

**Medomics *Candida albicans*/*Trichomonas vaginalis*/*Gardnerella vaginalis*
antigen Combo Test Kit (LFIA) Internal Evaluation Results Report**

**Medomics Medical
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The purpose of the internal evaluations were to compare the Meddomics *Candida albicans*/*Trichomonas vaginalis*/*Gardnerella vaginalis* Antigen Combo Test Kit (LFIA) performance with the results interpreted by microscopic examination of patients samples by trained laboratory technicians. The results of Nugent scores were obtained for Bacterial Vaginosis diagnosis, direct microscopic examination of wet mount slides was used for *Trichomonas vaginalis* diagnosis, and Gram staining results were interpreted for *Candida albicans*, respectively. The sensitivity and specificity of the performance of the Medomics Combo Kit were summarized.

A total of 388 clinical patients samples were collected. Duplicated test results were not included in the data summary. Due to patients' data privacy protection act, only patients' age were collected. All other information was blinded for Medomics Medical personnels during the sample collection. Table 1 summarizes the patients age ranges enrolled in the study.

Diagnosis	Sample Size	Total Cases	Age Min	Age Max	Average Age
VVC	93	97	20	56	37.5
BV	106	120	21	57	37.4
TV	70	80	19	56	38.6
VVC+BV	4				
BV+TV	10				
Negative	105		20	55	37.9
Total	388				

The following tables summarize the comparison results:

	Gram staining Result		
	Positive	Negative	Total
Medomics <i>Candida albicans</i> antigen test result			
Positive	90	23	113
Negative	7	268	275
Total	97	291	388
*95% Confidence Interval			
Sensitivity	92.78% (85.70%~97.05%)		
Specificity	92.10% (88.38%~94.92%)		

PPV	79.65% (71.04%~86.64%)		
NPV	97.45% (94.83%~98.97%)		
Accuracy	92.27% (89.15%~94.72%)		
Kappa value	0.81		

Nugent Scoring Result			
Medomics <i>Gardnerella vaginalis</i> antigen test result	Positive	Negative	Total
Positive	118	20	138
Negative	2	248	250
Total	120	268	388
*95% Confidence Interval			
Sensitivity	98.33% (94.11%~99.80%)		
Specificity	92.54% (88.71%~95.38%)		
PPV	85.51% (78.51%~90.92%)		
NPV	99.20% (97.14%~99.90%)		
Accuracy	94.33% (91.54%~96.41%)		
Kappa value	0.87		

Microscopic examination Result			
Medomics <i>Trichomonas vaginalis</i> antigen test result	Positive	Negative	Total
Positive	79	0	79
Negative	1	308	309
Total	80	308	388
*95% Confidence Interval			
Sensitivity	98.75% (93.23%~99.97%)		
Specificity	100.00% (98.81%~100.00%)		
PPV	100.00% (95.44%~100.00%)		
NPV	99.68% (98.21%~99.99%)		
Accuracy	99.74% (98.57%~99.99%)		
Kappa value	0.99		

In a separate internal study, a total of 206 patients samples were collected (data previously presented). The following tables summarized both 388+206 = 594 samples performance results.

	Gram staining Result		
Medomics <i>Candida albicans</i> antigen test result	Positive	Negative	Total
Positive	116	26	142
Negative	18	434	452
Total	134	460	594
*95% Confidence Interval			
Sensitivity	86.57% (79.60% ~ 91.84%)		
Specificity	94.35% (91.83% ~ 96.28%)		
PPV	81.69% (74.33% ~ 87.68%)		
NPV	96.02% (93.78% ~ 97.62%)		
Accuracy	92.59% (90.18% ~ 94.57%)		
Kappa value	0.79		

	Nugent Scoring Result		
Medomics <i>Gardnerella vaginalis</i> antigen test result	Positive	Negative	Total
Positive	142	47	189
Negative	4	401	405
Total	146	448	594
*95% Confidence Interval			
Sensitivity	97.26% (93.13% ~ 99.25%)		
Specificity	89.51% (86.29% ~ 92.19%)		
PPV	75.13% (68.34% ~ 81.12%)		

NPV	99.01% (97.49%~99.73%)	
Accuracy	91.41% (88.87%~93.54%)	
Kappa value	0.79	

	Microscopic examination Result		
	Positive	Negative	Total
Medomics <i>Trichomonas vaginalis</i> antigen test result			
Positive	119	0	119
Negative	5	470	475
Total	124	470	594
*95% Confidence Interval			
Sensitivity	95.97% (90.84%~98.68%)		
Specificity	100.00% (99.22%~100.00%)		
PPV	100.00% (96.95%~100.00%)		
NPV	98.95% (97.56%~99.66%)		
Accuracy	99.16% (98.05%~99.73%)		
Kappa value	0.97		

Conclusion:

Overall the Medomics Combo kit demonstrated good and acceptable sensitivity and specificity results using clinical specimens, as compared to conventional microscopic examination results. For *Candida albicans*, the Medomics kit might showed less than 85% PPV as compared to Gram staining microscopic examination results. During the product development phase, the Medomics team did adjust the sensitivity of *C. albicans* detection for the assay, due to the fact that low numbers of *C. albicans* might be as a part of normal flora for the vaginal microbiomes ecosystem in some subjects. Gram stain might have picked up those low number *C. albicans* in these patients' samples. Furthermore, other species of *Candida* might have been also picked up by Gram staining as yeast-like microscopic observation results.

Medomics will continue to evaluate the VVC/BV/TV Combo kit with larger sample size study. If for any reason, we encounter less than optimal performance results, please be assured that we will immediately adjust and optimize the performance of the assay, as a part of continuous improvement and in order to provide high quality products for the clinicians and for the patients.