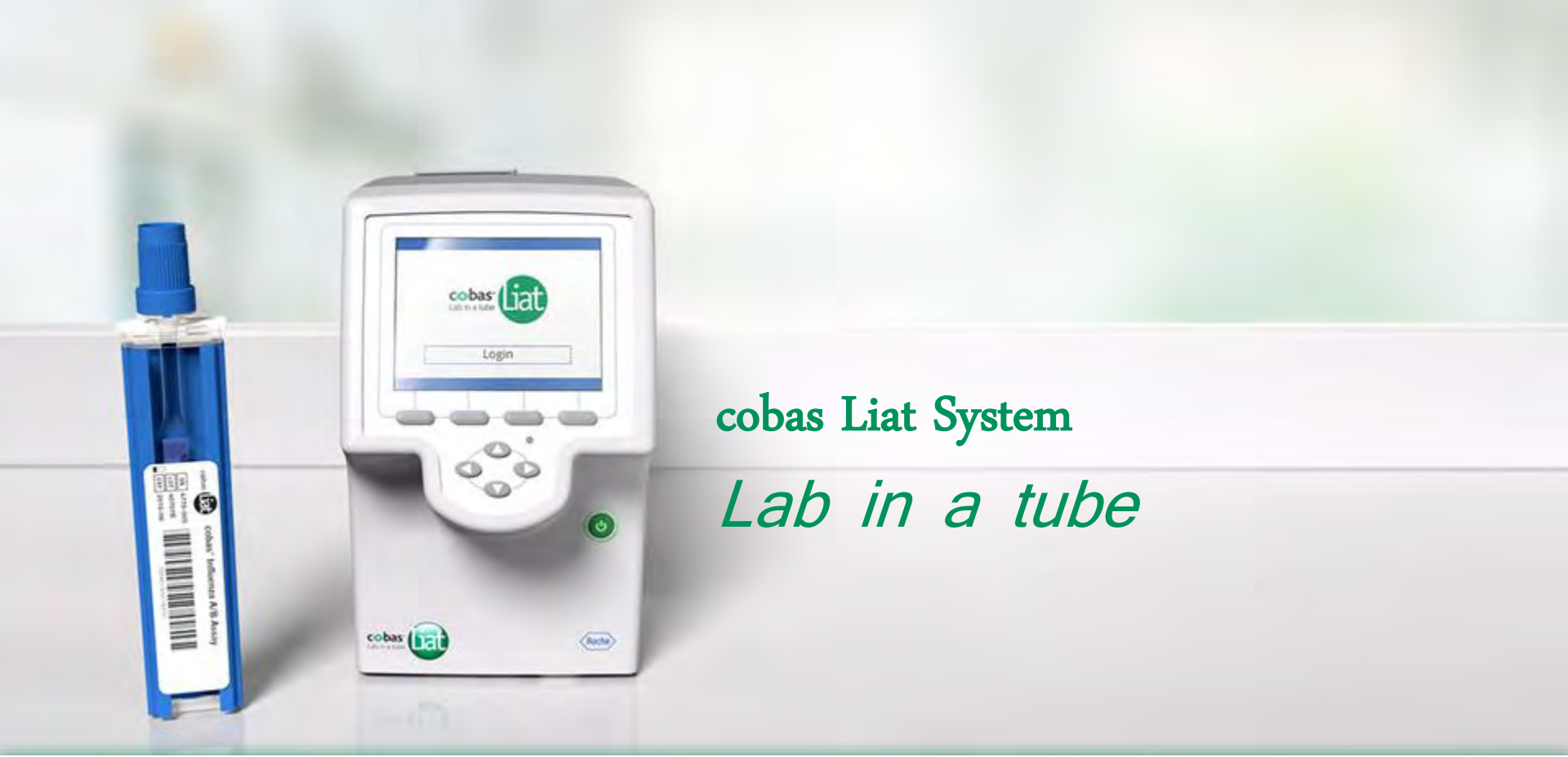


cobas Liat System

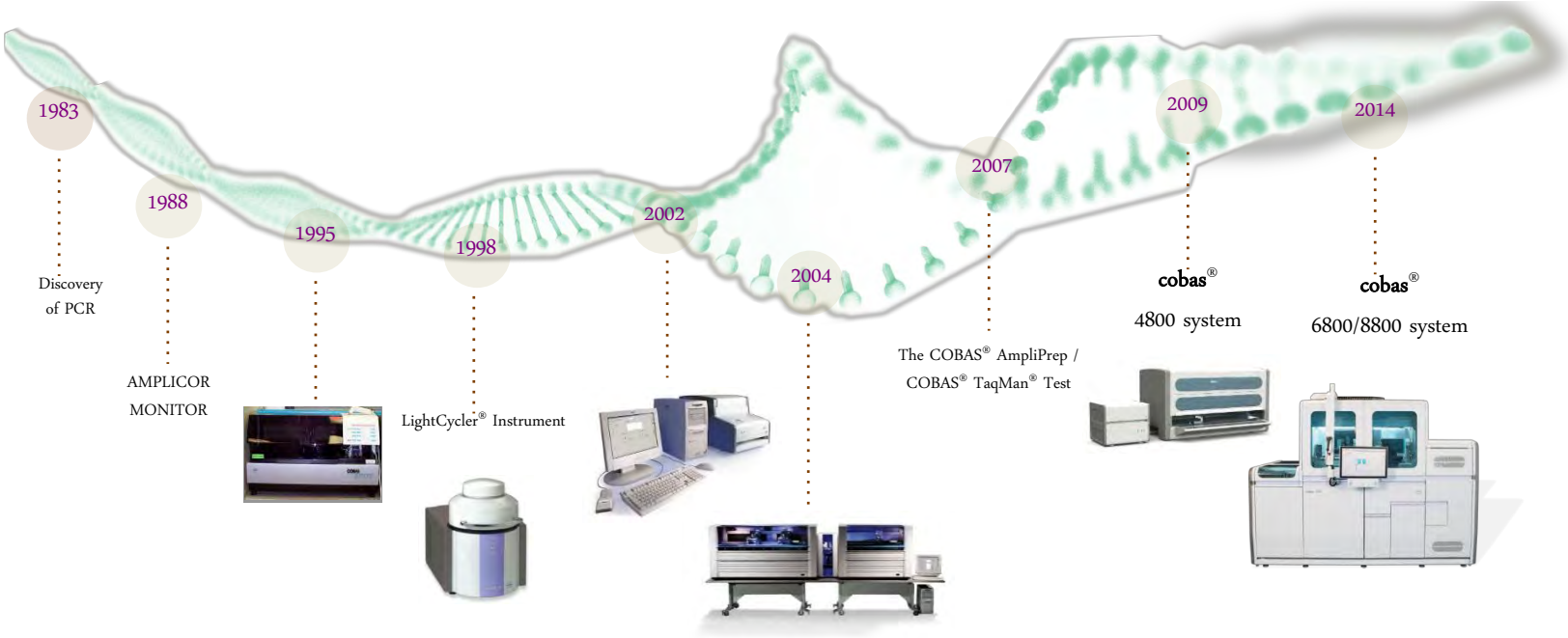
Lab in a tube

Roche

cobas Liat
Lab in a tube

Roche Molecular Diagnostics

A rich history of innovation in PCR & molecular automation



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cobas® Lab in a tube Liat

Today, we put a Lab In A Tube.

and deliver real-time PCR results less than 30 minutes*.

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* Depends on different assays

cobas® Liat® System

Key features

IT connectivity

ANALYZER

ASSAY TUBE

Fast Turn Around Time

Ease of Use

Lab Quality Performance

*cobas® Strep A ~15 min; cobas® Influenza A/B, cobas® Influenza A/B & RSV and cobas® Cdiff ~20 min; In Development: cobas® MRSA/SA & cobas® HIV-1/2 Qual

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System Overview

cobas® Liat® System

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cobas® Liat® System

A complete solution from sample in to result out

cobas® Liat® System

cobas® Liat® System

cobas® Liat® Analyzer + **cobas® Liat® System assay tube**

Compact, innovative **real-time PCR** platform designed for **on-demand STAT testing**, enabling **confidence** in rapid patient management, at the point of care or in the laboratory.

19.0 cm

11.4 cm

ANALYZER

ASSAY TUBE

A pencil-sized, flexible single-use tube acts as the sample vessel and contains all assay reagents pre-packed in tube segments

*Currently available in the U.S.

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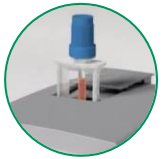
cobas® Liat® Analyzer

Assay tube entry door

Intuitive touchscreen display



Touchscreen soft keys

Function buttons

Navigation buttons

Laser barcode scanner

Power on/off

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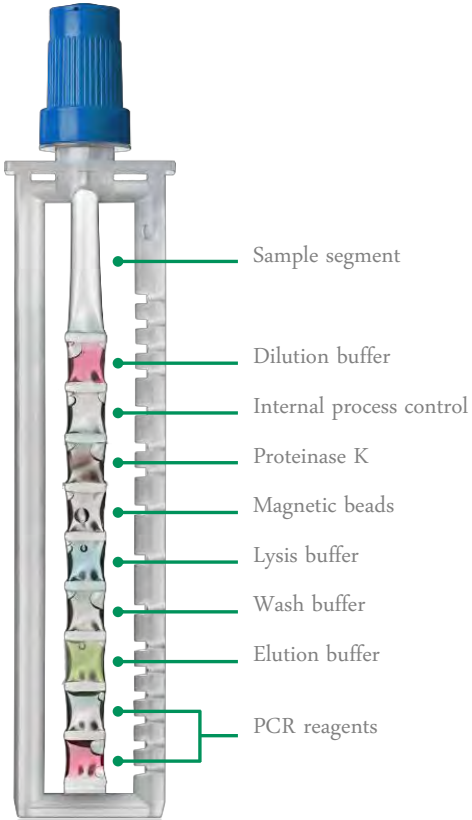
Assay tube

Pre-packed reagents in a single assay tube

Automated sample preparation & silica bead-based nucleic acid extraction in tube

Completely closed system



*Some assay tubes include dilution buffer and/or Uracyl N Glycosylase enzyme. **Contents varies by assay and coloring is for illustrative purposes only.**

*Contents varies by assay and coloring is for illustrative purposes only.

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cobas® Lab in a tube Liat

Secure and Simple Workflow

Results in
30 MINUTES
or less*

Sample

Add patient sample to the **cobas**® Liat ® assay tube with provided transfer pipette

Scan

Scan assay tube using built-in barcode scanner

Start

Insert assay tube into the **cobas**® Liat ® Analyzer

* Varies by assay

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cobas® Liat® System

A complete solution from sample in to result out

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Software

Assay reagent lot checks & internal control processed with every sample

QUALITY CONTROL

Secured login & keyed user roles for operation and report review

USER SECURITY

Sample process monitoring and “insufficient sample volume” warnings

VOLUME SENSING

Comprehensive self-monitoring and continuous self-calibration

REAL-TIME MONITORING

Auto analysis, interpretation & reporting; no user interpretation required

AUTOMATED DATA INTERPRETATION

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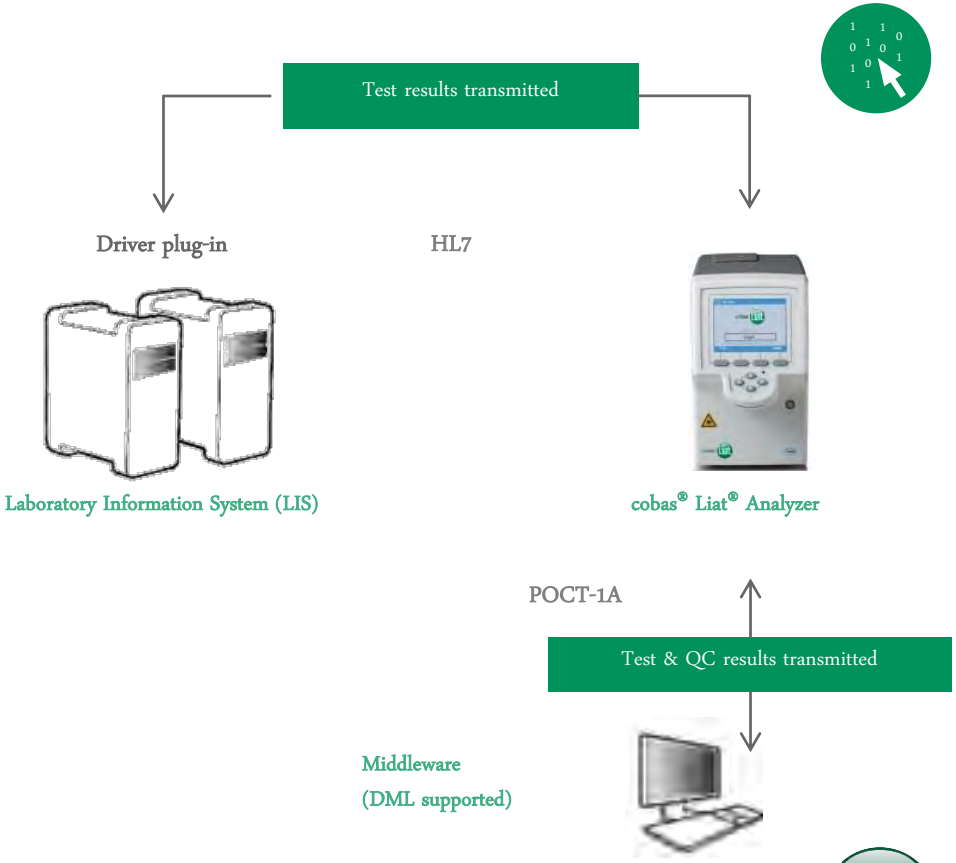
Connectivity

The **cobas**® Liat ® Analyzer supports HL-7 protocol and the POCT1-A Standard*

Available driver:

cobas IT1000

*Please reference the latest **cobas**® Liat® Analyzer Host Interface Manuals for EDI and DML full technical details



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A complete solution from sample in to result out

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Secure and Simple Workflow

Results in
30 MINUTES
or less*

Intuitive touchscreen user interface

Step-by-step guided instructions

No operator intervention or interpretation

No laptops or additional equipment required

* Varies by assay

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Assay Menu

Respiratory

- Influenza A/B
- Strep A
- Influenza A/B & RSV

HAI

- Cdiff
- MRSA/SA

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Assay Menu

Results in
30 MINUTES
or less*

Respiratory

- Influenza A/B — 20min
- Strep A — 15min
- Influenza A/B & RSV — 20min

HAI

- Cdiff — 20min
- MRSA/SA — 30min

Future pipeline

- Pertussis
- HIV-qual

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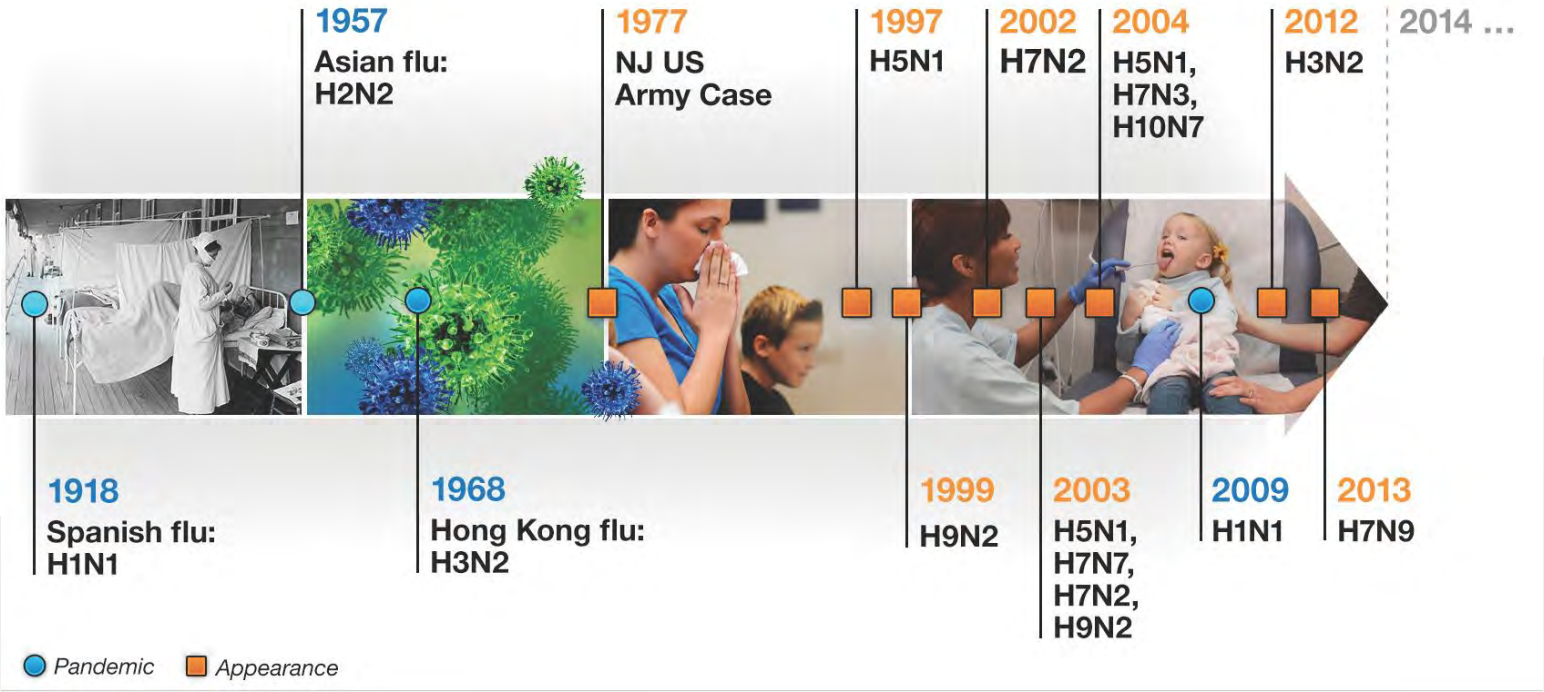
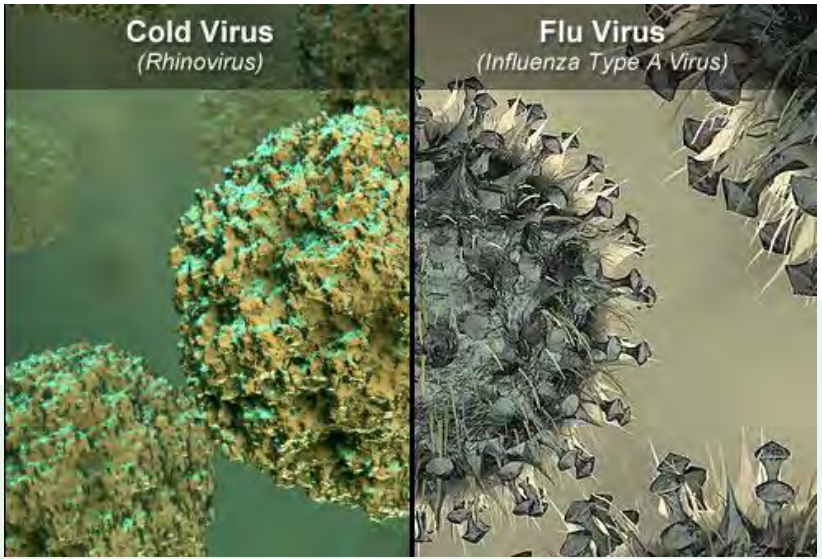
Influenza: Evolution in Action

Emerging Flu Strains are a Constant Challenge



it a Cold or Flu?

COLD	SYMPTOM	FLU
YES	STUFFY OR RUNNY NOSE	SOMETIMES
YES	SNEEZING	SOMETIMES
YES, with green or yellow gunk	COUGH	YES, a dry cough
YES	SORE THROAT	SOMETIMES
MILD head & body aches	BODY ACHES	SEVERE aches all over
NO	NAUSEA	SOMETIMES
RARE for adults	FEVER	YES
NO	CHILLS & SWEATS	YES
SLOWLY, over a few days	WHEN DO THE SYMPTOMS COME ON?	FAST, within hours

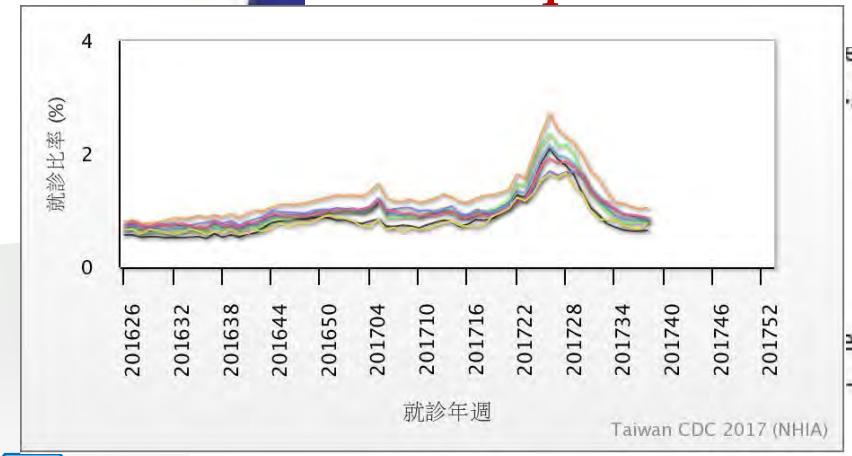


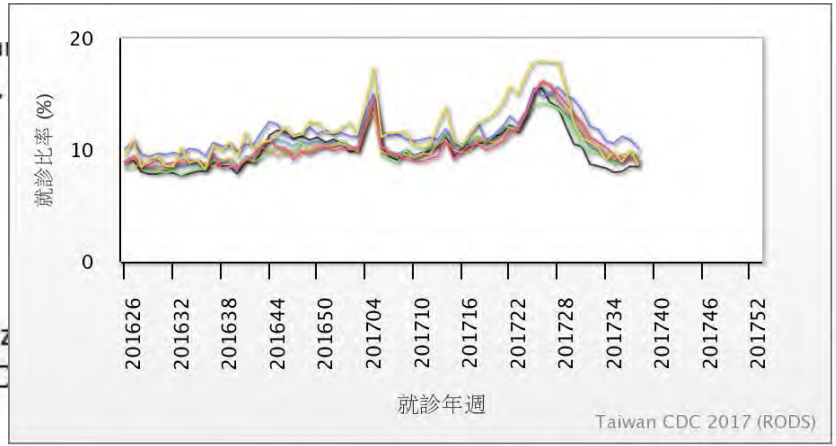
cobas® Liat Lab in a tube

Flu Season

Aid in diagnosis

If non-pattern in geography or in season, diagnostic tool is required





For Roch
The cobas

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Influenza Test	Advantages	Disadvantages	
Rapid influenza diagnostic tests Antigen detection (EIA) Neuraminidase detection assay	Fast (10-30 min) High specificity	Low-to-moderate sensitivity False negative results No subtyping	Point-of-Care Tests
RT-PCR Conventional gel-based PCR Real-time RT-PCR Multiplex PCR	Fast (20 min-6 h) High sensitivity Very high specificity	Expensive Trained technologist	Point-of-Care Tests Laboratory-Based Tests
Immunofluorescence Direct fluorescent antibody Indirect fluorescent antibody staining	Moderately high sensitivity High specificity	Moderate (2–4 h)	Laboratory-Based Tests
Viral culture Shell vial culture Isolation in cell culture	Moderately high sensitivity Highest specificity	Slow (1–14 days)	Laboratory-Based Tests (for public health surveillance)

cobas® Influenza A/B

Key specifications

Instrument	**cobas®** Liat® Analyzer
Viral RNA coverage	Influenza type A | Influenza type B
Collection device	Nasopharyngeal Swabs
Media Type	Universal Transport Media (UTM)
Test kit configuration	20 **cobas®** Liat® assay Tubes
Reagent	Ready to use enclosed in **cobas®** Liat® assay tube
Storage conditions	2-8°C
Shelf life	19 months
Performance	Superior sensitivity and specificity than other mPoC and Rapid PoC tests; equivalent to routine laboratory PCR
Limit of detection	Influenza A: 10^{-2}-10^{-1} $TCID_{50}$/mL. | Influenza B: 10^{-3}-10^{-1} $TCID_{50}$/mL.
Result	Influenza A: Detected or Not Detected | Influenza B: Detected or Not Detected
Time to result	~20 minutes

Source; **cobas®** Influenza A/B Product package insert

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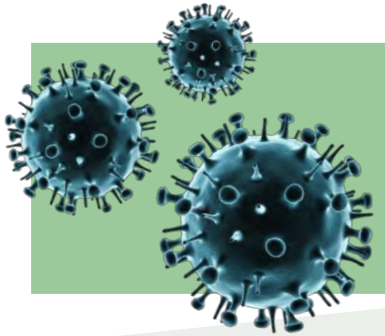
cobas® Influenza A/B

Assay Design

INFLUENZA A/B	TARGETS		INTERNAL PROCESS CONTROL
	M gene Inf A	NS gene Inf B	Bacteriophage

Source; cobas® Influenza A/B Product package insert

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cobas® Influenza A/B

Sample collection

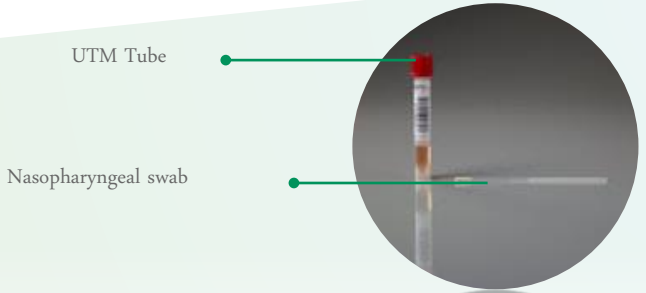
For the testing of the **cobas®** Influenza A/B, the sample collection method is a nasopharyngeal swab.
These are considered are the most sensitive method for detecting upper respiratory viral infections[1]

1. **Tilt the patient's head** back at a 70° Angle
2. **Insert the swab** into the nostril straight back
3. **Rotate the swab gently** for 5-10 seconds
4. **Remove swab** and place swab into the **transport media tube**
5. **Break the swab shaft** and leave the swab inside the tube
6. UTM media with sample is **ready for testing**

Key Points

Other sampling methods for Influenza testing are nasal swabs or nasal aspirates. Those have not been validated on the **cobas®** Liat® System.

If a sample in UTM media is not tested immediately, it can be stored at 2-8C for up to 72 hours.



http://jcm.asm.org/content/51/11/3880.long
http://www.ncbi.nlm.nih.gov/pubmed/22723469

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cobas® Influenza A/B

Strain coverage

Influenza A seasonal H1	Influenza A seasonal H3	Influenza A 2009 H1N1	Influenza B
A/Brisbane/59/2007	A/Brisbane/10/2007	A/NY/01/2009	B/Florida/04/06
A/New Caledonia/20/99	A/Alice	A/NY/02/2009	B/Malaysia/2506/04
A/Solomon Island/3/2006	A/MRC2	A/NY/03/2009	B/Florida/7/04
A/Mal/302/54	A/Hong Kong/8/68	A/New Jersey/8/76	B/Allen/45
A/Denver/1/57	A/Victoria/3/75	A/Swine/1976/31	B/GL/1739/54
A/FM/1/47	A/Wisconsin/67/05	A/Swine/Iowa/15/30	B/Taiwan/2/62
A/PR/8/34	A/Port Chalmers/1/73		B/Maryland/1/59
A/Weiss/43	A/Aichi/2/68		B/Mass/3/66
			B/HongKong/5/72
			B/Lee/40

The cobas® Influenza A/B Assay was evaluated with 22 Influenza A strains and 10 Influenza B strains.

Source; cobas® Influenza A/B Product package insert

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cobas® Influenza A/B

Clinical performance compared to culture

Influenza A

		Viral Culture		
		Positive	Negative	Total
cobas® Liat® System	Positive	77	15[a]	92
	Negative	2[b]	690	692
	Total	79	705	784

	%	95% CI
Sensitivity	97.5%	(91.2% - 99.3%)
Specificity	97.9%	(96.5% - 98.7%)

Key Point: The sensitivity of the **cobas®** Influenza A/B exhibits excellent performance when compared to viral culture in a prospective study of 784 patients.

Influenza B

		Viral Culture		
		Positive	Negative	Total
cobas® Liat® System	Positive	31	16[c]	47
	Negative	1[d]	736	737
	Total	32	752	784

	%	95% CI
Sensitivity	96.9%	(84.3% - 99.4%)
Specificity	97.9%	(96.6% -98.7%)

[a] Of 15 **cobas®** Liat positive, Culture negative specimens, 9 were positive and 6 were negative by PCR/sequencing;

[b] 2 **cobas®** Liat negative, Culture positive specimens were positive by PCR/sequencing;

[c] Of 16 **cobas®** Liat positive, Culture negative specimens, 14 were positive and 2 were negative by PCR/sequencing;

[d] 1 **cobas®** Liat negative, Culture positive specimens was positive by PCR/sequencing and was negative by lab-based RT-PCR.

.Source; **cobas®** Influenza A/B Product package insert

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Comparison of Alere and Liat with the FilmArray test for detection of Flu A/B

Comparison of Alere and Liat for influenza A virus

Alere or Liat result	No. with FilmArray result:		
	Positive	Equivocal	Negative
Alere			
Positive	56	1	0
Negative	21	2	49
Liat			
Positive	77	3	0
Negative	0	0	49

Comparison of Alere and Liat for influenza B virus

Alere or Liat result	No. with FilmArray result:	
	Positive	Negative
Alere		
Positive	15	0
Negative	1	113
Liat		
Positive	16	0
Negative	0	113

J Clin Microbiol. 2016 Nov; 54(11): 2763–2766.

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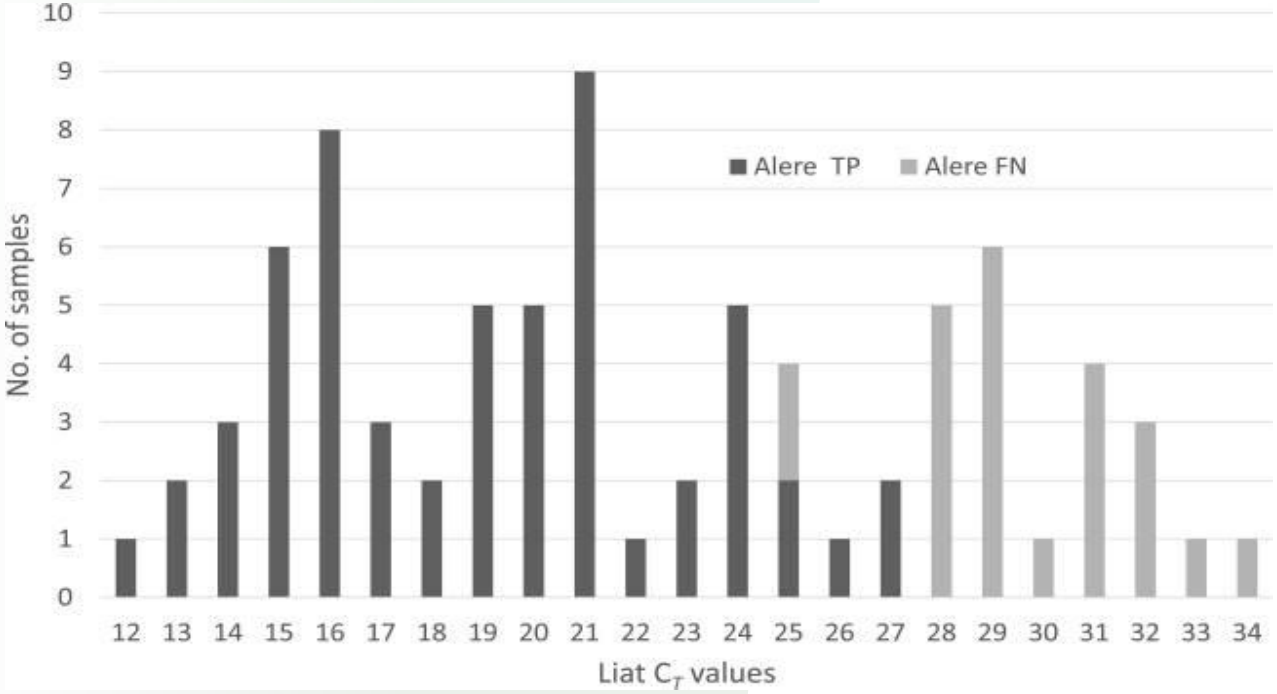
Frequency distribution of cycle threshold (CT) values for samples positive for influenza A virus



J Clin Microbiol. 2016 Nov; 54(11): 2763–2766.

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Multi-center evaluation of the cobas® Liat® Influenza A/B & RSV assay for rapid point of care diagnosis

Table 1
Point-of-care testing study site characteristics.

Site Location	Site Classification	Number of Samples Tested	Number of CLIA-Waived Test Operators
Virginia	Clinic	322	2N, 3 MA, 1 RA
Connecticut	Clinic	18	1N, 1 MA
South Florida Site 1	Clinic	149	1N, 1 MA
South Florida Site 2	Clinic	90	2 MA
Nebraska	Clinic	130	5 MA
Texas	Clinic	20	3N
Indiana	Clinic	56	1N, 2 MA
California	Clinic	138	2 MA
Ohio	Emergency Department	148	1N, 1 MA
Massachusetts	Emergency Department	243	1N 2 RA
New York	Emergency Department	295	6 RA
Central Florida	Emergency Department	47	1 NS, 1 RA

N-Nurse, MA-Medical Assistant, RA-Research Assistant/Study Coordinator, NS-Nursing Student.
The Virginia, California, and Nebraska sites tested both prospective and retrospectively included samples. All other sites tested prospective samples only.

Table 2
Patient demographics for prospectively collected NP swabs.

Age	Number of Prospective Samples	Percentage
≤5 years	320	23.5
6–21 years	408	30.0
22–59 years	505	37.1
≥60 years	128	9.4
Total	1361	
Sex		
Male	663	48.7
Female	698	51.3

Sensitivity & Specificity of cobas Liat Assay

Multi-Center Evaluation

Sensitivity and specificity of the cobas® Liat® Influenza A/B and RSV assay compared to ProFlu + (reference test) for prospectively collected fresh and retrospectively included frozen NP Swabs (All Samples).

Influenza A		Reference Test					
		Positive	Negative	Total		%	95% CI
Liat	Positive	267	34[a]	301	Sensitivity	99.6%	(97.9%–99.9%)
	Negative	1[b]	1352	1353	Specificity	97.5%	(96.6%–98.3%)
	Total	268	1386	1654[c]			

Influenza B		Reference Test					
		Positive	Negative	Total		%	95% CI
Liat	Positive	144	4[d]	148	Sensitivity	99.3%	(96.2%–99.9%)
	Negative	1[e]	1507	1508	Specificity	99.7%	(99.3%–99.9%)
	Total	145	1511	1656			

RSV		Reference Test					
		Positive	Negative	Total		%	95% CI
Liat	Positive	184	18[f]	202	Sensitivity	96.8%	(93.3%–98.8%)
	Negative	6[g]	1438	1444	Specificity	98.8%	(98.1%–99.3%)
	Total	190	1456	1646[h]			

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Sequencing analysis of discordant samples results

Multi-Center Evaluation

Table 7
Sequencing analysis of cobas® Liat® Influenza A/B and RSV assay positive and negative discordant samples following comparison to ProFlu+ (reference test) results.

	cobas® Liat®Positive ProFlu+ Positive	cobas® Liat® Positive ProFlu+ Negative	cobas® Liat® Negative ProFlu+ Positive	cobas® Liat®Negative ProFlu+ Negative
Influenza A	267	34	1	1352
Influenza A Sequencing Results	N/A	Positive: 15/34 Negative: 19/34 Indeterminate: 2/34	Negative: 1/1	N/A
Influenza B	144	4	1	1507
Influenza B Sequencing Results	N/A	Positive: 3/4 Negative: 1/4	Negative: 1/1	N/A
RSV	184	18	6	1438
RSV Sequencing Results	N/A	Positive: 7/18 Negative 11/18	Positive: 1 Negative: 5	N/A

Population with high risk of getting serious complications from the flu

- Adults ≥65
- Children ≤5
- Pregnant women
- Immunocompromised
- Chronic diseases

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Ideas & Conclusion

1. Need to focus on niche segment in hospital
   - ER
   - Specific Department in OPD
   - Hospitalized patients

2. Prevalence matters, cobas Liat can provide better PPV & NPV for the target population, provide better clinical value to the one who needs

3. In high prevalent scenario, the medical value is greater for cobas Liat Flu A/B system

4. The possibility for other assays?

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4300 Hacienda Drive
Pleasanton, CA USA

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Technical specifications

Dimensions

Height	19.0 cm (7.5”)
Width	11.4 cm (4.5”)
Length	24.1 cm (9.5”)
Weight	3.76 kg (8.3 lbs.)

Power

Input	100-240V AC /50-60Hz
Output	15V DC / 8.6A
Consumption	130 W on AC mains power
Safety class	II

Ports

USB	2 Universal Serial Bus (USB) (maximum load of 250 mA)
Ethernet	RJ-45, TCP/IPUSB

Temperature

Operating	15°C to 32°C (59 -90°F)
Storage	-12°C to +50°C (10-122°F)

Humidity

Operating	15% - 80% (non-condensing)
Storage	5% - 90% (non-condensing)

Altitude

2,000 m (6,500 ft.) above sea level

Result Storage

4GB SD card

Memory

256MB RAM / 512MB NAND Flash

Barcode reader

Class 2 Laser Product

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