

The promise of microsampling, delivered



Blood Collection Devices Powered by Volumetric Absorptive Microsampling (VAMS™) Technology





# out of the waiting room, into the living room

- Microsampling makes therapeutic drug monitoring and clinical trials simple and less disruptive – for everyone involved
- Patients and participants will experience new convenience, ease, and freedom – and stay closer to their families and communities
- Enables innovations in health and wellness testing, patient-centered care, and the quantified self
- An improved experience boosts adherence, compliance, and subject retention resulting in greater clinical insights from more frequent and timely specimen collections.



# take blood collection out of the clinic

- Microsampling enables access to hard-to-reach populations for healthcare and research
- Blood Collection can now be performed anywhere, at any time, by almost anyone
- Sampling can now occur on mountaintops, in the rainforest, or in isolated rural communities



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# small-volume sampling: what can 10-30 microliters do for you?

- Microsampling provides a better experience for vulnerable patients, especially children and the elderly
- Precise and volumetrically accurate samples provide data comparable to gold standard tests using plasma.
- This technology is compatible with a broad array of analytes and panels, with more being added all the time



# preclinical research: save time, save money, promote the 3Rs

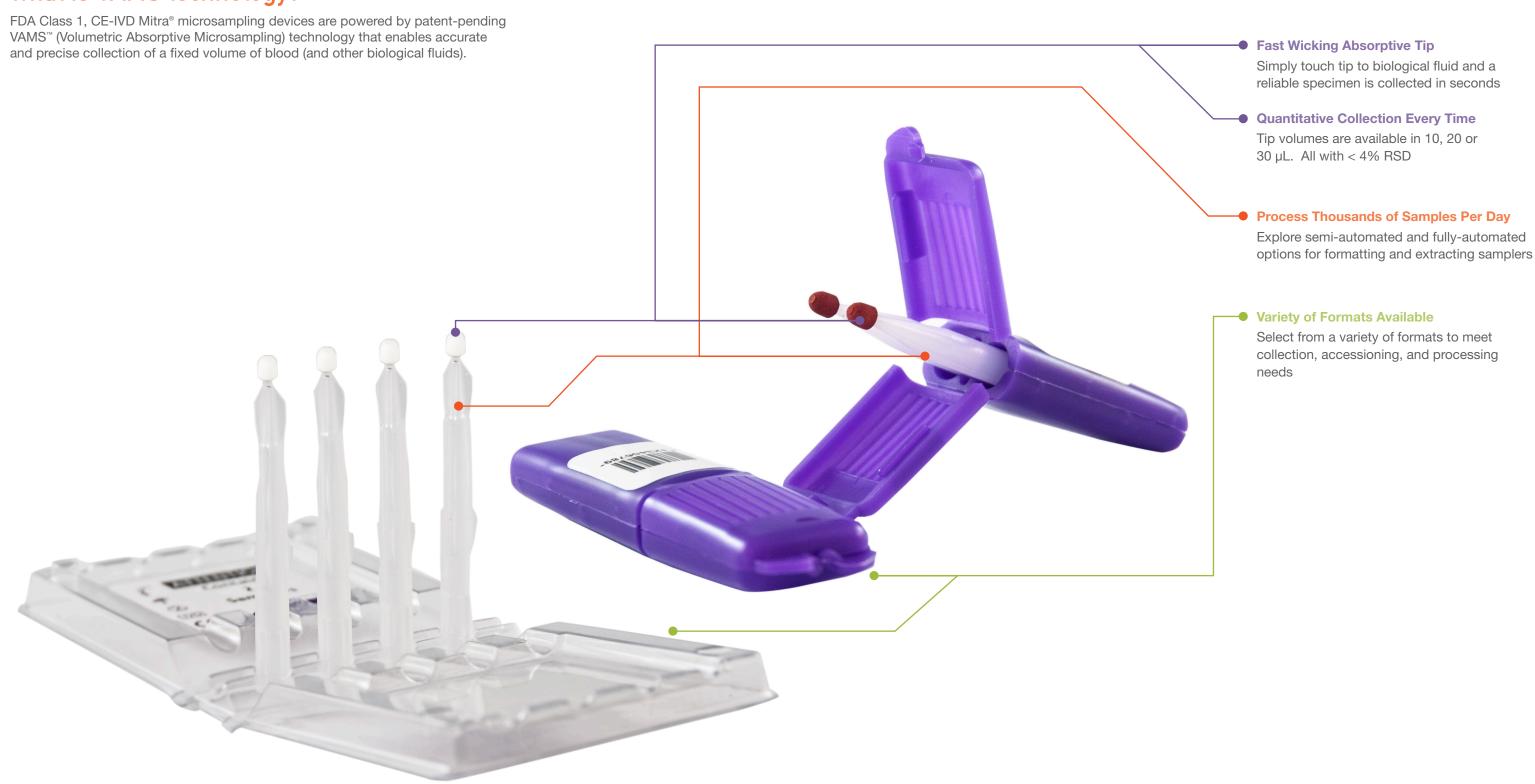
- Microsampling is your financial, ethical, and scientific advantage for animal testing
- Cut costs, simplify workflows, eliminate expensive equipment and time-consuming processing steps, and reduce reliance on satellite populations
- Sample from the same animal at multiple time points – get better data, use fewer animals, while working towards goals of replacement, reduction, and refinement.



# meet the Mitra® microsampling device



# what is VAMS technology?



# explore our patient- and lab-centered formats

Self and assisted sampling is easy and convenient with the user-friendly Mitra® clamshell and cartridge formats. With minimal training, almost anyone can collect accurate volume of blood.

Streamline microsample accessioning and extractions with the 96-Autorack formats. Both the fully loaded and empty options are compatible with 96-channel electronic pipette and liquid-handling instrumentation.

#### Clamshell

- Economical way to get started with microsampling
- Available in 2-, 3- or 4-sampler configurations for flexibility
- Select from 10, 20, or 30 μL collection volumes
- Customers use for animal research, academic research, and on-site studies

#### Cartridge

- User friendly format is well suited for unassisted remote collection
- Select from 10, 20, or 30 μL collection volumes, available in 2-sampler configuration
- Manage tracking and chain of custody with native barcoding
- Packaged in a resealable specimen bag containing desiccant for shipping samples to a central lab
- Customers use for clinical trials, remote patient monitoring, collection in low-resource regions

#### **Collection Kits**

- Simplify collection, storage, and shipment of biological specimens
- Lancets, Mitra devices, bandages, gauze, shipping envelopes – all the essentials for sample handling
- Available with clamshell or cartridge device formats
- Kits and instructions can be tailored based to your requirements
- Customers use for multi-site clinical trials, consumer wellness screening, and much more









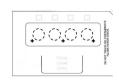
# Ready to order?

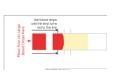
To receive your quote visit www.neoteryx.com/quote

### Mitra® collection devices vs. alternatives

VAMS<sup>™</sup> technology – the heart of all Mitra devices – revolutionizes specimen collection. It combines the best of wet sampling, microsampling, and dried blood spotting in a state-of-the-art collection device that is easy to implement both in the field and the lab.













COLLECTION	Mitra Device	Dried Blood Spot Card	Dried Plasma Card	Glass Capillary Tube	Blood Collection Tube	Micro Blood Colletion Tube
Non-invasive draw technique (e.g., finger-prick)	✓	✓	✓	<b>√</b>		✓
Quantitative volume collected	✓					
Easy self-collection outside of clinic	✓					
TRANSPORTATION / STORAGE						
Native barcode specimen tracking	✓				✓	✓
Ability to separate blood into plasma			<b>√</b>		<b>√</b>	<b>√</b>
Ship by post	✓	✓	<b>√</b>			
No cold-chain shipping required	✓	✓	<b>√</b>			
Specimen stability and storage at room temperature	✓	✓	<b>√</b>			
LABORATORY PROCESSING						
Compatible with standard liquid handling instrumentation	✓				<b>√</b>	<b>√</b>
Convenient offline, benchtop processing	✓					

The FDA Class 1 Mitra microsampler retains the advantages of Dried Blood Spot (DBS) cards and adds user convenience and volumetric accuracy, eliminating the hematocrit (HCT) effect and generating results that correlate with those from wet blood. Unlike DBS cards, Mitra devices are designed to be compatible with liquid handling instrumentation typically found in the lab so no capital investment is required for high-throughput processing.

## patient sampling workflow

Streamline workflows with dried blood microsampling while providing a simple, more economical, and more effective approach to clinical testing and research.

#### **Blood Collection Tubes**

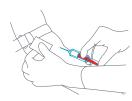
#### VS.

#### Mitra® Collection Devices





With Mitra devices donors collect their own precise volumes of blood, with only minimal training, whenever and wherever it's convenient.





Forgo venipuncture and simply prick the finger.



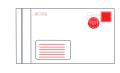






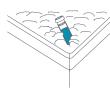
Mitra Microsamples dry under ambient conditions - there is no need for centrifuge, transfer, or freezing.





Transport Mitra® dried blood specimens via post - eliminate cold-chain shipping and courier costs.







Extract analytes from Mitra tips with common solvents - no thawing needed. Extractions can be automated.





Yield results that correlate with those obtained from whole blood/plasma workflows – for a wide range of analytes – through traditional techniques such as LC-MS/MS and immunoassay.

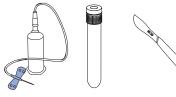
## animal sampling workflow

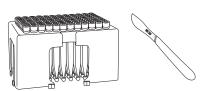
Mitra microsampling provides an ethical, scientific, and financial advantage for preclinical research while promoting compliance to NC3R guidelines. Eliminate processing steps, cut reliance on satellite populations, and reduce animal usage by up to sevenfold.

#### Traditional Blood Collection



#### Mitra® Collection Devices

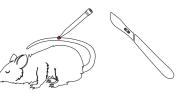




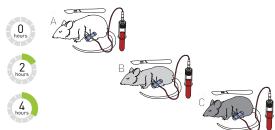
Mitra Microsampling eliminates the need for tubes, clips, and other equipment.



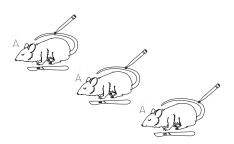




Preserve data integrity with less stress for animals. It's a better experience for lab professionals, too.







Sample the same animal at multiple time points to avoid inter-animal variability issues, preserve inventory, and comply with the 3Rs.

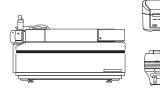






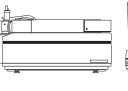


No processing, freezers, or couriers required. Let your microsamples dry under ambient conditions.











Use microsampling in conjunction with electrophoresis, PCR, LC/MS, and Next Generation Sequencing platforms.

## scientific validation for VAMS technology

# curious to know if your analyte is compatible with microsampling?

Most likely, it is! Dozens of references prove that a wide range of analytes can be extracted from the Mitra® microsampler. Third party journal citations substantiate the benefits and utility of microsampling for applications such as therapeutic drug monitoring, infectious disease research, and remote specimen collection.

Illicit Drugs cathinones, cannabinoids



#### **Therapeutic Drugs**

antibiotics, anti-pyschotics, anti-epileptics, sedatives, and many more



#### Proteins | Peptides

antibodies, peptide biomarkers, HbA1c, and more



#### Immunosuppressants

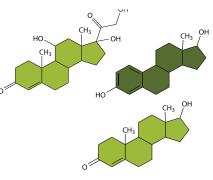
tacrolimus, sirolimus, methotrexate, and more



#### Vitamins | Supplements

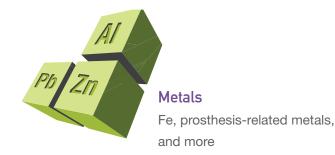
vitamin D3, Folate





#### Hormones | Steroids

estrogens, anabolic steroids, and more





#### Cytotoxins

saxitoxin, sulfur mustard albumin adducts

#### DNA / RNA miRNA, SNPSs and more



The Mitra Microsampler class I medical device is for direct specimen collection of blood and other biological fluids. It is not specific to any clinical test, and is not for use in diagnostic procedures. Use of the Mitra Microsampler in Laboratory Developed Tests (LDTs) requires further processing including the establishment of performance characteristics and successful validation by the laboratory in a manner consistent with CLIA requirements.



# it's a fact - stable dried blood specimens result in reliable data

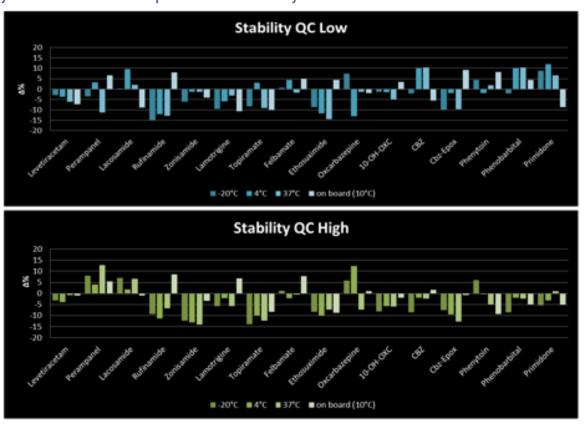
Several studies prove that bioanalytical data generated from specimens collected with a Mitra® device is accurate and dependable. When labs develop methods with simple and effective extraction protocols, the resulting analytical method will eliminate most forms of assay bias - such as hematocrit (HCT) and stability bias.

The below study is for a panel of **anti-epileptic drugs**, the method developed optimized extraction efficiency to be greater than 86% - as a result, there were no examples of HCT bias or stability bias that were outside the range of acceptability.

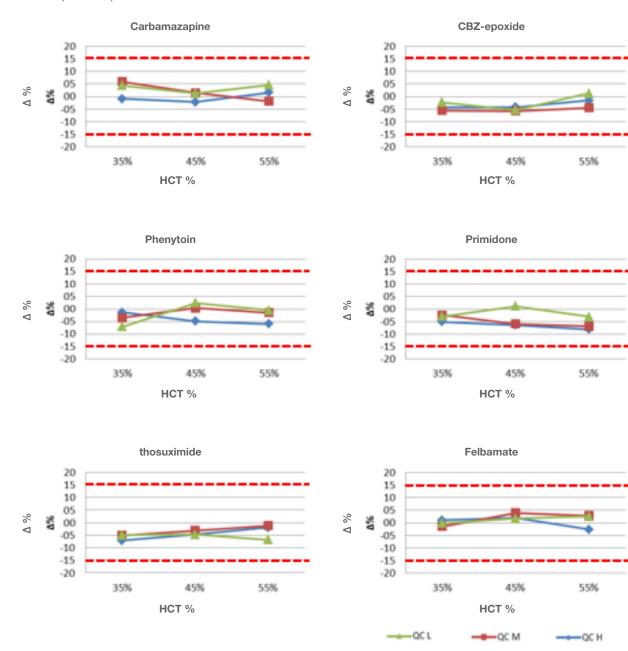
#### Evaluation of Matrix Effect (ME), Extraction Recovery (ER), and Process Efficiency (PE)

		LEV	РМР	ГСМ	RUF	SNZ	LTG	ТРМ	FBM	ЕХТ	охс	10-0H-0XC	CBZ	CBZ-E	PHT	PHB	PRM
	ME%	98	102	94	91	93	99	92	93	99	100	97	104	90	86	91	95
QC LOW	RE%	101	98	103	106	94	102	96	105	99	87	104	86	105	100	96	100
	PE%	99	99	97	96	88	102	88	97	98	87	101	89	94	86	87	94
	ME%	102	103	100	97	104	89	104	99	111	93	105	104	96	98	108	94
QC HIGH	RE%	95	100	102	112	97	112	99	100	102	94	105	94	105	101	102	102
mon	PE%	97	103	102	109	102	99	103	100	113	87	110	98	101	99	111	96

#### Stability Tests at Different Temperatures for Ten Days



#### No HCT Bias ( $>\pm15\%$ )



All data generated by Dr. Ugo de Grazia (Fondazione IRCCS Istituto Neurologico Carlo Besta)

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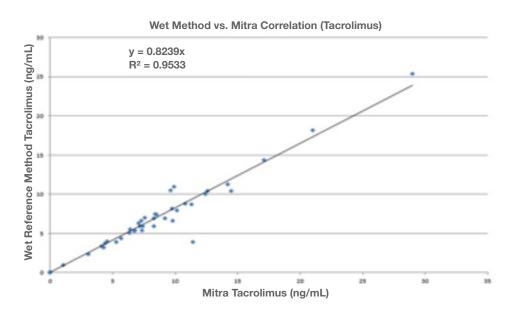
Explore more third party studies

www.neoteryx.com/data

# dried capillary blood vs. gold standard wet specimens

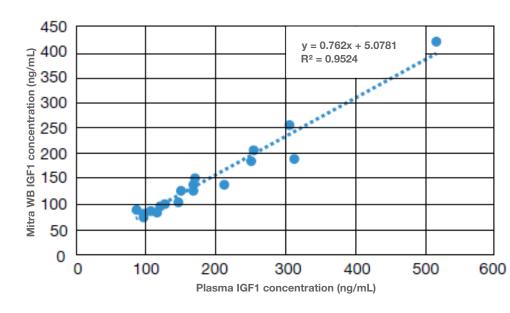
While lab reference values are established for assays run on traditional venipuncture specimens, there are many situations in which a capillary blood draw is advantageous. Research shows that capillary blood can yield high-quality results, which correlate to those associated with traditional venipuncture results. The blood plasma partitioning ratio will define the correlation between a plasma sample and dried blood sample. A bridging study defines the slope of a linear regression comparing the concentrations that would be determined from plasma to those determined from whole dried blood.

#### Immunosuppressive Drugs (Tacrolimus) | Protein Crash Extraction



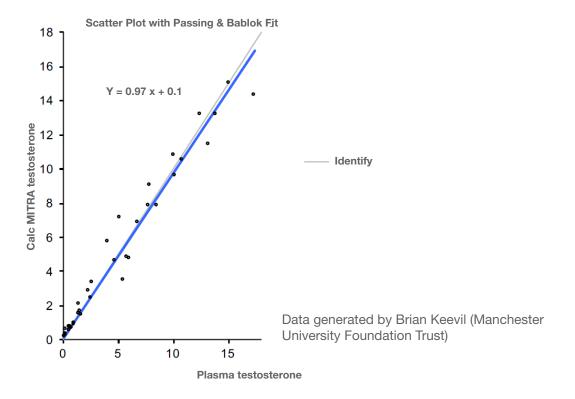
Data generated by Stephen Stephenson (Leeds Teaching Hospital)

#### Peptides/Proteins (IGF-1) | Aqueous Extraction

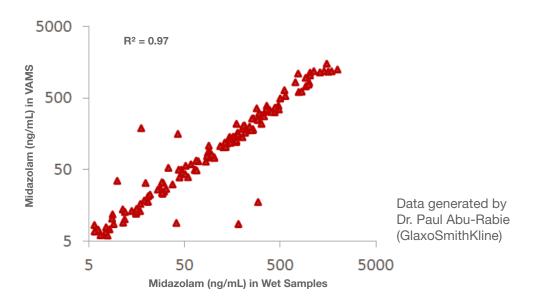


Data courtesy of The Christie Pathology Partnership LLP

#### Steroids (Testosterone) | Organic Extraction with Fit Correction



#### Therapeutic Drugs (Midazolam)



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Explore more Mitra to wet specimen correlation data

www.neoteryx.com/data

# evaluation and implementation



# what will $< 50 \mu L$ do for you?

www.neoteryx.com/start

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The Mitra Microsampling Device is patent pending and is an FDA listed Class 1 device (D254956). Neoteryx complies with FDA good manufacturing practices, CFR 820 regulations, and ISO 13485. The Mitra Microsampler Class I medical device is for direct specimen collection of blood and other biological fluids. It is not specific to any clinical test, and is not for use in diagnostic procedures. Use of the Mitra Microsampler in Laboratory Developed Tests (LDTs) requires further processing including the establishment of performance characteristics and successful validation by the laboratory in a manner consistent with CLIA requirements. © 2018 Neoteryx, LLC. All rights reserved.