in one-step: Provides specific information to clinicians
- Specific Tests for Emerging Drugs of Abuse: Buprenorphine, Ecstasy, Oxycodone, and Propoxyphene
- Rapid Results: Test results are available in 5 minutes
- Walk-away Flexibility: Test results readable for up to 1 hour
- Comprehensive Test Panels: Simultaneous detection of as many as 10 drugs per cassette
- One-step Test Protocol: Allows for easy training

TOX/See™ features a combination of the following drugs at these cut-off levels:

Amphetamines	AMP.....	1.000 ng/ml
	AMP300.....	300 ng/ml
Barbiturates	BAR.....	300 ng/ml
Buprenorphines	BUP.....	10 ng/ml
Benzodiazepines	BZO.....	300 ng/ml
Cocaine	COC.....	300 ng/ml
Ecstasy	MDMA.....	500 ng/ml
Methamphetamines	MET.....	1.000 ng/ml
	MET300.....	300 ng/ml
Opiates	OPI.....	300 ng/ml
Methadone	MTD.....	300 ng/ml
Phencyclidine	PCP.....	25 ng/ml
Tricycl. Antidepressants	TCA.....	1.000 ng/ml
Cannabinoids	THC.....	50 ng/ml



Ordering Information • CE Marked

194-5184	AMP.....	25 tests
194-5185	BAR.....	25 tests
194-5205	BUP.....	25 tests
194-5186	BZO.....	25 tests
194-5188	COC.....	25 tests
194-5224	MDMA.....	25 tests
194-5190	MET.....	25 tests
194-5191	MTD.....	25 tests
194-5192	OPI.....	25 tests
194-5194	PCP.....	25 tests
194-5234	TCA.....	25 tests
194-5187	THC.....	25 tests
194-5216	5-A: AMP-BZO-COC-OPI-THC.....	25 tests
194-5202	5-B: AMP-COC-MET-OPI-THC.....	25 tests
194-5182	8-A: AMP-BAR-BZO-COC-MET-OPI-MTD-THC.....	25 tests
194-5230	9-A: AMP-BAR-BZO-COC-MET-OPI-PCP-TCA-THC.....	25 tests
194-5207	10-A: AMP-BAR-BZO-COC-MDMA-MET-MTD-OPI-TCA-THC.....	25 tests
194-5228	10-B: AMP-BAR-BZO-COC-MET-MTD-OPI-PCP-TCA-THC.....	25 tests
194-5231	11-A: AMP300-BAR-BUP-BZO-COC-MDMA-MET300-MOP-MTD-TCA-THC.....	25 tests

