

An Independent Review of New & Blue



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Introducing bioTRADING

Pro-points. Worldwide Microbank Performance Portfolio



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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.

For demonstrations in Holland, please contact bioTRADING, tel 0297 286848, fax 0297 287570, email sales@biotrading.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,

Pro-Lab Diagnostics & bioTRADING form unique partnership at HET 2004



We are pleased to announce a new exclusive partnership between Pro-Lab Diagnostics and bioTRADING, for the promotion and supply of products manufactured and supplied by Pro-Lab Diagnostics in Holland.

We are delighted that bioTRADING will be distributing the products, and see this as an exciting new phase for us all. Please be assured that all supplies, service issues, pricing arrangements and technical support will be maintained to the highest possible standards that you deserve.

The excellent reputation of bioTRADING, together with its dynamic sales approach, reputation and credibility will, we believe, be of great benefit to you the customer.



All future orders for products manufactured by Pro-Lab Diagnostics should be sent directly to:

bioTRADING benelux B.V.,
P.O.Box 254, 3640 AG Mijdrecht,
phone 0297.286848,
fax 0297.287570,
e-mail sales@biotrading.com.

We wish bioTRADING, and you the customer, every success.

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.



Now Available Exclusively from bioTRADING

An update from the quality team.

Pro-Lab Diagnostics continues its dedication to achieving the highest possible standards of product performance and service to all of its customers on a world wide basis. We are pleased to advise that all members of the Pro-lab group are now registered under the guidelines of ISO9001:2000, and also the latest requirement of ISO13485, an achievement that we are all proud of.

By now, you will be familiar with the presence of the CE mark on over 1000 products manufactured and supplied by Pro-Lab Diagnostics in accordance with the In Vitro Diagnostics Directive published by the European Union. Changes will have been seen in the labelling of products and also in the format of the IFU (instructions for use), provided with all products. The supply of essential material safety data information, is also now supplied in the new required format. An example is shown below for Microbiology stains, with interpretation of the standard symbols.

Pro-Lab Diagnostics are proud to provide CE labelled products to our customers. Our willingness to proactively invest in this capability is one more reason customers turn first to Pro-Lab Diagnostics as a primary manufacturer and supplier of products for microbiology.

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

Product Description
Risk and Safety phrases
Catalogue Number
Specific Lot /Batch Number
Storage Temperature Range.
"CE" Mark
Manufacturer
Product Vol / Pack Size
For In-Vitro Diagnostics Use
Hazard Warning Symbol Area
Expiry Date, Year / Month
Refer to Instructions for Use

Testing Times for E.coli 0157:H7

Prolex® E.COLI 0157 LATEX TEST REAGENT KIT offers a rapid agglutination test kit for the presumptive identification of E.coli serogroup 0157.

Escherichia coli serotype 0157:H7 is a verotoxin producing (VT-producing) pathogen reported as an etiological agent in sporadic and outbreak cases of haemorrhagic colitis. It is also associated with haemolytic uraemic syndrome. Certain E.coli serotypes other than 0157:H7 also produce verotoxin. However, the diarrhoea caused by these other serotypes is not usually bloody. Additionally, E.coli serotype 0157:H7 does not ferment sorbitol whereas the majority of other serotypes do ferment sorbitol.

Therefore, if Sorbitol-MacConkey agar medium is used as a primary screen, the colonies of E.coli serotype 0157:H7 appear colourless (non-sorbitol fermenting colonies- NSFC) while colonies of other serotypes appear characteristically pink (sorbitol fermenting colonies-SFC).

The Prolex® E.coli 0157 latex kit reliably identifies E.coli strains associated with Haemorrhagic Colitis and Haemolytic Uraemic Syndrome.

Results can be obtained in two minutes with a single colony taken directly from selective agar. This unique reagent has also been developed to remove common cross reactions with other similar "O" and "H" antigens, in particular E.hermanii also a NSFC on Sorbitol-MacConkey agar.

Latex particles are coated with an antiserum against E.coli 0157 antigen. When the coated latex particles are mixed with fresh colonies of E.coli serotype 0157 the bacteria will bind to the antiserum, causing the latex particles to visibly agglutinate (positive reaction). Bacteria which are not 0157 serotype will not bind to the antiserum and will not result in agglutination (negative reaction).

Available in 50 and 100 test formats, each kit has a maximum shelf life of "two years" from date of manufacture, and includes mixing sticks, agglutination cards, positive and negative controls. Also available is a single latex reagent for the

identification of the E.coli flagella H7 antigen, allowing for the complete definitive identification of E.coli 0157:H7.

- | | |
|-------|---------------------------------|
| PL070 | E.coli 0157 Latex Kit 50 Tests |
| PL071 | E.coli 0157 Latex Kit 100 Tests |



Microbank® – World Wide Performance Portfolio.

Microbank®, the unique system manufactured by Pro-Lab Diagnostics for the long term survival and retrieval of bacterial and fungal cultures, is 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 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, and once completed will be available to all Microbank® users.

The MWWPP will include -

- 10 Years of successful storage data from the UK Anaerobic Reference Centre.
- 10 years of storage data for 100 strains of Neisseria gonorrhoeae, representing 8 protein IA serovars, and 14 protein IB serovars, at the Scottish Gonococcal Reference Laboratory.
- Long term storage of fastidious Campylobacter and Helicobacter.
- 10 Years of storage data for over 500 salmonella cultures held at the UK Salmonella Reference Centre.
- Many references and recommendations from reference and research collections around the world, including - Staphylococci spp, E.coli 0157, Pseudomonas spp, Campylobacter spp, Streptococci, Yersinia spp, Legionella spp, and many more.
- The quality and performance guarantee of the Microbank® system remains unchallenged, and we look forward to continually serving you and your valued culture collections.

Thank you for your continued support to the MWWPP.



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



For details of the Stain Connection in Holland, please contact bioTRADING email - sales@biotrading.com



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