



# EVALUATION OF THE VITROS® 3600 IMMUNODIAGNOSTIC SYSTEM†

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## Abstract

### EVALUATION OF THE VITROS® 3600 IMMUNODIAGNOSTIC SYSTEM

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**Background:** The VITROS® 3600 Immunodiagnostic System is a new platform that provides a high throughput and a broad menu of tests. We performed an evaluation study of the system that included precision, linearity, accuracy and method comparison studies utilizing other platforms.

**Methods:** Precision, linearity and accuracy studies were carried on the VITROS 3600 System (Ortho-Clinical Diagnostics, Rochester, NY, USA) according to CLSI protocols for TSH, FT3, FT4, HBsAg, anti HCV and NT-pro-BNP. The imprecision within run was calculated from results obtained by running patient samples with a high or a low concentration of the analyte of interest (n=20). Day to day imprecision runs were determined by running two or three control materials, in duplicate, over a period of 10 days and were provided by the manufacturer. For method comparison we used 99 - 122 patient samples from daily routine processing. The comparative platforms were the Cobas e411 (Roche Diagnostics, Mannheim, Germany) for TSH, FT3, FT4 and NT-pro-BNP and the AxSYM (Abbott, USA) for HBsAg and anti-HCV. The statistical analysis for TSH, FT3, FT4 and NT-pro-BNP was done by use of the Passing-Bablok procedure and for anti-HCV and HbsAg the qualitative results were compared after confirmation by PCR.

**Results:** For the imprecision within run we calculated CV between 1,5 and 15,2 %, while the imprecision from day to day delivered CVs between 1,2 and 17,1 % depending on the concentration of the analytes. The method comparisons showed slopes between 0,91 and 1,97. The coefficient of correlation was calculated to be between 0,706 (FT3) and 0,998 (NT-pro-BNP). The most differences were found for FT3 and FT4. For the correlation of anti-HCV results we found discrepancies in 8 of 106 patient samples. The AxSYM delivered positive results, which could not be confirmed by PCR. For HBsAg only 2 out of 122 patient samples showed a positive result on the AxSYM while the repeated measurement delivered a negative result.

**Conclusions:** The imprecision values were within acceptable ranges. In the method comparison we found some differences, which could be explained by different calibration and the use of different antibodies. Some interesting findings were observed in comparing 8 patient samples, which were found to be HCV positive on the AxSYM system while both the PCR and VITROS 3600 System delivered negative results.

## Introduction

The VITROS® 3600 Immunodiagnostic System (Ortho Clinical Diagnostics, Rochester, NY, USA) is a new platform that provides high throughput and a broad menu of tests. It combines the proven VITROS MicroWell, Intellicheck® and MicroSensor technologies used on other VITROS systems. We have carried out a performance evaluation study of the system.

## Aim

- To characterize the analytical performance of the system
- To compare the measurement of NT-pro-BNP, thyroid-stimulating hormone (TSH), free thyroxine (FT4) and free triiodothyronine (FT3) between VITROS® 3600 Immunodiagnostic System and Cobas e 411
- To compare the measurement of HBsAg and anti-HCV between VITROS 3600 immunodiagnostic System and AxSYM

## Material and Methods

- A total of about 99 - 122 de-identified patient serum samples were chosen randomly from the laboratory routine and assay measurements were carried out on VITROS 3600 Immunodiagnostic System (NT-pro-BNP, TSH, FT4, FT3, HBsAg, anti-HCV)<sup>††</sup> and Cobas® e 411 (NT-pro-BNP, TSH, FT4, FT3) or AxSYM® (HBsAg, anti-HCV) within 2h. Measurements with differences of >10% were repeated within 4h.
- Comparative analysis of 6 HCV conversion panels
- Calculation of intra-assay precision of 20 repetitive measurements
- Calculation of inter-assay precision of measurements performed on 10 consecutive days
- Calculation of accuracy of measurements performed on 10 consecutive days compared to target values of quality control materials
- Confirmation of linearity within the reportable range by serial dilution of a high concentration sample with a low concentration sample and linear regression analysis
- Correlation analysis between 2 instruments using the structural relationship model by Passing and Bablok

## Summary and Conclusions

- The precision of the tested methods meets diagnostic criteria.
- The tested methods are linear in the reportable range.
- A significant bias between the assays was found for thyroid hormones.
- The sensitivity of HBsAg and anti-HCV tests is comparable with established instruments.
- The VITROS 3600 Immunodiagnostic System is a reliable instrument for routine use in the laboratory for immunodiagnostic testing.

## Results

### HBsAg

HBsAg n = 122	POSITIVE AxSYM	NEGATIVE AxSYM
POSITIVE VITROS 3600	21	0
NEGATIVE VITROS 3600	2*	99

	Precision	Mean	CV (%)
Intra-assay		0.07	15.2
		3.5	2.8
Inter-assay		0.07	9.3
		3.5	2.4

\* 1 re-run on AxSYM® found to be negative, 1 repeated by PCR found to be negative

### Anti-HCV

Anti-HCV n = 106	POSITIVE AxSYM	NEGATIVE AxSYM
POSITIVE VITROS 3600	4	0
NEGATIVE VITROS 3600	8*	94

	Precision	Mean	CV (%)
Intra-assay		0.18	8.1
		6.3	2.7
Inter-assay		0.19	18.2
		6.4	4.5

\* 7 repeated by PCR found to be negative, 1 re-run on AxSYM® found to be negative

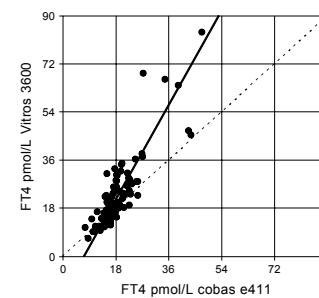
### HCV Seroconversion Panels

	62680 (6/1)*	61067 (10/4)	62886 (12/1)	60853 (9/1)	62804 (8/1)	61083 (13/1)
other	5	8-9	10	2-8	6-8	9-11
VITROS 3600	5	8	9	2	5	9
AxSYM	5	(8)	9	2	5	8

\* number of samples within the panel / first PCR-positive sample

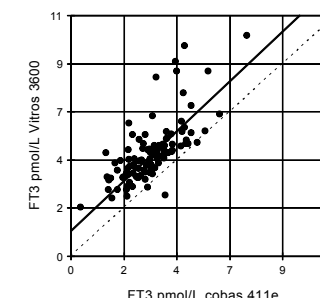
### FT4 (pmol/L)

	Precision	Mean	CV (%)
Intra-assay		11.4	2.3
		37.0	3.2
Inter-assay		6.9	3.5
		55.7	1.9



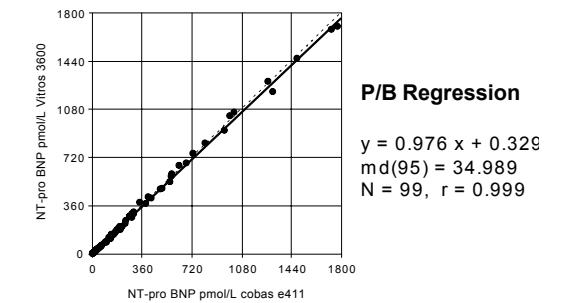
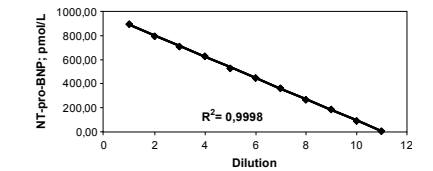
### FT3 (pmol/L)

	Precision	Mean	CV (%)
Intra-assay		3.1	5.2
		10.2	2.1
Inter-assay		3.7	3.9
		19.3	1.1



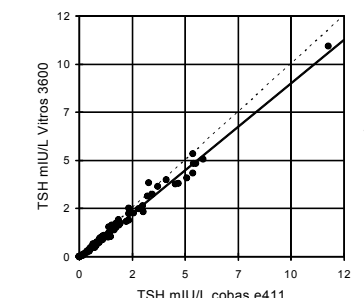
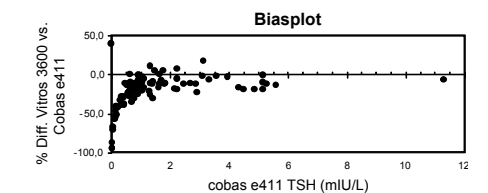
### NT-pro-BNP (pmol/L)

	Precision	Mean	CV (%)
Intra-assay		15.4	1.3
		567	1.5
Inter-assay		15.8	1.5
		691	2.1



### TSH (mIU/L)

	Precision	Mean	CV (%)
Intra-assay		0.37	1.7
		22.7	1.5
Inter-assay		0.05	4.3
		15.8	2.4



† Part of External Trials and was Supported Partially by Ortho-Clinical Diagnostics  
 ††Product Availability Subject to Local Regulatory Requirements