Product information
STANDARD EXTRACTION KITS – SE001 / SE002

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BACKGROUND & PRODUCT OVERVIEW

Accurate and reliable nucleic acid extraction is essential for molecular diagnostic workflows. Improved PCR sensitivity and specificity make nucleic acid quality critical for accurate diagnosis.

Traditional manual DNA/RNA extraction procedures, such as spin-column or organic-solvent methods, are labor-intensive, prone to contamination, and generate variability between operators. These limitations have driven the transition toward **automated magnetic-bead extraction systems**, which ensure standardization, reproducibility, and full traceability across runs.

Within this context, Vircell has developed the **STANDARD EXTRACTION KITS (SE001/ SE002)** as an optimized, ready-to-use solution for automated extraction and purification of DNA/RNA from human clinical samples.

Designed to work with the **MagXtract® 3200** and **MAELSTROM 48** systems, these kits form part of Vircell's Molecular Complete Solution, enabling a consistent, standardized, and fully automated workflow from sample to result, particularly when combined with the VIRPLEX® RT-PCR diagnostic panels.

The extraction kits are validated for a broad spectrum of clinical specimens, including respiratory, urogenital, cerebrospinal, and gastrointestinal among other samples, and demonstrate **robust performance.**

VIRCELL STANDARD EXTRACTION KITS (SE001/ SE002)

Name / Reference / Intended Use / Test Type

Name and reference: STANDARD EXTRACTION **PLATE** (SE001)
STANDARD EXTRACTION **TUBE** (SE002)

Intended Use: The STANDARD EXTRACTION KITS are intended for **in vitro diagnostic use** in the automated extraction and purification of nucleic acids (DNA/RNA) from human biological specimens. The extracted material is suitable for use in **downstream nucleic acid amplification assays**, particularly VIRPLEX RT-PCR kits (Vircell).

Regulatory status: CE (CE-IVDR)

Test principle

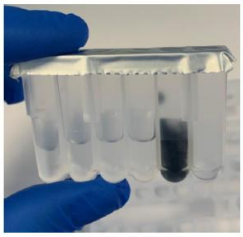
The kits use **nanomagnetic bead technology** to isolate and purify nucleic acids from the sample. The extraction process includes the following steps:

1. **Lysis** – chemical and mechanical disruption of cells to release nucleic acids.
2. **Binding** – nucleic acids bind to magnetic beads under optimized conditions.
3. **Washing** – multiple washing steps remove inhibitors and impurities.
4. **Elution** – purified nucleic acids are eluted in buffer, ready for amplification.

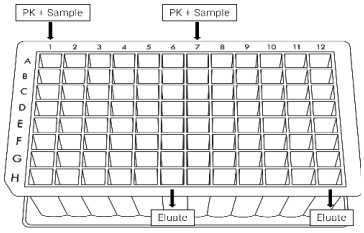
All steps are performed automatically by the **MagXtract® 3200** or **Maelstrom™ 4800/4810 instrument** using the prefilled reagents in the extraction plate or tube format.

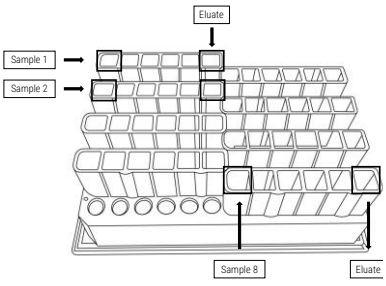
Components and appearance. Transport and storage requirements.

Both formats contain the same reagents and chemistry; the only difference is the physical configuration, allowing adaptation to different throughput and workflow needs — the TUBE format for individual extractions and the PLATE format for processing up to 16 samples simultaneously.

Kit appearance		Ref.	Pack size	Kit contents
STANDARD EXTRACTION PLATE 		SE001	96 tests	**[1]** VIRCELL STANDARD EXTRACTION PLATE: 6 x plate with 96 wells containing buffers to perform nucleic acid extraction. **[2]** VIRCELL TIPS PLATE: 1 x plate with 96 tips.
STANDARD EXTRACTION TUBE 		SE002	96 tests	**[1]** VIRCELL STANDARD EXTRACTION TUBE: 8 x 12 strips of 6 wells containing buffers to perform nucleic acid extraction. **[2]** VIRCELL TIPS TUBE: 2 x 48 tips plate. **[3]** VIRCELL TUBE GRID: 1 x 2 tube grids.

Well	Buffer
1/7	Lysis buffer (LB)
2/8	Washing buffer 1 (WB1)
3/9	Washing buffer 2 (WB2)
4/10	Washing buffer 2 (WB2)
5/11	Magnetic beads (MB)
6/12	Elution buffer (EB)





REAGENT STABILITY

Transport at room temperature. Store **at 15–35°C**. Use VIRCELL STANDARD EXTRACTION PLATE/TUBE within **one hour** after removing the aluminium foil.

SAMPLES STABILITY

Purified DNA:

- 2–8°C for up to 72 hours
- –20°C or lower for up to 2 months

Avoid more than five freeze–thaw cycles.

Purified RNA:

- 2–8°C for up to 72 hours
- –70°C or lower for up to 2 months

Avoid more than five freeze–thaw cycles.

Special materials required but not provided:

- Microbiological safety cabinet.
- Maelstrom™ 48 series (TANBead) or MagXtract® 3200 system (Chroma ATE).
- Precision micropipettes.
- Sterile tips with aerosol barrier.
- Vortexer.
- Proteinase K (ref. Vircell VPRK).
- Positive and negative extraction control (recommended).

WORKFLOW ON MAELSTROM™ 48 SERIES

1. **Plate/tube preparation**: Remove the aluminium foil from the extraction plate/tube and add 10 µL of Proteinase K to the lysis buffer well.
2. **Sample loading**: Add 300–600 µL of sample, depending on sample type.
3. **Automated run**: The system executes lysis, binding, washing, and elution steps automatically.
4. **Eluate recovery**: 60–70 µL of purified DNA/RNA are obtained, ready for use in downstream PCR.

WORKFLOW ON MAGXTRACT® 3200

1. **System loading:** load all the reagents and the samples following the instructions provided with the instrument to run the extraction and PCR set-up.
2. **Automated run**: The system performs Proteinase K and sample loading, extraction steps, eluate recovery and PCR set-up automatically.

60–70 µL of purified DNA/RNA are obtained, ready for use in downstream PCR.
The system provides full traceability, minimal manual steps, and reproducible results.

PERFORMANCE SUMMARY

The performance of the STANDARD EXTRACTION KITS was evaluated using the MagXtract® 3200 and Maelstrom™ 48 series, and VIRPLEX RT-PCR assays.

The results were as follows:

- **Method performance:** linear correlation with a $R^2 \geq 0.990$.
- **Precision:** CV ≤ 5.2% across runs, days and reagent lots.
- **Method comparison:** Agreement ≥ 93.5% compared with the GXT NA Extraction Kit was obtained from a total of 302 human clinical samples of different types.
- **No cross-contamination** detected during extraction procedure.
- **No interference** from common substances found in clinical samples was detected.
- **Compatibility** with commonly used transport media was assessed (Aptima®, eNAT®, ESwab®, Σ-Transwab®, Vircell Transport Medium).

METHOD COMPARISON

A total of 302 human clinical samples were analyzed in the performance evaluation. Agreement with the results obtained with GXT NA Extraction kit (Hain Lifescience GmbH, Bruker) with different sample types were analyzed. The agreement for each sample type is provided in the following table:

Sample type	Target	Positive samples No.	Negative samples No.	Agreement (%)
BAL	*Pneumocystis jirovecii*	9	13	100
Ulcer	Herpes virus 1	10	10	100
Nasal wash	Respiratory syncytial virus	17	15	96.9
Naso/Oropharyngeal swab	SARS-CoV-2	9	22	96.8
Perianal/rectal swab	*Mycoplasma genitalium*	11	20	93.5
Serum/plasma	Hepatitis D virus	12	17	100
Sputum	*Mycobacterium*	12	10	100
Stool	Norovirus	12	18	96.7
Urethral swab	*Neisseria gonorrhoeae*	15	15	100
Urine	*Chlamydia trachomatis*	14	14	100
Cervical/vaginal swab	*Candida albicans*	17	10	100

For more performance information check the instructions for use.

COMPATIBILITY

- **Extraction Systems:** MagXtract® 3200 and Maelstrom™ 48 series.
- **PCR Kits:** Fully compatible with the entire **VIRPLEX RT-PCR portfolio**.

For any use other than the validated applications, the performance must be validated by the user.

MARKET CONTEXT AND POSITIONING

The global market for nucleic acid extraction systems is dominated by magnetic-bead technologies due to their flexibility, automatization, scalability and reproducibility. Major competitors include:

- **Qiagen QIAsymphony® platforms** (Qiagen,Germany)
- **NucliSENS easyMAG** (bioMérieux, France)
- **Hain Lifescience GXT NA Extraction Kit** (Bruker, Germany)
- **MagNA Pure LC Total Nucleic Acid Isolation Kit** (Roche, Switzerland)
- **KingFisher™ Viral RNA/DNA Kit** (Thermo Fisher, USA)
- **TANBead OptiPure Kits** (Taiwan)
- **STARMag cartridge** (Seegene, Korea)

Vircell STANDARD EXTRACTION KITS offer:

- **Ready-to-use, prefilled reagents**, that eliminate reagent mixing and minimize pipetting steps.
- **Fully compatibility with MagXtract® 3200 system** which provides full LIS bidirectional connectivity through VirCom software.
- **Broad specimen coverage**, validated for multiple human sample types and pathogens.
- **Mid-throughput scalability**, ideal for clinical labs processing 16 to 48 samples per day.
- **Optimized cost efficiency,** allowing flexible reagent use per strip to reduce cost per sample.
- **No wastage of reagents**, optimized reagent utilization.
- **Enhanced analytical sensitivity** through a concentration factor of 4- to 9-fold.
- **Rapid extraction time**, delivering purified nucleic acids within 15 to 35 minutes depending on sample type and protocol used.

These features position SE001 and SE002 as versatile, high-performance CE-IVDR extraction reagents, offering laboratories a standardized solution.