

Dear Doctor,

**Re: New Molecular Assay for Chlamydia and Neisseria gonorrhoeae:
Gen-Probe Aptima Combo 2® Assay**

We are changing our PCR assay for the detection of Chlamydia (CT) and Neisseria gonorrhoeae (GC) infections. The new assay will be the **Gen-Probe Aptima Combo 2® Assay** and it will replace the Roche Cobas Amplicor PCR assay.

The change to this assay will take place from Monday 28th May 2007.

The Aptima® Assay amplifies ribosomal RNA (rRNA) rather than DNA. As there is much more rRNA present, the assay is more sensitive. In addition the assay uses TMA (transcription mediated amplification) technology and can achieve a 10 billion-fold amplification of the target rRNA.

The advantages of this assay over previous assays are:

- Significantly **improved sensitivity** of the assay. For genital specimens, sensitivity is 95.9% for CT and 97.8% for GC and specificity is >98% for both organisms. There is also increased sensitivity for eye, anal and throat swabs.
- **Wider range of specimens:** vaginal swabs and ThinPrep liquid Pap specimens, as well as the usual first part urine (FPU), endocervical and urethral swabs,.
- **Faster turn around time** for results
- Virtually **eliminates inhibition** and cross-reactivity problems
- **Both CT and GC assays** can be performed on the same tube, at the same time, if requested.

Collection of Specimens

Specimen collection methods will be different but made simpler by the easy-to-use collection kits, which will be supplied.

- See attached: **Aptima® – Specimen Collection Guide For Chlamydia and Gonorrhoea**
- NOTE: To prevent breakdown of the target RNA, the specimen must be placed in the buffered Aptima® collection tube as soon as is practicable.

Also attached is our updated '**Fact Sheet for the Collection of Genital Specimens for STI**'. This replaces the previous Fact Sheet for STIs sent out towards the end of 2006.

Please contact the Medical Microbiologists, Gillian Wood, Caroline Reed or Chandrika Perera, if there are any questions on this issue. Their contact numbers are 03 9244 0339 or 1800 138 006.