PERFORMANCE OF THE AMPLIVUE® TRICHOMONAS ASSAY FOR THE DETECTION OF *TRICHOMONAS VAGINALIS* IN WOMEN FROM VAGINAL SPECIMENS

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BACKGROUND

- The AmpliVue® Trichomonas Assay (Quidel) is a new rapid test for qualitative detection of *Trichomonas vaginalis* (TV) DNA
- The assay is based on BioHelix's Helicase-Dependent Amplification (HDA) technology in conjunction with a disposable lateral-flow detection device
- The assay targets a conserved repeat sequence of the *T. vaginalis* DNA
- Total turn-around time of approximately 45 minutes
- Assay combines three steps:
  1) simple sample preparation with one-step dilution/heating
  2) isothermal DNA amplification of target sequences specific to *T. vaginalis* by HDA
  3) lateral-flow strip based colorimetric detection in a self-contained, disposable device

OBJECTIVE

The objective of this study was to compare the performance of the AmpliVue Trichomonas Assay with the comparators: wet preparation, InPouch™ TV culture, and APTIMA TV (ATV)

METHODS

- Three (3) clinician collected vaginal swabs were obtained and tested from women attending STD, family planning, and OB/GYN clinics
- The AmpliVue Trichomonas Assay results were compared to a patient infection status (PIS) as determined by the results from wet mount microscopic examination and/or culture
- At least one of these tests was required to be positive to establish an infected patient status

RESULTS

A total of 1132 patients (373 symptomatic and 759 asymptomatic patients) were included in the study. 4 specimens (0.35%) yielded invalid results in the AmpliVue assay and have been removed for further analysis.

Performance Characteristics of the AmpliVue® Trichomonas Assay compared to Patient Infection Status (Wet Prep and/or TV Culture Positive) by Symptom Status (TP: true pos, FP: false pos, TN: true neg, FN: false neg, PPV & NPV: positive and negative predictive value)

Symptom Status	N	TP	FP	TN	FN	Prev%	Sensitivity%	Specificity%	PPV %	NPV %
Asymptomatic	755	69	12	674	0	9.1	100	98.3	85.9	100
Symptomatic	373	62	6	305	0	16.7	100	98.1	91.2	100
All	1128	131	18*	979	0	11.6	100	98.2	87.9	100

* Nine (9) specimens were positive by the ATV assay, nine (9) specimens were negative by the ATV assay

The same 1132 patients were tested by both AmpliVue and the ATV assays. 4 specimens (0.35%) yielded invalid results in the AmpliVue assay and 2 specimens (0.18%) yielded invalid results in the ATV assay. The 6 specimens have been removed from further analysis.

Performance Characteristics of the AmpliVue® Trichomonas Assay compared to the APTIMA TV (ATV) by Symptom Status. (PPA & NPA: % positive & negative agreement. PPV & NPV: positive and negative predictive value)

Symptom Status	N	TP	FP	TN	FN	Prev%	PPA (%)	NPA (%)	PPV (%)	NPV (%)
Asymptomatic	753	75	6	661	11	11.4	87.2	99.1	92.6	98.4
Symptomatic	373	64	4	298	7	19.0	90.1	98.7	94.1	97.7
All	1126	139	10	959	18	13.9	88.5	99.0	93.3	98.2

CONCLUSIONS

- The Amplivue Trichomonas Assay identified all of the culture and wet mount positive cases of Trichomonas infection and substantially more as shown by the strong agreement with APTIMA TV.
- This study provides evidence of new diagnostic options and indicates better performance of amplified testing for detection of TV in symptomatic and asymptomatic women.
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