Trichomonas vaginalis Nucleic Acid Clearance Following Treatment of HIV Negative Women

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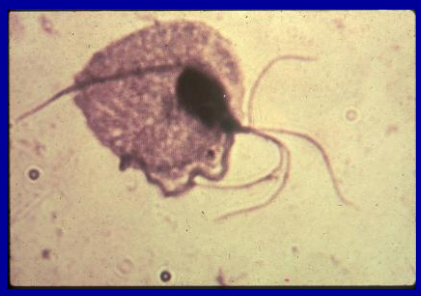
Disclosure: Consultant to Hologic/Gen-Probe

Trichomonas vaginalis



Diagnosis

- Wet mount
- Culture
- Point of care antigen detection
- DNA probes
- Nucleic acid amplification tests

Gen-Probe Aptima *Trichomonas vaginalis* (GPATV) Assay

- Targets ribosomal RNA.
- Chemistry - transcription mediated amplification.
- High sensitivity and specificity
- FDA cleared and EU CE marked

Study Design

- Primary study – Randomized trial of the single 2 gram dose of metronidazole vs. the 500 mg twice daily for 7 days regimen in HIV negative women.
- This sub study was designed to determine rate of clearance of rRNA following treatment.
  - Enrolled women returned to clinic to self obtain a vaginal swab weekly for 4 weeks.
  - Sexual histories were obtained at each visit and women were excluded from further participation following unprotected sexual intercourse.
  - Specimens were tested using the GPATV assay

Patient Population

- 65 women enrolled in the randomized treatment trial agreed to participate in the clearance study.
- One woman withdrew from the study and 3 were withdrawn for non-compliance with treatment.
- 4 women did not return for any follow-up visits.

Characteristics of the 57 women completing at least 1 follow-up visit

- 96% were African American.
- Mean age was 31.2 +/- 10.9 years
- Nugent score distribution:
  - Normal 3 (5%)
  - Intermediate 24 (47%)
  - BV 30 (53%)
- Treatment assignments
  - Single dose 35 (61%)
  - 7 day course 22 (39%)

Women Censored from the Clearance Study

- Five women were culture positive at the first or second follow-up visit and were dropped.
- An additional 5 had unprotected sex prior to the first return visit.
- 47 women returned for at least one follow-up visit prior to sexual re-exposure.

Results

Visits	Total Evaluable	TMA Positive	% Clearance
Week 1	38	8	79%
Week 2	34	1	97%
Week 3	26	0	100%
Week 4	28	0	100%

Clearance of *T. vaginalis* DNA Detected by PCR

Days Since Treatment	Cumulative Clearance Rates
0-6	40%
7-13	75%
8-20	86%
21-27	93%
28-34	97%

Williams JA, et al. Sex Transmit Dis 2014; 41: 215-19

Conclusions

- Within 3 weeks following completion of metronidazole treatment *T. vaginalis* rRNA as measured by the GPATV assay appears to be cleared from vaginal secretions
- If these data can be confirmed, this assay may be useful for *T. vaginalis* tests-of-cure.

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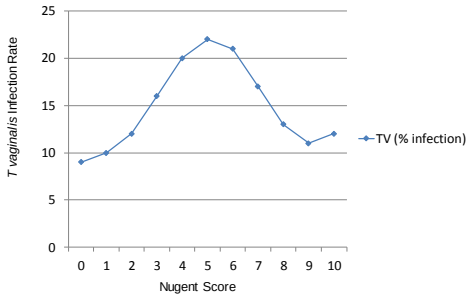
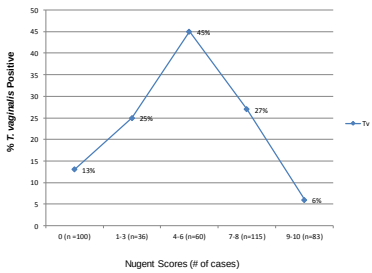
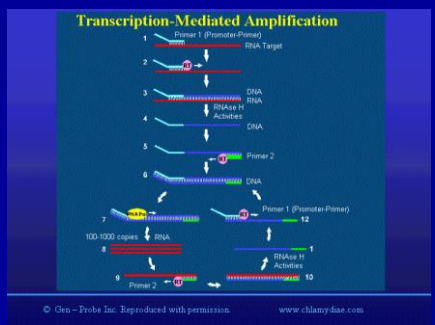
T. vaginalis Prevalence Detected by Culture in 7,918 Pregnant Women Stratified by Nugent Score

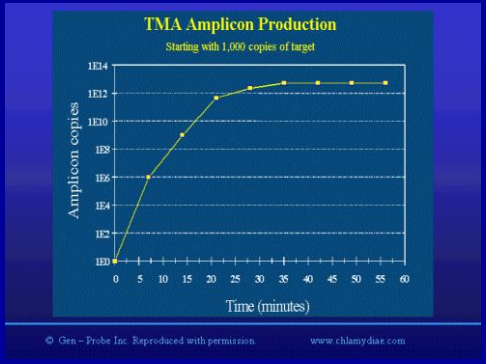


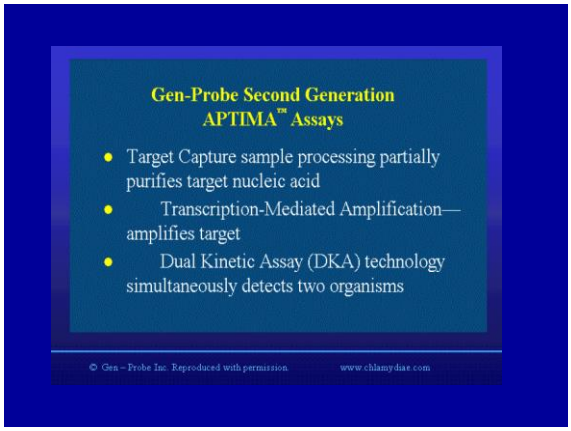
Hillier SL, et al. Am J Obstet Gynecol. 1992, 166: 938.

Prevalence *T vaginalis* detected by Culture in 394 Women Evaluated at the New Orleans STD Clinic Stratified by Nugent Score





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