



Aptima Assay Dr Paul Bartley

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) are among the most prevalent sexually transmitted pathogens worldwide. Most of these infections occur in sexually active younger patients and are asymptomatic. Undiagnosed and untreated infections lead to epidemic spread and a high risk of bacterial invasion of the upper genital tract. Upper genital tract infections in women are characterised by pelvic inflammatory disease, ectopic pregnancy, and tubal infertility. Because of the very high asymptomatic infection rates in both genders, there is great interest in establishing screening programs in select populations.

PCR-based testing has revolutionised diagnosis for CT with significant improvements in diagnostic sensitivity and specificity (compared to DFA-based assays). Culture of urethral, vaginal or endocervical swabs remains the gold standard for NG diagnosis. Culture facilitates accurate diagnosis and also antimicrobial susceptibility testing – crucial for Public Health purposes and the evaluation of empiric therapy. However, PCR-based detection in urine, cervical and vaginal specimens has an important role, especially where prevalence is high or where there may be delay between specimen collection and processing. Typically, the sensitivity of PCR for CT detection is approximately 90 to 95% and for NG it is 80 to 85%. Specificities for both tests are >99%. The point prevalence of NG in all specimens referred to QML Pathology is 2% and for CT 7-10%.

QML Pathology is about to implement a new testing method for the molecular diagnosis of CT and NG from male and female urines and genital specimens. The APTIMA Combo 2 (AC2) assay (Gen-Probe Incorporated) detects CT and NG ribosomal RNA (rRNA) by a transcription-mediated amplification (TMA) technique from standard genital and urine specimens simultaneously. All specimens submitted for CT and/or NG PCR will be tested for both pathogens. This testing strategy meets Commonwealth Regulatory guidelines for nucleic acid detection assays.

QML Pathology has recently evaluated this new technology against older PCR-based methods in nearly 3000 clinical specimens. Our evaluation has demonstrated a 100% sensitivity and 99.8%

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specificity for CT (compared with 90% and 100% for the PCR-based method) and 100% sensitivity and specificity for NG (compared with 86% and 100% for PCR).

This new technology will substantially reduce false positive results and dramatically reduces the frequency likelihood of invalid results due to inhibitors within the specimen.

This test should be used for the detection of CT and NG in first-catch urine (FCU) and swab specimens (male urethra, female endocervix or high-vagina).

This assay performs equally well for both CT and NG detection in either FCU or swab specimens from both men and women regardless of symptoms. Therefore the collection of FCU from both asymptomatic and symptomatic patients produces accurate results with improved patient convenience.

NOTE: Vaginal, endocervical or male urethral swabs should still be submitted for NG culture.

It would be helpful if referring clinicians would request both CT and NG PCR with each submitted specimen.

Swab specimens (blue – male; pink – female) should be inserted into the accompanying tube of liquid preservative immediately after collection. The dry swabs currently used are not considered optimal for the new assay. The collection tube containing the liquid preservative is specific for this assay, and is unsuitable for all other molecular tests.

Interpretation: A positive test confirms the presence of CT or NG. However, a negative test does not absolutely exclude infection.

Please contact your local Medical Liaison Officer for a copy of this test collection guide. For further queries regarding testing please contact Dr David Drummond, Dr Renu Vohra or Dr Paul Bartley on (07) 3840 4444.

Collection Statement Information

Request forms, sample collection and labelling are areas of transfusion practice that are crucial to patient safety and quality outcomes. Morbidity and mortality still occurs due to failure of correct patient identification at the time of sample collection, infusion of the wrong product or infusion to the wrong patient.

In October 2001, the ASBT (Australian Society of Blood Transfusion) in conjunction with the NHMRC, released clinical transfusion practice guidelines that have a direct bearing on aspects of pretransfusion testing, particularly in regard to documentation of the transfusion process.

Blood Bank laboratories are accredited by NATA against ANZSBT (Australian and New Zealand Society of Blood Transfusion) Guidelines for Pretransfusion Testing 4th Edition 2002 with an Amendment Note 2004.

These guidelines are minimum requirements which all Pathology laboratories must adopt in order to maintain NATA accreditation.

The guidelines are strict when it comes to the information required on request forms and on patient specimens and are summarised below.

Request Forms

The request form must clearly identify the patient and include in legible form:

- Patient surname, given name in full
- Date of birth
- Date and time of collection
- Name of requesting physician and signature
- Hospital and ward
- Details of the request, i.e. type and no. of blood products required
- Special requirements, eg. irradiated and/or CMV negative
- Date and time blood is required
- Type of surgery or Clinical diagnosis and indication for transfusion
- Signature of the collector on the sample to confirm the correct labelling of the sample and correct identification of the patient at the time of collection
- The collector must also sign a statement on the request form as follows:

Person Drawing Blood:

I certify that the blood specimen(s) accompanying this request was drawn from the patient named above and I established the identity of this patient by direct inquiry and/or by inspection of wrist band and immediately upon the blood being drawn I labelled the specimen(s).

Signature

This Certification statement now appears on the QML Pathology Request Form

In emergency situations, where the patient's identity is unknown, an alternative reliable documented method of identification shall be substituted and be reliably linked to the patient's name once available.

Other information should include:-

- Previous transfusion history
- Known red cell antibodies
- Pregnancies
- Gender

Sample Collection and Labelling

The patient's identity must be positively confirmed at the time of sample collection by asking the patient (if conscious and rational) to spell their surname, given name(s), state their date of birth and by checking the identity label securely fastened to the patient (if available).

- Serum (red top) or plasma (edta pink top) may be used for pretransfusion testing. Pink EDTA samples are sample of choice
- SST (gel) tubes are unacceptable and may result in false negative results in antibody detection

Following collection and before leaving the patient, the tube(s) containing the sample(s) must be legibly labelled with:

- i. Patient's surname, given name in full and date of birth
- ii. Legible signature or initials of the collector must appear on the sample tube
- iii. Date and time of collection

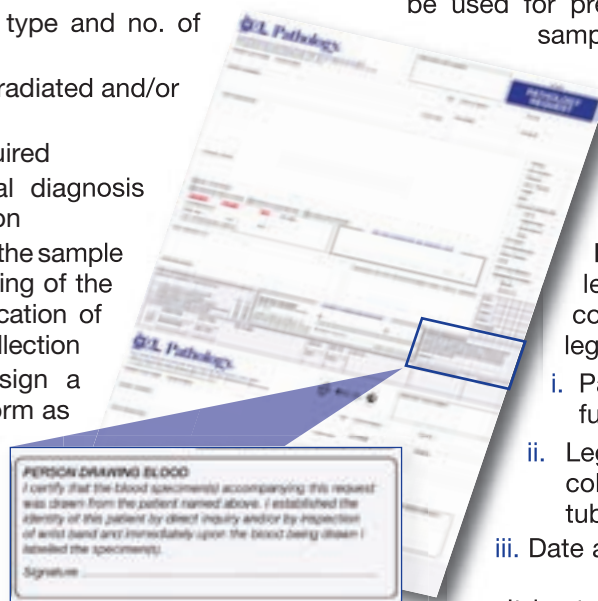
- It is strongly recommended that hospital labels should not be used, but if used they must conform to requirements (i) to (iii) listed above.

- Samples that do not conform to these labelling requirements will require recollection
- Unlabelled samples will be rejected
- The request form and sample tube must carry identical patient identification information

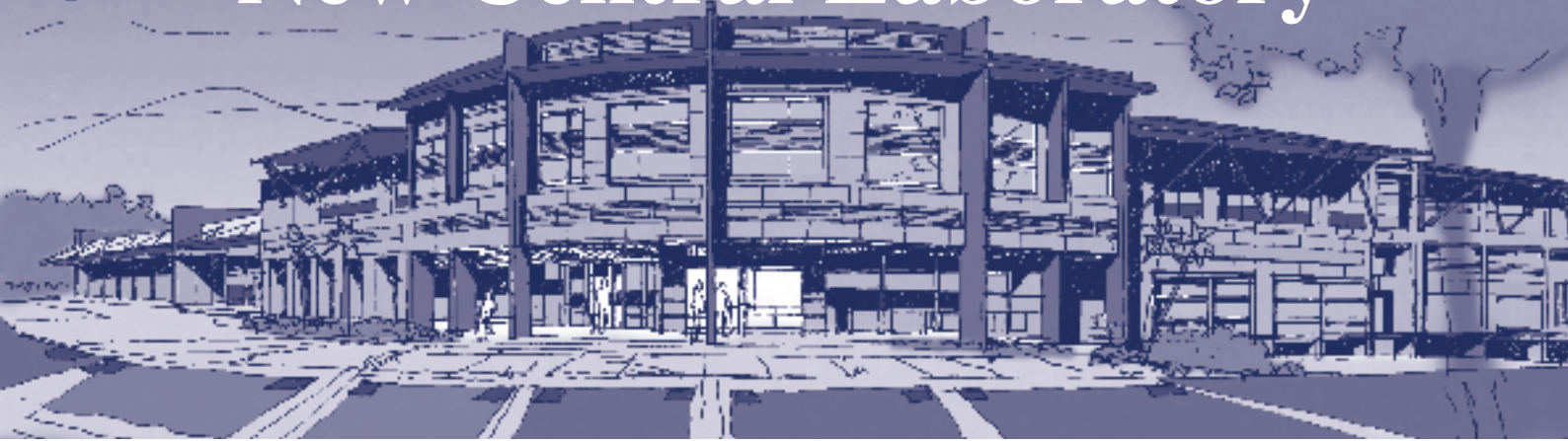
The new form is currently available and should be used from now on for all requests. If you are yet to receive any copies of the updated form, please order some through doctor's stores and you will automatically be issued with the most recent form available.

References:

- ANZSBT Guidelines for Pretransfusion Testing 4th Edition 2002
- ANZSBT Guidelines for Pretransfusion Testing 4th Edition - Amendment Note 2004.



Construction has begun in Murarrie for our New Central Laboratory



Two years ago QML Pathology made a two-fold commitment to the medical community. Firstly we agreed to expand our regional network in order to service the needs of provincial practitioners more effectively. With the opening of a laboratory in Mackay, one pending in Toowoomba and a 21% increase in the number of collection centres placed in regional areas, we have and will continue to develop our regional operations. Secondly we committed to invest in the provision of a new central laboratory. Following much planning the second component of our commitment is beginning to take shape.

Earlier this year we announced the development of a new state-of-the-art laboratory which is due to be completed by Easter 2006. We have spent two years searching for a location which will provide the best possible site to meet the needs of our referring doctors for provision of exceptional service and efficient turnaround times. The new lab needed to be in a central location, with easy access to northern and southern suburbs of Brisbane, both coastal regions and the airport. Filling all these criteria, the decision was finally made to secure a site at Murarrie adjacent to the Gateway Bridge.

With all this in mind, the most important aspect is how the relocation will affect our referring doctors.

Will it affect the range of testing?

QML Pathology currently processes the largest range of onsite testing by any private pathology laboratory. Unlike recent trends in Australia, the relocation of our lab will not result in the centralisation of any current onsite testing to a national body.

Will it affect turnaround times, especially if I practice in the city?

Due to the time critical nature of the QML Pathology blood bank, this component of the current lab will remain in an inner city location. While the space is yet to be finalised, this means one of the current inner-city stat labs will increase its operating hours to 24 hours - 7 days a week. This will allow for continuity of service to Brisbane hospitals and practices, ensuring urgent overnight specimens receive the attention required.

With every consideration given to increased accuracy and performance, the purpose built laboratory will allow for the duplication and combination of current testing systems. The extra time and preparation put into considering the layout of each department will allow for a faster throughput of specimens. An example of this will be a haematology analyser incorporating four cell counters and three slide makers on a single track system. The singular components of this system will combine to become 13 metres long, making it one of the largest testing systems in the world with a total value of almost \$1 million and enabling reduced testing times. This is one of the many areas which will allow for productivity improvements at the new laboratory.

Will there be service disruption during the move?

A dedicated team of professionals has been assembled to ensure all aspects of the move allow for the most effective and efficient relocation of the laboratory. The move has been scheduled to take place over Easter 2006, due to the reduced amount of specimens for processing that is generally observed during the holiday period. In addition to this there had been a duplication of several key machines to allow for ongoing throughput of specimens during the relocation and calibration of other systems at the new facility.

QML Pathology is committed to investing major resources in the medical community, aiming to provide a professional, expert testing facility that is second-to-none.

Diabetes Pack

Australia is 'caught up' in the same epidemic of diabetes that is affecting other 'first world' countries. It is currently stated that at least 7.5% of Australians over the age of 20 years have diabetes although half are yet to be diagnosed.

With the high rate of diabetes diagnosis in Australia growing, QML Pathology is pleased to announce the release of our latest information pack focussing on the diagnosis and treatment of diabetes. The Diabetes Pack will be available in the coming month and is another great tool of reference and education for GP's and Specialists alike.

In this series of brief publications, we will review the diagnosis of diabetes in the non-pregnant and pregnant states, expand on new developments in the investigation of Type 1 (insulin dependents) diabetes, refer to the assessment of diabetic control including the use of the diabetes recall program and discuss assessment of diabetes-associated tissue damage. Written by QML Pathology's own experts and with additions from Diabetes Australia, this pack contains all the relevant and most current information regarding types 1 and 2 diabetes and their diagnosis, ensuring you can offer the fullest in patient care.



Please contact your local QML Pathology Medical Liaison Officer to obtain a copy of this pack.



Doctors' Notice Board

Dr Sharon Xian Li, Obstetrician/Gynaecologist, is pleased to advise that she is commencing private practice at:

- Hospital Consulting Suite
Sunnybank Private Hospital
245 McCullough St, Sunnybank
- Monash IVF
McCullough Centre, Sunnybank

Dr Li's interests include infertility, IVF, Uro-Gynaecology, Prolapse and Colposcopy. For appointments please telephone (07) 3344 9453.

May/June Events...

St Andrew's War Memorial Hospital CPD Weekend

Date: 4th – 5th June

Venue: Hyatt Regency, Cooloom

Topics: Category 1:
Mental Health Workshop

Category 2:
Orthopaedics, Thyroid, Influenza,
Cardiac, Haemorrhoids

Contact: Julie Coningham

Phone: (07) 3834 4293

Rural Doctors Association of Queensland (RDAQ) 2010: A Rural Odyssey, Preparing for the Future

Date: 10th – 12th June

Venue: Shangri-La Resort, Cairns

Topics: Indigenous Health, Plastic
Surgery, Cardiac Medicine,
Musculoskeletal Medicine, Rural
Practice, Infectious Disease

Contact: Catherine Lubans

Phone: (07) 3105 7800

9th Annual Update in Gastroenterology and Hepatology

Date: 11th – 13th June

Venue: Hyatt Regency, Cooloom

Topics: IBD, Crohn's Disease, Refractory
Colitis, Liver Disease, PSC

Contact: Jayne Kidd

Phone: (07) 5548 6199

AMAQ Foundation Charity Golf Day

Date: 23rd June

Venue: Pacific Golf Club, Mt Gravatt

Contact: Neil Mackintosh

Phone: (07) 3872 2222

QML Pathology.



This newsletter has been prepared and published by QML Pathology for the information of referring doctors. Although every effort has been made to ensure that the newsletter is free from error or omission, readers are advised that the newsletter is not a substitute for detailed professional advice.

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