

LEADing precision in infectious disease diagnostics

geneLEAD[®] VIII & SMD lead kits



The geneLEAD® VIII¹ is a fully automated molecular diagnostics platform that integrates nucleic acid extraction and real-time PCR in one streamlined system or as independent modules. With lyophilised SMD lead kits², it ensures reliable high-quality results, minimal hands-on time, and reduced costs.

Designed for diagnostic laboratories, geneLEAD® VIII bridges the gap between point-of-care solutions and high-throughput systems with a large footprint, offering both flexibility and dependable performance in a compact format across a wide range of applications.

Why labs choose geneLEAD® VIII and SMD lead kits

✓ Proven performance you can rely on

- Turnaround ~120 min, hands-on time under 5 min
- Processes 1 to 8 samples per run with seamless LIS integration
- 6-channel multiplex PCR for broad coverage assays
- Reproducible results, validated across multiple test types
- Includes HEPA filter and UV light for robust contamination prevention



Designed for
lab efficiency

✓ Integrated internal controls – every run, every sample

- Internal sample control (ISC): ensures sample collection and sample integrity
- Internal process control (IPC): detects PCR inhibition within each reaction
- Minimises invalid results and repeated testing, ensuring diagnostic confidence
- Lyophilised format for easy handling and room-temperature storage

✓ EQA³-validated accuracy

- SMD lead kits achieved 100% concordance for all core and training samples with a detection score of 'perfect' - results verified by the EQA providers QCMD and INSTAND

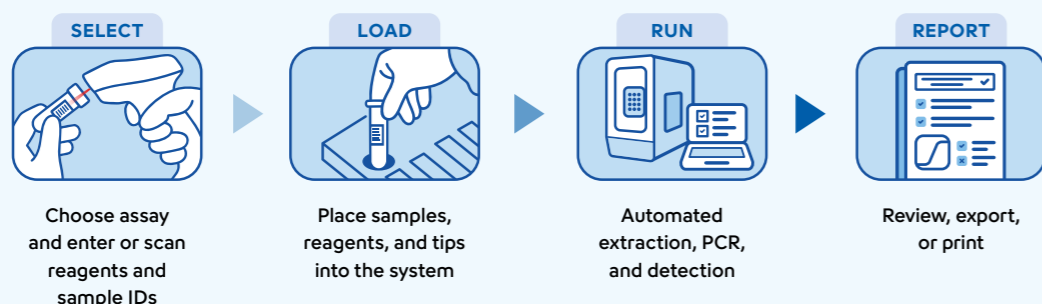
✓ Modular system architecture

- Nucleic acid extraction and PCR can be performed together or independently
- Extracted eluate compatible with NGS and other downstream applications

✓ Independent & scalable

- Compatible with broader lab workflows and assays
- Network up to six independent benchtop devices for higher throughput

geneLEAD® VIII workflow



SMD lead kit test menu:



Respiratory	Code	Targets	Benefits
SMD lead respiraRNA 3.0	S01084	Influenza A (M), Influenza B (NEP), RSV A/B (G)	Multiplex RNA assay for rapid seasonal respiratory diagnosis
SMD lead respiraScreen 1	S01129	Influenza A (M), Influenza B (NEP), RSV A/B (G), SARS-CoV-2 (E, S)	One test for flu, RSV, and COVID-19 in differential diagnosis
SMD lead Bordetella	S01109	<i>B. pertussis</i> (IS481), <i>B. parapertussis</i> (IS1001), <i>B. holmesii</i> (hIS1001/IS481)	Differentiates <i>Bordetella</i> species for accurate cough diagnosis
SMD lead MTC/NTM/MAC	S01114	MTC (IS6110), NTM (16S), MAC (ITS)	Differentiates TB, NTM, and MAC in one test



Neurological and Skin	Code	Targets	Benefits
SMD lead HSV/VZV	S01116	HSV-1 (US4), HSV-2 (US4), VZV (OR6)	Differentiates herpesvirus infections in neurological and dermatological cases



Gastrointestinal	Code	Targets	Benefits
SMD lead C. diff	S01147	Toxin A (tcdA), Toxin B (tcdB)	Rapid detection of toxigenic <i>C. difficile</i>
SMD lead gastroplex Virus	S01086	Norovirus GI/GII (RdRp), Rotavirus (NSP3), Adenovirus (hexon)	Multiplex detection of leading viral gastroenteritis pathogens



Hospital-Acquired Infections	Code	Targets	Benefits
SMD lead MRSA seqc	S01140	SCCmec/orfX junction, mecA, mecC	Direct detection of MRSA and resistance markers



Sexually-Transmitted Infections	Code	Targets	Benefits
SMD lead STI 1	S01144	<i>C. trachomatis</i> (ytfF), <i>M. genitalium</i> (16S), <i>N. gonorrhoeae</i> (rpoC)	Multiplex STI detection in a single assay
SMD lead STI 2	S01145	<i>T. vaginalis</i> (ITS), <i>M. hominis</i> (16S), <i>U. parvum</i> and <i>U. urealyticum</i> (ureC).	Multiplex STI detection in a single assay

Ordering information

Material	Product hierarchy	Tests per unit	Ref code
geneLEAD® VIII	MAIN INSTRUMENT		A2700
magDEA Dx SV	CONSUMABLES	48	E1300
geneLEAD® VIII Consumable Set	CONSUMABLES	48	F8900
geneLEAD® VIII PCR Reaction Cassette Set	CONSUMABLES	192	F8840
geneLEAD® VIII PCR-Reagent-Cassette	CONSUMABLES	192	F8820
SMD lead kits	KITS	96	Information listed above



Discover more
on our website:
sysmex-europe.com/genelead-viii

¹ Compliant with In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746

² The SMD lead kits are for in vitro diagnostic use as according to IVDD (Regulation 98/79/EC (IVDD). These tests are for professional use only and is not intended for self-testing or over-the-counter use.

³ EQA – External Quality Assessment, QCMD & INSTAND – non-profit international EQA providers: QCMD (Quality Control for Molecular Diagnostics) – www.qcmd.org, INSTAND e.V. – www.instand-ev.de

Distributor EMEA: Sysmex Europe SE · www.sysmex-europe.com

Manufacturer Kit: gerbion GmbH & Co. KG · www.gerbion.de

Manufacturer geneLEAD: Precision System Science Co., Ltd. · www.pss.co.jp

You will find your local Sysmex representative's address under www.sysmex-europe.com/contacts