MagXtract© 3200 System: Molecular Diagnostic Equipment

KEY FEATURES

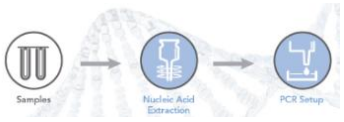
MagXtract © 3200 System is an innovative platform for molecular diagnostics . It integrates sample processing from the primary tube, nucleic acid extraction , and PCR preparation , ensuring full traceability throughout the process . The system generates templates compatible with various thermocyclers . Nucleic acid extraction is based on magnetic nanoparticle technology, facilitating efficient DNA/RNA isolation and purification.

Unlike labor-intensive manual diagnostic techniques prone to errors , this automated device from Vircell offers a fast and straightforward solution for processing multiple samples simultaneously . It minimizes human errors and reduces sample preparation time for PCR amplification by utilizing pre-dispensed, ready-to-use reagents.

System Highlights::

Full Automation

- Primary sample dispensing
- Extraction process automation.
- PCR plate preparation
- Pre-dispensed lyophilized extraction and PCR reagents ready to use.



MagXtract 3200

CE IVD FDA

Patented Pipetting Technology

- Processes volumes from 5 to 1000 µL,.
- Effectively preventing aerosol contamination

User-friendly

- Intuitive navigation menu available in Spanish and English languages

Time Efficiency

- End-to-end traceability, from primary tube.
- Processing up to 32 samples within 60 minutes.

Vircell Real-Time PCR Kits enable one-step amplification and detection of infectious disease-causing microorganisms in human samples Main features:

Targets

Multiplex PCR: Detects multiple targets in one or two reaction tubes per sample.

Compatibility

Compatible with Bio-Rad (CFX96 Touch™/ CFX Opus 96) and Azure Biosystems (Azure Cielo 6) thermocyclers.

Contents

Lyophilized master mix and positive control for stability and cost reduction.

RTPCR Kits

Validated references RTPCR002-LP/LPD, RTPCR 003-LP/LPD, RTPCR 004-LP, RTPCR 005- LPD, RTPCR006-LPD, RTPCR007-LPD, RTPCR021-LPD, RTPCR016-LPD y RTPCR022-LP-R.

REALTIME PCR KIT

CE IVD

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PERFORMANCE EVALUATION

➢ Precision

Reproducibility and repeatability were assessed using four SARS -CoV -2-positive samples across three instruments with the **SARS-CoV-2 PLUS UK REALTIME PCR KIT** (RTPCR 009 -LPD) and Bio -Rad CFX 96 thermocycler . Results showed a coefficient of variation CV % below 1.9% for the *E* and *ORF1ab* genes.

Additionally , the repeatability and reproducibility of the equipment were analyzed using the kit's positive control, resulting in a CV% below 1.1.

Figure 1. Comparison of Ct values obtained for each sample across the three instruments for the *E* gene.

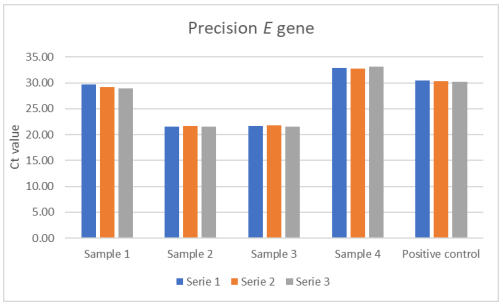
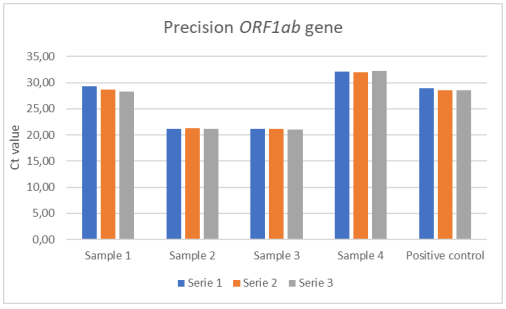


Figure 2. Comparison of Ct values obtained for each sample across the three instruments for the *ORF1ab* gene.



➢ Cross-Contamination

Four SARS -CoV -2-positive samples (Ct range 18-30) and four alternating negative samples were analyzed on three instruments using the **SARS -CoV -2 PLUS UK REALTIME PCR KIT** and the CFX 96 Thermocycler (Bio-Rad) .

No cross -contamination was detected.

➢ Linearity

Linearity was assessed using four serial dilutions of a SARS -CoV -2-positive sample in two MagXtract © 3200 Systems with the **DIRECT SARS -CoV -2 REALTIME PCR KIT**

RTPCR002-LP on the CFX96.

The correlation coefficient (R^2) exceeded 0.9992 for both target genes.

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Figure 3. Amplification curves and regression analysis for the *N* and *E* targets in instrument 1.

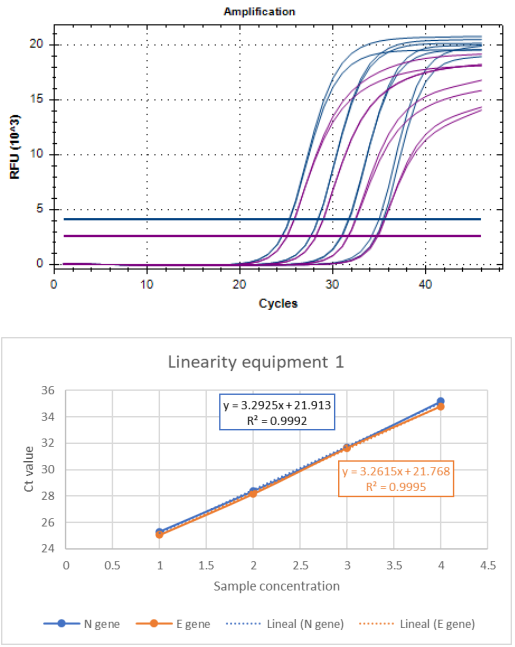
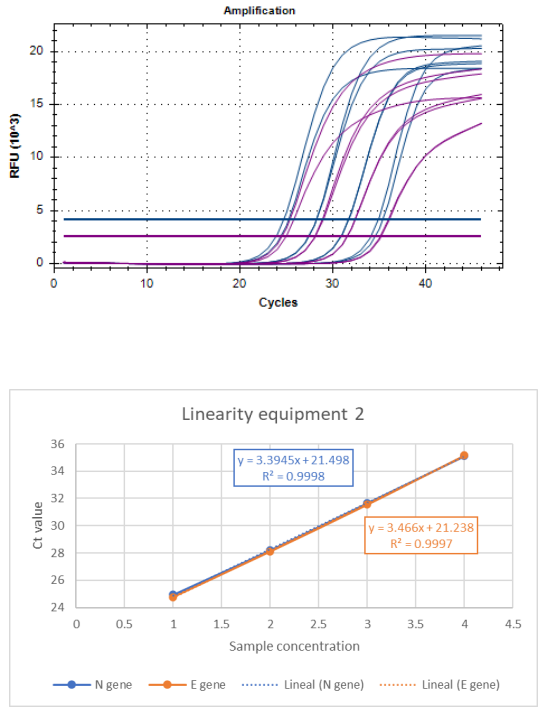


Figure 4. Amplification curves and regression analysis for the *N* and *E* targets in instrument 2.



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➢ Clinical Sensitivity and Specificity Compared to a Commercial Reference Kit

The sensitivity and specificity were analyzed throughout the entire process using multiple groups of clinically positive and negative samples, previously characterized with a reference extraction and PCR system. All assays were performed on the Bio-Rad CFX96 thermocycler.

The **VAGINAL PANEL REALTIME PCR KIT (RTPCR005-LPD)** was used to analyze 72 vaginal swab samples previously tested with the Allplex™ Vaginitis Screening Assay (Seegene) after extraction using the STARlet platform . A 92.9% concordance was obtained.

Table 1. Results obtained with the RTPCR005-LPD kit compared to the reference method.

			RTPCR005-LPD	
			Positive	Negative
Reference method	Bacterial Vaginosis	Positive	27	0
		Negative	3	26
	Candida species	Positive	45	0
		Negative	1	26
	Trichomonas vaginalis	Positive	9	0
		Negative	2	61

A total of 27 perianal swab samples and 24 urine samples were analyzed using the **CT/NG/TV/MG REALTIME PCR KIT** (RTPCR 006-LPD). Out of the 51 samples , 42 were positive and 9 were negative . These samples were previously characterized using the Allplex ™ CT /NG /MG /TV Assay (Seegene). A 94 .1 % concordance was obtained.

Table 2. Results obtained with the RTPCR006-LPD kit compared to the reference method.

		RTPCR006-LPD	
		Positive	Negative
Reference method	Positivo	41	1
	Negative	2	7

A total of 51 samples, previously characterized using the Allplex ™ Genital Ulcer Assay (Seegene), were tested with the **GENITAL ULCER REALTIME PCR KIT** (RTPCR007-LPD). The analysis included 40 genital ulcer samples and 13 perianal swab samples , with 34 positive and 19 negative results . A 98.0% concordance was obtained.

Table 3. Results obtained with the RTPCR007-LPD kit compared to the reference method

		RTPCR007-LPD	
		Positive	Negative
Reference mehod	Positive	31	1
	Negative	0	19

➢ Clinical Sensitivity and Specificity with Inoculated Real Samples

To validate the processing on the equipment MagXtract © 3200 System with different sample types a validation was conducted by testing the following kits using negative clinical samples inoculated with inactivated culture.

A total of 46 serum and plasma samples were analyzed , including 30 positive samples inoculated with cultures of the different viruses detected by the **ZIKV /DENV /CHIKV REALTIME PCR KIT** (RTPCR 004-LP) and 16 negative samples. A 95.7% concordance was obtained

		RTPCR004-LP	
		Positive	Negative
Reference method	Positive	30	0
	Negative	2	14

Similarly , 45 sputum samples were analyzed , including 30 positive samples inoculated with cultures of the different mycobacteria detected by the **MYCOBACTERIUM REALTIME PCR KIT** (RTPCR 016-LPD) and 15 negative samples. A 100% concordance was obtained.

		RTPCR016-LPD	
		Positive	Negative
Reference method	Positive	30	0
	Negative	0	15

A total of 65 cultured isolate samples were tested using the **MTBC SPECIES REALTIME PCR KIT** (RTPCR 022-LP-R), including 40 positive and 25 negative samples. A 96 .9% concordance was obtained.

		RTPCR022-LP	
		Positive	Negative
Reference method	Positive	40	0
	Negative	2	23

➢ Comparison with Another Extraction System: Maelstrom™ 4800 (TanBead)

A comparative study was conducted between the MagXtract© 3200 System and the Maelstrom™ 4800 extraction system (TanBead).

The MagXtract © 3200 System performs the entire process , from primary sample processing to PCR preparation , whereas the Maelstrom ™ 4800 system is limited to nucleic acid extraction only.

The analytical sensitivity as well as the clinical sensitivity and specificity of both systems were determined and compared.

Analytical Sensitivity

The limit of detection (LoD) for both systems was determined using serial dilutions of a quantified SARS -CoV -2 sample with the **DIRECT SARS -CoV -2 REALTIME PCR KIT** (ref. RTPCR 002-LP) on the Bio-Rad CFX96 thermocycler.

Both systems demonstrated equal sensitivity for the two SARS-CoV-2 targets included in the RTPCR kit.

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Figure 5. Comparison of Ct values obtained for each sample concentration for the *N* gene

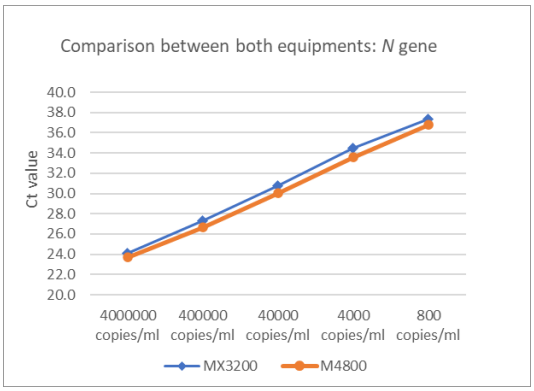
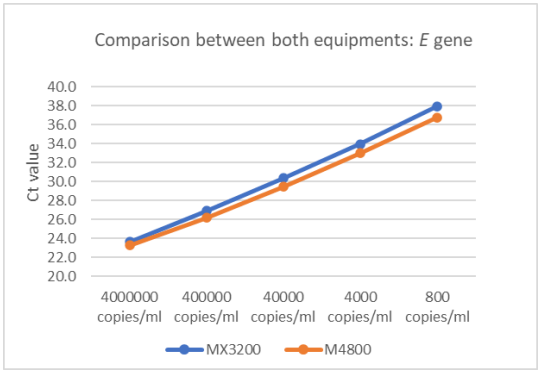


Figure 6. Comparison of Ct values obtained for each sample concentration for the *E* gene.



Clinical Sensitivity and Specificity

The sensitivity and specificity of the various RTPCR kits validated for use with the MagXtract © 3200 System were analyzed and compared to the Maelstrom™ 4800 (TANBead) system with multiple groups of clinically positive and negative samples for various microorganisms included in the kit were analyzed. All assays were performed on the Bio-Rad CFX96 thermocycler, following the RTPCR kit's instructions for use.

A total of 70 vaginal swab samples were analyzed using the **VAGINAL PANEL REALTIME PCR KIT** (RTPCR 005-LPD). Additionally , 32 nasopharyngeal /oropharyngeal swabs were tested for SARS -CoV -2 using the **DIRECT SARS -CoV -2 REALTIME PCR KIT** (RTPCR 002-LPD), **SARS-CoV-2-FLU-RSV REALTIME PCR KIT** (RTPCR 003-LPD), and **SARS - CoV -2-FluA -FluB -RSV REALTIME PCR KIT** (RTPCR 021-LPD).

Furthermore, 27 perianal swab samples and 24 urine samples were analyzed with the **CT/NG/TV/MG REALTIME PCR KIT (**RTPCR 006 -LPD). Lastly , 51 samples were tested using the **GENITAL ULCER REALTIME PCR KIT** (RTPCR 007 -LPD), including 40 genital ulcer samples and 13 perianal swabs

A total concordance of 93% was obtained between both methods.

CONCLUSIONS

The MagXtract© 3200 System is a precise, linear, and cross-contamination - free system , compatible with multiple sample types , demonstrating over 92 % concordance compared to other methods.

Similarly , the results obtained with the MagXtract © 3200 System are comparable to those of the semi -automated Maelstrom™ 4800 platform.

The MagXtract© 3200 System enables full automation of the process, from primary sample processing to PCR preparation, ensuring traceability throughout the assay and minimizing human error.

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