

### PATENT PENDING

### REVOLUTIONARY, YET ABSURDLY SIMPLE DRIED MATRIX MICROSAMPLING DEVICE

- $\bullet$  Collect a 10  $\mu L$  Dried Sample Every Time
- Goodbye Ice, Centrifuges, and Freezers
- Easier and Faster than DBS Cards
- No Volumetric Blood Hematocrit Bias
- Supports NC3R Initiatives

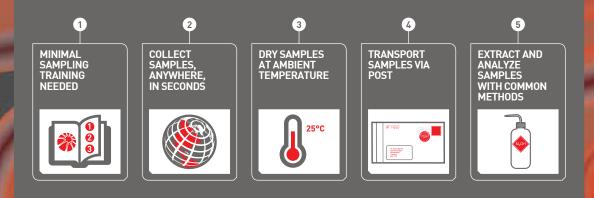




### A NEW ERA OF DRIED MATRIX MICROSAMPLING

### Welcome to ABSURDLY SIMPLE Microsampling

Easily and economically collect, transport, extract, and analyze  $10\mu$ L, dried matrix biological fluid samples to generate dependable, quantitative bioanalytical data with reduced or eliminated blood hematocrit bias.



Try absurdly simple microsampling in your lab today -You'll know exactly what we mean!

2

Mitra (RUO) is developed and manufactured by Neoteryx LLC. Mitra (RUO) is distributed and supported by Phenomenex. The Mitra (RUO) Microsampling Device is for research-use-only (RUO) and should serve no medical purpose. It should not be used with the intent or in the course of clinical diagnosis, treatment, or care of humans or animals.

© 2014 Phenomenex, Inc. All rights reserved.



REVOLUTIONARY TECHNOLOGY, SIMPLE DESIGN	4	
COLLECT A 10 µL, DRIED SAMPLE EVERY TIME	5	-
SIGNIFICANT COST AND TIME SAVINGS	6	
STREAMLINED WORKFLOW	7	
AUTOMATABLE 96-WELL PLATE FORMAT	8	
SAMPLE ANYWHERE CLAMSHELL FORMAT	9	
CONSISTENT SAMPLE QUALITY WITH GOOD LINEARITY	10	
REDUCED OR ELIMINATED BLOOD HEMATOCRIT BIAS	11	
RESOURCES	12	
ORDERING INFORMATION	14	

## TABLE OF CONTENTS

Phenomenex | WEB: www.phenomenex.com



### REVOLUTIONARY TECHNOLOGY, SIMPLE DESIGN

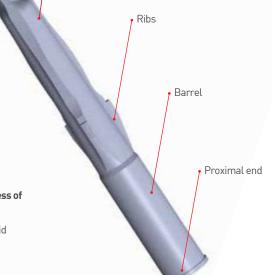
Based on Volumetric Absorptive Microsampling (VAMS<sup>™</sup>) technology, the patent-pending Mitra (RUO) Microsampler is a simple, elegant device attuned to biological fluid collection. The design features facilitate high-throughput sample processing, fluid draws from live hosts or tubes, and the ability to collect precise microsamples with limited training and no specialized lab equipment.



### SAMPLER BODY FEATURES

Leverage Existing Liquid Handlers to Increase Sample Processing Throughput

- Ribs prevent sample from contacting walls of extraction plate and clamshell
- Barrel can be labeled or written on
- Proximal end fits standard 20-200 µL pipette head



### SAMPLER TIP FEATURES

Collect 10 µL Every Time in Seconds Regardless of Blood Hematocrit Level

- Hydrophilic porous material rapidly wicks fluid
- Fixed, highly reproducible internal volume
- Dries in 2 hours or less
- Dried samples are not a biohazard eliminating special transportation needs and costs
- Extraction follows simple, automatable procedure

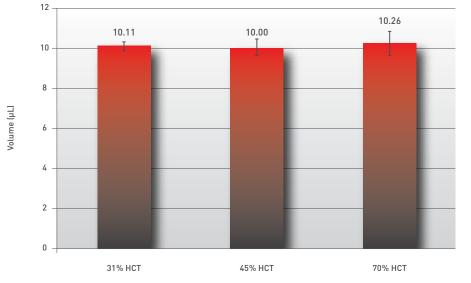


### WHY 10 µL?

For drug development and other research studies where the therapeutic range is in the  $\mu$ g / mL range - a 10  $\mu$ L microsample is sufficient. In addition, you can achieve more consistent and better quality data with serial vs. composite sampling. Lastly, microsamples are a huge leap forward in animal welfare by reducing the number of animals needed for testing to a fraction supporting the NC3R initiatives to Replace, Refine, and Reduce.



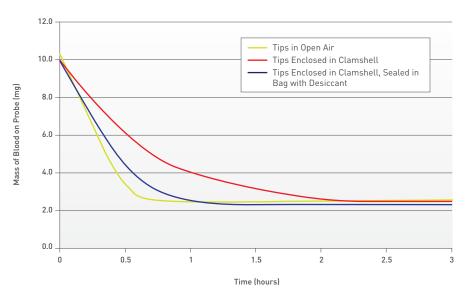
#### CONSISTENTLY COLLECT DEPENDABLE MICROSAMPLES



Volume of Whole Blood Collected With the Mitra Microsampler vs. Hematocrit (HCT) Percentage

The overall average volume collected is  $10.1 \,\mu$ L with an overall relative standard deviation (RSD) of 4.0% illustrating that the Mitra Microsampler dependably collects  $10 \,\mu$ L every time regardless of blood hematocrit level.

#### **COLLECTED SAMPLES DRY IN 2 HOURS OR LESS**



Time Required for Mitra Microsamping Tips to Dry after Sampling

All three scenarios evaluated in the drying time study were done under ambient conditions at 10% humidity and room temperature. Complete dryness was achieved in two hours or less in each instance, even when Mitra Microsampling Tips were not directly exposed to open air.

COLLECT A 10 µL, DRIED SAMPLE EVERY TIME WITHOUT VOLUMETRIC BLOOD HEMATOCRIT BIAS

5



### SIGNIFICANT COST AND TIME SAVINGS

The Mitra (RUO) Microsampler combines the best of wet sampling, microsampling, and dried blood spotting into one, state-of-the-art collection device that is extremely simple to use. Massive cost and time savings can be achieved when using the Mitra (RUO) Microsampler as opposed to other typical collection techniques.

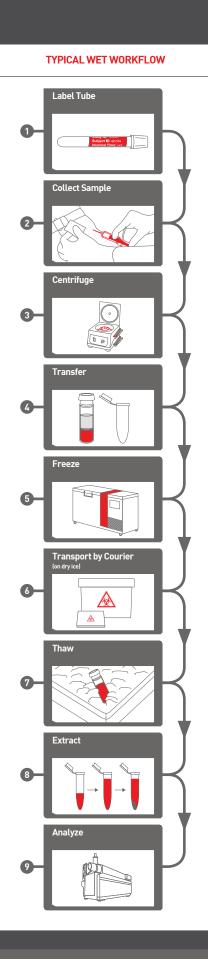
#### COMPARISON OF THE MITRA MICROSAMPLING DEVICE TO COMMON SAMPLING TECHNIQUES

	Mitra (RUO) Microsampler	Dried Blood Spotting (DBS)	Traditional Wet Sampling
Collects a fixed volume of blood, regardless of blood hematocrit	$\checkmark$		
Can be transported without dry ice or biohazard needs	$\checkmark$	$\checkmark$	
Direct sampling approach (e.g. finger or tail prick)	$\checkmark$	$\checkmark$	
Robust, consistent sampling technique with minimal training needed	$\checkmark$		
No sample processing required (e.g. centrifugation, isolation, spot punching, etc.)	$\checkmark$		

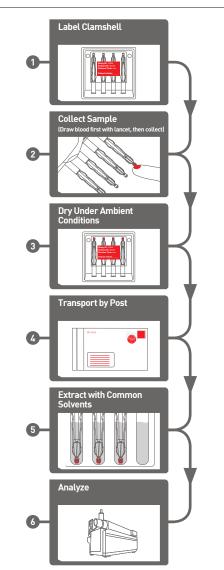
Q: How much money and time would you save if you no longer had to transport samples on dry ice or by courier? If you didn't have to do reworks? If you didn't have to pre-process your samples?

### A: The savings are shocking!









### STREAMLINED WORKFLOW

### Is it really that simple?

It sure is. Download the Quick Start Guide at www.phenomenex.com/ mitra/resources to confirm.



### AUTOMATABLE 96-WELL PLATE FORMAT

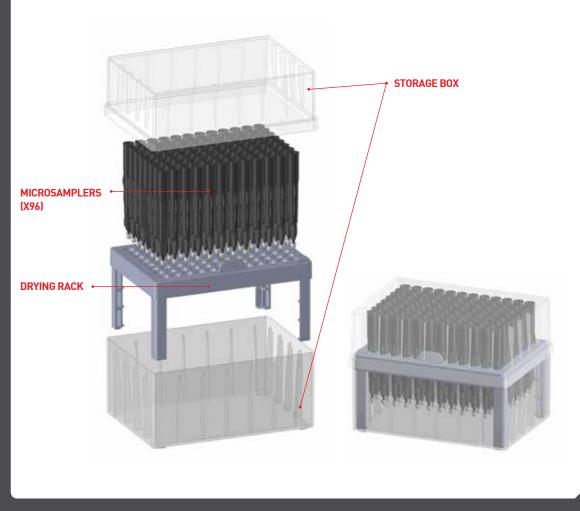
The Mitra (RUO) Microsampling Device is available in two formats: a 96-Well Plate assembly and a 4-Pack Clamshell. Your research requirements such as sample size, subject type, sample collection location, and throughput needs will dictate the best format to use.

#### **96-WELL PLATE FORMAT**

This format has standard indexing and fits SBS footprint of your liquid handler when used with the Mitra Deck Adapter, resulting in faster sample processing by using plate mapping software and instrumentation already present in your lab.

#### **RECOMMENDED FOR:**

- Discovery and pre-clinical drug research environments
- Animal studies in drug development
- Automated sample processing
- Method development



The Mitra Sampling Tool assists in picking up the Mitra Samplers from the 96-well drying rack and can also be used to take the sample.





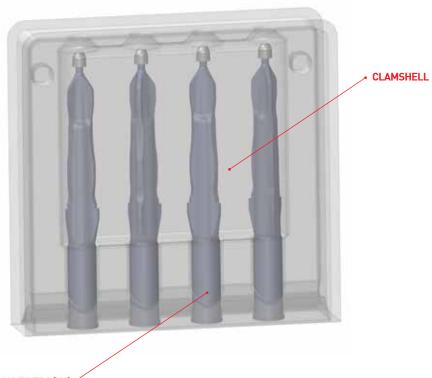


#### **4-PACK CLAMSHELL FORMAT**

Collect study samples in clinical trials anytime, anywhere by anyone with this practical, user-friendly format, which requires minimal training for robust sampling technique. Simply apply patient label to clamshell, open, collect samples, close, let dry, and drop in the mail.

#### **RECOMMENDED FOR:**

- Clinical Trial sample collection
- At-home or remote location sample collection for drug clinical trial participants



SAMPLE ANYWHERE CLAMSHELL FORMAT

See Mitra (RUO) Microsampling Device formats in action in the product demonstration videos!

www.phenomenex.com/mitra

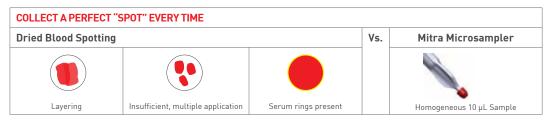
MICROSAMPLERS (X4) •



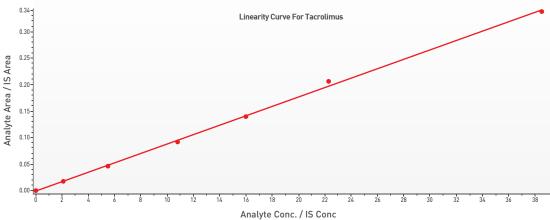
### CONSISTENT SAMPLE QUALITY WITH GOOD LINEARITY

10

The Mitra (RUO) Microsampling Device reduces or eliminates the volumetric blood hematocrit assay bias problem associated with dried blood spotting (DBS) cards resulting in accurate and dependable bioanalytical data. In addition, because the Mitra (RUO) Microsampler collects a fixed volume every time, sample quality is always consistent and no punching is required.

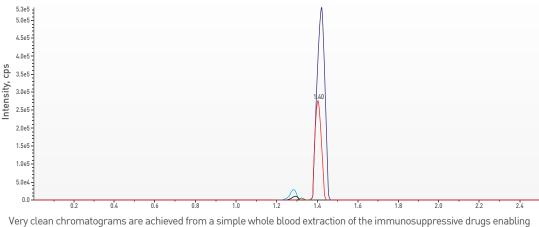


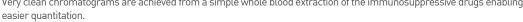




Good linearity was found for 3 immunosuppressive drugs tested (Cyclosporine, Sirolimus and Tacrolimus). The above example is for Tacrolimus where linearity was achieved across the full calibration range ( $2.1-38.5 \mu g/L$ ). Furthermore, the curve showed an r value of 0.9993 showing good precision and no positive or negative bias.

Typical Chromatogram Of Antirejection Drugs From A Whole Blood Mitra Extraction





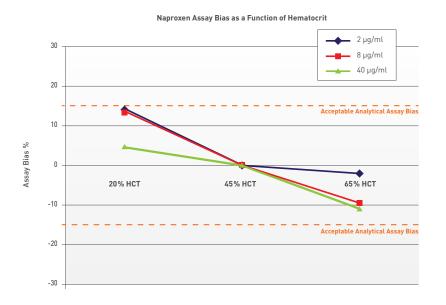
Acknowledgements Data generated at St James's hospital Leeds UK by Stephen Stephenson.



# CASE STUDY: Naproxen Extractions from Whole Human Blood Collected With the Mitra Microsampling Device

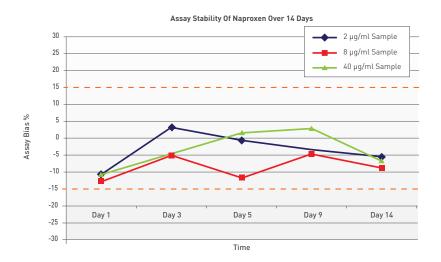
Therapeutic concentration ranges for Naproxen are used to evaluate both assay bias and stability. The extraction methodology is a common one using methanol and 15 minutes of vortexing for all the data. Optimization to any extraction protocol can greatly improve the overall analytical assay bias.

#### ACCEPTABLE ASSAY BIAS WITH GENERIC EXTRACTION PROTOCOL



Hematocrit bias at three different concentrations of Naproxen (2, 8, and  $40\mu g$  / mL) and three different levels of blood hematocrit (20%, 45%, 65%) is illustrated. A ±12% assay bias is the maximum observed which is within the typical ±15% accuracy accepted for analytical assays.

#### DEPENDABLE SAMPLE STABILITY



This graph illustrates on-tip stability of 45% hematocrit blood for an analysis of Naproxen over 14 days. All the data fits within the  $\pm 15\%$  assay bias requirement illustrating that the stability of the assay is good for at least up to 2 weeks.

FIT COMFORTABLY WITHIN BIAS LIMITS WITH COMMON EXTRACTION PROTOCOLS

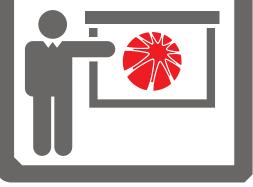


### RESOURCES

12

# IN-LAB DEMONSTRATIONS & SEMINARS

# PRODUCT EVALUATIONS





#### **IN-LAB DEMONSTRATIONS & SEMINARS**

We'll bring absurd simplicity right to your doorstep! Try the Mitra (RUO) Microsampler out for yourself, in your lab, with your samples. No time for a visit? We can hold an on-line seminar too. Let us know what works best.

#### **PRODUCT EVALUATIONS**

We know that the Mitra (RUO) Microsampler sounds too good to be true. However, we're so confident in the simplicity and performance of the device we will let you try it out on us\*. Request a FREE 96-well plate assembly to evaluate in your lab.

\*Limit one 96-well plate evaluation device per company. Free sample subject to availability. Subject to Phenomenex Standard Terms and Conditions, which may be viewed at www.phenomenex.com/TermsandConditions



### RESOURCES



#### **TECHNICAL SUPPORT**

Let us put you first! Our team of technical consultants are available to provide unlimited, personalized support to help you implement Mitra (RUO) Microsampling in your lab. From sample collection questions to extraction method development help to analytical result troubleshooting we are committed to getting your question answered, fast and friendly.

#### LITERATURE, VIDEOS, & MORE

This brochure hopefully got you excited about the potential of the Mitra (RUO) Microsampling Device to revolutionize your sample collection and analysis. But, we know you probably need a little more. Visit www.phenomenex.com/ mitra to access product videos, peer-authored journal references, and technical literature all about Mitra. Have Questions? Want to set up a Deminar? Get in touch with us at: mitrasales@phenomenex.com



### ORDERING INFORMATION



The Mitra (RUO) Microsampling Device is guaranteed to collect a precise volume. If your Mitra Microsamplers do not consistently collect a precise volume, send in your data within 45 days for a full refund.

Product	Part No.	Description	Unit	Typical Uses
	9R-K002-CA	Mitra (RUO) 10µL Microsampling Device 96-Well Plate Assembly	1 ea	For high-throughput environments (e.g. discovery labs) For animal studies in drug development For method development
	9R-K002-CD	Mitra (RUO) 10µL Microsampling Device 96-Well Plate Assembly	12/pk	
	9R-K002-BF	Mitra (RUO) 10µL Microsampling Device 4-Pack Clamshell	60/pk	For sample collection in clinical trials, including: Direct sampling At-home sampling Remote locations
	AK-9268-A	Mitra Drying Rack 96-Well Plate	1 ea	To organize sampling for high-throughput environments



Product	Part No.	Description	Unit	Typical Uses
	АК-9269-А	Mitra SBS Deck Adapter 96-Well Plate	1 ea	For mounting 96-well plate on deck of liquid handlers
	АК-9270-А	Mitra Sampling Tool	1 ea	To easily manipulate and transfer samplers in 96-well plate assembly
	AH0-8636	96-Well Collection Plate 2 mL round well with round bottom	50/pk	To perform extractions prior to analysis

Terms and Conditions

Subject to Phenomenex Standard Terms & Conditions, which may be viewed at www.phenomenex.com/TermsAndConditions. Trademarks

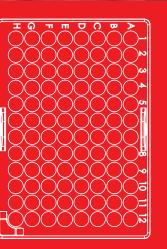
Mitra and VAMS are trademarks of Neoteryx LLC. Phenomenex is a registered trademark of Phenomenex, Inc. Disclaimer

Disclaimer The Mitra (RUO) Microsampling Device is patent pending and for research-use-only (RUO) and should serve no medical purpose. It should not be used with the intent or in the course of clinical diagnosis, treatment, or care of humans or animals. © 2014 Phenomenex, Inc. All rights reserved. ORDERING INFORMATION

15







### **REVOLUTIONARY, YET ABSURDLY SIMPLE** DRIED MATRIX MICROSAMPLING

### Australia

t: 02-9428-6444 f: 02-9428-6445 auinfo@phenomenex.com

#### Austria

t: 01-319-1301 f: 01-319-1300

### anfrage@phenomenex.com

- Belgium
- t: 02 503 4015 (French) t: 02 511 8666 (Dutch) f: +31 (0)30-2383749 beinfo@phenomenex.com

### Canada

t: (800) 543-3681 f: (310) 328-7768 info@phenomenex.com

#### Denmark

t: 4824 8048 f: +45 4810 6265 nordicinfo@phenomenex.com

#### Finland

t: 09 4789 0063 f: +45 4810 6265 nordicinfo@phenomenex.com

#### France

t: 01 30 09 21 10 f: 01 30 09 21 11 franceinfo@phenomenex.com

### Germany

- t: 06021-58830-0 f: 06021-58830-11
- anfrage@phenomenex.com India
- t: 040-3012 2400 f: 040-3012 2411 indiainfo@phenomenex.com

### Ireland

t: 01 247 5405 f: +44 1625-501796 eireinfo@phenomenex.com

### Italy

- t: 051 6327511
- f: 051 6327555 italiainfo@phenomenex.com

### phenomenex .breaking with tradition<sup>sw</sup>

### www.phenomenex.com

Phenomenex products are available worldwide. For the distributor in your country, contact Phenomenex USA, International Department at international@phenomenex.com

- Luxembourg t: +31 (0)30-2418700 f: +31 (0)30-2383749 nlinfo@phenomenex.com
  - Mexico

t: 001-800-844-5226 f: 001-310-328-7768 tecnicomx@phenomenex.com

#### The Netherlands

t: 030-2418700 f: 030-2383749 nlinfo@phenomenex.com

#### New Zealand

t: 09-4780951 f: 09-4780952 nzinfo@phenomenex.com

#### Norway

- t: 810 02 005 f: +45 4810 6265
- nordicinfo@phenomenex.com

### Puerto Rico

t: (800) 541-HPLC f: (310) 328-7768 info@phenomenex.com

### Sweden

t: 08 611 6950 f: +45 4810 6265 nordicinfo@phenomenex.com

### **United Kingdom**

t: 01625-501367 f: 01625-501796 ukinfo@phenomenex.com

#### **United States**

t: (310) 212-0555 f: (310) 328-7768 info@phenomenex.com

### All other countries: Corporate Office USA

- t: (310) 212-0555 f: (310) 328-7768
  - info@phenomenex.com

BR22720914\_W