

Quotient banks on biodiagnostics

Edited by Carren Bersch, Editor

This month, *MLO* is pleased to introduce to its International Corner Mick Hannan, vice president of Marketing, at Quotient Biodiagnostics, headquartered in Newtown, PA. Mr. Hannan answers several questions about Quotient Biodiagnostics' global activities that are sure to interest readers.

MLO: While there is much being made by many organizations that "global" is a relatively new way of doing business, it appears that Quotient Biodiagnostics has been global since its inception, by virtue of its R&D and operations arm, Alba Bioscience, conducting business commercially worldwide. Your website mentions that Alba, was originally established in Scotland in the 1940s to manufacture blood-typing reagents but has grown to serve not only the U.K. market but markets worldwide, mostly on an OEM basis. So, Quotient Biodiagnostics is now moving into America, to serve customers directly, is that correct?

Hannan: Alba Bioscience, originally part of the Scottish National Blood Transfusion Service, was privatized and subsequently purchased by Quotient in 2007. Alba, for much of its existence both as a public and private entity, has been operating solely as a global original equipment manufacturer (OEM), manufacturing and developing products for major transfusion companies that were sold under those companies' labels in more than 30 countries throughout North America, Europe, and Asia. In 2007, Alba was purchased by the U.K.-based company Quotient Bioscience, which in early 2009 reorganized into two distinct businesses: 1) Quotient Bioresearch, which is a contract research organization focused on drug development — everything from lead optimization to late-phase clinical trials and sports medicine, primarily drug testing for the horse- and dog-racing industries. 2) Quotient Biodiagnostics, which is the transfusion diagnostics division, of which Alba is the manufacturing and R&D arm, and 'Quotient Biodiagnostics' is the name to our end-user customers. Quotient Biodiagnostics' president and CEO, Jeremy Stackawitz, is located in the U.S. but, as you would imagine, spends quite a bit of time in the U.K.

MLO: With the announcement of the formation of Quotient Biodiagnostics, we are, of course, interested in your varied products and how those affect all things "medical

laboratory." Can you tell us when you were FDA-licensed and began to provide products for the American marketplace? Your April 7, 2009, press release indicated that you expect to expand your existing range of products over the next 12 to 18 months — almost a year has passed since that announcement. Can you tell our American readers exactly what products they could expect to purchase from Quotient Biodiagnostics presently and in the near future? Have

many American labs been introduced to Quotient Biodiagnostics' products in this last year and, if so, what is the feedback you are getting from them in terms of performance, and results.

Hannan: Quotient Biodiagnostics received Food and Drug Administration (FDA) approval on Oct. 16, 2009, for its first Biologics License Application (BLA) covering 15 monoclonal antibodies for use as blood typing reagents. These ALBAclone products include seven antisera for ABORh blood typing as well as eight products for typing rare antigens. Quotient also has some enhancement media and control products approved via 510k, as well as two specialty products. One is the ALBAclone Advanced Partial RhD Typing kit, for identifying weak and partial D variants — this is a product most likely to be used in the reference laboratory setting. The second is the Quant-Rho FITC Anti-D product for quantifying fetomaternal bleeding via flow cytometry to establish the proper dosage for Rh immune globulin. Quotient has nearly 40 additional products in various stages of review at the FDA. These include red cell products (reverse typing, antibody screens, and panels), anti-human globulin, and a number of additional rare polyclonal

and monoclonal antisera. We expect the full portfolio to be available by the end of 2010.

MLO: Have the same products you are offering in the USA been available in Europe and in other countries through Alba or Quotient, or are those totally different types of products than the ones you have introduced in America? Can you describe what your Evaluation Program means for a potential customer?

Hannan: Almost all products have been on the market already in Europe or elsewhere for several years, either under the Alba Bioscience or one of the other major transfusion companies' labels. There may have been some slight varia-



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tions made for the U.S. market in formulation, instructions for use, name, etc. Our Evaluation Program has been established to allow interested laboratories to try out our product vs. their current suppliers' risk-free, and with minimal hassle. We will provide the ALBAclone products to laboratories to evaluate. If, as we expect, the product meets specifications, we would expect to receive an order, especially given our very competitive prices. If, for whatever reason, the lab does not want the product, it can simply return the product at no charge. In addition, as much of the time and effort of doing an evaluation is the thinking and set-up time of the protocol and how exactly the evaluation will be conducted, our technical director — who has 20 years experience with a hospital laboratory and 15 more years in quality and compliance with the American Red Cross — created a starting-point protocol to help meet the needs of most labs. She is also available through our Technical Service line to help walk laboratories through the process, as needed, in addition to full product support, if and when labs begin to use them regularly.

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MLO: In terms of the types of products, are the needs of medical laboratories in other countries different from those in the United States? In developing countries, are there perhaps one or two products used more frequently than those used in Europe or in America? Do you use different marketing techniques for each region or for each country when you begin to distribute your products?

Hannan: Transfusion diagnostics needs are essentially the same throughout the world — to provide reliably safe transfusions to customers. There are some geographical variations, however, with regard to the frequency of certain antigens and antibodies as well as levels of automation. Also, pricing is highly variable. Our product line is primarily aimed at laboratories that do substantial manual typing and screening, either as their primary means of diagnosis or as backup to an automated system to clarify discrepant or unusual results. This means that in many cases our products are more relevant in the U.S. vs. our home market of Europe, because Europe is a much more automated market, whereas 60% to 70% of the U.S. market is manual. This has much to do with the decentralized nature of U.S. demographics vs. Europe where medical care is much more centralized in large centers.

Another area where our European heritage may be an advantage is in the area of D antigen detection. The European market for historical reasons has been much more focused on the detection of various weak and partial D variants than the U.S. That, however, is changing, and we provide a product line that is specialized in this area.

We have four anti-sera to detect D antigen, including the world's only monoclonal antibody that detects the DVI variant through direct agglutination. We also have the ALBAclone Advanced Partial RhD Typing kit that identifies partial RhD

types, generally giving comparable results to molecular analysis at a fraction of the cost. Finally, we have the Quant-Rho FITC Anti-D product which quantifies fetomaternal hemorrhage by *in vitro* labeling of RhD positive cells for analysis by flow cytometry, allowing better dosing decisions for Rh immune globulin.

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Our marketing approach in the U.S. is also different. This is actually our second time launching our ALBAclone products here in the U.S. Originally, Alba tried to apply a European strategy in the U.S. by commercializing through an agent. That did not gain much traction, as the U.S. medical community demands more on-hand infrastructure and support than that method could provide. As a result, we regrouped, and with the approval of this first set of products, we are building our own direct infrastructure here, complete with a direct sales force and dedicated technical and customer service. The focus of our marketing is to emphasize the quality of our products — given our years of experience and the fact that we are the second largest manufacturer of blood-banking monoclonal antibodies in the world; emphasize our focus on customer service — which we believe has been lacking in the U.S. market — and a competitive price. As mentioned, outside the U.S. and the U.K., we are primarily an OEM supplier to other transfusion diagnostics companies that would be in charge of commercialization.

MLO: What challenges do Quotient Biodiagnostics' representatives overseas face personally and professionally as part of the organization's global outreach? What challenges did/does the organization face in developing its global business? Of all the details that one must confront in mastering global outreach, what are the "Top 3" suggestions you would give a newly minted Quotient Biodiagnostics' employee who was pursuing the American arm of the business?

Hannan: Because our business outside the U.S. and U.K. is primarily as an OEM supplier, we do not have a direct sales force in those regions. Our challenges in coming to the U.S. are that the market has essentially been divided between two or three companies for a long time. While many laboratories have told us that they are desperate for another supplier, blood bankers are by definition a careful and conservative group. This deliberateness results in some inertia to evaluate new suppliers.

We have to be sure that:

1. laboratories are knowledgeable of our years of experience manufacturing and developing products;
2. we as a company ensure that we are always thinking about how can we provide superior customer service; and
3. we demonstrate the value we can bring to a laboratory.

Then we simply to provide tools that enable laboratories to evaluate our products as quickly and easily as possible. □

Learn more about Quotient Biodiagnostics at www.quotientbd.com.