WhitePaper

How to Create a Patient-centered Lab with Breakthrough Blood Collection Technology:

Microsampling takes blood collection out of the clinic

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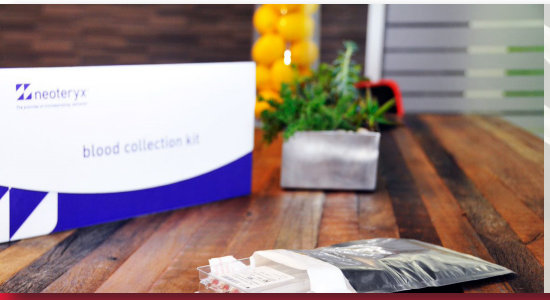


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Chapter 1

The Rise of Patient-centered Care

"The global movement toward patient-centered care will affect everyone, starting in the clinical lab."

The future of healthcare is about giving people the agency and the tools to participate actively in their own treatment experiences, in the clinic and beyond. The global movement toward patient-centered medicine will affect everyone, starting in the clinical lab.

Patient-centered care (otherwise known as a "patient-centric" approach to medicine, healthcare, and the associated processes and technology) represents a paradigm shift in how patients, providers, and other participants think about the processes of treatment and healing.

Defined by the Institute of Medicine as the act of "providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions," patient-centered care prizes transparency, compassion, and empowerment. The rise of patient-centered care makes way for a healthcare system designed to optimize the agency and comfort of the most important and vulnerable people in the equation: patients, their families, and their communities.

Patient-centered care is a far-ranging new view of healthcare that resists simple summation. But there are a few consistent core ideas that guide this new style of care.

Chief among these is a respect for patient comfort, convenience, and preferences. This entails coordinating and integrating treatment with

a patient's existing lifestyle, including family life and any activities and surroundings that help keep the patient whole.

It is possible to provide convenient, effective, and even excellent care without disrupting a patient's life.

"It is possible to provide convenient, effective, and excellent care without disrupting a patient's life."

Innovation in this area is moving quickly. Therefore, it is essential for practitioners and other professionals to educate themselves on emerging trends and technologies that can facilitate more patient-centered approaches. The easier an innovation is for patients to understand and learn to use, the more widely it is likely to proliferate.

How Patient-centered Care Works Better for Everyone

Understanding patient-centered approaches to care isn't just about keeping up with the latest trends. These principles have always had serious, practical implications for how labs deliver care and get results. Now is the time to master them.

Increased comfort and convenience lead to a better patient experience. A better patient experience leads to improved adherence, compliance, and subject retention. And that leads to better results for all concerned.

Improved patient compliance is an essential factor for better clinical outcomes. It results in improved treatment efficiency and safety. It just makes everything easier.

A positive patient experience demands much more than just the best healthcare from a clinical standpoint. It involves every step of the treatment, including how easy it is to schedule and complete the appointment as well as understand and follow the treatment plan.

Chapter 2

The Rise of Remote Patient Monitoring

"RPM is so beneficial for patients, healthcare professionals, and researchers that is has touched off a wave of innovation."

More researchers and technicians, and the clinicians who rely upon them, are adopting and adapting to new technologies that improve the quality of patient care. This has led to the proliferation of technologies based around the concept of *remote patient monitoring (RPM).*

Remote patient monitoring encompasses a broad range of approaches, from the use of mobile devices to monitor heart rate and exercise levels to the remote collection of blood and other biological specimens using techniques such as *microsampling.*

Remote patient monitoring makes many aspects of healthcare less invasive and intrusive for patients. Patients can participate in their care from the comfort and privacy of their own homes, or from anywhere they are. The expenses and opportunity costs associated with travel and long wait times are minimized. Patients take greater agency in their treatment, maintain greater stability, and are often happier than those who need to travel to have illnesses and chronic conditions monitored.[1] This type of monitoring can lead to better engagement of patients and improved satisfaction levels, as well as higher oversight of the patient.

The approach is so beneficial for patients, healthcare professionals, and researchers that it has touched off a wave of innovation. The market intelligence company Transparency Market Research forecasts significant future growth in this area of the field.[2] A report published in 2014 forecast that the remote patient monitoring market will rise by

at least 14 percent between 2014 and 2020. If the forecast holds true, then this market sector would be worth an estimated $1 billion by 2020, after being valued at about a third of that in 2013.

The rise in conditions such as heart disease, diabetes, and respiratory disease are highlighting the need to formulate modern approaches to healthcare and research across the globe. Remote monitoring devices that are part of this leap into the future include heart monitors, body temperature monitors and hematology monitors.

"The blood sampling event is simply too important too ignore."

The ability of patients to collect blood samples in their own homes and to safely send them away for testing that offers a significant opportunity for further innovations in clinical testing and patient care. The blood sampling event is simply too important to ignore.

Remote blood sampling uses microsampling technology, which can be easily used by patients themselves, in their homes. Such an approach is less invasive than traditional blood collection and is better suited for small children, and those who experience needle anxiety.

From the perspective of those collecting and analyzing samples, this approach provides a reliable and economical collection, shipping and storage solution, as well as new opportunities to gather stable samples in low-resource regions. Microsampling is a field-changing technology that can answer the challenges of the changing remote patient monitoring requirements.

Chapter 3

So, What is Microsampling, Exactly?

"Remote sampling offers flexibility to maintain comfort and deal with life's demands."

Taking Blood Collection Out of the Clinic

The Mitra® microsampling device is a novel, user-friendly, deceptively simple device. It allows participants to self-collect a volumetrically accurate blood specimen at home or anywhere that is convenient. The microsampling process effectively retains the logistical benefits of working with dried blood but solves for its limitations. Most importantly, it enables clinical labs to deliver reliable results.

After light training, participants are ready to self-collect a volumetrically accurate blood sample, any time, every time – whether they're in rural areas, in low-resourced regions, or homebound. Thus, remote sampling offers flexibility to maintain comfort and deal with life demands. Mitra collection kits offer participants the ability to simply sample-and-send, while eliminating costs and complexities associated with cold chain shipping.

The implications in areas such as therapeutic drug monitoring (TDM), which require regular sample collection for extended periods of time, are potentially transformative.

This convenient alternative to clinic visits is a crucial key to running a patient-centered lab.

A Brief History of Dried Blood Collection

"Decades ago, dried blood spot technology represented a tremendous leap forward."

Decades ago, when dried blood spot (DBS) technology debuted, it represented a tremendous leap forward in specimen collection. No longer would patients be necessarily subject to the stressful and painful venipuncture required for wet blood collection. With the prick of a finger, a specimen could be collected and transported using specialized cards and filter paper. In forward-thinking clinical labs invested in bettering patient experience, capillary blood collection showed tremendous promise.

However, through the years, several frustrating limitations have hindered widespread adoption of traditional DBS technology.

Persistent difficulties with cards and filter paper, most notably volumetric hematocrit bias[3], has long prevented clinical laboratories from establishing satisfying correlations between results generated from capillary blood and those from wet blood and plasma so that established reference ranges would remain relevant. The equipment used for card punching and automation costs a lot, and it doesn't integrate seamlessly with installed specimen processing lines.

Chapter 4

The Volumetric Hematocrit Bias

"The hematocrit bias is the most consistent frustration."

The hematocrit bias, or hematocrit effect, is the most persistent frustration that has held back widespread proliferation of DBS cards.[3]

Hematocrit is, in short, the volume percentage of red blood cells in a blood sample. Viscosity determines how well the blood spreads on the filter paper used in DBS. Blood hematocrit generally has an inverse relationship to how far the blood spreads following the sampling event. Blood with a high hematocrit level results in a smaller dried blood sample, and a lower hematocrit level results in larger-size samples.

The hematocrit bias refers to effect of this relationship on the quality and reliability of data generated from such samples. An unevenly spread sample can easily lead to a disproportionate result. It can be difficult to extract the appropriate amount of the required analyte from the surface of the DBS card. Caked-up dried blood on the surface of a DBS card can cause even greater problems.

Automation Hurdles

Automation is the future. Why? Because it reduces friction and human effort, and brings our work closer to the ideals of accuracy and consistency. In all scientific endeavors, improving consistency and accuracy is always the goal.

To meet the throughput demands of specimen processing and analysis at larger scales, automation is required. This is another factor that has debilitated the widespread adoption of dried blood sampling using

cards and filter paper. For labs processing hundreds to thousands of samples per day, it is simply too much of a challenge to automate at scale.

"DBS, in many cases, simply does not scale."

For those who have tried, automation solutions for DBS card workflows have remained stubbornly disruptive and costly, and have forced some labs to implement some seriously heavy machinery.

For DBS cards, the industry-standard configuration consists of four spot cards. For purposes of extraction, these cards must be punched by a machine and the samples must be transferred to 96 well plates.

This raises obvious logistical problems. It opens the door for cross-contamination, creating troublesome uncertainty and doubt around the concerns of consistency and accuracy. Even in the best cases, it hampers throughput, creates friction, and sours user experience.

Some DBS card automation systems include robotic handling and storage of cards, a built-in camera to ensure tracking and consistency before and after sample extraction, a washing station, and a cumbersome extraction process involving clamps, pumps, and trap columns.

Without a more effective automation solution, DBS, in many cases, simply does not scale.

The Challenge

Since the dawn of dried blood collection, its central challenges have been daunting and frustrating in their simplicity.

"How can we make it pleasant to use, so that people will want to use it?"

How do we perform the process of dried blood sampling in such a way that, to the best of our ability, ensures consistency and accuracy?

Furthermore, how do we make it user-friendly enough that labs, clinicians, and patients will want to adopt it, implement it, and take advantage of its potential to deliver better results? What does this technology look like? How is it configured? How can we make it pleasant to use, so that people will want to use it?

Chapter 5

VAMS™: What It Is and How It Works

"VAMS increases the accuracy, consistency, and efficiency of dried blood specimen collection."

Volumetric Absorptive Microsampling (VAMS™) technology was developed to solve for the limitations of the old, familiar versions of DBS technology. VAMS facilitates the collection of quantitative, volumetrically accurate specimens of blood or other biological fluid, in amounts of 10, 20, or 30 microliters, depending on the device tip selected.

VAMS allows for the elimination of venipuncture and collection tubes, along with cold-chain shipping and storage and other expensive and cumbersome steps in the collection process.

Simply put, VAMS increases the accuracy, consistency, and efficiency of dried blood specimen collection, for a simpler and more reliable process and workflow than was previously thought possible.

VAMS is the system of innovation that powers FDA Class 1, CE-IVD Mitra® microsampling devices. Sold in various configurations and amenable to easy use and downstream automation, Mitra devices

enable accurate and precise collection of fixed volumes of blood and other biological fluids.

Features that set the Mitra device apart include a fast-wicking, absorptive tip for collecting volumetrically accurate samples. In the sampling event, the user simply applies this tip to biological fluid, and a reliable specimen is collected in seconds. After that, just sample and ship – samples don't need extra time to dry, and they can be sent to the lab through simple post, with no special requirements. The entire process is simple enough for almost anyone.

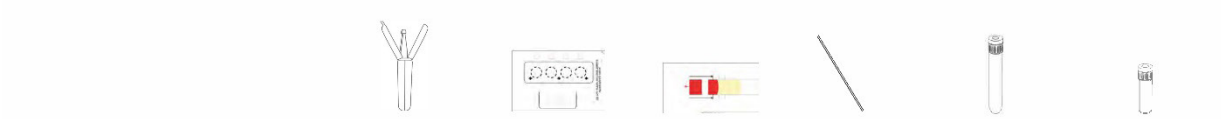
"The Mitra device provides the key benefits of working with dried blood, but with a volumetrically accurate, stable dried blood spot."

Mitra devices are available in patient- and lab-centered formats. Patient-centered formats (including the clamshell and cartridge formats) are design for easy sampling at home or anywhere outside the lab, with minimal training and no hassle. Lab-centered formats allow for streamlined microsample accessioning and extraction - the 96-Autorack format is ideal for this. Both the fully loaded and empty options are compatible with 96-channel electronic pipette and liquid-handling instrumentation.

Depending on the product and configuration, samples can be tracked using native barcodes. For medium- to high-throughput labs, extraction automation solutions allow for the processing of hundreds or thousands of samples per day.

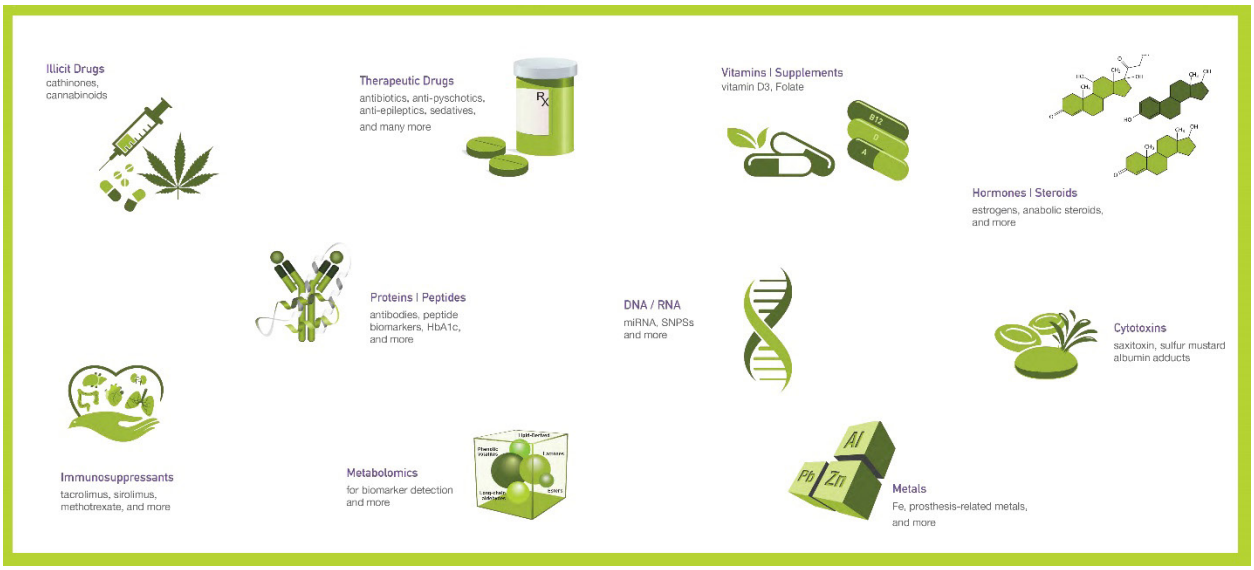
The Mitra device provides the key benefits of working with dried blood, but with a volumetrically accurate, stable dried blood spot that reduces the incidence of reworks.

VAMS technology 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)	✓	✓	✓	✓		✓
Quantitative volume collected	✓					
Easy self-collection outside of clinic	✓					
TRANSPORTATION / STORAGE						
Native barcode specimen tracking	✓				✓	✓
Ability to separate blood into plasma			✓		✓	✓
Ship by post - non-biohazard	✓	✓	✓			
No cold-chain shipping required	✓	✓	✓			
Specimen stability and storage at room temperature	✓	✓	✓			
LABORATORY PROCESSING						
Compatible with standard liquid handling instrumentation	✓				✓	✓
Convenient offline, benchtop processing	✓					

Dozens of references prove that a wide range of analytes can be extracted from the Mitra® microsampler tip, with new analytes being added all the time.



Chapter 6

Microsampling: Preferred by Patients

"The patients have spoken."

Even in its older and less advanced forms, dried blood spot sampling has been shown to slice lab costs by cutting down on unnecessary clinic visits and the associated expenditure of resources, which can instead be applied to improving patient satisfaction.

According to our own internal patient satisfaction surveys, there is another, more important way in which microsampling facilitates a more patient-centered lab. Simply put, patients prefer it.

While some have some initial trepidation about pricking their own skin with a lancet, 70% of surveyed patients report themselves "comfortable" or "very comfortable" with the overall process of collecting their own blood, via a finger-prick, in their own homes.

86% of patients find it "easy" or "very easy" to collect the drop of blood using the Mitra microsampling device. 92% report that it is "easy" or "very easy" to get the blood on the tip of the device, signifying a smarter sampling event and an improved experience at the most crucial moment of the process.

We always intended for the microsampling procedure to be a more user-friendly alternative to older, more intrusive or cumbersome methods. We believe we have achieved that, and it is good to know that our patients agree.

55% of surveyed patients who used the device declared themselves "likely" or "very likely" to choose microsampling over traditional venipuncture. And a whopping 93% said they would be "likely" or "very likely" to choose microsampling over venipuncture were they making the choice on behalf of a child. This speaks to the powerful applications for microsampling technology in the fraught realm of pediatric care.

"Microsampling is strongly preferred over older methods, probably because it was designed with simpler, more convenient sampling in mind."

The patients have spoken. Microsampling is strongly preferred over older methods, probably because it was designed with simpler, more convenient sampling in mind.

This is one reason, and perhaps the most important reason, that microsampling is a key part of creating a more patient-centered lab.

Technical Evidence for Efficacy

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.

Stable dried blood specimens have been proven to generate reliable data that correlates with the "gold standard" associated with wet blood.

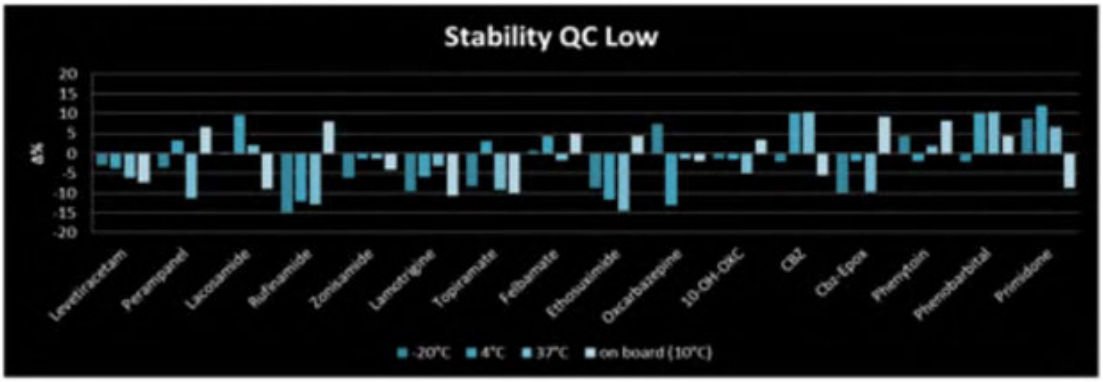
Several studies prove that bioanalytical data generated from specimens collected with a Mitra® device is accurate and dependable. When labs develop methods with simple and effective extraction protocols, the resulting analytical method will eliminate most forms of assay bias, including hematocrit and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

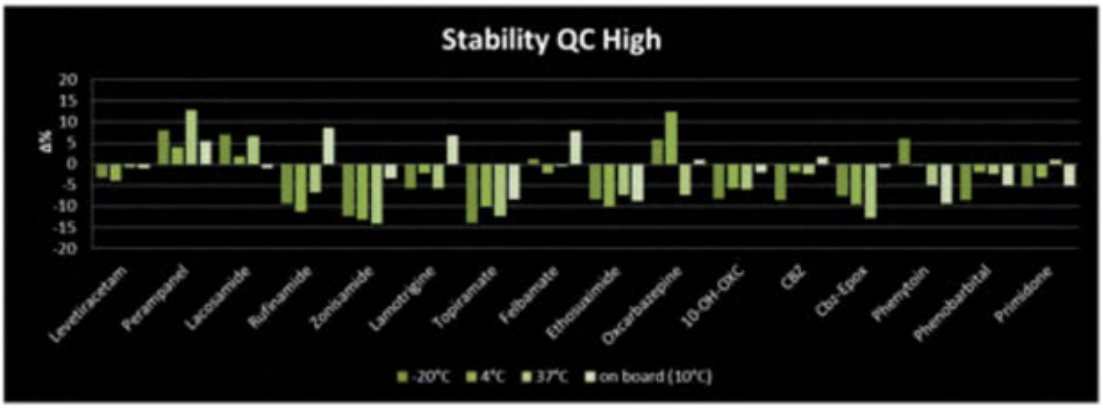
The study excerpted below is for a panel of anti-epileptic drugs, the method developed optimized extraction efficiency to be greater than 86% - as a result, there were no examples of HCT bias or stability bias that were outside the range of acceptability.

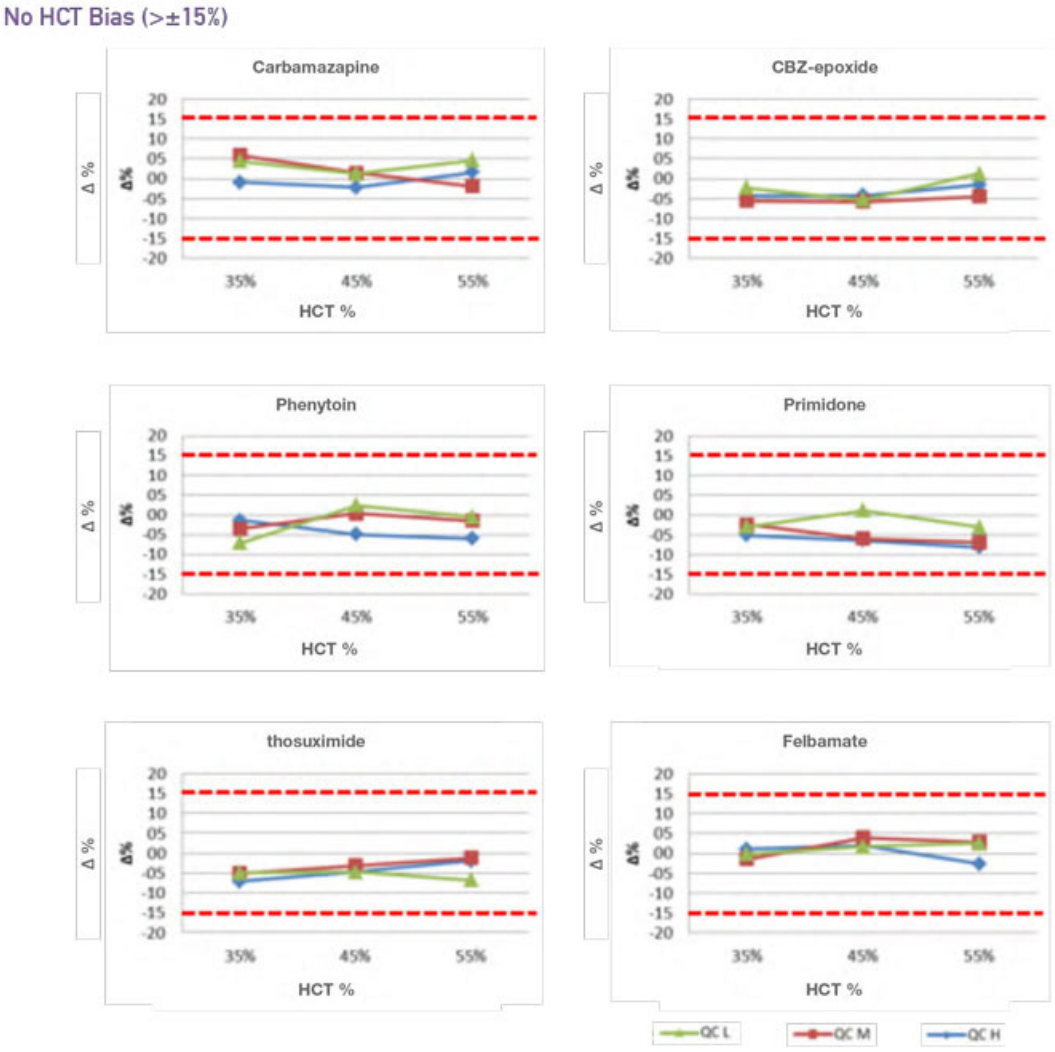
Evaluation of Matrix Effect (ME), Extraction Recovery (ER), and Process Efficiency (PE)

		LEV	PMP	LCM	RUF	ZNS	LTG	TPM	FBM	EXT	OXC	10-OH-OXC	CBZ	CBZ-E	PHT	PHB	PRM
QC LOW	ME%	98	102	94	91	93	99	92	93	99	100	97	104	90	86	91	95
	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
QC HIGH	ME%	102	103	100	97	104	89	104	99	111	93	105	104	96	98	108	94
	RE%	95	100	102	112	97	112	99	100	102	94	105	94	105	101	102	102
	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





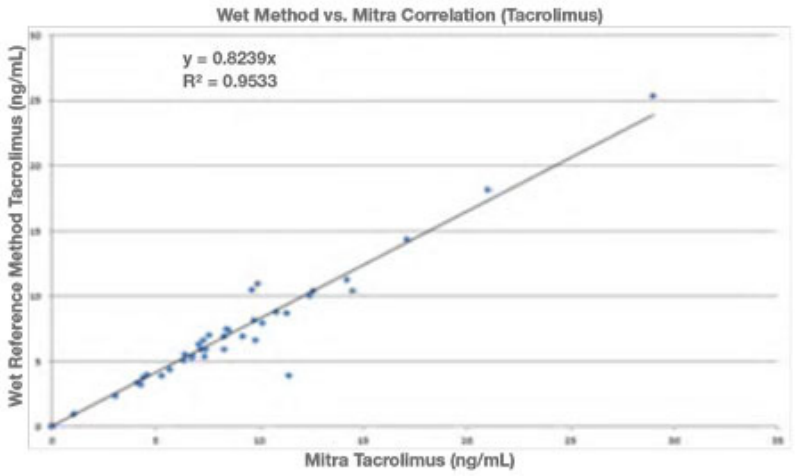


All data generated by Dr. Ugo de Grazia (Fondazione IRCCS Istituto Neurologico Carlo Besta)

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.

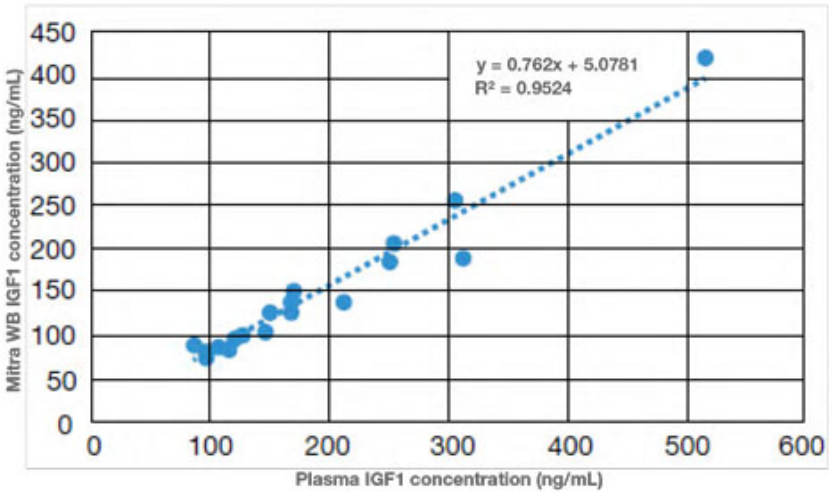
The below-excerpted bridging study defines the slope of a linear regression comparing the concentrations that would be determined from plasma to those determined from whole dried blood.

Immunosuppressive Drugs (Tacrolimus) | Protein Crash Extraction



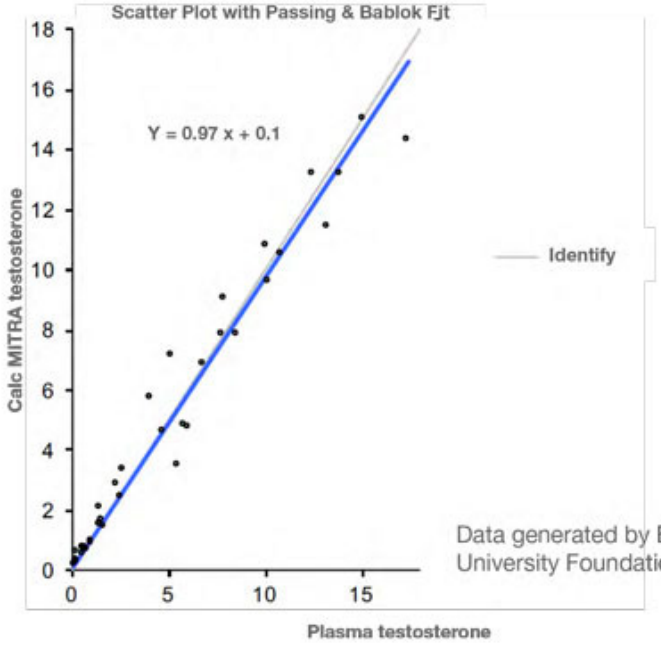
Data generated by
Stephen Stephenson
(Leeds Teaching Hospital)

Peptides/Proteins (IGF-1) | Aqueous Extraction



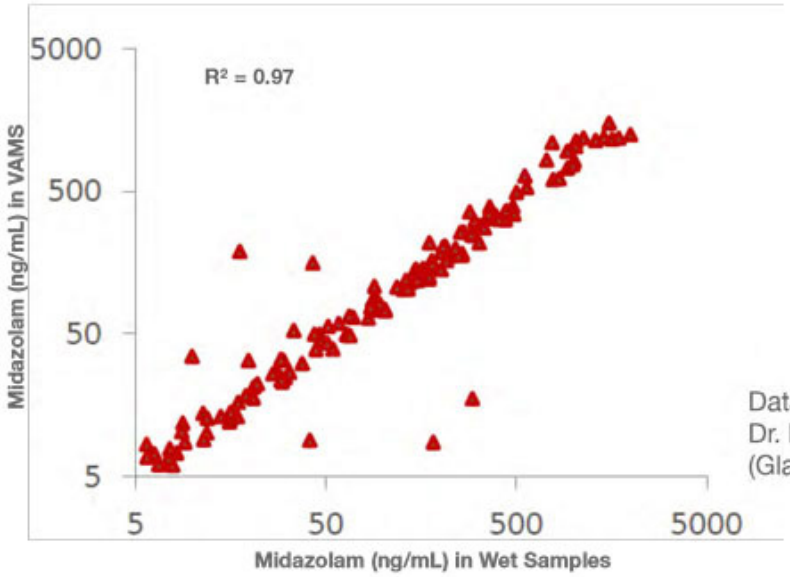
Data courtesy of
The Christie Pathology
Partnership LLP

Steroids (Testosterone) | Organic Extraction with Fit Correction



Data generated by Brian Keevil (Manchester University Foundation Trust)

Therapeutic Drugs (Midazolam)



Data generated by Dr. Paul Abu-Rabie (GlaxoSmithKline)

Microsampling In the Clinical Lab

Clinical and hospital labs are where it all comes together.

In patient-centered medicine, comfort and convenience are paramount. Remote sampling makes things easier for patients, which boosts adherence and compliance, helping labs get better results.

"Things are getting smaller. Simpler. Easier to use."

But the positive affect on patients goes further than this. By empowering patients to collect their own samples, remote sampling makes them more active participants in their own care. When they can participate in the process – with microsampling, they can perform the sampling event for themselves, and understand directly how simple yet vital it is – they can gain a greater appreciation for their own care, their own biology, and their own lives.

From telemedicine to remote patient monitoring, from health and wellness to the "lab on a chip," the dominant trend in healthcare technology is that things are getting smaller. Simpler. Easier to use.

Of course, these objectives must be perused without sacrificing accuracy and consistency. If anything, the new generation of patient-centered medical innovations must be more accurate and more consistent. That, along with savings on cost and labor, is the most important reason to improve efficiency.

Enabling remote specimen collection is one step in a process of streamlining, simplification, and modernization. It may be the most important step, opening new frontiers for research and care. But we emphasize that it is only one step.

Neoteryx was created to deliver on the promise of microsampling. It develops, manufactures, and distributes the technology that makes microsampling a reality. It does not perform testing, or do anything else with the specimens themselves – it leaves that up to its diverse array of high-profile partners and customers.

"Neoteryx was created to deliver on the promise of microsampling."

Chapter 7

The Road to Deployment: A Tested Step-by-step Customer Roadmap

"Customers who succeed in implementing microsampling come from all sorts of backgrounds and verticals."

Neoteryx has seen a range of customers achieve remarkable success with microsampling technology. Keys to a successful implementation include enthusiastic buy-in at the executive level, a willingness to take an intelligent short-term risk in service to a long-term vision, and a commitment to scientific rigor at every step.

Customers who succeed in implementing microsampling come from all sorts of backgrounds and verticals, but most follow a common trajectory on their way from becoming aware of microsampling to deploying it in their own laboratories and facilities.

Here are four steps most of our customers have gone through as phases of their journeys to microsampling success.

1. Education

Thanks to the marvels of the internet, it is easily possible for all of those who are sufficiently interested to educate themselves in depth on microsampling technology, at no cost. All they have to do is dig into our extensive library of resources, including background information, supporting data, and past models for future success.

"In concert with our R&D team, you will develop a robust bioanalytical method."

At some point in the education process, it will be time to speak with a Microsampling Specialist in person to determine what microsampling solution will best address your unique situation. This often begins with a phone call or teleconference, which can be easily scheduled.

2. Evaluation

In the evaluation phase, you may receive your complimentary introductory sample of Mitra product and use tested step-by-step protocols to perform simple proof-of-concept studies using your devices.

After an initial hour-long teleconference, expect periodic check-ins to walk you through any areas in which you need help, leading to a mid-point review and a concluding review of your data set when it is time for you to move on to the validation phase.

3. Validation

In concert with the R&D team, you will develop a robust bioanalytical method. Meanwhile, your Microsampling Specialist will be there to help work through the logistics of commercialization.

By the end of your validation, you will have accurately judged the quality, reliability, and consistency of the results you generated from the method you employed.

4. Deployment

"Smarter, more convenient specimen collection—anywhere, anytime, by almost anyone."

You are now ready to commercialize your use of Mitra microsampling devices and Volumetric Absorptive Microsampling technology for smarter, more convenient specimen collection — anywhere, anytime, by almost anyone.

Chapter 8

Some Frequently Asked Questions

"Ample research shows that dried blood microsamples from a fingerstick can yield quality results."

For those curious about what microsampling is and how it works, Neoteryx has many resources available on neoteryx.com, in their growing resource library, and on their FAQ page. However, when the time comes to use this technology, more complex questions often arise.

In their work helping large and small organizations adopt breakthrough microsampling technology, they've witnessed recurrent patterns in what sorts of questions are salient. Some frequent concerns many initially face about microsampling include:

Does dried capillary blood correlate to wet venous blood? And is 10, 20, or 30 µL enough?

Ample research shows that dried blood microsamples from a fingerstick can yield quality results which correlate to or may even match values from traditional blood collection methods. The literature available is broad and shows the relevance of microliter volume specimens in clinical and preclinical applications. Download the VAMS™ publication list and review these comparative studies to see what others have achieved.

Have any organizations successfully implemented dried blood microsampling?

Yes. Organizations, from academic research institutions to commercial clinical reference labs, are successfully deploying this nontraditional specimen collection technology. Examples include Exagen Diagnostics, Charles River Labs, Quest Diagnostics, Altasciences, and many others.

Is the Mitra Microsampler a registered medical device?

Yes, it is an FDA listed Class 1 device (D254956) as well as a registered CE IVD. Neoteryx complies with FDA good manufacturing practices, CFR 820 regulations, and ISO 13485.

Is Mitra microsampling more expensive than my current collection method?

On average, the cost is $2.50 per test, and initial validation requires an upfront investment of time and resources. However, any initial friction is well worth it. Mitra microsampling technology saves money (e.g., no cold-chain shipping or storage), labor (e.g., compatible with typical liquid handling instrumentation), and resources (e.g., use non-clinical staff to collect specimens) over time.This allows for future growth.

How much time will it take to implement microsampling technology?

Based on client experiences, the process to thoroughly explore the applicability of Mitra microsampling typically takes 6-8 months and is divided into three phases.

Education [1 - 2 weeks]: The introductory phase is your opportunity to familiarize yourself with what can and can't be done with dried blood microsamples.

Evaluation [4 - 6 weeks]: In this second phase, a microsampling specialist will guide and support you through extraction, linearity, and signal-to-noise studies.

Validation [6 - 8 months]: In this final phase, you'll perform a complete method validation including stability testing and correlation studies. Work closely with your microsampling specialist to plan for commercialization.

When you're ready to move forward – or if you still have more questions – contact your Microsampling Specialist for a consultation.

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Appendices

A-1
About Emerson Dameron
Content Marketing Manager, Neoteryx

Emerson Dameron is a writer, storyteller, and content strategist. He joined Neoteryx in 2016 to help consolidate its industry knowledge and share its story with the world of healthcare. In collaboration with Neoteryx scientists, researchers, and executives, his work helps Neoteryx fulfill its mission as a leader in healthcare technology and facilitating more patient-centered clinical labs around the world, through various channels and relationships. He has previous experience in technology, business, wellness, entertainment, design, and automation. He holds a degree in journalism from the University of Georgia and lives in Los Angeles. He acknowledges the assistance of Dr. Stuart Kushon PhD (Chief Scientific Officer at Neoteryx), Dr. James Rudge PhD (Technical Director at Neoteryx), and Cathy Cordova (Director of Marketing at Neoteryx) in creating this document.

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About Neoteryx

Neoteryx was founded in 2014 to develop, manufacture, and sell the Mitra® microsampling device, which enables the collection of blood anywhere, at any time, by anyone. Microsampling facilitates an easier and more comfortable donor experience, particularly for children and the elderly. This novel technology also contributes to expanding participant outreach, eliminates costs and hassles associated with cold-chain shipping, and enables collection of blood specimens at home or in other settings outside of the clinic. It is based in Torrance, California, with a worldwide focus and presence.

Neoteryx began as a spin-off of Phenomenex, a global leader in novel analytical chemistry solutions with over 30 years of proven innovation in the separation sciences.

Four years of internal research and development, along with a co-development program between Phenomenex and major American and European pharmaceutical companies, resulted in the revolutionary Volumetric Absorptive Microsampling (VAMS™) technology. This technology and related intellectual property developed at Phenomenex was transferred to Neoteryx, which now manufactures products for the collection, storage, and transport of biological fluids.

Neoteryx's first product release, in July of 2014, was the Mitra® Microsampling Device, which collects 10 or 20 µL of fluid in seconds without volumetric blood hematocrit bias.

Find out more at:
https://www.neoteryx.com/
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A-3
About *DARK Daily*

DARK Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession. New developments, new technology, and changing healthcare trends make it imperative to stay informed to be successful. At the same time, the Internet, cell phones, blackberries, laptop computers and wireless devices are overwhelming any one individual's ability to absorb this crushing Tsunami of data.

"Dark Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession."

DARK Daily is a quick-to-read, easy-to-understand alert on some key development in laboratory medicine and laboratory management. It has no counterpart in the lab world. Why? Because it is produced and written by the experts at THE DARK REPORT and The Dark Intelligence Group, who know your world, understand your needs and provide you with concise, processed intelligence on only those topics that are most important to you!

You will find *DARK Daily* to also be an exceptionally valuable resource in laboratory and pathology management. Some of the lab industry's keenest minds and most effective experts will be offering their knowledge, their insights and their recommendations on winning strategies and management methods. Many of these experts are unknown to most lab directors. As has proven true with THE DARK REPORT for more than a decade, *DARK Daily* will be your invaluable— and unmatched—resource, giving you access to the knowledge and experience of these accomplished lab industry professionals.

A-4
About The Dark Intelligence Group, Inc. and THE DARK REPORT

"Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner."

The Dark Intelligence Group, Inc., is a unique intelligence service, dedicated to providing high-level business, management and market trend analysis to laboratory CEOs, COOs, CFOs, pathologists and senior-level lab industry executives. Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner. This gives them first access to new knowledge, along with the expertise they can tap to keep their laboratory or pathology organization at the razor's edge of top performance.

It offers qualified lab executives, pathologists and industry vendors a rich store of knowledge, expertise and resources that are unavailable elsewhere. Since its founding in 1996, The Dark Intelligence Group and THE DARK REPORT have played instrumental roles in supporting the success of some of the nation's best-performing, most profitable laboratory organizations.

The Dark Intelligence Group (TDIG) is headquartered in Austin, Texas. This location makes it very accessible for any laboratory organization seeking input, insight and support developing their business operations, creating effective business strategies and crafting effective sales and marketing programs that consistently generate new volumes of specimens and increasing new profits. The Dark Intelligence Group, Inc. owns and operates two Web sites in the TDIG Website network:

THE DARK REPORT

http://www.DarkReport.com

DARK Daily
Clinical Laboratory and Pathology News/Trends

http://www.DarkDaily.com

A-5
About the *Executive War College on Laboratory and Pathology Management*

Every spring since 1996, the lab industry's best and brightest gather at the *Executive War College on Laboratory and Pathology Management* to learn, to share and to network. Many consider it to be the premier source of innovation and excellence in laboratory and pathology management.

Each year, a carefully selected line-up of laboratory leaders and innovators tell the story of how their laboratories are solving problems, tackling the toughest challenges in lab medicine and seizing opportunities to improve clinical care and boost financial performance. The *Executive War College* is the place to get practical advice and solutions for the toughest lab management challenges. A unique case study format brings participants face-to-face with their most successful peers. They tell, first hand, how their laboratory solved intractable problems and successfully used new technology.

Many lab management secrets are shared, along with specific "what-not-to-do's" gained from hard-won experience! It's not pie-in-the-sky theory, but useful knowledge that can be put to use in any lab. The *Executive War College* offers superlative networking, with lab administrators and pathologists attending from countries as far away as the United Kingdom, Germany, Brazil and Australia. It makes the *Executive War College* a melting pot for all the best ideas, new lab technologies and management strategies now reshaping the laboratory industry. It's also become a recruiting ground used by headhunters and major lab organizations.

In the United Kingdom, The Dark Intelligence Group and the Association of Clinical Biochemists (ACB) have co-produced a meeting every February since 2003. Known at *Frontiers in Laboratory Medicine* (FiLM), it attracts laboratory leaders and innovators in the United Kingdom. Also featuring a case study format, this meeting pioneered the international laboratory side-by-side case study, where a North American laboratory and a United Kingdom laboratory prepare a comparison of best practices and an operational assessment of their two organizations.

In September 2005, a laboratory management meeting called *Executive Edge* was conducted in Toronto, Ontario, Canada, by The Dark Intelligence Group and QSE Consulting. It provided pathologists and lab directors in Canada with a customized meeting devoted to the strategic and operational issues of laboratory management in Canada.

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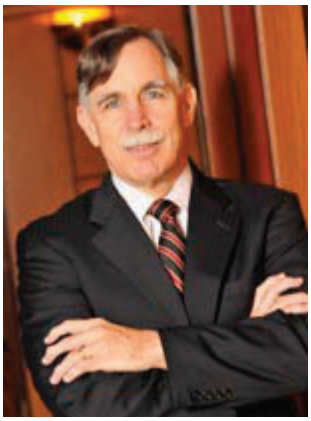
About The Editor: Robert L. Michel



Robert L. Michel is a respected commentator, consultant, author, editor, speaker, and entrepreneur. He is a leading expert on the management of clinical laboratories and anatomic pathology group practices.

Lab Industry Leader and Consultant

Michel is Editor-In-Chief of The Dark Report <http://www.darkreport.com/index.htm> and President of The Dark Intelligence Group, Inc. Over the past three decades, he has provided strategic and tactical management services to a wide variety of companies, ranging from Fortune 100 firms like Procter & Gamble and Financial Corp. of America to leading laboratories ranging from Nichols Institute to hospital and health system laboratory organizations. He has a special talent for spotting new business opportunities in clinical diagnostics and identifying winning strategies to pursue them.

Some of his current and past clients include: Meridia Health System (Cleveland, OH), PACLAB Regional Laboratory Network (Seattle, WA), Consultants in Laboratory Medicine (Toledo, OH), PAML, Inc.(Spokane, WA), UMASS Healthcare Reference Laboratories (Worcester, MA), Ortho-Clinical Diagnostics (Raritan, NJ), Pathology Service Associates (Florence, SC), DIANON Systems, Inc, (Stratford, CT), Beaumont Health System (Detroit, MI), MedTox Laboratories, Inc. (St. Paul, MN), Joint Venture Hospital Laboratory Network (Detroit, MI), Bayer Diagnostics (Tarrytown, NY), Bio-Reference Laboratories, Inc. (Elmwood Park, NJ), Specialty Laboratories, Inc., (Santa Monica, CA), National Health Service-Pathology Services (London, England), Doctor's Laboratory (Valdosta, GA), Sysmex Corporation (Mundelein, IL), Pathologist's Medical Laboratory (La Jolla, CA), Abbott Laboratories (Abbott Park, IL), St. John Clinical Laboratory Pathology Laboratory (Detroit, MI), Esoterix, Inc.(Austin, TX), Beckman Coulter Corporation (Fullerton, CA), Health Care Systems, Johnson & Johnson (Atlanta, GA), ARUP Laboratories, Inc. (Salt Lake City, UT), Institute for Quality in Laboratory Medicine (Atlanta, GA), and American Society of Clinical Pathology (ASCP-Chicago, IL).

Michel was first to identify and describe many of the widely-used management strategies in the operation of clinical laboratories and pathology practices. He has one of the best track records of predictions in laboratory management over the past decade and a half.

Michel is a member of the Clinical Laboratory Management Association <http://www.clma.org/> (CLMA), the American Association of Clinical Chemistry <http://www.aacc.org/AACC/> (AACC), Specialized Information Publishers Association <http://www.newsletters.org/> (SIPA).

Popular Journalist, Author & Editor

Michel writes and edits The Dark Report <http://www.darkreport.com/>, a business intelligence service for pathologists and laboratory executives that, over its eleven years of publication, has garnered national and international respect of its ground-breaking coverage of events and industry trends within the laboratory profession.

International Meeting Innovator, Public Speaker

Michel is the Founder and Director of the Executive War College on Lab and Pathology Management <http://www.executivewarcollege.com/>. First conducted in 1996, this gathering has become the premier forum for laboratory management in the world. For pathologists, he developed the Pathologist's Income Symposium a meeting series which is exclusively focused on helping pathologists increase their practice income, as well as their professional income. Every September he hosts a meeting by The Dark Report called Lab Quality Confab <http://www.labqualityconfab.com/>. It is an annual gathering dedicated to advancing the knowledge, skills, and effectiveness of quality management practitioners in diagnostic medicine. Programs, LEAN information, and training are designed for every level of management and all levels of knowledge and experience. Diagnostic medicine, particularly the services of clinical laboratory, pathology, imaging, and radiology, make up the primary emphasis of the Lab Quality Confab.

Since 2004, he has co-produced Frontiers in Laboratory Medicine <http://www.frontiersinlabmedicine.com/> (FiLM) in the United Kingdom with the Association of Clinical Biochemists <http://www.

acb.org.uk/>. This meeting has quickly earned a reputation as the best source of laboratory best practices in Europe. In 2005, Michel co-produced Executive Edge <http://www.exec-edge.com/> in Canada with QSE Consulting. This meeting about strategic laboratory management innovations in Canada proved popular and is repeated in the fall since 2005.

Michel is regularly asked to address laboratory industry groups. In addition to regular speaking engagements throughout the United States, he has traveled to Brazil, England, Canada, Australia, Korea, Japan, Ireland, and South Africa to address laboratory audiences in those countries. Meeting participants regularly rate Michel's presentations as one of the best at the event.

Experienced Educator, Strategist, and Business Facilitator

Over the past decade and a half, Michel has been invited to provide Grand Rounds and teach clinical laboratory and pathology management at the pathology departments of such medical schools as University of Minnesota, University of California at Los Angeles and University of Texas Southwest/Houston. He has provided strategic assessments to laboratory organizations, IVD manufacturers, pathology groups, information technology vendors, biotech companies, and diagnostic start-up companies. He is regularly asked to facilitate strategic management retreats and business planning meetings for such clients as PAML, OML, Sysmex Corporation.

Michel received his B.A. in Economics from the University of California at Los Angeles. He is a native of Santa Ana, California and currently lives and works in Austin, Texas.

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