

Testing Times for E.Coli 0157



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Microbank® – Now recognised as the international choice.

Microbank® presents a unique ready-to-use system designed to simplify the storage and retrieval of bacterial and fungal cultures, now recognised as the first choice for reliability, quality and guaranteed performance.

Comprised of a unique cryovial system incorporating treated beads and a specially developed cryopreservative solution. Microbank® continues to provide a more reliable means of maintaining important cultures than repetitive subculture, which can result in contaminated cultures, lost organisms or changed characteristics. The specially formulated preservative ensures longer survival of fastidious cultures and higher quantitative recoveries. Each 2ml Microbank® vial contains approximately 25 beads, providing repeated cultures of the original organism using a simple procedure.

Microbank® is the only system with an extensive collection of reference data available for many bacteria and fungi, including numerous fastidious species, collected from dedicated users over many years throughout the international field of diagnostic, research and educational microbiology.

This data has been collected with the help of many customers, to whom we are grateful, using the "Microbank® World Wide Performance Portfolio", featured in earlier editions of "The Pulse". This data is now available to all users upon request, and includes submissions from internationally recognised reference centres with valuable collections stored on the Microbank® system.

To register for your copy, call the Sales Co-ordination desk on 0151 353 1613 or email uksupport@pro-lab.com.

Popular applications of the Microbank® system include the storage and regular retrieval of bacterial cultures required for internal quality control of microbiological media, either prepared within the laboratory or supplied to the laboratory from commercial sources, and the control of specific microbiological procedures within the day to day laboratory routine. Included in this edition of "The Pulse", we are pleased to introduce a suggested scheme developed by Mr. Peter Taft whilst working at the Bury District General Hospital, Lancashire UK.

Robert Rae

CEO-Pro-Lab Group of Companies



Welcome to the current edition of "The Pulse". Once again we are pleased to offer an update of our activities, and also introduce our U.S facility. Recent expansions within all divisions of the Pro-Lab Diagnostics Group, have allowed for increased production capacity and product development capabilities, further details of which we look forward to sharing with you all on a personal level in the very near future. We also take this opportunity to thank all of our customers for their continued support, and look forward to being of continued service to you all in the future in the ever changing field of microbiology.



"Since the first Sheffield Microbe in 1986, the aim of the 'Microbe' committee has been to provide a high quality, value for money, symposia for anyone working in the field of medical microbiology. This years conference from 9-12th September is no exception, and is held at the usual venue, Ranmoor House, Sheffield. Anyone who has attended previous Microbe conferences can expect the usual high standard of topical

microbiology lectures presented by leaders in their field. There is also an excellent trade show supported by over 35 companies, to whom we offer our sincere thanks for their continued support, and of course the usual action packed and varied social programme to suit all tastes."

Mick Bell- Microbe Committee.

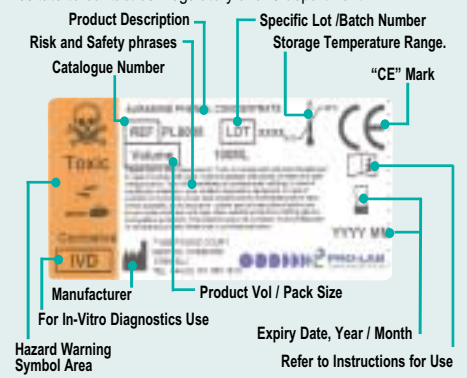
An update from the quality team.

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.



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 aren't 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



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.



Microbe 2004 September 9th - 12th 2004, Ranmoor House, Sheffield, UK.



Medica International Diagnostics Forum. November 24th - 27th 2004, Dusseldorf.



Health Protection Agency Annual Scientific Conference. September 13th - 14th 2004, Warwick, UK.



Wessex Applied Microbiologists Meeting. April 15th - 17th 2005. Southampton Novotel, UK. www.wam2005.org



Lab '04. September 14th -16th 2004. Lillestrom, Norway.



British Society of Microbial Technology 20th Annual Scientific meeting. May 2005, Colindale, UK. www.bsmt.org.uk



Southwest Association of Clinical Microbiology. Annual Conference September 15-18 2004. Texas, USA.



105th Meeting. American Society of Microbiology. June 5th - 9th 2005. Atlanta, USA.



National Laboratory Managers Meeting. October 28th-29th 2004. HPA Colindale, UK.



Institute of Biomedical Sciences Congress. September 26th - 28th 2005. International Convention Centre Birmingham, UK.



South-eastern Association of Clinical Microbiology. Annual Conference 3rd - 6th November 2004. South Carolina. USA.

An Internal Quality Assessment Scheme for Clinical Bacteriology using Microbank®

One definition of quality is meeting the pre-determined requirements of users of a product or service. An effective quality management system (QMS) determines the needs and expectations of users and determines the processes, responsibilities, and resources required to meet quality objectives. In the laboratory, quality control (QC) procedures should be used in conjunction with external and internal quality assessment (QA), audit, and equipment monitoring as an integral part of the QMS. QC allows the day-to-day monitoring of assay, operator, and equipment performance. It should detect both random and systematic errors.

Criteria for QC material In general QC material should:

- Be independent of kit controls
- Be stable over a long period of time
- Be of sufficient volume to monitor within and between kit and reagent batches
- Give results within a clinically significant range (for bacteriological cultures, this means target organisms)

It is the availability of suitable QC material that presents a problem in developing a suitable internal QA scheme in clinical bacteriology. One scheme that has been established for QA in clinical bacteriology involves the original specimen being anonymised and then re-submitted for analysis (1). However, problems associated with this type of QC material include:

- Failure to meet at least two of the criteria listed above
- Repeat inoculation of a swab onto a second set of plates may present a different picture (depending on the number of organisms originally present)
- A high percentage of bacteriology samples are negative, and this does not challenge the ability to isolate 'target' organisms
- Although this type of scheme assesses reproducibility, it does not detect systematic errors (because you don't know what you might be missing)

Use of simulated specimens using Microbank® beads.

We evaluated an alternative scheme over a six-month period using simulated specimens preserved on Microbank® beads. Seven simulated specimens were prepared as follows:

- Using freshly isolated colonies, a suspension of the target organism was prepared equivalent to a 2 McFarland standard in a Microbank® vial.
- To simulate a clinical specimen, colonies of typical mixed normal flora were then added to make the final suspension equivalent to a 5 McFarland standard (see Table 1)
- Mix thoroughly, and decant all the beads and suspension into a petri dish
- Using sterile forceps, place each bead into individual cryo-tubes Label, and store at -80c

Mr Peter Taft



Specimen Type	Target Organism(s)	Other Organisms Present
1. Throat swab	Group A Streptococci	Mixed oral flora
2. Throat swab	C.diphtheriae	Mixed oral flora
3. Sputum	H.influenzae	Mixed oral flora
4. Sputum	Strep pneumoniae	Mixed oral flora
5. Wound swab (burn)	Staph aureus, Ps aeruginosa	Coagulase negative Staph
6. Faeces	Group D Salmonella	E.coli, Proteus mirabilis
7. Faeces	E.coli O157	E.coli (sorbitol positive)

Day to day use

Each of the seven simulated specimens were processed once per week as follows:

- Remove a vial from the -80c freezer and allow to warm to room temperature
- Add 1ml of nutrient broth to the bead and mix
- Inoculate a routine set of plates using a swab dipped into the broth
- Enter the specimen details onto the laboratory computer using agreed format

Results

Over the six month period (June 2003 – Dec 2003) the target organism(s) was isolated and correctly identified from 100% of six out of the seven simulated specimens. On two occasions we failed to isolate the H.influenzae from specimen number three.

Discussion

Once prepared these simulated samples are simple to set up, record, and score. They are also inexpensive. They realize all the criteria described above for QC material. Drawbacks include the fact that these are not real specimens, and that after 'pooling' some organisms may survive better than others at -80c. We now need to try some fastidious organisms such as N.gonorrhoeae, Campylobacter sp, and anaerobic organisms. It could be argued that staff will soon get to know which organisms are present in these samples. However, this argument could be also applied to most QC material used in Haematology and Clinical Chemistry and is not relevant unless a 'blame culture' exists in the organization. Used properly a successful internal QA scheme will increase confidence in results, and in conjunction with external QA, and audit, identify problems and measure effectiveness of solutions.

1. Constantine CE, Amphlet M, Farrington M, et al. Development of an internal quality assessment scheme in a clinical bacteriology laboratory. J Clin Pathol 1993; 46: 1046-1050

Coming up in the next issue ...

- Testing times for Vancomycin Resistance.
- Prolex® Blue Staph - The Next Generation.
- International News.
- Legionella - A new challenge.

EXPANDED FACILITIES

Recent investments made throughout the Pro-Lab group have led to major expansions in production, research and development, and distribution capabilities.



The European facility based in Neston, Cheshire UK has recently opened a new distribution warehouse primarily to supply the ever increasing demand for Prolex Latex Agglutination Systems throughout Europe, in particular the Prolex® New and Blue Streptococcal grouping System (emailprolexblue@pro-lab.com).

This expansion has also led to an increased capability in production of ready to use and concentrated microbiology stains in all traditional sizes and also in kit format. As can be seen from the "action shots" included here, this has allowed Pro-Lab Diagnostics to work actively in the supply of large national, international, and government supply contracts.

Pro-Lab Diagnostics extends a very warm welcome to our new Southeast (US) Sales Representative, Ms. Sonja Shelstad. Sonja comes to us with a combined Science and Sales background from Esoterix Lab - Austin TX and as a graduate of one of the top schools in the United States - The University of Texas at Austin! Contact - email: ussupport@pro-lab.com.

In addition to all of the above divisional changes, our head office facilities in Richmond Hill, Toronto Canada, not be left out, have recently completed a considerable expansion in laboratory, production, research and training facilities. Once again, our willingness to proactively invest in these capabilities gives reasons for customers to turn first to Pro-Lab Diagnostics as a primary manufacturer and supplier of products for microbiology.

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