

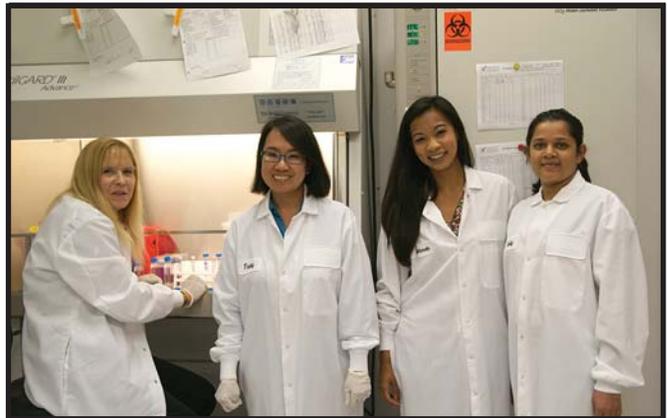
Case Study: Success with CHANG MARROW™



ResearchDX takes Personalized Medicine to the Next Level

Irvine Scientific's CHANG MARROW™ Bone Marrow Culture Medium is the product of choice for ResearchDx.

ResearchDx is a Contract Diagnostics Organization (CDO) that offers integrated diagnostics research, licensed and accredited clinical laboratory services, manufacturing, and consulting.



Leading their Industry

ResearchDx is the leading Contract Diagnostics Organization (CDO) for the biopharmaceutical and diagnostic industries. They provide integrated, turn-key, flexible services to meet their customers' objectives, and manage the entire diagnostic development process from initial assay concept and discovery through clinical research to regulatory approval. ResearchDx truly takes diagnostics R&D to the next level.

A Vital Service

In the era of personalized medicine, biopharmaceutical companies need partners that can easily and readily adapt to meet new or unexpected challenges during the development process. Traditional Contract Research Organizations cannot meet all the demands of developing companion diagnostics. ResearchDx offers integrated services within one organization, and can design, manage, and coordinate all aspects of the development of a diagnostic product.

Philip D. Cotter, PhD, FACMG, FFSc (RCPA)

Dr. Cotter is a Principal and Co-Founder of ResearchDx, and Laboratory Director of Pacific Diagnostics Clinical Laboratory in Irvine, CA – a subsidiary of ResearchDx. Dr. Cotter has been published extensively in the areas of cytogenetics, molecular genetics, prenatal diagnosis, and oncology.



Dr. Cotter says, "We do a lot of clinical trial work, and a large percentage is in the molecular oncology space, but also in some of the more highly complex esoteric genetic testing space. If you ask me what my average day looks like, no two days are really the same – but days usually include some case review and I also do a lot of consulting for clients. So a big part of my day is working with clients on regulatory issues, licensure, or helping clients validate assays and open clinical labs."

Using Irvine Scientific

ResearchDx uses CHANG MARROW™ for their bone marrow cultures. "It's a specialty item with some distinct differentiators that I like. We also choose to get our basal media and buffers from Irvine Scientific. We do a fair amount of tissue culture work and stem cell karyotype analysis for various clients – and we grow a lot of exotic cell lines for various customer projects. With rare exceptions, we buy almost all of our culture products from Irvine Scientific," says Dr. Cotter.



Laboratory Profile

- Located in Irvine, CA
- Opened in 2008
- Services include:
 - Assay development, platform evaluation, and validation
 - Management of all levels of regulatory compliance, processes, applications, and approvals, including FDA submissions for 510(k) or Premarket Approval (PMA) clearances
 - CLIA approved and CAP accredited Clinical Laboratory services
 - GMP manufacturing services
- Uses Irvine Scientific CHANG MARROW™ Bone Marrow Culture Medium with Gentamicin, basal media, and buffers

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This is not to say that they didn't look at other brands. According to Dr. Cotter, "We chose CHANG MARROW™ because it's comparable to, or even better quality than, other media, and the price is more competitive. You can't beat that. I've observed that there are noticeably fewer no-growers with CHANG MARROW™ compared to a competitor product. We even ran a side-by-side study of about 50 cases, and with Irvine Scientific, there is a performance difference.

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Customer Service Matters

Good customer service is something that is often overlooked by companies. Dr. Cotter says, "Irvine Scientific's customer service is above the norm in my opinion. By comparison, I don't believe I've ever received a call from other vendors. We are definitely not high-maintenance, but it is nice to have a vendor who checks up on you – one who cares about your needs and wants to know how everything is going with the products. It makes a difference. And Irvine Scientific is a great company to work with."

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Dr. Cotter adds, "The three things that I look for in a vendor are quality product, competitive pricing, and customer service. With Irvine Scientific, I get all three. I have had zero problems whatsoever, and I really like the quality. All of the products that I get from Irvine Scientific consistently do exactly what I expect them to do, and the pricing is competitive."



It Ultimately comes down to the Patient

Labs always strive to obtain the best possible results in the shortest amount of time. According to Dr. Cotter, "Anything that allows us to get quality results quickly is good for the patient. The way I think of it is, CHANG MARROW™ results are one piece of the diagnosis puzzle – and, together with the other pieces – this helps us find the right diagnosis, which drives finding and providing the best treatment for the patient. Anytime you're missing any one of those pieces, it's clearly to the detriment of the patient. So your choice of media is one of those important pieces of the equation."

"The fact that we have seen fewer culture failures is substantial to our business – it's good for us and it's good for the patient too. Sometimes labs and businesses can lose the perspective that, after all, somebody has cancer. We need to do the absolute best job we can, because it may provide a significant result that can help the individual patient."

www.irvinesci.com

Irvine Scientific - Corporate

2511 Daimler Street
Santa Ana, CA 92705
USA
Phone: 1 (949) 261-7800
Toll Free: 1 (800) 437-5706
Fax: 1 (949) 261-6522
www.irvinesci.com

Irvine Scientific - Ireland

Unit 31, Newtown Business & Enterprise Park
Newtownmountkennedy
County Wicklow
Ireland
Phone: +353 1 281 99 20
Fax: +353 1 281 99 28
Email: cgriffin@irvinesci.com

Irvine Scientific - Japan

3-17-35 Niizo-Minami
Toda-Shi
335-0026 Saitama
Japan
Phone: +81 48 433 2063
Fax: +81 48 433 2112
www.isjpn.co.jp



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