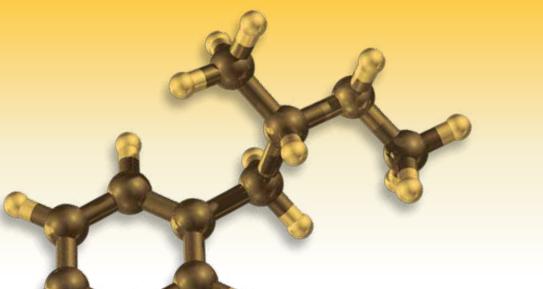


new art laboratories



LUCIO®-DRUG ELISA

Heterogeneous Enzymatic Immunoassays for Drug Analysis



Rapid Tests

Drug Laboratory Diagnostics

Medical Laboratory Diagnostics

Laboratoryservice

Consulting & Service



nal von minden

Your partner in professional diagnostics

We help you care!

For over 30 years, innovative products and excellent customer service have been the cornerstone of our enterprise. The relationship with our customers sets us aside and has shown us to be the market leader in the field of rapid tests for drug and medical analysis.

Through close collaboration with you, we have been able to optimise our portfolio and keep up to date with ongoing developments within the health market. We endeavour to remain the most innovative option and your first choice for all questions on the topic of medical rapid tests.

We have a presence throughout Europe from nine locations, as well as through our subsidiaries, offering an extensive network of customer service advisors and field representatives. This allows us to operate throughout Europe and the world, offering direct and personal solutions, and individual solutions.

Quality Assurance

We understand our responsibility as a manufacturer of *in-vitro* diagnostics. For this reason, the quality of our products and customer service is of utmost importance.

Our quality management system has been EN ISO 13485 and ISO 9001 certified since 2003, and is reviewed by TÜV Rheinland on a yearly basis. Internal audits, an extensive process map and corrective-and-preventative system help us to maintain the highest standards.

Our products, in line with European IVD-directives, are CE certified and have proven their capabilities on the market over many years. We take part in proficiency tests regularly and with great success.







nal von minden management team (from left) Sandra von Minden, Roland Meißner and Thomas Zander



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nal von minden GmbH

Your specialist in high quality and cost-efficient medical diagnostics!

We consistently use our capabilities, our knowledge and our experience to widen and refine our portfolio and processes. Our contact with you, the customer, as well as your suggestions, are critical in achieving this. In co-operation with you, we can achieve innovative solutions to meet your requirements. As your long-standing partner, we want to be the best - not just to satisfy your needs, but to inspire you too.

Our brochures are available in thirteen languages: German, English, French, Spanish, Italian, Polish, Dutch, Czech, Finnish, Portguese, Swedish, Danish and Russian. Further information on our extensive product range can be found on our website at www.nal-vonminden.com, or you can contact us directly at info@nal-vonminden.com







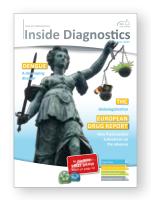


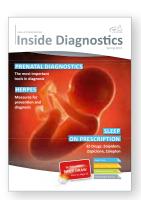
Inside Diagnostics - Your customer magazine

Three times a year we bring you fascinating articles on current topics, detailed background information and news from the world of diagnostics, as well as a brief update from the company.











Introduction

Over 80 million people - equivalent to a quarter of European adults - have consumed illegal drugs according to the European Commission. In 2014, 3.4 % of adult (15 - 64 years old) deaths were attributed to an overdose.

These figures clearly show the great need for drug analysis. Topics such as workplace testing and public security are becoming increasingly important, and in turn, so is the search for inexpensive and reliable methods to make the screening process more effective.

Our LUCIO®-Drug ELISAs provide a method to ensure a trusted result and reduce the costs by prescreening your samples with our cost-efficient assays. Thereby unnecessary GC/MS or LC/MS analyses can be avoided. From a financial point of view, an analysis performed by our LUCIO®-Drug ELISAs is > 85 % cheaper than by LC/MS, and becomes cost-efficient for a negative samples rate above 10.5 %. Additionally, all negative samples can be ruled out for further testing and merely positive ones have to be confirmed.

We offer LUCIO®-Drug ELISA kits for over 100 different parameters including common types of drugs like

amphetamines and buprenorphine as well as special parameters like zolpidem and methylphenidate.

To complete our portfolio with tests for new psychoactive substances (NPS), as a response to the developments of the European drug market, we distribute ELISA kits for the new drugs such as synthetic cannabinoids, synthetic cathinones and designer benzodiazepines.

In addition we offer our full support when it comes to plan the automation for your laboratory. We can provide you with a non-binding offer that is tailored to your individual needs.



Societies

We are partners, sponsors or members of the following societies and fora:

- **TIAFT:** The International Association of Forensic Toxicologists
- **EWDTS:** European Workplace Drug Testing Society
- GTFCh: Gesellschaft für Toxikologische und Forensische Chemie
- IATDMCT: International Association of Therapeutic Drug Monitoring & Clinical Toxicology
- **SoFT:** Society of Forensic Toxicologists
- SoHT: Society of Hair Testing
- IFDAT: International Forum for Drug & Alcohol Testing
- SFTA: Société Française de Toxicologie Analytique
- **DGKL:** Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V.
- DGRM: Deutsche Gesellschaft für Rechtsmedizin
- DGS: Deutsche Gesellschaft für Sucht

You can regularly visit us at their events!

Test Principle

LUCIO®-Drug ELISA uses the heterogeneous enzyme linked immunosorbent assay (ELISA) technology.

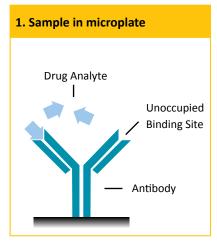
This robust technique is commonly used in laboratory analysis and toxicology for the detection of drugs and their metabolites in various sample materials. LUCIO®-Drug ELISAs have a high sensitivity level.

Sample material is pipetted into micro plates coated with drug specific antibodies. The target analytes contained in the sample material serve as antigens reacting with the antibodies of the micro well.

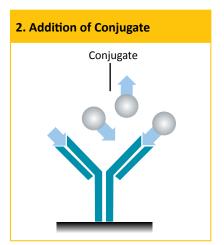
Now horseradish peroxydase (HRP), an enzyme bound to an analyte molecule (conjugate), is added to the well. The conjugate competes with the analytes of the sample material for the available binding sites of the antibodies. In the next step unbound material is washed out and a chromogenic substrate is added (TMB).

In case of antibody-conjugate interaction TMB is oxidized by the bound peroxydase, leading to a colour development. The reaction is terminated by addition of stop solution.

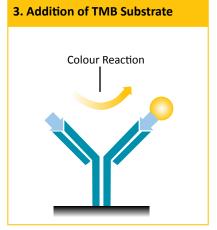
The intensity of the colour is indirectly proportional to the amount of the target analyte contained in the sample. The absorbance is measured using a microtiter plate reader at 450 nm.



Analyte is bound by antibody.



Analyte competes with conjugate for free binding sites on the antibody.



Conjugate and unbound sample analytes are washed out. Colour reaction of the conjugate enzymes and TMB substrate.



LUCIO®-Drug ELISA

We offer a comprehensive range of ELISAs for different biological matrices (blood, urine, oral fluid and hair). Over 100 assays for drugs and their metabolites have been developed to examine virtually any sample type relevant for a forensic laboratory. This includes the following groups:

- · Anabolic steroids and beta-agonists
- Antidepressants and sedatives
- Anti-inflammatories
- Antipsychotics
- Designer drugs (new psychoactive substances included)
- Drug facilitated sexual assault (sedatives)
- Hallucinogens and anaesthetic
- Analgesics
- Pain management and prescriptions
- Stimulants

Thanks to the configuration of the assay as a "direct" ELISA (competitive assay, without secondary antibody) the protocol essentially consists of only three steps. Furthermore, the ready to use reagents, guarantee simple and cost-efficient application of the assays in your lab, whether in manual mode or automated on a wide range of liquid handling stations.

The special advantage of our ELISAs, and thus the benefit for you as a user in the lab, attributed to the excellent sensitivity, in a variety of sample matrices, in concerted and effective protocols for the entire workflow – from sample collection to confirmation analysis.

For more information on the drug analysis and about the drugs, you are welcome to download and read our book "Analysis of Drugs and Medicines" and our compendium about the drugs and their metabolites, both available on our website www.nal-vonminden.com. The book is available for download in the 4th revised edition.

Product Overview

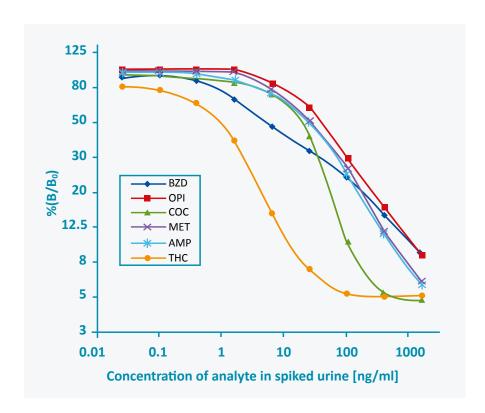
Our LUCIO®-Drug ELISA Kits are available in configurations consisting of 1 or 5 microtiter plates (96 well Costar plate, in 12 strips of 8 break-away wells). Additionally, our ELISA kits are compatible with different matrices (e.g. blood, urine, hair, among others) and due to their high sensitivity, compatible with a broad range of cut-offs (including SAMSHA, EWDTS, SOHT and DRUID).

The variable cutoff concept: Based on multiple analyses every LUCIO®-Drug ELISA has a predefined range of drug amount in the micro-well that will generate an immunoassay response that is statistically

and significantly different from the zero dose signal (B0) (20-70% of B0). This range is reflected in a drug-specific dose-response curve indicating optimal drug amount required for drug analysis per LUCIO®-Drug ELISA. This optimal dose-response can be predicted through the I-50, which reflects 50 % of B0.

The appropriate amount of target analyte, necessary for induction of the corresponding immunoassay responses (around the 50 % of B0) can be achieved by volume variation of the commonly diluted specimen.

See example of dose response curves below:





Depressants

Barbiturates

REF 1690401, I-50: 970 pg/well, calibration with secobarbital

	EWDTS Urine	Blood	EWDTS Oral Fluid	Hair
Cut-off (ng/mL)	200	100	60	1.0
Dilution	1:5	1:5	1:5	none
Sample Volume (μL)	25	50	80	40

Benzodiazepines (detects also Designer-Benzodiazepines)

REF 1690501, I-50: 58.1 pg/well, calibration with oxazepam

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	Hair
Cut-off (ng/mL)	200	50	10	0.05
Dilution	1:5	1:5	1:5	none
Sample Volume (μL)	25	10	30	50

Buprenorphine

REF 1691501, I-50: 8.2 pg/well, buprenorphine

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	5	1	5	0.01
Dilution	1:10	1:5	1:5	none
Sample Volume (μL)	15	40	10	40

Fentanyl

REF 1691801, I-50: 5.6 pg/well, calibration with fentanyl

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	20	2	1	0.05
Dilution	1:50	1:5	1:5	1:2
Sample Volume (μL)	15	15	25	10

Flunitrazepam

REF 1694001, I-50: 82 pg/well, calibration with flunitrazepam

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	Hair
Cut-off (ng/mL)	200	50	10	0.05
Dilution	1:50	1:10	1:5	none
Sample Volume (μL)	20	15	40	80

Hydromorphone

REF 16912601, I-50: 3.3 pg/well, calibration with hydromorphone

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	50	10	1	0.2
Dilution	1:500	1:50	1:5	1:10
Sample Volume (μL)	30	15	15	10

Ketamine

REF 1692401, I-50: 140 pg/well, calibration with ketamine

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	15	10	10	0.5
Dilution	1:10	1:5	1:5	none
Sample Volume (μL)	90	70	70	14

Methadone

REF 1690601, I-50: 4.8 pg/well, calibration with methadone

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	300	10	50	0.2
Dilution	1:500	1:20	1:500	1:10
Sample Volume (μL)	10	10	50	12

Methadone/LAAM

REF 16912601-1, I-50: 4.8 pg/well, calibration with methadone

	Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	300	10	50	0.2
Dilution	1:500	1:20	1:500	1:10
Sample Volume (μL)	10	10	50	12

Opiates

REF 1690301, I-50: 178 pg/well, calibration with morphine

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	300	10	40	0.2
Dilution	1:20	1:5	1:5	none
Sample Volume (μL)	10	90	20	40



Oxycodone/Oxymorphone

REF 1690801, I-50: 13 pg/well, calibration with oxycodone

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	100	10	4	0.2
Dilution	1:100	1:10	1:5	1:5
Sample Volume (μL)	10	10	15	20

Tramadol

REF 1694201, I-50: 970 pg/well, calibration with tramadol

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	300	40	50	1.0
Dilution	1:5	1:5	1:5	none
Sample Volume (μL)	15	100	100	50

Trazodone

REF 16911801, I-50: 750 pg/well, calibration with trazadone

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	300	50	50	1.0
Dilution	1:5	1:5	1:5	none
Sample Volume (μL)	10	75	75	40

Tricyclics Group

REF 1691701, I-50: 12.6 pg/well, calibration with imipramine

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	300	25	25	0.1
Dilution	1:500	1:20	1:20	1:2
Sample Volume (μL)	20	10	10	10

Zolpidem

REF 1694101, I-50: 22 pg/well, calibration with zolpidem

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	50	20	10	0.05
Dilution	1:20	1:10	1:5	none
Sample Volume (μL)	10	10	10	20

Hallucinogens

Dextromethorphan

REF 1696401, I-50: 22 pg/well, calibration with dextromethorphan

	Urine	Blood	Oral Fluid	SoHT Hair
Cut-off (ng/mL)	10	50	50	0.05
Dilution	1:5	1:20	1:20	none
Sample Volume (μL)	10	10	10	20

LSD

REF 1692101, I-50: 31.5 pg/well, calibration with LSD

	Urine	Blood	Oral Fluid	SoHT Hair
Cut-off (ng/mL)	1	2.0	2.0	0.1
Dilution	1:5	1:5	1:5	none
Sample Volume (μL)	100	60	60	20

Synthetic Cannabinoids JWH-250

REF 1692701, I-50: 19.75 pg/well, calibration with JWH-250

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	10	5	2	0.02
Dilution	1:5	1:5	1:5	none
Sample Volume (μL)	10	50	100	50

Synthetic Cannabinoids JWH-018

REF 1692601, I-50: 19.6 pg/well, calibration with JWH-018

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	10	5	2	0.02
Dilution	1:5	1:5	1:5	none
Sample Volume (μL)	10	50	100	50

Synthetic Cannabinoids UR-144/XLR-11

REF 1692501, I-50: 8 pg/well, calibration with UR-144 N-pentanoic acid

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	10	5	1	0.02
Dilution	1:20	1:5	1:5	none
Sample Volume (μL)	15	10	75	20



Synthetic Cathinone

REF 1693001, I-50: 6 pg/well, calibration with R(+) Methcathinone

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	5	10	5	0.02
Dilution	1:10	1:20	1:10	none
Sample Volume (μL)	10	10	10	15

Cannabinoids (THC)

REF 1690701, I-50: 5 pg/well, calibration with THCCOOH

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	50	1	10	0.05
Dilution	1:100	1:5	1:20	1:5
Sample Volume (μL)	10	25	10	10

Prescription drugs

Bronchodilators (e.g. Salbutamol)

REF 1694901, I-50: 10 pg/well, calibration with terbutaline

	Urine	DRUID Blood	Oral Fluid	SoHT Hair
Cut-off (ng/mL)	5	1	1	0.02
Dilution	1:10	1:5	1:5	none
Sample Volume (μL)	20	50	50	25

Stimulants

Amphetamine

REF 1690101, I-50: 100 pg/well, D-amphetamine

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	500	20	40	0.2
Dilution	1:10	1:10	1:10	none
Sample Volume (µL)	10	30	15	15

Cocaine/Benzoylecgonine

REF 1690201, I-50: 68 pg/well, calibration with benzoylecgonine

	EWDTS Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	300	10	30	0.5
Dilution	1:50	1:5	1:5	1:2
Sample Volume (µL)	10	30	10	15

Cotinine (urine)

REF 1691301, I-50: 80 pg/well, calibration with (-) Cotinine

	Urine	DRUID Blood	Oral Fluid	SoHT Hair
Cut-off (ng/mL)	200	20	20	0.5
Dilution	1:50	1:10	1:10	1:5
Sample Volume (μL)	20	40	40	40

Methamphetamine/MDMA

REF 1691101, I-50: 74 pg/well, calibration with D-methamphetamine

	Urine	DRUID Blood	EWDTS Oral Fluid	SoHT Hair
Cut-off (ng/mL)	500	20	40	0.2
Dilution	1:100	1:10	1:5	none
Sample Volume (μL)	15	40	10	20

Methylphenidate

REF 1692301, I-50: 29.4 pg/well, calibration with methylphenidate

	Urine	Blood	Oral Fluid	Hair
Cut-off (ng/mL)	1000	5	5	0.1
Dilution	1:500	1:10	1:5	none
Sample Volume (μL)	15	60	30	15

Note: The presented dilutions and sample volumes were calculated according to the presented example cut-off. In the case of hair, the dilutions were calculated for 20 mg of hair, a standard methanolic extraction and resuspension in 1 mL of buffer.



Automation

Our support includes the individual planning and establishing of the automation in your laboratory.

The technical implementation is of course also part of our service package. Depending on laboratory size and sample throughput we are providing various automation options suitable for any constellation.

We can offer everything from a simple washer/reader solution for a small sample throughput, to the Tecan Freedom EVOlyzer® for over 150.000 samples a day, from half-automated to fully automated.

No matter how high or low your sample throughput is we will have a solution for you!

If your laboratory is already fully equipped we also offer technical assistance in the creation, validation and implementation of analytical protocols for our immunoassays.

Our application experts are happy to help you with any technical question via telephone, e-mail or a visit in your laboratory.





Deutschland (Headquarters)

Carl-Zeiss-Strasse 12, 47445 Moers Tel.:.....49 2841 99 820-0 Fax:.....49 2841 99 820-1 Friedenstrasse 32, 93053 Regensburg
Tel.:.....+49 941 290 10-0
Fax:....+49 941 290 10-50

info@nal-vonminden.de www.nal-vonminden.de



Belgique / België

Français:

Nederlands:

Gratis Tel:	0800 780 85
Fax:	+31 70 3030 775
verkoop.dept@nal-vo	onminden.nl
www.nal-vonminder	n.nl

Česká republika

www.nal-vonminden.cz				
czech@nal-vonminden.com				
Bezplatný fax:	.800	143	686	
Bezplatný tel.:	.800	143	685	

Danmark

www.nal-vonminden.dk
distribution@nal-vonminden.dk
Fax:+31 7030 30775
Gratis nummer:80888753

Deutschland

www.nal-vonminden.de
vertrieb.abt@nal-vonminden.de
Gratis-Fax:0800 589 2023
Gratis-Tel.: 0800 589 2022

España

www.nal-vonmin	den.es
ventas@nal-vonm	ninden.es
Fax directo:	+49 941 290 10-50
Tel. directo:	.+49 941 290 10-761
Fax gratuito:	900 984 992
Tel. gratuito:	900 938 315

France

www.nal-vonminden.fr
dept.ventes@nal-vonminden.fr
Fax international:+49 941 290 10-50
N° international:+49 941 290 10-739
Fax gratuit:0800 909 493
Numéro vert:0800 915 240

Ireland

www.nal-vonminden.com
sales-dept@nal-vonminden.com
Freefax: 1800 555 080
Freephone: 1800 555 008

Italia

Numero verde:800 789 129
Fax gratuito:800 789 130
vendite.dipt@nal-vonminden.it
www.nal.vonmindon.it

Luxembourg

www.nal-vonminden.fr	
dept.ventes@nal-vonminden.fr	
Fax gratuit:	800 261 79
Numéro gratuit:	800 211 16

Nederland

Gratis Tel:	0800 022 2890
Gratis Fax:	0800 024 95 19
verkoop.dept@nal	-vonminden.nl
www.nal-vonmind	en.nl

Norge

Österreich

Gratis Tel:	0800 291 565
Gratis Fax:	0800 298 197
vertrieb.abt@nal-vo	nminden.de
www.nal-vonminde	en.de

Polska

www.nal-vonminden.nl	
sprzedaz.dept@nal-vonminden.pl	
Bezpłatny fax:00800 4911	L594
Bezpłatny tel.:00800 4911	1595

Portugal

Tel. gratuito:800 849 230	
Fax gratuito:800 849 229	
Tel. direto:+49 941 290 10-735	
Fax direto:+49 941 290 10-50	
vendas@nal-vonminden.pt	
www.nal-vonminden.pt	

Schweiz / Suisse / Svizzera

Deutsch:

Gratis-Tel.:	0800 832 164
Gratis-Fax:	0800 837 476
info@nal-vonminde	n.de

www.nal-vonminden.de

Français:

Numéro gratuit:	0800 564 720
Fax gratuit:	0800 837 476
dept.ventes@nal-vonn	ninden.fr

www.nal-vonminden.fr

Italiano:

Numero verde:	0800 832 2146
Fax gratuito:	0800 837 476
vendite.dipt@nal-vo	nminden.it
www.nal-vonminde	n.it

Suomi

www.nal-vonminden	.com/fi
myynti.dept@nal-vor	minden.com
Ilmainen Fax:	0800 918262
Ilmainen Puh:	0800 918263

Sverige

www.nal-vonminden.se
sweden@nal-vonminden.com
Gratis Fax:020 798292
Gratis Tel.:020 790906

United Kingdom

www.nal-vonminden.com	
sales-dept@nal-vonminden.com	
Freefax:0808 234 161	18
Freephone: 0808 234 123	37

