

INTRODUCTION

• bioNexia hCG Urine and bioNexia hCG Combo are rapid one-step chromatographic tests for the qualitative detection of human chorionic gonadotropin (hCG) in urine only and urine or serum respectively

• These tests are dedicated to rapid qualitative detection of hCG to aid in the early detection of pregnancy

• This study conducted at Biomnis laboratory (Lyon, France) compares the performance of bioNexia hCG rapid tests with two other rapid pregnancy tests commercially available from Alere (Clearview) and Quidel (QuickVue)

• The detection level of all tests for both samples is 25 mIU/ml

MATERIALS AND METHODS

➤ Test comparison using urine specimens:

• bioNexia hCG Urine was compared to Clearview hCG Urine test and QuickVue One-Step urine test

• bioNexia hCG Combo was compared to Clearview 25 hCG Combo and QuickVue One-Step hCG Combo

• 240 frozen urine specimens used for the comparison study were classified based on clinical data:

- ❖ 100 urine specimens from pregnant women > 8 weeks after last menstrual period
- ❖ 10 urine specimens from pregnant women 5-8 weeks after last menstrual period
- ❖ 68 urine specimens from post-menopausal women
- ❖ 62 urine specimens from women on contraceptive pills

Modus operandi for urine specimens:

Urine specimens were assayed in a single blind test on the 6 rapid tests without any prior hCG quantification due to the unavailability of such validated assay on the market

➤ Test comparison using serum specimens:

• bioNexia hCG Combo was compared to Clearview 25 hCG Combo and QuickVue One-Step hCG Combo

• 289 frozen serum specimens were simultaneously assayed for hCG values using the VIDAS® instrument and reagents (bioMérieux) and classified as follows:

- ❖ Negative specimens: hCG value < 25m UI/mL (n=183)
- ❖ Positive specimens: hCG value ≥ 25m UI/mL (n=106)
- ❖ Sub-groups included serum specimens from:
 - Post-menopausal women (n=20)
 - Cyclical women on contraceptive pills (n=20)
 - Post in-vitro fertilization women (n=31)

Modus operandi for serum specimens:

Serum specimens were assayed in a single blind test on the 3 rapid tests evaluated



bioNexia hCG Urine

bioNexia hCG Combo

RESULTS

Table 1: Qualitative comparison of pregnancy tests on urine samples

bioNexia hCG Urine		QuickVue One-Step hCG Urine		Clearview hCG Urine	
		Positive	Negative	Positive	Negative
		Positive	116	3	117*
Negative	0	121	1	120	
Positive agreement		100% [96.9-100.0]		99.2% [95.4-100.0]	
Negative agreement		97.6% [93.1-99.5]		98.4% [94.2-99.8]	
Overall agreement		98.8% [96.4-99.7]		98.8% [96.4-99.7]	

* One sample from a post-menopausal woman was found positive with the Clearview cassette

bioNexia hCG Urine has an overall agreement of 98.8% compared to QuickVue and Clearview

Table 2: Qualitative comparison of combo pregnancy tests on urine samples

bioNexia hCG Combo		QuickVue One-Step hCG Combo		Clearview 25 hCG Combo	
		Positive	Negative	Positive	Negative
		Positive	116	1	117
Negative	0	123	0	123	
Positive agreement		100% [96.9-100.0]		100% [96.9-100.0]	
Negative agreement		99.2% [95.6-100.0]		100% [97.1-100.0]	
Overall agreement		99.6% [97.7-100.0]		100% [98.5-100.0]	

bioNexia hCG Combo has an overall agreement of 99% compared to QuickVue and Clearview on urine samples

Table 3: Qualitative comparison of combo pregnancy tests on serum samples

bioNexia hCG Combo		QuickVue One-Step hCG Combo		Clearview 25 hCG Combo	
		Positive	Negative	Positive	Negative
		Positive	110	2	111
Negative	1*	176	2**	175	
Positive agreement		99.1% [95.1-99.9]		98.2% [98.8-99.8]	
Negative agreement		98.9% [96.0-99.9]		99.4% [96.9-100.0]	
Overall agreement		99% [97.0-99.8]		99% [97.0-99.8]	

* One sample measured at 3.84mIU/ml on the VIDAS was found positive with the QuickVue cassette
** Two samples measured at 2.32mIU/ml and 8.41mIU/ml on the VIDAS were found positive with the Clearview cassette

bioNexia hCG Combo has an overall agreement of 99% compared to QuickVue and Clearview on serum samples

Table 4: practicability of pregnancy tests

	Kit handling	Specimen transfer	Result reading and interpretation
bioNexia	+++	++	++
QuickVue	+	+++	+++
ClearView	++	++	++

Rapid tests (urine and combo) from bioNexia and QuickVue were the most convenient to use:

- QuickVue includes a dropper which significantly avoids bubble formation during specimen transfer on the rapid test
- bioNexia has a convenient and optimized packaging

ClearView rapid tests were less convenient to use based on these practicability criteria.

CONCLUSIONS

The results of this evaluation suggest that bioNexia hCG Urine and Combo have at least an equivalent performance to two other commercially available rapid tests.

The kit is easy to use compared to the two other commercially available rapid tests.