GeneXpert[®] Xpress CLIA Waived Molecular Testing Everywhere



Standardized, CLIA Waived molecular testing across hospitals, specialty clinics, physician office labs, and emergency departments.





Random Access

Robust Design

GeneXpert[®] Xpress

Compact Design

- Scalable design 2-module and 4-module options available for customized throughput needs
- **Reduced footprint** built in barcode scanner and touchscreen tablet
- Random access true on-demand, walkaway testing system
- Built-in redundancy each module operates as its own independent analyzer

Simple, Integrated Workflow

- Run up to 4 tests at one time
- No specialized training or daily maintenance required
- Operator and QC lockout available
- Bi-directional interface to LIS (HL7, ASTM)
- Remote IT troubleshooting
- Simplified remote printing

Simple Workflow and Proven Cartridge Technology

Simplified workflow – as easy as 1, 2, 3

- Single-use, self-contained cartridge reduces waste and risk of contamination
- Integrated QC in every cartridge
- Ability to standardize inventory management







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3



GeneXpert[®] Xpress Menu

28°C

All reagents can be stored at room temperature (2-28°C)

No confirmation required for negative results*

Xpert[®] Xpress Flu Positive results in as soon as 20 minutes[^]

CPT CODE: 87502-QW

- Real-time RT-PCR molecular test results
- Sample Types Nasal Swab, Nasopharyngeal Swab
- Detects viral RNA, enabling better detection of seasonal mutations of the flu virus

Performance	Positive Percent Agreement	Negative Percent Agreement
Influenza A	98.2%	97.9%
Influenza B	97.8%	99.5%

Xpert[®] Xpress Flu/RSV Positive results in as soon as 20 minutes[#]

CPT CODE: 87631-QW[†]

Specificity

94.1%

- One Cartridge. One Sample. Three Results
- Sample Types Nasal Swab, Nasopharyngeal Swab
- Detects viral RNA, enabling better detection of seasonal mutations of the flu virus

Performance	Positive Percent Agreement	Negative Percent Agreement
Influenza A	98.1%	98.1%
Influenza B	100%	99.1%
RSV	98.4%	99.3%



Xpert[®] Xpress Strep A **CPT CODE: 87651-QW** Positive results in as soon as 18 minutes[^]

- Confirmatory molecular test results*
- Sample Type Throat Swab (E-swab in liquid Amies)

Performance	Sensitivity
Strep A	99.4%

Coming Soon[‡]

Xpert[®] Xpress CT/NG, Xpert[®] Xpress Multiplex Vaginal Panel, and Xpert[®] Xpress GBS

US-IVD, For In Vitro Diagnostic Use.

- * Follow-up testing by culture is required if the Xpert Xpress Strep A test result is negative and clinical symptoms persist, or there is an outbreak of acute rheumatic fever (ARF)"
- ^ With early assay termination (EAT) for positive results.

- The CPT for Flu/RSV (87631-QW) is reported when both targets are ordered by the clinician and performed. When only Flu is ordered and performed, CPT code 87502-QW is reported. When Only RSV is ordered and performed, CPT code 87634 is reported.
- ± The product information is intended to outline our general product direction and it should not be relied upon in making a purchasing decision

as the development, release, and timing of any of our products remains at our discretion and is also subject to regulatory review



[#] With early assay termination (EAT) for positive Flu or for positive RSV only. Reporting negatives and combined Flu and RSV results in 30 minutes.

Xpert® Xpress Menu Information Catalog Number

Test Name	Description	Catalog Number
Xpert® Xpress Flu	10 Tests	XPRSFLU-10
Xpert® Xpress Flu/RSV	10 Tests	XPRSFLU/RSV-10
Xpert Nasal Sample Collection Kit	100 Nasal Swabs & UTM Kits	SWAB/F-100
Xpert Nasopharygeal Sample	100 Nasopharyngeal Swabs & UTM Kits	SWAB/B-100
 Xpert® Xpress Strep A	10 Tests	XPRSTREPA-10
Xpert® Xpress Strep A	120 Tests	XPRSTREPA-120
Collection and Transport Device	50 ESwab™ Liquid Amies Collection & Transport Devices	480CFA

GeneXpert® Xpress Systems and Connectivity Specifications

System	Description	Instrument Dimensions	Catalog Number
GeneXpert® Xpress IV-2	2-module system	11.5" w x 18" h * x 16" d *	GXIV-2-CLIA
GeneXpert® Xpress IV-4	4-module system	11.5" w x 18" н * x 16" с *	GXIV-4-CLIA

	LIS Connectivity	Data Management Middlewear^
GeneXpert [®] Xpress	Bi-directional	RALS, Telcor, UniPOC, Aqure, RelayMed

US-IVD. For In Vitro Diagnostic Use.

* Average System Height and Depth based on touch screen angle.

^ Please contact your sales representitive for a full list of LIS and POC data management connectivity solutions.

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