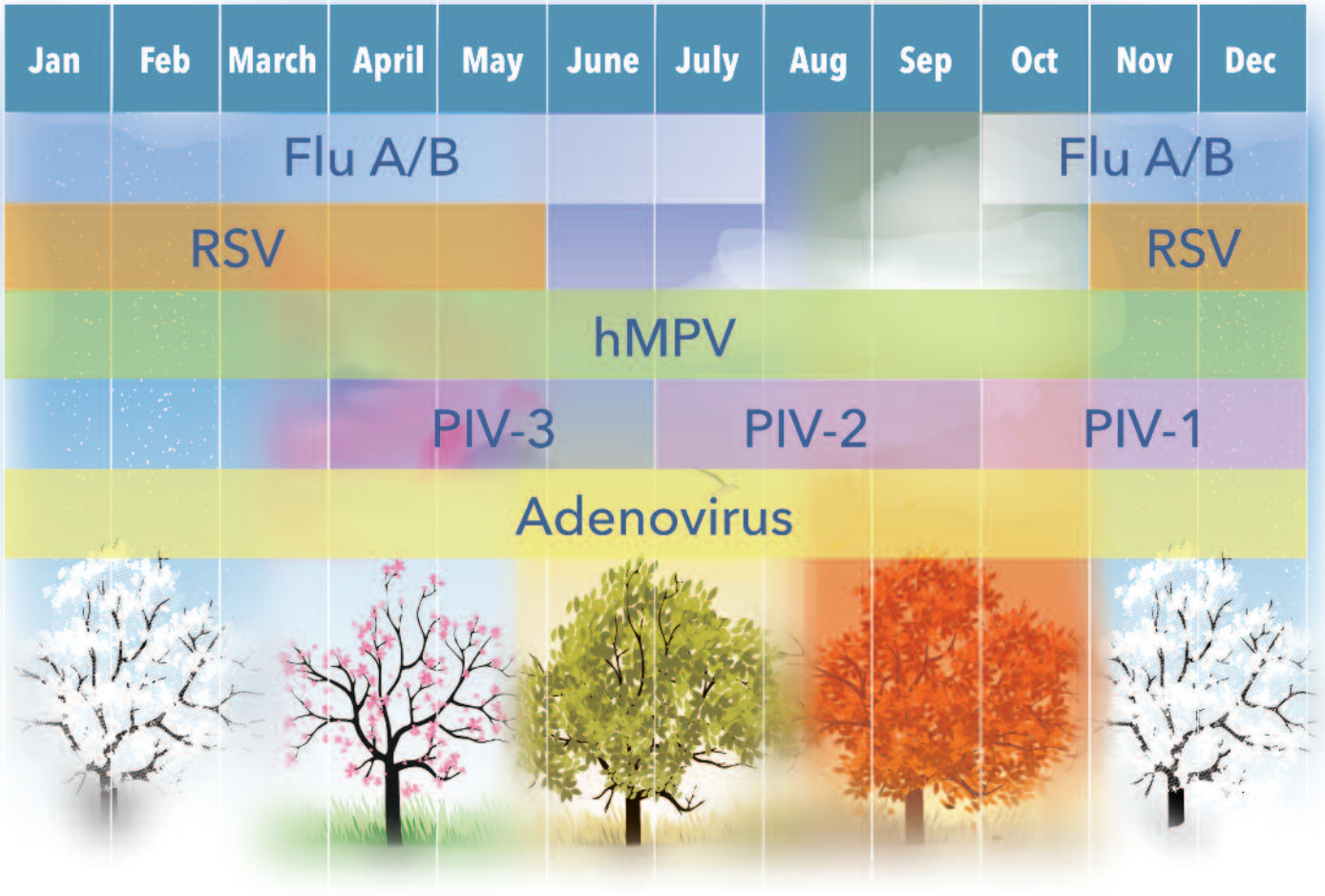

A test for every season

All the answers when you want them, individual answers when you need them.

Lyra real-time PCR respiratory assays are an open platform solution for high throughput, high quality molecular testing to detect and identify up to eight respiratory pathogens. With the fluctuations in lab demand and the seasonality of respiratory tract viral infections, this suite of assays provides labs flexibility in testing. Focused on optimizing a lab's workflow; the assays can be easily implemented with minimal steps, easy refrigerated storage, and room temperature procedures.

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Real-Time Results.
Ready-to-Use Assays.

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Workflow benefits of Lyra real-time PCR Respiratory assays

Feature	Benefit
One step reagent set-up	Rehydration solution is simply added to the lyophilized master mix.
Speed	Results in less than 75 minutes after extraction.
Easy training	Simplified and uniform workflow with standard pipetting volumes.
Refrigerated storage	No freezer needed. 2°C to 8°C storage.
Long shelf life	2-year shelf life from date of manufacture.
Room temperature set-up	No ice or cooling block required.
Flexible 96-test format	Kit includes vials of 12x8 master mix, rehydration solution and liquid process controls.
Multi-well panels	Standardized thermocycling conditions allow for batches with other multiplexed assays effectively providing a panel of results.
One extraction for multiple assays	The internal control is universal for the Lyra respiratory assays. A single extraction per specimen saves time and money.

Applied Biosystems 7500 Fast Dx	Clinical Performance		
	Sensitivity/PPA	**Specificity/NPA**	**Comparator**
Influenza A	100%	98.5%	FDA Cleared RT-PCR device
Influenza B	95.50%	97.8%	FDA Cleared RT-PCR device
RSV	98.60%	96.8%	DSFA and Cell Culture w/DFA
hMPV	98.00%	98.9%	FDA Cleared RT-PCR device
Adenovirus	100%	95.5%	CDFA with SDFA
Parainfluenza-1	100%	98.8%	DSFA and Cell Culture w/DFA
Parainfluenza-2	100%	94.0%	DSFA and Cell Culture w/DFA
Parainfluenza-3	100%	100%	DSFA and Cell Culture w/DFA

Assay	Control Set
Influenza A+B Assay # M100 (96T Kit)	Quidel Molecular Influenza A+B Control Set # M106
RSV+hMPV Assay # M103 (96T Kit)	Quidel Molecular RSV+hMPV Control Set # M107
Adenovirus # M113 (96T Kit)	Quidel Molecular Adenovirus Control Set #M110
Parainfluenza Virus # M114 (96T Kit)	Quidel Molecular Parainfluenza Virus Control Set #M115

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US

C. difficile

For the qualitative detection and identification of toxigenic *Clostridium difficile* bacterial DNA using real time PCR

- Less than 70 minute turn-around time from sample to answer
- 3 step sample preparation
  - No heat step
  - No timed step
  - No vortexing or centrifugation
- For use on the Applied Biosystems® 7500 series of instruments, QuantStudio™ Dx Real-Time PCR Instrument, and Cepheid SmartCycler® II

Workflow benefits of Lyra Direct real-time PCR assays

Feature	Benefit
Three-step sample prep	No timed, heat or vortexing steps
One step reagent set-up	Rehydration solution is simply added to the lyophilized master mix
Speed	Results in less than 70 minutes
Easy training	Simplified and uniform workflow with standard pipetting volumes
Refrigerated storage	No freezer needed. 2°C to 8°C storage
Long shelf life	2-year shelf life from date of manufacture
Room temperature set-up	No ice or cooling block required
Flexible 96-test format	Kit includes vials of 12x8 master mix, rehydration solution and liquid process controls. Sample preparation kit includes all consumables

Clinical performance

Tissue Culture Cytotoxin							95% CI	
Lyra Direct C. difficile Assay on the QuantStudio Dx		POS	NEG	Total	Sensitivity	93.3%	86.9%	96.7%
	POS	98	45*	143	Specificity	93.4%	91.3%	95.0%
	NEG	7**	638	645				
	Total	105	683	788				

*Of the forty-five (45) discordant specimens (Quidel Molecular Positive/Direct Culture Negative) reported, forty-four (44) were tested with a FDA-cleared molecular device. Thirty-five (35) of these specimens were positive for *C. difficile*, and nine (9) were negative. The remaining specimen was unavailable for testing.
**Seven (7) discordant specimens (Quidel Negative/Direct Culture Positive) reported were tested with a FDA-cleared molecular device. Two (2) of these specimens were found positive for *C. difficile*, and five (5) were negative.

Enriched Toxigenic Culture							95% CI	
Lyra Direct C. difficile Assay on the QuantStudio Dx		POS	NEG	Total	Sensitivity	87.3%	81.1%	91.6%
	POS	137	8*	145	Specificity	98.7%	97.5%	99.4%
	NEG	20**	626	646				
	Total	157	634	791				

*Eight (8) discordant specimens (Quidel Molecular Positive/Enriched Toxigenic Culture Negative) reported were tested with a FDA-cleared molecular device. Two (2) of these specimens were positive for *C. difficile*, and six (6) were negative.
**Seventeen (17) out of twenty (20) discordant specimens (Quidel Negative/ Enriched Toxigenic Culture Positive) reported, were tested with a FDA-cleared molecular device. Three (3) specimens were unavailable for testing. Eleven (11) of these specimens were found negative for *C. difficile*, and six (6) were positive.

Lyra Direct C. difficile Assay – 96-ReactionKit: Cat. #M105
Quidel Molecular Direct Rapid DNA Stool Sample Prep Kit: Cat. #M207
(required for M105)
Quidel Molecular C. difficile External Controls – 40-Reaction Kit: Cat. #M108

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HSV 1+2/VZV

For the qualitative detection and identification of Herpes simplex virus 1 and 2 and Varicella zoster virus using real time PCR

- One hour turn-around time from sample to answer.
- No vortexing or centrifugation.
- Validated on the Applied Biosystems® 7500 Fast Dx, QuantStudio™ Dx Real-Time PCR Instrument and Cepheid Smartcycler® II.

Workflow benefits of Lyra Direct real-time PCR assays

Feature	Benefit
One step reagent set-up	Minimal hands-on time.
Speed	Results in less than 60 minutes.
Easy training	Simplified workflow with standard pipetting volumes.
Refrigerated storage	No freezer needed. 2°C to 8°C.
2-year shelf life	Reduce waste and reordering.
Room temperature set-up	No ice or cooling block required.
Flexible 96-test format	Avoid aliquoting and miimize reagent cost.

Clinical performance

Applied Biosystems® 7500 Fast Dx, refer to Package Insert for additional performance claims.

Cutaneous Lesions

HSV-1 Results			
Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS® HSV ID and D³ Typing Test		
	Positive	Negative	Total
Positive	24	3*	27
Negative	0	252	252
Total	24	255	279
Sensitivity	24/24	100%	
Specificity	252/255	98.8%	

*One (1) of the three (3) positives was positive by an additional RT-PCR assay.

HSV-2 Results			
Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and D³ Typing Test		
	Positive	Negative	Total
Positive	34	8*	42
Negative	1**	236	237
Total	35	244	279
Sensitivity	34/35	97.1%	
Specificity	236/244	96.7%	

*Seven (7) of the eight (8) positives were positive by an additional RT-PCR assay.
**One (1) of the one (1) negative was positive by an additional RT-PCR assay.

VZV Results			
Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and D³ Typing Test		
	Positive	Negative	Total
Positive	26	7*	33
Negative	1**	189	190
Total	27	196	223
Sensitivity	26/27	96.3%	
Specificity	189/196	96.4%	

*Seven (7) of the seven (7) positives were positive by an additional RT-PCR assay.
**One (1) of the one (1) negative was positive by an additional RT-PCR assay.

Mucocutaneous Lesions

HSV-1 Results			
Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS® HSV ID and D³ Typing Test		
	Positive	Negative	Total
Positive	98	10*	108
Negative	5**	531	536
Total	103	541	644
Sensitivity	98/103	95.1%	
Specificity	531/541	98.2%	

*Ten (10) of the ten (10) positives were positive by an additional RT-PCR assay.
**Five (5) of the five (5) negatives were positive by an additional RT-PCR assay.

HSV-2 Results			
Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and		
	Positive	Negative	Total
Positive	93	16*	109
Negative	2**	533	535
Total	95	549	644
Sensitivity	93/95	97.9%	
Specificity	533/549	97.1%	

*Sixteen (16) of the sixteen (16) positives were positive by an additional RT-PCR assay.
**Two (2) of the two (2) negatives were positive by an additional RT-PCR assay.

VZV Results			
Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and D³ Typing Test		
	Positive	Negative	Total
Positive	4	3*	7
Negative	0	423	423
Total	4	426	430
Sensitivity	4/4	100%	
Specificity	423/426	99.3%	

*Three (3) of the three (3) positives were positive by an additional RT-PCR assay.

Lyra Direct HSV 1+2/VZV Assay – 96-Reaction Kit: Cat. #M102
Quidel Molecular HSV 1+2/VZV External Controls – 10-Reaction Kit: Cat. #M121

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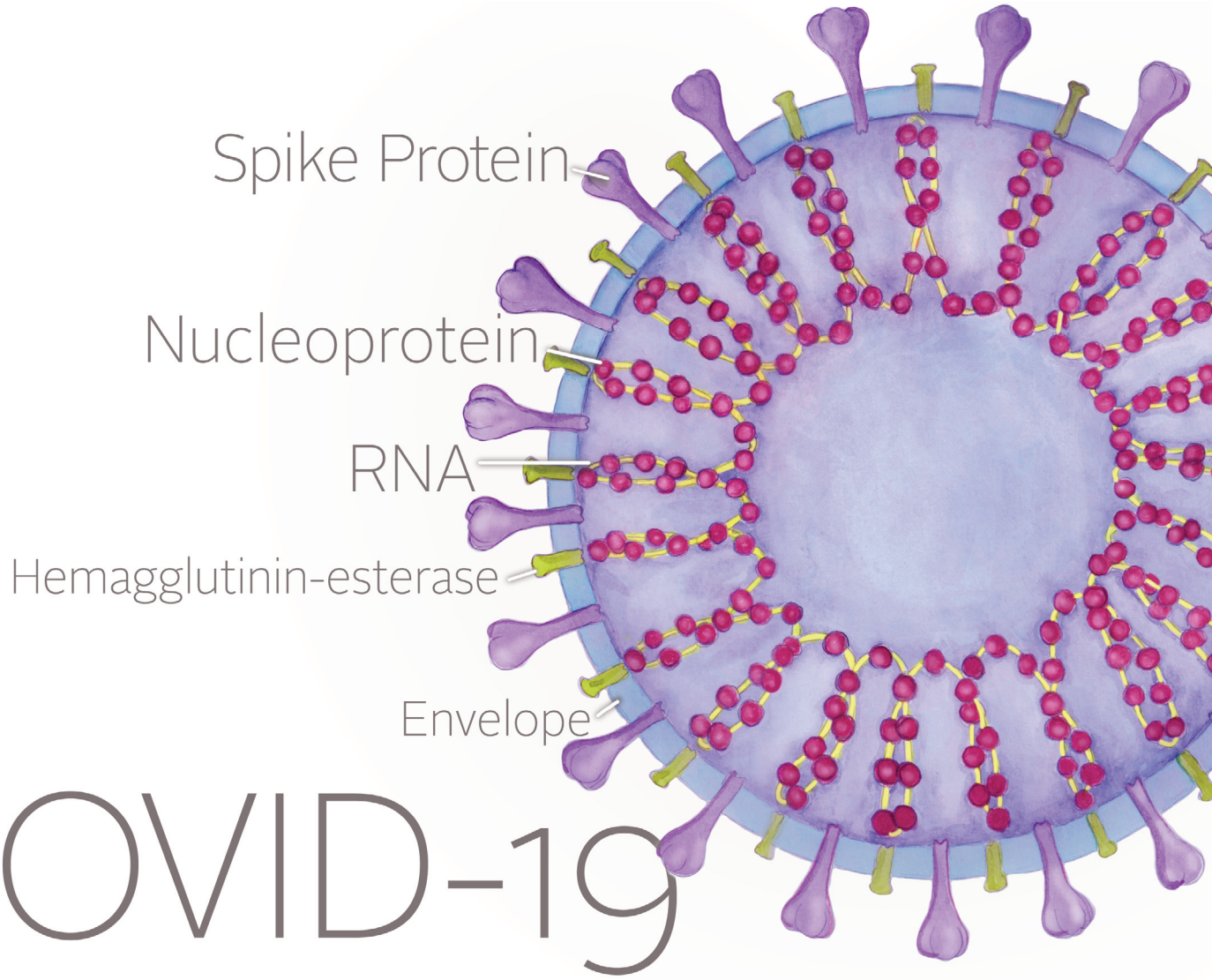


COVID-19

Lyra SARS-CoV-2 Assay

Lyra Direct SARS-CoV-2 Assay

EMERGENCY USE AUTHORIZATION

Qualitative real-time PCR tests providing accurate detection and identification SARS-CoV-2

Lyra SARS CoV-2 and Lyra Direct SARS CoV-2 assays utilize Real Time PCR that targets the conserved non-structural polyprotein (pp1ab) of the SARS CoV-2 virus for the accurate detection of the 2019 novel coronavirus that causes COVID-19.

The Lyra Direct SARS-CoV-2 Assay eliminates the need for RNA purification, allowing for simple manual sample processing before the sample is added to the Master Mix.

The Lyra SARS-CoV-2 assays are focused on optimizing a lab's workflow to make these tests simple and easy to implement.

Workflow Benefits

Feature	Benefit
Multiple sample types	Nasopharyngeal, oropharyngeal, or nasal swab specimens for ease of collection.
Actionable timeframe	Results in less than 75 minutes once placed in thermocycler.
Flexible workflows	The Lyra Direct Assay allows for workflow flexibility to support low to high testing volumes.
Open platform solution	Allows for easy implementation to existing extraction processes or thermocycler.
Flexible 96-test format	Kit contains all reagents to run 96 tests – with the external controls included

Lyra SARS-CoV-2

Currently EUA on the following systems:
Applied BioSystems® 7500 Fast Dx
Applied Biosystems 7500 Standard
QuantStudio Real-Time PCR Instrument
Roche LightCycler® 480,
BiRad CFX96 Touch
Qiagen Rotor-Gene-Q.

Lyra Direct SARS-CoV-2

Currently EUA on the following systems:
Applied Biosystems®7500 Fast Dx
Applied Biosystems 7500 Standard
Roche LightCycler® 480 Instrument II
Roche cobas® z 480
Qiagen Rotor-Gene® Q
Bio-Rad CFX96 Touch™
Thermo Fisher QuantStudio™ 7 Pro

Lyra SARS-CoV-2 Clinical Performance*

A study using ninety-two positive contrived samples created by spiking ninety-two individual clinical samples determined to be negative for SARS-CoV-2 by the Lyra SARS-CoV-2 Assay prior to spiking with one of three concentrations of genomic SARS-CoV-2 RNA. All ninety-two contrived samples were positive in the Lyra SARS-CoV-2 Assay.

Sample RNA Concentration	# Positives/# Tested	Mean SARS-CoV-2 Ct	%CV
unspiked	0/92	NA	NA
1x LoD (8.00E-01 cp/µL)	44/44	26.9	5.7
3x LoD (2.40E00 397 cp/µL)	24/24	22.8	3.4
5x LoD (4.00E00 cp/µL)	24/24	22.4	3.0

Performance against the expected results are:

PPA – 92/92 = 100% (95% CI: 95.99%-100%)

NPA – 92/92 = 100% (95% CI: 95.99%-100%)

Lyra Direct SARS-CoV-2 Clinical Performance*

A study using thirty positive nasopharyngeal contrived samples were created by spiking thirty individual clinical samples determined to be negative for SARS-CoV-2 by the Lyra Direct SARS-CoV-2 Assay prior to spiking with one of two concentrations of gamma-irradiated SARS-CoV-2. Twenty-nine of thirty contrived samples were positive in the Lyra Direct SARS-CoV-2 Assay.

Clinical evaluation in spiked nasopharyngeal swab specimens

Sample RNA Concentration	# Positives/# Tested	Mean SARS-CoV-2 Ct	%CV
unspiked	0/30	NA	NA
1x LoD (3.40e+4 cp/mL)	19/20	27.06	6.6
5x LoD (1.7E+5 cp/mL)	10/10	23.51	4.7

Performance against the expected results are:

PPA – 29/30 = 97% (95% CI: 83.3%-99.4%)

NPA – 30/30 = 100% (95% CI: 88.6%-100%)

A study using fifteen positive oropharyngeal contrived samples were created by spiking fifteen individual clinical samples determined to be negative for SARS-CoV-2 by the Lyra SARS-CoV-2 Assay prior to spiking samples with one of three concentrations of gamma-irradiated SARS-CoV-2. Fifteen of fifteen contrived samples were positive in the Lyra Direct SARS-CoV-2 Assay.

Clinical evaluation in spiked oropharyngeal swab specimens

Sample RNA Concentration	# Positives/# Tested	Mean SARS-CoV-2 Ct	%CV
unspiked	0/8	NA	NA
1x LoD (3.40e+4 cp/mL)	7/7	23.2	5.1
10x LoD (3.4e+5cp/mL)	4/4	20.1	0.6
100x LoD (3.4e+6cp/mL)	4/4	17.1	0.5

Performance against the expected results are:

PPA – 15/15 = 100% (95% CI: 79.6%-100%)

NPA – 8/8 = 100% (95% CI: 67.6%-100%)

*Refer to the Package Insert for more information.

Lyra Assays

Lyra

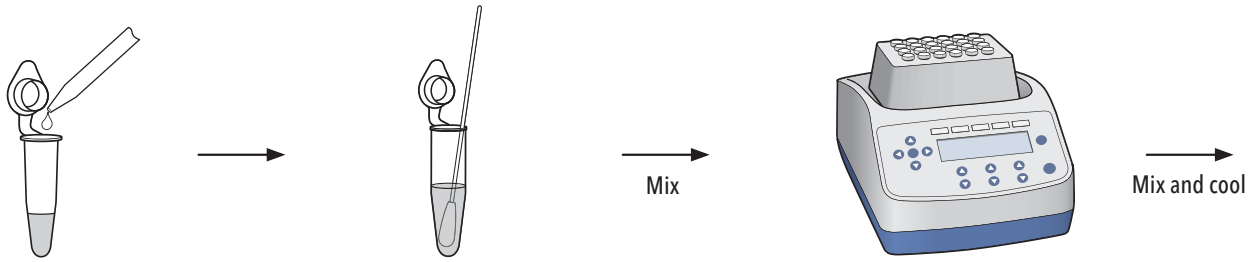
Cat. #	Description	Kit Size
M120	**Lyra SARS-CoV-2 Assay (includes controls)**	**96-Reaction Kit**
M939	**Lyra SARS-CoV-2 Assay and Transport Media with Flocked Swab Set 100 swabs | 100 transport media**	**96-Reaction Kit**
M938	**Lyra SARS-CoV-2 Assay and Transport Media with Mini-tip Flocked Swab Set 100 swabs | 100 transport media**	**96-Reaction Kit**
M100	Lyra Influenza A+B Assay	96 Reaction Kit
M106	Quidel Molecular Influenza A+B Control Set	
M103	Lyra RSV + hMPV Assay	96-Reaction Kit
M107	Quidel Molecular RSV + hMPV Control Set	
M113	Lyra Adenovirus Assay	96-Reaction Kit
M110	Quidel Molecular Adenovirus Control Set	
M114	Lyra Parainfluenza Virus Assay	96-Reaction Kit
M115	Quidel Molecular Parainfluenza Virus Control Set	

Lyra Direct

Cat. #	Description	Kit Size
M124	**Lyra Direct SARS CoV-2 Assay (includes controls)**	**96 Reaction Kit**
M942	**Lyra Direct SARS CoV-2 Assay (includes controls) Microfuge Tube Nasal/Oropharyngeal Swabs and Transport Tubes**	**96 Reaction Kit**
M943	**Lyra Direct SARS CoV-2 Assay (includes controls) Microfuge Tube Nasopharyngeal Swabs and Transport Tubes**	**96 Reaction Kit**
M944	**Lyra Direct SARS CoV-2 Assay (includes controls) Microwell Nasal/Oropharyngeal Swabs and Transport Tubes**	**96 Reaction Kit**
M105	Lyra Direct C. difficile Assay	96-ReactionKit
M207	Quidel Molecular Direct Rapid DNA Stool Sample Prep Kit (required for M105)	
M108	Quidel Molecular C. difficile External Controls	40-Reaction Kit
M102	Lyra Direct HSV 1+2/VZV Assay	96-Reaction Kit
M121	Quidel Molecular HSV 1+2/VZV External Controls	10-Reaction Kit
M112	Lyra Direct Strep Assay	96-Reaction Kit
M111	Quidel Molecular Strep A+G Control Set	10-Reaction Kit

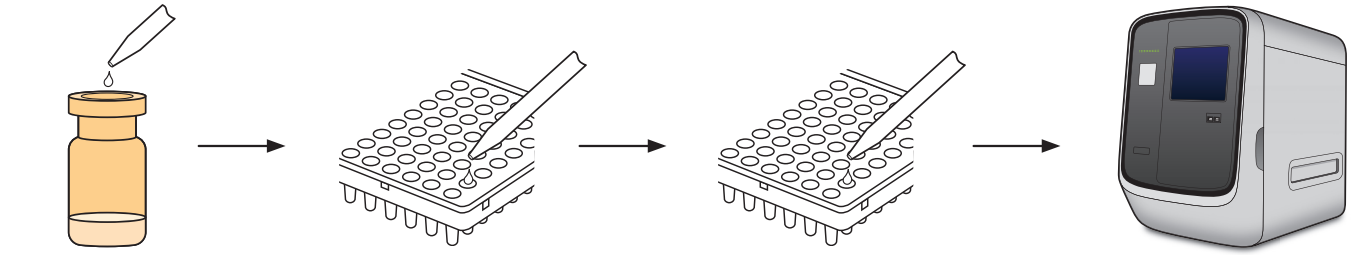
Lyra Direct Microfuge Tube Format – Patient Sample

Sample Preparation



Add Process Buffer | Swirl Swab in Process Buffer | Heat for 10 minutes at 95˚C

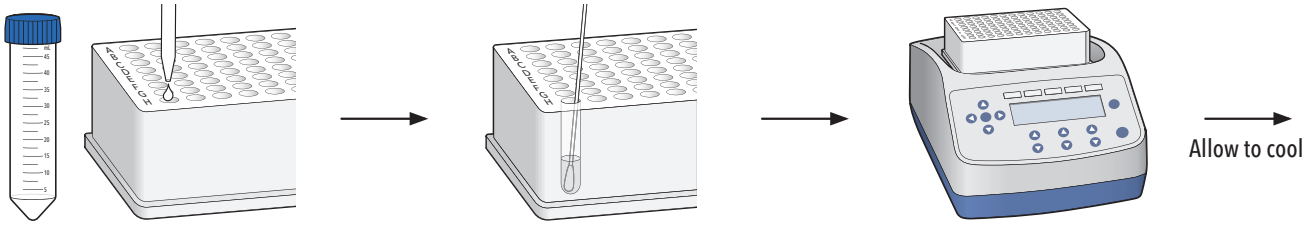
Amplification and Detection



Rehydrate Master Mix | Add to PCR Plate | Vortex sample and add to PCR Plate | Place on Thermocycler

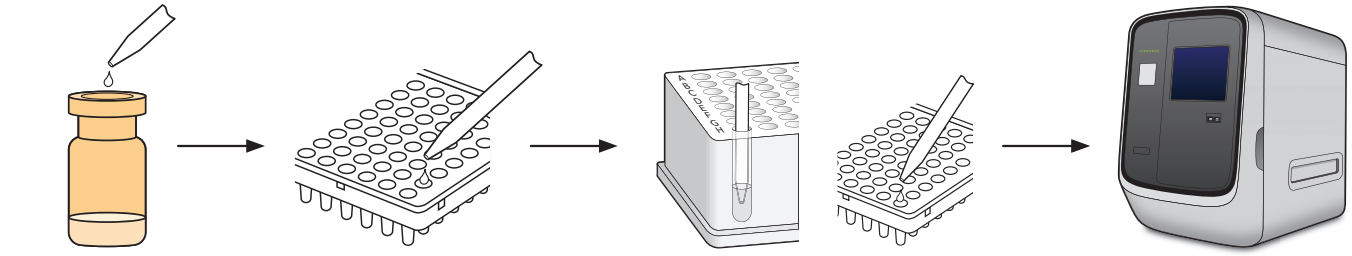
Lyra Direct Microwell Workflow – Patient Sample

Sample Preparation



Add Process Buffer | Swirl Swab in Process Buffer | Thermomix @ 95°C – 10 minutes

Amplification and Detection



Rehydrate Master Mix | Add to PCR Plate | Mix Sample then add to PCR plate | Place on Thermocycler

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Strep

For the qualitative detection and identification of Group A and pyogenic Group C and G Streptococcus bacterial DNA using real time PCR

- Lyra Direct Strep detects those strains of Group A, C and G which have been shown to cause acute pharyngitis and does not detect those shown to be normal flora.
- Molecular detection gives a fast answer with clear, fully objective results.
- Faster, simplified workflow with less hands on time than culture.
- Superior sensitivity to culture. Various culture media can inhibit or promote different growth, confusing diagnosis
- Studies have shown groups other than A can be pyogenic and proper detection can speed recovery.

Workflow benefits of Lyra Direct real-time PCR assays

Feature	Benefit
One step reagent set-up	Minimal hands-on time.
Speed	Results in less than 1 hour.
Easy training	Simplified workflow with standard pipetting volumes.
Refrigerated storage	No freezer needed.
2-year shelf life	Reduce waste and reordering.
Room temperature set-up	No ice or cooling block required.
Flexible 96-test format	Avoid aliquoting and minimize reagent cost.

Clinical performance

Overall performance of Lyra Direct Strep Assay for Group A β-hemolytic Stretococcus

		Composite Culture					95% CI	
		POS	NEG	Total	Sensitivity	**96.5%**	91.3%	98.1%
Lyra Direct Strep	POS	109	24	133	Specificity	**98%**	97%	98.6%
	NEG	4	1156	1160				
	Total	113	1180	1293				

Overall performance of Lyra Direct Strep Assay for Pyogenic Group C and β-hemolytic Stretococcus

		Composite Culture					95% CI	
		POS	NEG	Total	Sensitivity	**95.7%**	88.1%	98.5%
Lyra Direct Strep	POS	67	21	88	Specificity	**98.3%**	97.4%	98.9%
	NEG	3	1202	1205				
	Total	70	1223	1293				

Lyra Direct Strep Assay – 96-Reaction Kit: Cat. #M112
Quidel Molecular Strep A+G Control Set – 10-Reaction Kit: Cat. #M111

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