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Robert Rae

CEO-Pro-Lab Group of Companies



Welcome to Pro-Lab Diagnostics. Originally established in 1974 the Pro-Lab Group of companies is dedicated to the provision of high quality, cost effective immunodiagnostic products. We trust that you will enjoy the update provided here, and look forward to being of continued service to the exciting industry in which we have all chosen to work.

The “Past” & “Future” of Streptococcal Grouping

Classification of beta haemolytic streptococci into serogroups based upon cell wall antigenic polysaccharides was first described by Lancefield (1933). Each “Lancefield Group” was described by a letter, however only a few are clinically significant in the field of human diagnostic microbiology, Lancefield groups A, B, C, D, F and G.

The identification of these clinically significant Lancefield groups forms an integral part of the routine microbiology carried out in today's busy diagnostic testing laboratories. With increasing pressure for results to be made available faster, whilst maintaining specificity and sensitivity, Pro-Lab Diagnostics is dedicated to researching this area.

The identification of clinically significant streptococci and their group specific carbohydrate antigens has traditionally been demonstrated by a number of techniques including group specific precipitation, fluorescent antibody sera and agglutination tests with antigen extracted from organisms using enzymes. This latter method became common in numerous laboratories offering results after 20 - 30 minutes incubation at 37°C. An alternative to the enzyme extraction procedure was to use Nitrous Acid extraction. This offered the advantage of speed, whilst reducing the incubation time to only a few minutes, and could be carried out at room temperature. A disadvantage to the method was its inability to detect D antigen in streptococcal or enterococci, and concerns were also raised over the use of nitrous acid.

Prolex® New and Blue, developed by Pro-Lab Diagnostics, offers a breakthrough in routine streptococcal grouping. Results can now be obtained instantly at room temperature for all six clinically significant Lancefield group streptococci including group D.

This breakthrough has been made possible by the development of a set of unique modified acid extraction reagents. Following a simple instant extraction procedure at room temperature, results are clearly visible when the extracted carbohydrate antigen is mixed with specific

antibody coated latex particles. As the name of the kit suggests, the coated latex particles also harbour new innovations. The use of specific sized blue carboxylated latex particles, coated with antibody using a proprietary technique, offers clearer and faster agglutination reactions against a white background.



Prolex® New and Blue is available in kit format, as single reagents, or as custom designed kits allowing customers to select the groups required. The reputation of New and Blue is growing rapidly throughout the international market as more and more clinical laboratories introduce this new innovative method to their daily routines.....don't miss out, Streptococcal grouping has changed !

Samples and introductory demonstrations are available on request, please contact the sales team or simply email prolexblue@pro-lab.com.

(Clinical trial data is available on request from Pro-Lab Diagnostics)



An Independant Review of New & Blue

By Steve Davies, Biomedical Scientist Grade 3, at the Microbiology Department, Northern General Hospital, Sheffield (formerly Sheffield Public Health Laboratory).



Above: Steve Davies & Staff

I was approached by Pro-Lab Diagnostics, to enquire if I would be interested in evaluating the new Prolex®-Blue Streptococcal Grouping kit, against three rival kits that are in world-wide use. This was a brave decision as previously, in the Yorkshire region, we had been one of the few laboratories, who hadn't moved over to the Prolex®-White kit. It was obviously going to be very time consuming, to extensively evaluate the kit, so I enlisted the help of four experienced colleagues working at the former Sheffield Public Health Laboratory, namely Julie Gear, Lindsay Hall, Clare Mason and Sharon McIntyre. The paper presenting the results of the study has been accepted for publication in a future edition of the Biomedical Scientist Journal. A brief summary of our results follows

except group F. The Prolex®-Blue and the three rival kits all performed well, with regard to identifying the correct serogroup. However, two of the kits, Prolex®-Blue and an enzyme-based alternative manufacturer kit produced the better results in terms of overall identifications and speed of agglutination. Of importance, the Prolex®-Blue gave rapid agglutination results with Lancefield Group A beta haemolytic streptococci. It also successfully sero-grouped the majority of enterococci, possessing the Group D antigen, which is obviously unusual for an acid-based extraction kit. As Prolex®-Blue offered the advantage of instant results at room temperature, without the need for incubation, it was introduced for routine use within our laboratory. We have subsequently been using Prolex®-Blue successfully for approximately 12 months. In addition, the kit can either be purchased in standard format or in a customised Strep-Select format that allows the user to choose their own combination of 'grouping' reagents. In summary, I have no hesitation in recommending Prolex®-Blue to other workers involved in the time-consuming function of 'grouping' beta-haemolytic streptococci.

We investigated approximately 300 strains of recently isolated beta haemolytic streptococci. Each of the medically important serogroups was well represented,

Exhibition Update

Pro-Lab Diagnostics will be supporting the following scientific meetings in the very near future. Further details can be obtained from our customer support desk on 0151 353 1613, fax 0151 353 1614, or uksupport@pro-lab.com/exhibitions.



September 15-17th 2003. HPA Conference, Warwick. Pro-Lab Diagnostics is pleased to support the first scientific conference of the newly established Health Protection Agency (HPA) which was created on 1st April 2003.



September 29th - October 1st 2003. Institute of Biomedical Science Congress, ICC, Birmingham. An important date for all Biomedical Scientists. Visit the Pro-Lab Diagnostics booth to experience the Strep-Tease. Visit Booth No. 208.



November 19th - 22nd November 2003. Medica, Dusseldorf. The International Diagnostics Forum. Visit Booth No. 3A72.



May 23rd - 27th 2004, New Orleans, United States of America. American Society of Microbiology 104th Annual General Meeting.



September 9th -12th 2004, Ranmoor House, Sheffield. Always popular, always successful. Visit www.microbe.org.uk for full details.

VLA Profile



The Veterinary Laboratory Agency is an executive agency of DEFRA (Department for Environmental, Food and Rural Affairs), with scientific origins dating back to 1894. Many animal health scientific challenges have been tackled over the years and success stories include the eradication or control of classical swine fever, anthrax, rabies, tuberculosis, Newcastle disease, warble fly and brucellosis.

These achievements have earned the VLA an international reputation for scientific excellence as it has led the world in developing new techniques for the diagnosis and management of animal disease. VLA scientists have had a significant influence on the development of animal health policy in both the UK and Europe and the laboratory has achieved World Reference Laboratory status for many important diseases.

As an Agency, VLA also has the opportunity to broaden its customer base by providing services to the private sector.

During the early 1990's, through detailed discussions with Pro-Lab Diagnostics, a need was identified for a reliable commercial source of high quality slide agglutination antisera for the serological typing of salmonella isolates in the field of diagnostic microbiology. The combination of the expertise of the Salmonella Reference Laboratory at VLA Weybridge, the skills of the VLA Business Services Division, and the internationally recognised reputation of Pro-Lab Diagnostics as a leading manufacturer and supplier of kits and reagents for in-vitro diagnostic use in microbiology, led to the formation of a unique relationship.

This relationship has now flourished, and will soon celebrate its 10th anniversary. "Vision" Salmonella Slide Agglutination Antisera now enjoy an international reputation, based upon quality, service and reliability. The range of antisera available has been carefully chosen to reflect the needs of today's microbiologist. Full details for the range is available from Pro-Lab Diagnostics.

In addition to the extensive range of Salmonella Sera available, Pro-Lab Diagnostics also supplies antisera for the serological identification of Shigella, and the identification of common pathogenic Clostridia or their toxins.



INTRODUCING NEW STAFF: CLAIRE BURROWS



Pro-Lab Diagnostics is pleased to introduce Claire Burrows, our latest addition to the technical sales team. Claire graduated from university achieving full honors in Microbiology, followed by a post graduate certificate, before starting her career in microbiology in Wolverhampton. Having gained extensive experience in this field, Claire's career then progressed into technical sales and marketing with a leading supplier of analytical reagents before joining Pro-Lab Diagnostics in 2002.

Claire brings a wealth of experience to the company and has responsibility for the promotion and technical support of all products manufactured and supplied by Pro-Lab Diagnostics to the London and South East regions.

An Update from the Quality Team

Pro-Lab Diagnostics is dedicated to achieving the highest possible standards of product performance and service to all of its' customers on a world wide basis. Having initially achieved registration under ISO9001:1994, we are pleased to advise that all members of the Pro-Lab Group now operate under the ISO9001:2000 standard, an additional achievement that we are proud of. Further to this, preparations will soon be completed for registration to ISO13485.

The In Vitro Diagnostics Medical Device Directive was published by the the European Union in 1998. Currently, all countries in the European Economic Area are in transition phase, diligently preparing for the full implementation of the directive by December 7th 2003.

In accordance with the requirements of the directive, all products manufactured by Pro-Lab Diagnostics after the 7th of December 2003 will carry the CE mark. There is then a further two year period during which products manufactured or placed in the market place before the 7th December can still be used or placed in service.

Customers will not see any changes in the packaging of our products, however labelling and technical insert requirements will be different in accordance with the directives' standardised requirements. It is intended that instructions for use (IFU's) will be supplied on pocket sized compact discs (CD), allowing convenient access for all customers to all IFU's for products manufactured by Pro-Lab Diagnostics on a single CD. This CD will also allow convenient access to many other documents such as material safety data sheets, performance characteristics data, reference material, associated product details and much more.

Should you have any questions, or require any further guidance in relation to the above quality standards and the CE mark, please do not hesitate to contact our regulatory affairs department.



Microbank® – World Wide Performance Portfolio. Pro-points

Microbank®, the unique system manufactured by Pro-Lab Diagnostics for the long term storage and retrieval of bacterial and fungal cultures, will soon be celebrating its' 10th birthday. Comprised of a unique cryovial system incorporating treated beads and a special cryopreservative solution, that ensures longer survival of fastidious cultures and higher quantitative recoveries. Numerous references are now available for the performance of Microbank® in many recognized centres of excellence and reference centres around the world.

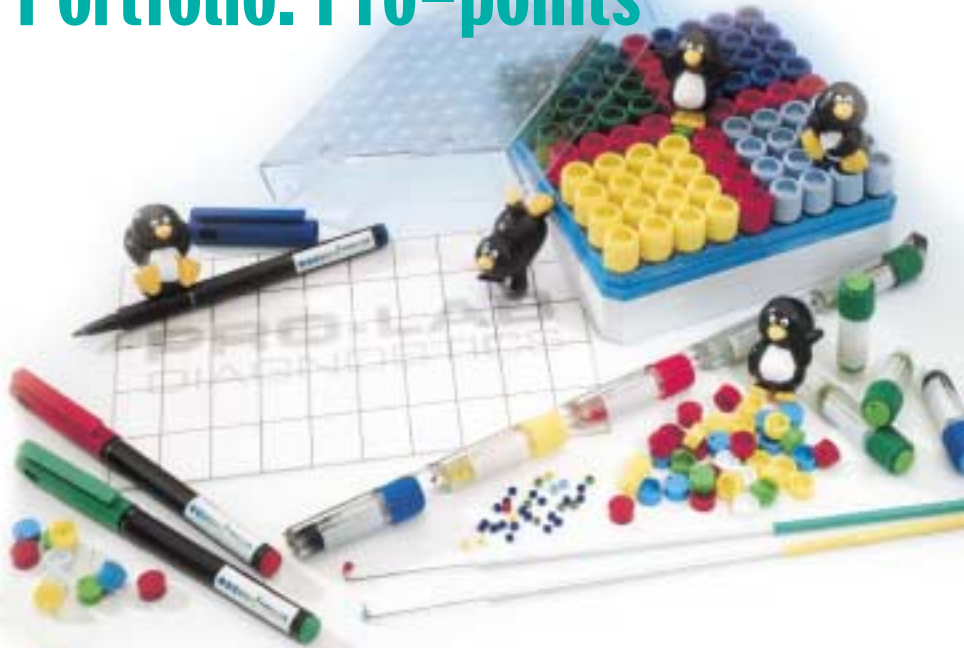
To celebrate 10 years of unparalleled success, the Microbank® World Wide Performance Portfolio is being updated with the help of all customers on a global scale. Once completed copies will be made available free of charge.

In addition to this, as a reward to the loyal users of the Microbank®, we are pleased to advise the introduction of the "Pro-Points" loyalty scheme.

Simply by completing the enclosed registration form / MWVPP data submission, you will receive your registration card, and an initial allocation of Pro-Points to be applied to a collector card. You will also of course be making a valuable contribution to the performance portfolio. All data will be treated in the strictest confidence and will only be used for collation into the main databank.

Pro-Points can then be collected with all purchases of Microbank® and associated products. As a reward for loyalty to Microbank®, and your valuable culture collection, completed cards can then be exchanged personally with your local technical representative for the Microbank® Accessory Pack shown above. This pack includes the Microbank® storage box with tube retrieval tool, Microbank® Cryopen, Microbank® Cryocane, Microbank® Cap Colour Coders, and the unique "Microbank® Bead Extraction Tool."

Thank you for your continued valued support.



Product details

| | | | |
|---------|---------------------------------------|-------------------------------|-------------|
| PL160B | Microbank® | Blue Colour Coded Beads | 50 vials |
| PL160G | Microbank® | Green Colour Coded Beads | 50 vials |
| PL160R | Microbank® | Red Colour Coded Beads | 50 vials |
| PL160Y | Microbank® | Yellow Colour Coded Beads | 50 vials |
| PL160LB | Microbank® | Light Blue Colour Coded Beads | 50 vials |
| PL160M | Microbank® | Mixed (10 vials each colour) | 50 vials |
| PL155-1 | Cryoblock Insulated Aluminium Block | | 20 Wells |
| PL165 | Laminated Log Book | | 12 Charts |
| PL166 | Aluminium Cryocanes | | 12 Canes |
| PL169B | Microbank® Freezer Storage Box - Blue | | 9 x 9 Wells |
| PL169R | Microbank® Freezer Storage Box - Red | | 9 x 9 Wells |

The Stain Connection

Pro-Lab Diagnostics is now recognised as a leading supplier of an extensive range of microbiology stains in both ready to use and concentrated format. All stains are manufactured to the highest standards in our own purpose designed facilities, using the finest raw materials and subject to strict quality control and filtering prior to dispatch to the customer. The product range has increased over the years reflecting the changing needs of the market place with the addition of more stains in convenient 100ml concentrated formats that are simply diluted to 1 litre working volumes. The use of concentrated stain reduces shipping costs and storage space, whilst offering added convenience to the end user. New formulations have also been introduced to enhance performance whilst maintaining classical staining results. New products have also been added to the range in response to changing market demands such as Polychrome Methylene Blue (B.anthraxis stain), Sudan Black, Sandifords stain, Liqui-Iodi Fortis and many more.

The Stain Connection from Pro-Lab Diagnostics, offers a unique service which allows the customer to select their annual requirements on a fully flexible service and delivery arrangement. All stock handling and delivery schedules are taken care of by a dedicated customer service representative when you join the Stain Connection. For further details of Stain Connection membership, and the service and supply advantages it can offer, please contact our customers services department on **Tel 0151 353 1613**, **Fax 0151 353 1614**, **email stainconnection@pro-lab.com**.

Also available, immersion oil (PL396) in convenient 25ml dropper bottles, call customer services for sample availability



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