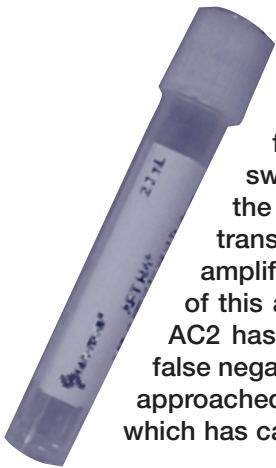




Aptima Assay

A REVIEW OF THE FIRST FOUR MONTHS

Microbiology Department



Beginning in June this year, QML Pathology introduced a new molecular based methodology for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing from male and female urine and swab samples. This test was the Aptima® Combo 2 assay (AC2); for further details please see the May 2005 edition of the QML Pathology newsletter – www.qml.com.au. This assay utilises transcription mediated amplification (TMA), a variant of the polymerase chain reaction (PCR) to amplify and detect rRNA simultaneously for the two target organisms. During our initial evaluation of this assay, it was found to have superior performance in comparison to our previous assay. The AC2 has increased sensitivity, specificity and is less prone to sample inhibition which may lead to false negative results. Sensitivity and specificity data from our initial evaluation of almost 3000 samples approached 100% for both organisms. QML Pathology is the first laboratory in Australia to use this test which has captured a significant portion of the US and European markets.

Table 1 is a review of our results comparing data from pre-introduction of the AC2 assay (January 2003 to May 2005) to that post introduction (June 2005 to September 2005).

The data looks convincing but it needs to be interpreted with caution until we have gathered more results using the Aptima assay. There have been world wide reports of increases in sexually transmitted infections which may account for some of the dramatic increase in positivity seen to date. However the increased identification of *N. gonorrhoeae* produces some important data. Our testing and reporting of *N. gonorrhoeae* results satisfies the current requirements of regulatory bodies. These regulations require that all positive results are repeated using an alternate assay which utilises a different genomic target.

The dual testing of both pathogens offered by the Aptima assay has shown that of the 151 samples tested

| | Prevalence | |
|----------------------|-----------------------------------|-----------------------------------|
| | <i>Chlamydia trachomatis</i> (CT) | <i>Neisseria gonorrhoeae</i> (NG) |
| Jan 03 - May 05 | 5.62% | 1.14% |
| Jun 05 - Sep 05 | 6.69% | 1.33% |
| Change in Prevalence | 18.98% | 16.92% |

Table 1: Prevalence of CT & NG pre and post introduction of the Aptima Assay

as positive for *N. gonorrhoeae*, 37 (25%) were detected when no specific request for molecular testing was made by the clinician. Culture was not requested in 15 (40%) of these cases, 14 (38%) cases had positive cultures and the remaining 8 (22%) were culture-negative for *N. gonorrhoeae*. This indicates that gonorrhoeae would not have been definitively diagnosed in over 15% of cases without the Aptima assay.

18% of our male cases with gonorrhoeae had a concurrent *C. trachomatis* infection. In female patients, this figure is 47%. Further analysis demonstrated that *N. gonorrhoeae* is cultured in 72% of AC2 positive samples from males but in only 23% of female patients when a culture has been performed. These results support the utility of molecular testing for the diagnosis of *N. gonorrhoeae*.

continued inside...

Also in this issue:

eGFR Update: "Now what do I do with it?"

QML Pathology New Central Lab Update

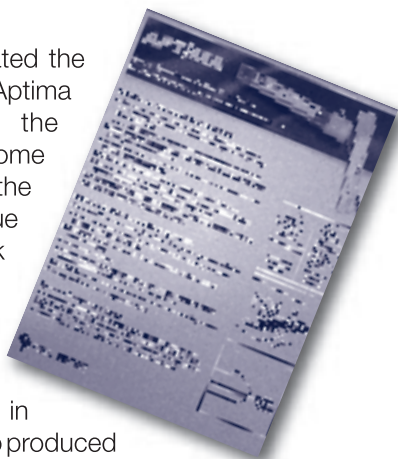
Changes to "High-Risk" HPV testing

QML Pathology's Christmas Donation 2005

Introducing our Influenza Pack

from front page...

While results have indicated the clinical superiority of the Aptima product, unfortunately the product has provided some difficulty when labelling the transport tubes. This issue has been referred back to the manufacturer; however it can be managed through the use of a permanent marker. In order to assist in resolving this we have also produced sheets of labels that can be applied to the product. To obtain these please contact your local Medical Liaison Officer or nearest laboratory. (Note: care must be taken to ensure that the labels are not applied over the clear section of the collection tube).



As further data becomes available we will continue to keep you updated on the results produced by the assay. However, to date it appears very promising that this assay is producing superior results for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG).

New Central Laboratory

Excitement and anticipation is rapidly building for the impending move of our central laboratory to Murarrie in April 2006. While the move to our purpose built laboratory is still months away, we are committed to ensuring every aspect of our service continues to meet and exceed your expectations. With this in mind preparations are being made to ensure testing remains accurate and timely. In order to achieve this, a number of vital activities are occurring.



I have the estimated GFR....now what do I do with it?

This question has been one of the most frequent which we in the laboratory have received since the inclusion of the estimated glomerular filtration rate (eGFR) on all reports of adults which include the serum creatinine.

The Working Party met last year and after an appropriate period of discussion and education, the change was implemented by most laboratories in the last month or so. However we still lack "official" guidelines as to what to do with the occasional unexpected outcome – the eGFR that is surprisingly low in the otherwise healthy older patient, or the value that has changed significantly since last reported.

I am told that these guidelines are to follow from the Working Party, but I have not yet heard when they are expected. Thus, it might be appropriate to produce some "common sense" suggestions for how to deal with this question when it arises. We received some assistance from a document (eGFR GP Management Card) produced and published by the Kidney Check Australia Taskforce. A copy is available on the Kidney Health Australia website - www.kidney.org.au via the Health Professionals and eGFR Resource link.

- If the **eGFR is below 30 mL/min/1.73m²** and the patient is not already in the care of a nephrologist, it would be appropriate to proceed with the referral. This patient has a significant renal impairment and is approaching levels of function for which dialysis may have to be considered.
- If the **eGFR is 30-59 mL/min**, it is appropriate to check for reversible causes of renal dysfunction (e.g. diabetes mellitus, uncontrolled hypertension or renal

infection) and either treat the cause or if already under treatment, optimise the treatment and then review in a further 3 months[#]. If the eGFR appears relatively stable, I would recommend continuing 3 monthly reviews. However, if it appears to have fallen by 15% or more between visits, even if still exceeding 30 mL/min, referral to a nephrologist would be appropriate.

- If the **eGFR is 60 mL/min or more**, renal function is essentially normal or only mildly impaired. If there are other reasons for concern, further renal investigation (such as urinary protein, albumin, microscopy and culture, etc) may be indicated, but otherwise, standard practices of patient review (such as annual review of health including blood pressure, glucose and lipids, etc) would appear appropriate.

Of course if there is any specific cause for concern such as the finding of a reduced eGFR in a young person, it would be appropriate to arrange for early nephrologist referral.

If you have concerns regarding your patient's eGFR result please contact one of our Chemical Pathology team on (07) 3840 4444.

[#] *If the low eGFR is a new finding and unexplained, it would be appropriate to review the eGFR (i.e. repeat the E/LFT) in a week having established that the patient is well. In patients with relatively mild renal impairment, factors such as dehydration, sudden falls in blood pressure etc. may lead to significant but reversible falls in renal function.*

Dr Charles Appleton
Pathologist in Charge, Biochemistry Department



All QML Pathology laboratories are being prepared for increased specimen analysis in the period leading up to the move. This will have a significant impact on our transition to the new laboratory, ensuring it remains smooth and successful. To compliment this, our Stat Laboratories will continue the processing of urgent specimens at a local level to assure their timeliness. Connecting all laboratories to the skills and equipment located centrally will be our extensive courier network. Currently we have installed processes to make certain that courier runs continue to serve medical practitioners

expectations while coinciding with suitable specimen delivery to Murarrie.

With the external structure almost complete, the new laboratory promises to be a milestone in our 80 year history. Set to be one of the biggest laboratories in the Southern Hemisphere, it is an achievement we look forward to celebrating with you in the very near future.



Changes to “High-Risk” HPV testing

as “Test of Cure” following treatment for High Grade Cervical lesions

As you may know, the recent release of the Medicare Schedule of Fees (operative from November 1, 2005) contains a new item number which may effect your pathology ordering for certain patients.

This item is number 69486: A test for high risk human papilloma virus (HPV) in a patient who:

- Has received excisional or ablative treatment for high grade intraepithelial abnormalities of the cervix within the last two years; *or*
 - Within the last two years has had a positive HPV test after excisional or ablative treatment for high grade intraepithelial abnormalities of the cervix
- to a maximum of 2 of this item in a 24 month period

If you are ordering this test and the patient is eligible for a medicare rebate under the new rules, it will be necessary for you to specify this on the request form. If you request a test for “high risk” HPV, but do not specify the patient fits these conditions, your patient will be ineligible for a Medicare rebate and automatically billed the full amount of \$100.

In order to assist you with this we can supply a sheet of stickers indicating that you are requesting the test in compliance with the conditions mentioned above. This will result in your patient being appropriately “billed”. To organise this please contact you local Medical Liaison Officer.

If you deem that there are clinical indications for the test that fall outside the definition of the schedule, unfortunately that remains non-rebatable. In this circumstance you may want to make your patient aware of the \$100 charge.

Currently the test performed is the Digene Hybrid Capture which may be collected into a ThinPrep vial. If you wish to also have a ThinPrep Pap test done from the vial, this must be specifically requested and will incur a fee of \$29 which remains non-rebatable. (Other tests for infections such as Chlamydia, Gonococcus etc can also be done from the ThinPrep vial and will be billed appropriately).

The NH&MRC’s new “Guidelines for the Management of Asymtomatic Women with Screen Detected Abnormalities” will result in some changes to follow-up recommendations and reporting terminology when they are implemented in 2006. We will endeavour to notify you as soon as these changes come into practice. For further queries please don’t hesitate to contact your local Medical Liaison Officer or the Cytology Department at your local laboratory.

Dr Gordon Wright
Pathologist in Charge, Cytology Department

Christmas Donation ... creating life-changing experiences

Christmas is an opportunity to show genuine appreciation for those individuals who have supported you throughout the year. Historically QML Pathology has expressed our thanks with a small token of appreciation for members of the medical community. However for the past two years, we have been fortunate to have the opportunity to convey our thanks through a donation to those in the community who are less privileged than ourselves. Your support of this endeavour is admirable, and it is only through your continued patronage that we have the opportunity to make a difference to the lives of others. As a result of your continued support for this initiative in 2005 the Queensland Hear & Say Centre and Angel Flight will have the chance to convert \$50 000 into life-changing experiences.

The Hear & Say Centre

Oral communication is an incredible asset and one so often unappreciated by those born with the ability to hear and speak. In Australia, 2-3 out of every 1000 children are born with some level of hearing loss. However, this disability needn't be one which adversely affects these children's lives forever. The Hear & Say Centre provides programs Queensland wide through its centres in Brisbane, Gold Coast, Sunshine Coast, Cairns and the Darling Downs to help teach children to listen and speak. The Centre was established in the 1990s to teach children to listen and speak using new hearing technology. In fact, the Hear & Say Centre is now one of the leading Auditory-Verbal and cochlear implant centres in the world, recognised internationally for excellence in clinical outcomes achieved for children with hearing loss.

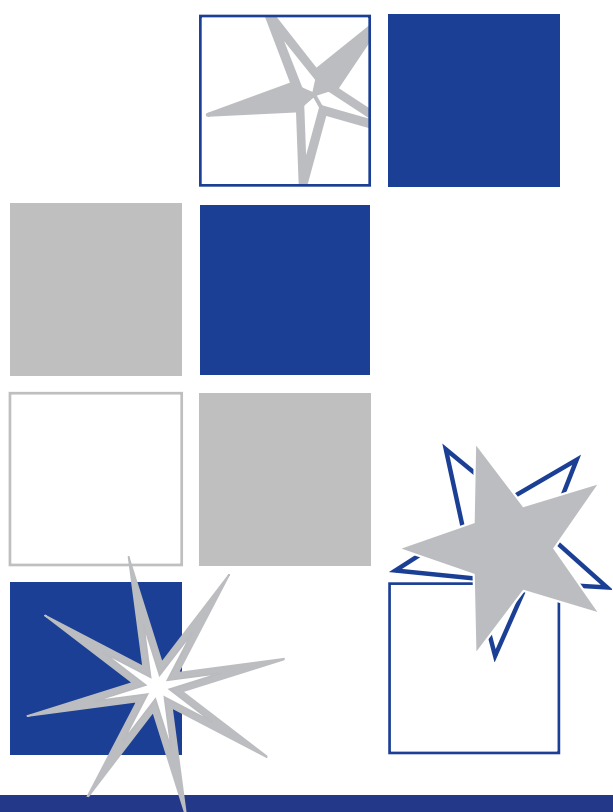
However, this intensive and highly specialised program comes at a substantial cost to the centre and it is only through fundraising and community / corporate support that Hear & Say is able to continue to operate. This year, QML Pathology is proud to be making a donation to the Hear & Say Centre which will be used specifically to help these children in need. Founder and Clinical Director of the Hear and Say Centre, Dimity Dornan said "QML Pathology's donation will enable us to provide this program for three children, directly affecting their lives and giving them the chance to reach their potential." With the help of the Medical Community, QML Pathology is pleased to be able to help the Hear & Say Centre do what they do best...teaching children with hearing loss to listen and speak. For further information or to make a donation call (07) 3870 2221 or email to fundraising@hearandsaycentre.com.au.

Angel Flight

Critical illness and debilitation are not confined to the city. It affects people whether they are in Brisbane or the vast reaches of outback Birdsville. The unfortunate fact is that our regional centres are not always equipped to treat their local residents, and thus many are forced to endure long uncomfortable road travel and have lengthy separations from their family for treatment in metropolitan hospitals. Recognising that illness is traumatic enough without the absence of loved ones, Angel Flight was established. Angel Flight assists with non-emergency flights for financially and medically needy people, making necessary medical treatment available to everyone, no matter their residential location. Such is the need for this service, since its inception in 2003, over 800 patients have benefited from Angel Flight's missions.

Angel Flight pilots donate their time, their skills and the bulk of their aircraft costs for each flight. However, according to Founder and Chairman of Angel Flight, Mr Bill Bristow, through joining with the Medical Community in donating to Angel Flight, QML Pathology is able to help alleviate some of this financial burden. "Our pilots are the real heroes of the organisation, and QML Pathology's donation will help ensure we can continue to support the Angel Flight pilots' massive contribution to the community. A portion of the donation will go towards paying for 50% of the fuel they use when they conduct an Angel Flight. This donation will also help maintain our Support Centre based in Brisbane that runs on a very small infrastructure and is currently coordinating up to 100 flights a month."

QML Pathology is pleased to join with the Medical Community to help these worthy charities achieve their vision and make the lives of those less privileged a little more comfortable. For further information or to make a donation call (07) 3852 3300 or email to mail@angelflight.org.au.



Influenza Pack

Influenza is associated with significant morbidity and mortality in the elderly and in those with underlying risk factors, e.g., cardio respiratory, renal, metabolic diseases and the immunocompromised. Even in healthy subjects, influenza can lead to significant morbidity and economic loss through medical costs and time off work.



Avian influenza – H5N1 subtype of influenza A dominates the thoughts of the medical and wider public both local and global at present. The clinical presentation of avian influenza is usually like typical human influenza, but the presentation can vary depending on the avian subtype.

In this series of brief publications we will review the history of flu pandemics, the current situation with avian influenza, diagnosis and testing options for influenza and protocol in the event of a pandemic situation. Written by QML Pathology's own experts and with additions from the Communicable Disease Unit, this pack contains all the relevant and most current influenza information, ensuring you can offer the fullest in patient care.

Your QML Pathology Medical Liaison Officer will contact you shortly to ensure you obtain a copy of this pack.

Have you got the Winning Ticket?

While the Christmas donation is a fabulous opportunity to give back to the community, we can't forget the hardworking doctors and practice staff that support QML Pathology over the year. To show our appreciation we are giving every practice the chance to win 1 of 18 Christmas hampers jam-packed with goodies for the festive season.

Over the month of November your local Medical Liaison Officer will be registering each practice for a chance to win one of these gourmet hampers. In early December a winner will be drawn from each of the 18 regions. If you have won your MLO will arrive bearing the good news in mid-December!

Good luck and best wishes for the festive season.

THE ASHINTOSH TRUST & MATER FOUNDATION presents 

VIM & TONIC

THE JAMES MORRISON SEXTET
with the QUEENSLAND MEDICAL ORCHESTRA playing at

THE "BRISVEGAS ROYALE" CASINO

Brisbane Convention & Exhibition Centre, South Bank

11 DECEMBER 2006
at 6.30 for 7.00pm

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Come by with us for an unforgettable night of cool tunes, swinging casino music and exquisite food, as Las Vegas comes to Brisbane for one night only!

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Tickets \$85 - includes deluxe cocktail, food and unlimited beer, wine and bubbly - seating in tables of 10
 Tickets \$35 - general seating (consult only)
 For more information email orchestra@qml.org.au or call 0402 432 135
 Tickets available from Ticketek on 131 951 or www.ticketek.com

WHERE THE ODDS ARE STACKED IN YOUR FAVOUR!



Doctors' Notice Board

Consultant Psychiatrist **Dr Michele Calvird** has begun private practice at the Toowong Specialist Centre - Toowong Private Hospital, 496 Milton Road, Toowong.

Ph: (07) 3721 8011 or
Fax referrals to: (07) 3721 8015

Dr Karen Richardson, Consultant Physician - Internal Medicine, would like to announce she has now split her practice between Townsville and the Gold Coast.

Practicing full time on the Gold Coast, her clinic is based at:

- Suite 4, Level 1, AHC House, 14 Carrara St, Benowa

She will also be conducting a 2 day clinic monthly at:

- QML Pathology Consulting Suite
40 Kirwan Plaza, Thuringowa Drive, Kirwan

Ph: (07) 5539 4923 (All appointments)

Fax: (07) 5539 4935

Mobile: 0413 777 263 (Private)

healthmechanics@yahoo.com.au

Dr Cameron Cooke, Consultant Orthopaedic Surgeon, commenced practice at at North West Specialist Centre in March 2005.

Areas of specific interest are:

- Hip and Knee surgery
- Orthopaedic Trauma of the Lower Limb
- Arthroscopic Knee Surgery

Appointments can be made by phoning (07) 3353 9850.

Dr David Sillar, Urological Surgeon, is pleased to advise he will be commencing full time practice at the southern end of the Gold Coast. He will be operating at the John Flynn Hospital and Tweed/Murwillumbah Hospitals.

- Suite 8/38-44 Boyd Street, Tweed Heads
- Murwillumbah Specialist Medical Centre, Carinya Building, Cnr King and Commercial Rd, Murwillumbah

Ph: (07) 5599 1395 (All appointments)

Fax: (07) 5599 1373

COLLECTION CENTRE NEWS

For the convenience of our doctors and patients, we have listed the latest changes to QML Pathology's network of clinics:

NEW CLINICS

Scarborough (07) tba

Unit 1, 107 Landsborough Ave
Mon - Fri 8.00am - 12.30pm
1.30pm - 4.00pm

Windsor (07) 3357 8617

Shop 414C, Homezone Windsor,
142 Newmarket Rd
Mon - Fri 8.00am - 12noon
12.30pm - 4.00pm

*Please contact your local branch
for further information.*

CLINIC CHANGES

Albany Creek (07) 3325 0822

1/720 Albany Creek Rd
Mon - Fri 8.00am - 1.15pm
1.45pm - 4.00pm

Clifton Beach (07) 4055 3013

Clifton Village Shopping Centre,
Captain Cook Highway
Mon - Fri 8.00am - 12noon
1.00pm - 5.00pm
Saturday 8.00am - 12noon

Mossman (07) 4098 1650

Shop 1, Sugarland Arcade,
14 Front Street
Mon - Fri 7.30am - 12.30pm
1.30pm - 4.00pm
Saturday 8.00am - 11.30am

Redcliffe Lab (07) 3284 6666

Peninsula Specialist Centre,
Cnr George & Florence Sts
Mon - Fri 7.00am - 6.00pm
Sat 7.00am - 1.00pm
Public Holidays 8.00am - 12noon

Smithfield (07) 4038 1827

Smithfield House,
(service road off Stanton Rd)
Captain Cook Highway
Mon - Fri 8.00am - 12.30pm
1.30pm - 4.30pm

Trinity Beach (07) 4055 6853

Shop 10, Coastwatchers
Shopping Centre, 1 Rabaul Street
Mon - Fri 7.30am - 1.30pm
2.00pm - 6.00pm
Saturday 8.30am - 12.30pm

