

External Quality Assessment Scheme

Influenza virus A and B, antigen detection Round 1, 2023

Specimens

Please find enclosed 3 simulated swab samples S001, S002 and S003.

Caution

Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. According to the sample manufacturer the specimens do not contain viable microbes. However, no known test method can offer complete assurance that the specimens will not transmit any infectious diseases.

Examinations

Influenza A, antigen detection

Influenza B, antigen detection

Not for patient use.

Storage and use

After arrival, the samples should be stored at +2...30 °C, and used as soon as possible, preferably within a week. Analyse as patient samples and follow the instructions given by the test manufacturer.

Handling instructions for the swab samples:

1. Open the foil package. Pay attention to avoid contamination.
2. Remove the swab from the foil package and place the swab into a sample collection tube / transport media. If the method you are using does not specify the sample volume, dip the swab in ≤0.5 mL of transport medium. Incubate the sample for 1-2 minutes at room temperature. Rotate the swab to dislodge as much material as possible. Remove the swab by pressing it towards the walls of the elution vial. You can also cut the swab into the sample collection tube.
3. Recap the collection tube and mix thoroughly.
4. Proceed with detection step by using the test volume specified in the assay instruction for use.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your test from the registry, please contact the EQA Coordinator. All reported examinations will be scored.

S001



S002



S003



2023-01-31

INSTRUCTIONS

Product no. 5671
LQ774823011-013/CA
UN3373

Subcontracting: Sample pretesting

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **February 27, 2023.**

The expected results of the round are published in LabScala in the View Reports section by March 2, 2023.

Inquiries

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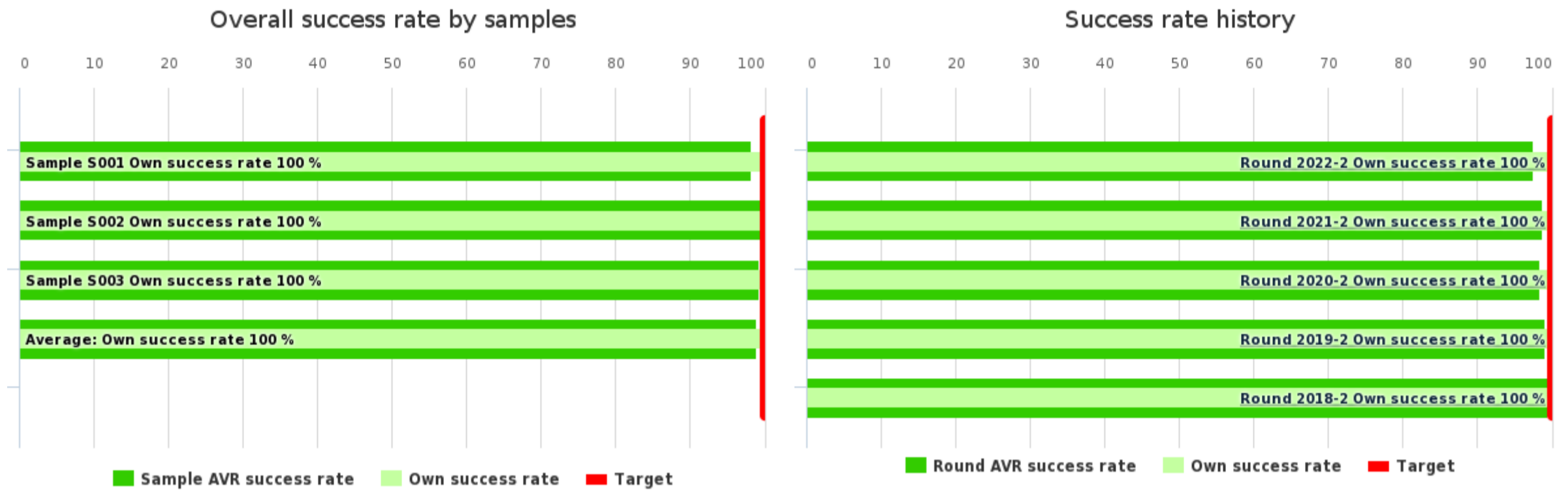
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Influenza virus A+B, antigen detection, February, 1-2023	390	370	94.9 %

Summary

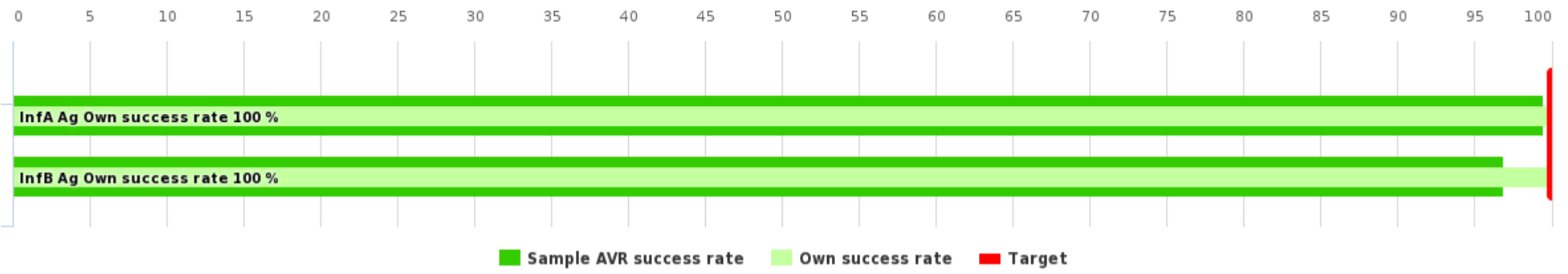


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	4	4	100 %	1.8 %	98.2 %
Sample S002	4	4	100 %	0.5 %	99.5 %
Sample S003	4	4	100 %	0.7 %	99.3 %
Average:			100 %	1 %	99 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-2	1-1	100 %	2.5 %	97.5 %
Round 2021-2	1-1	100 %	1.2 %	98.8 %
Round 2020-2	1-1	100 %	1.5 %	98.5 %
Round 2019-2	1-1	100 %	0.9 %	99.1 %
Round 2018-2	1-1	100 %	0.5 %	99.5 %

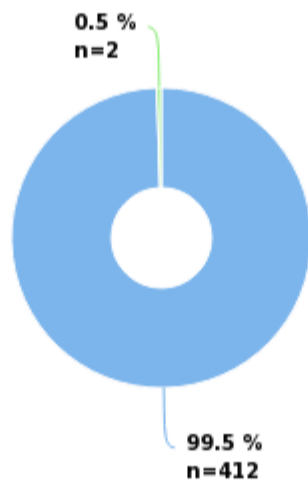
Sample S001

Sample S001 success rate



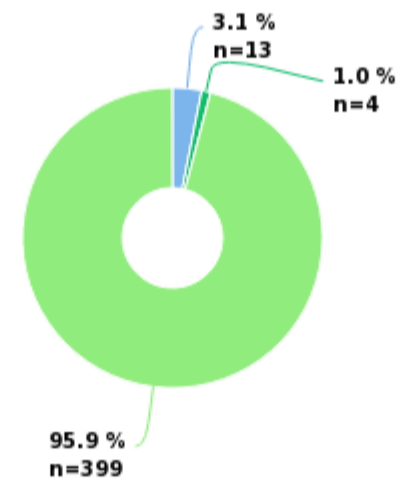
Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	InfA Ag	2	2	100 %	0.5 %	99.5 %	414
	InfB Ag	2	2	100 %	3.1 %	96.9 %	416
Total:		4	4	100 %	1.8 %	98.2 %	830

Sample S001 InfA Ag



■ Negative ■ Positive

Sample S001 InfB Ag



■ Negative ■ Weak positive ■ Positive

InfA Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		412		2	2	100 %	0 %	100 %
		Abbott BinaxNOW Influenza A&B		27					
		Acro Biotech Influenza A+B Rapid Test Dipstick		3					
		ArcDia mariPOC Quick Flu+		14					
		ArcDia mariPOC Quick Flu/RSV		15					
		ArcDia mariPOC Respi		2					
		ArcDia mariPOC Respi+		18					
		BD Veritor System Flu A+B Kit		47					
		Biomaxima Influenza A+B cassettes		2					
		Biosynex COMBO COVID-FLU-RSV BSS		8					
		Biosynex INFLUENZATOP		6					
		Biosynex INFLUENZATOP BSS		38					
		Biotical Health Influenza A+B card		1					
		Certest Influenza A+B		8					
	<input checked="" type="radio"/>	Coris BioConcept Influenza A+B K-SeT		3					
		Hangzhou AllTest Influenza A+B Rapid Test		7					
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
		Humasis Influenza A/B Antigen Test		1					
		Hydrex Influenza A/B Test		1					
		Intermed Diagnostik Nord Influenza A+B		2					
		LumiraDx SARS-CoV-2 & Flu A/B		4					
		Medix Biochemica Actim Influenza A&B		83					
		Meridian Bioscience TruFlu		1					

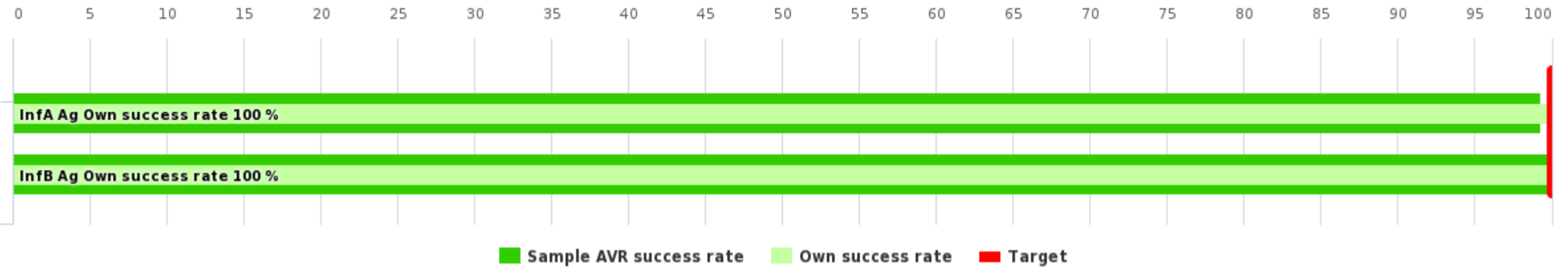
		nal von minden NADAL Influenza A+B	6						
		Quidel Sofia Influenza A+B FIA	30						
		Screen Italia SCREEN TEST FLU A/B	1						
		SD Biosensor STANDARD F Influenza A/B FIA	15						
		SD Biosensor STANDARD Q Influenza A/B Test	2						
		Sekisui Diagnostics OSOM Influenza A&B	1						
		Sekisui Diagnostics OSOM Ultra Flu A & B Test	2						
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test	49						
		Servibio Influenza A+B Color	2						
		Standard Diagnostics SD Bioline Influenza Ag	1						
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic	3						
		Vidia Rapid-VIDITEST Influenza A+B	2						
		Virusys NCP ELISA	2						
		Vitassay Influenza A+ B Double test	2						
		Vitro Bio Chem Vitrotrack Influenza A+B	1						
	Positive		2		-				0 %
		Certest Influenza A+B	1						
		Medix Biochemica Actim Influenza A&B	1						
	Total:		414		2	2	100 %	0.5 %	99.5 %

InfB Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		13		-				0 %
		Abbott BinaxNOW Influenza A&B		2					
		ArcDia mariPOC Quick Flu/RSV		4					
		ArcDia mariPOC Respi+		1					
		BD Veritor System Flu A+B Kit		2					
		Certest Influenza A+B		1					
		Medix Biochemica Actim Influenza A&B		2					
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		1					
	Weak positive		4		-				100 %
		Abbott BinaxNOW Influenza A&B		3					
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		1					
	<input checked="" type="radio"/> Positive		399		2	2	100 %	0 %	100 %
		Abbott BinaxNOW Influenza A&B		22					
		Acro Biotech Influenza A+B Rapid Test Dipstick		3					
		ArcDia mariPOC Quick Flu+		14					
		ArcDia mariPOC Quick Flu/RSV		11					
		ArcDia mariPOC Respi		2					
		ArcDia mariPOC Respi+		17					
		BD Directigen Flu A+B		1					
		BD Veritor System Flu A+B Kit		45					
		Biomaxima Influenza A+B cassettes		2					
		Biosynex COMBO COVID-FLU-RSV BSS		8					
		Biosynex INFLUENZATOP		6					
		Biosynex INFLUENZATOP BSS		38					
		Biotical Health Influenza A+B card		1					
		Certest Influenza A+B		7					
		<input checked="" type="radio"/> Coris BioConcept Influenza A+B K-SeT		3					
		Hangzhou AllTest Influenza A+B Rapid Test		7					
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
		Humasis Influenza A/B Antigen Test		1					
		Hydrex Influenza A/B Test		1					
		Intermed Diagnostik Nord Influenza A+B		2					
		LumiraDx SARS-CoV-2 & Flu A/B		4					
		Medix Biochemica Actim Influenza A&B		84					
		Meridian Bioscience TruFlu		2					
		nal von minden NADAL Influenza A+B		6					

	Quidel Sofia Influenza A+B FIA		30					
	Screen Italia SCREEN TEST FLU A/B		1					
	SD Biosensor STANDARD F Influenza A/B FIA		15					
	SD Biosensor STANDARD Q Influenza A/B Test		2					
	Sekisui Diagnostics OSOM Influenza A&B		2					
	Sekisui Diagnostics OSOM Ultra Flu A & B Test		3					
	Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		45					
	Servibio Influenza A+B Color		2					
	Standard Diagnostics SD Bioline Influenza Ag		1					
	Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3					
	Vidia Rapid-VIDITEST Influenza A+B		2					
	Virusys NCP ELISA		1					
	Vitassay Influenza A+ B Double test		2					
	Vitro Bio Chem Vitrotrack Influenza A+B		1					
Total:		416		2	2	100 %	3.1 %	96.9 %

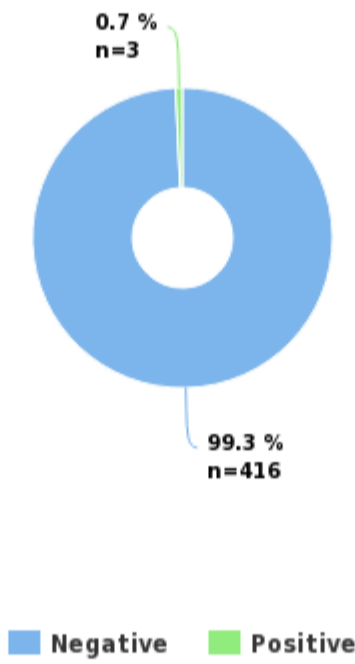
Sample S002

Sample S002 success rate

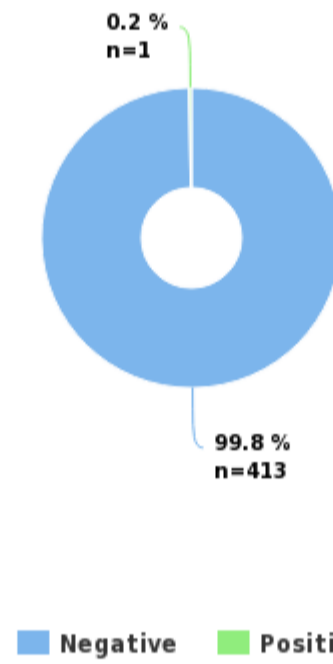


Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	InfA Ag	2	2	100 %	0.7 %	99.3 %	419
	InfB Ag	2	2	100 %	0.2 %	99.8 %	414
Total:		4	4	100 %	0.5 %	99.5 %	833

Sample S002 InfA Ag



Sample S002 InfB Ag



InfA Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		416		2	2	100 %	0 %	100 %
		Abbott BinaxNOW Influenza A&B		26					
		Acro Biotech Influenza A+B Rapid Test Dipstick		3					
		ArcDia mariPOC Quick Flu+		15					
		ArcDia mariPOC Quick Flu/RSV		14					
		ArcDia mariPOC Respi		2					
		ArcDia mariPOC Respi+		18					
		BD Veritor System Flu A+B Kit		49					
		Biomaxima Influenza A+B cassettes		2					
		Biosynex COMBO COVID-FLU-RSV BSS		8					
		Biosynex INFLUENZATOP		7					
		Biosynex INFLUENZATOP BSS		38					
		Biotical Health Influenza A+B card		1					
		Certest Influenza A+B		8					
	<input checked="" type="radio"/> Positive	Coris BioConcept Influenza A+B K-SeT		3					
		Hangzhou AllTest Influenza A+B Rapid Test		7					
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
		Humasis Influenza A/B Antigen Test		1					
		Hydrex Influenza A/B Test		1					
		Intermed Diagnostik Nord Influenza A+B		2					
		LumiraDx SARS-CoV-2 & Flu A/B		4					
		Medix Biochemica Actim Influenza A&B		85					
		nal von minden NADAL Influenza A+B		6					

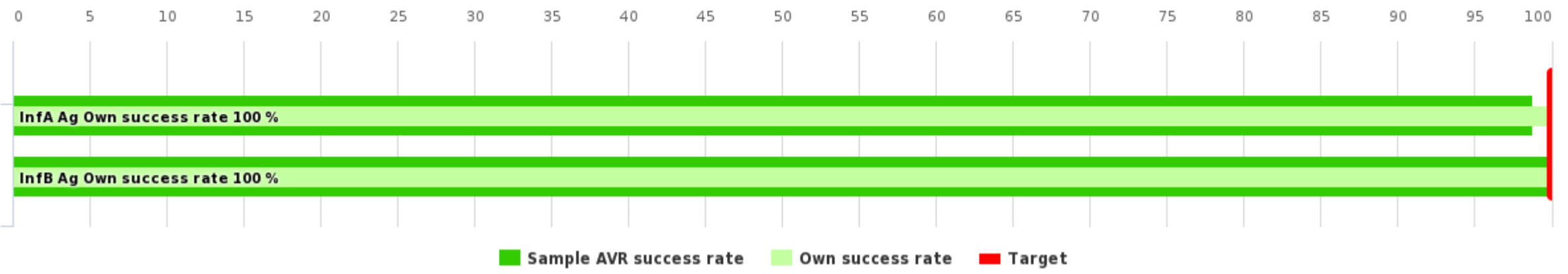
		Quidel QuickVue Influenza A&B		1					
		Quidel Sofia Influenza A+B FIA		31					
		Screen Italia SCREEN TEST FLU A/B		1					
		SD Biosensor STANDARD F Influenza A/B FIA		15					
		SD Biosensor STANDARD Q Influenza A/B Test		2					
		Sekisui Diagnostics OSOM Influenza A&B		1					
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		1					
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		50					
		Servibio Influenza A+B Color		2					
		Standard Diagnostics SD Bioline Influenza Ag		1					
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3					
		Vidia Rapid-VIDITEST Influenza A+B		2					
		Virusys NCP ELISA		1					
		Vitassay Influenza A+ B Double test		2					
		Vitro Bio Chem Vitrotrack Influenza A+B		1					
	Positive		3		-				0 %
		Medix Biochemica Actim Influenza A&B		1					
		Meridian Bioscience TruFlu		1					
		Virusys NCP ELISA		1					
	Total:		419		2	2	100 %	0.7 %	99.3 %

InfB Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		413		2	2	100 %	0 %	100 %
		Abbott BinaxNOW Influenza A&B		26					
		Acro Biotech Influenza A+B Rapid Test Dipstick		3					
		ArcDia mariPOC Quick Flu+		15					
		ArcDia mariPOC Quick Flu/RSV		14					
		ArcDia mariPOC Respi		2					
		ArcDia mariPOC Respi+		18					
		BD Veritor System Flu A+B Kit		48					
		Biomaxima Influenza A+B cassettes		2					
		Biosynex COMBO COVID-FLU-RSV BSS		8					
		Biosynex INFLUENZATOP		7					
		Biosynex INFLUENZATOP BSS		38					
		Biotical Health Influenza A+B card		1					
		Certest Influenza A+B		7					
		<input checked="" type="radio"/> Coris BioConcept Influenza A+B K-SeT		3					
		Hangzhou AllTest Influenza A+B Rapid Test		7					
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
		Humasis Influenza A/B Antigen Test		1					
		Hydrex Influenza A/B Test		1					
		Intermed Diagnostik Nord Influenza A+B		2					
		LumiraDx SARS-CoV-2 & Flu A/B		4					
		Medix Biochemica Actim Influenza A&B		83					
		Meridian Bioscience TruFlu		2					
		nal von minden NADAL Influenza A+B		6					
		Quidel Sofia Influenza A+B FIA		32					
		Screen Italia SCREEN TEST FLU A/B		1					
		SD Biosensor STANDARD F Influenza A/B FIA		15					
		SD Biosensor STANDARD Q Influenza A/B Test		2					
		Sekisui Diagnostics OSOM Influenza A&B		2					
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		2					
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		47					
		Servibio Influenza A+B Color		2					
		Standard Diagnostics SD Bioline Influenza Ag		1					

		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3					
		Vidia Rapid-VIDITEST Influenza A+B		2					
		Virusys NCP ELISA		1					
		Vitassay Influenza A+ B Double test		2					
		Vitro Bio Chem Vitrotrack Influenza A+B		1					
	Positive		1		-				0 %
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		1					
	Total:		414		2	2	100 %	0.2 %	99.8 %

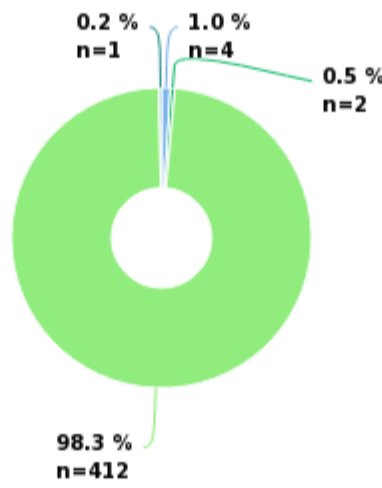
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	InfA Ag	2	2	100 %	1.2 %	98.8 %	419
	InfB Ag	2	2	100 %	0.2 %	99.8 %	414
	Total:	4	4	100 %	0.7 %	99.3 %	833

Sample S003 InfA Ag



Sample S003 InfB Ag



Legend for InfA Ag: Negative (blue), Weak positive (green), Positive (light green), Invalid result (dark green)

Legend for InfB Ag: Negative (blue), Invalid result (dark blue)

InfA Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		4		-				0 %
		Abbott BinaxNOW Influenza A&B		1					
		BD Veritor System Flu A+B Kit		1					
		Medix Biochemica Actim Influenza A&B		1					
		Meridian Bioscience TruFlu		1					
	Weak positive		2		-				100 %
		Abbott BinaxNOW Influenza A&B		1					
		Medix Biochemica Actim Influenza A&B		1					
	Positive		412		2	2	100 %	0 %	100 %
		Abbott BinaxNOW Influenza A&B		23					
		Acro Biotech Influenza A+B Rapid Test Dipstick		3					
		ArcDia mariPOC Quick Flu+		14					
		ArcDia mariPOC Quick Flu/RSV		15					
		ArcDia mariPOC Respi		2					
		ArcDia mariPOC Respi+		18					
		BD Veritor System Flu A+B Kit		48					
		Biomaxima Influenza A+B cassettes		2					
		Biosynex COMBO COVID-FLU-RSV BSS		8					
		Biosynex INFLUENZATOP		7					
		Biosynex INFLUENZATOP BSS		38					
		Biotical Health Influenza A+B card		1					
		Certest Influenza A+B		9					
		Coris BioConcept Influenza A+B K-SeT		3					
		Hangzhou AllTest Influenza A+B Rapid Test		7					

		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
		Humasis Influenza A/B Antigen Test		1					
		Hydrex Influenza A/B Test		1					
		Intermed Diagnostik Nord Influenza A+B		2					
		LumiraDx SARS-CoV-2 & Flu A/B		4					
		Medix Biochemica Actim Influenza A&B		84					
		nal von minden NADAL Influenza A+B		6					
		Quidel Sofia Influenza A+B FIA		32					
		Screen Italia SCREEN TEST FLU A/B		1					
		SD Biosensor STANDARD F Influenza A/B FIA		14					
		SD Biosensor STANDARD Q Influenza A/B Test		2					
		Sekisui Diagnostics OSOM Influenza A&B		1					
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		2					
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		49					
		Servibio Influenza A+B Color		2					
		Standard Diagnostics SD Bioline Influenza Ag		1					
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3					
		Vidia Rapid-VIDITEST Influenza A+B		2					
		Virusys NCP ELISA		2					
		Vitassay Influenza A+ B Double test		2					
		Vitro Bio Chem Vitrotrack Influenza A+B		1					
	Invalid result		1		-				0 %
		SD Biosensor STANDARD F Influenza A/B FIA		1					
	Total:		419		2	2	100 %	1.2 %	98.8 %

InfB Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		413		2	2	100 %	0 %	100 %
		Abbott BinaxNOW Influenza A&B		25					
		Acro Biotech Influenza A+B Rapid Test Dipstick		3					
		ArcDia mariPOC Quick Flu+		14					
		ArcDia mariPOC Quick Flu/RSV		15					
		ArcDia mariPOC Respi		2					
		ArcDia mariPOC Respi+		18					
		BD Veritor System Flu A+B Kit		48					
		Biomaxima Influenza A+B cassettes		2					
		Biosynex COMBO COVID-FLU-RSV BSS		8					
		Biosynex INFLUENZATOP		7					
		Biosynex INFLUENZATOP BSS		38					
		Biotical Health Influenza A+B card		1					
		Certest Influenza A+B		8					
		<input checked="" type="radio"/> Coris BioConcept Influenza A+B K-SeT		3					
		Hangzhou AllTest Influenza A+B Rapid Test		7					
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
		Humasis Influenza A/B Antigen Test		1					
		Hydrex Influenza A/B Test		1					
		Intermed Diagnostik Nord Influenza A+B		2					
		LumiraDx SARS-CoV-2 & Flu A/B		4					
		Medix Biochemica Actim Influenza A&B		83					
		Meridian Bioscience TruFlu		2					
		nal von minden NADAL Influenza A+B		6					
		Quidel Sofia Influenza A+B FIA		32					
		Screen Italia SCREEN TEST FLU A/B		1					
		SD Biosensor STANDARD F Influenza A/B FIA		14					
		SD Biosensor STANDARD Q Influenza A/B Test		2					
		Sekisui Diagnostics OSOM Influenza A&B		2					

		Sekisui Diagnostics OSOM Ultra Flu A & B Test		3					
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		47					
		Servibio Influenza A+B Color		2					
		Standard Diagnostics SD Bioline Influenza Ag		1					
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3					
		Vidia Rapid-VIDITEST Influenza A+B		2					
		Virusys NCP ELISA		1					
		Vitassay Influenza A+ B Double test		2					
		Vitro Bio Chem Vitrotrack Influenza A+B		1					
	Invalid result		1		-				0 %
		SD Biosensor STANDARD F Influenza A/B FIA		1					
	Total:		414		2	2	100 %	0.2 %	99.8 %

Report Info

PARTICIPANTS

Altogether 390 laboratories from 16 countries participated in this EQA round.

REPORT INFO

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green color and laboratory's own result with a black radio button . In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

SCORING

The round is scored based on test results when 60% or more of the participants report the expected result and when at least three results are reported. The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample success rates.

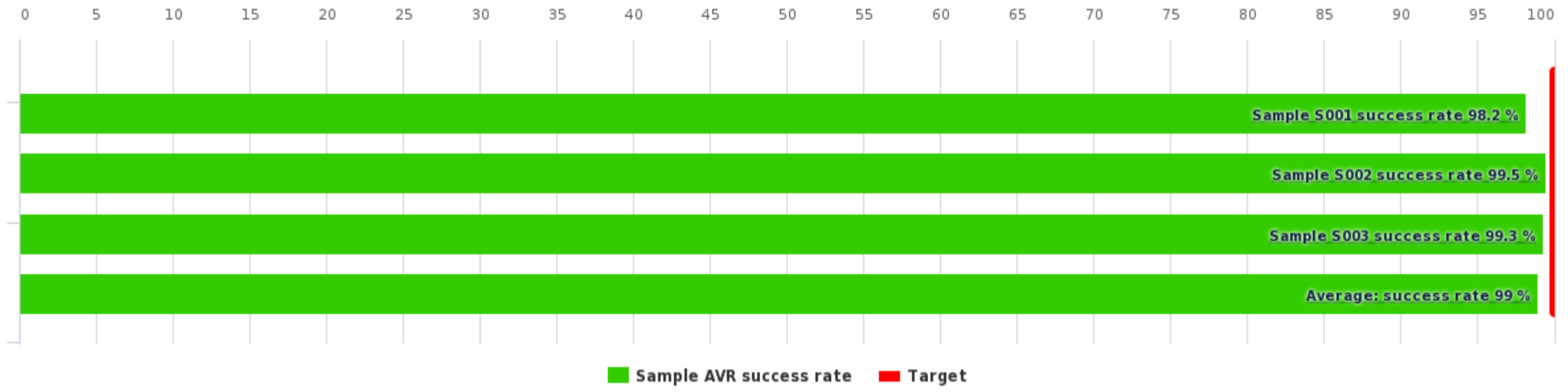
The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Influenza virus A+B, antigen detection, February, 1-2023	390	370	94.9 %

Summary

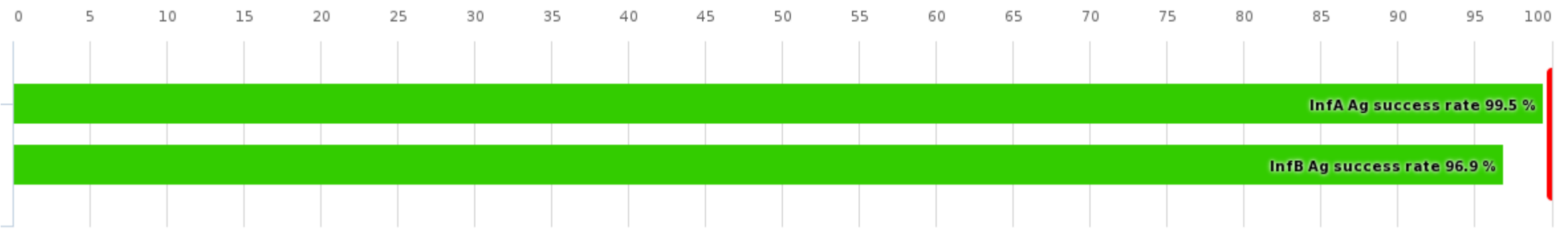
Overall success rate by samples



Summary	AVR success rate
Sample S001	98.2 %
Sample S002	99.5 %
Sample S003	99.3 %
Average:	99 %

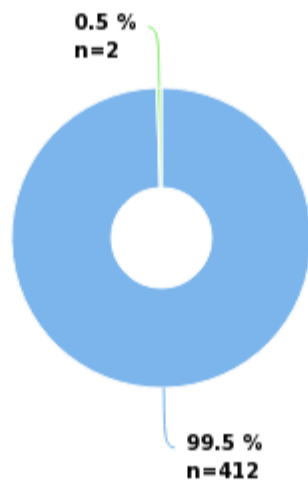
Sample S001

Sample S001 success rate



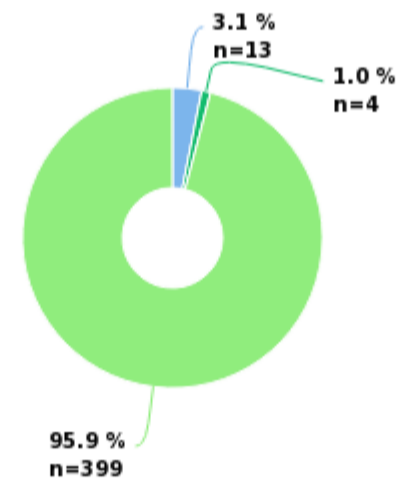
Sample S001 results	Responded	AVR success rate	Count
	InfA Ag	99.5 %	414
	InfB Ag	96.9 %	416
	Total:	98.2 %	830

Sample S001 InfA Ag



■ Negative ■ Positive

Sample S001 InfB Ag



■ Negative ■ Weak positive ■ Positive

InfA Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		412		100 %	2
		Abbott BinaxNOW Influenza A&B		27		
		Acro Biotech Influenza A+B Rapid Test Dipstick		3		
		ArcDia mariPOC Quick Flu+		14		
		ArcDia mariPOC Quick Flu/RSV		15		
		ArcDia mariPOC Respi		2		
		ArcDia mariPOC Respi+		18		
		BD Veritor System Flu A+B Kit		47		
		Biomaxima Influenza A+B cassettes		2		
		Biosynex COMBO COVID-FLU-RSV BSS		8		
		Biosynex INFLUENZATOP		6		
		Biosynex INFLUENZATOP BSS		38		
		Biotical Health Influenza A+B card		1		
		Certest Influenza A+B		8		
		Coris BioConcept Infla A+B K-SeT		3		
		Hangzhou AllTest Influenza A+B Rapid Test		7		
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
		Humasis Influenza A/B Antigen Test		1		
		Hydrex Influenza A/B Test		1		
		Intermed Diagnostik Nord Influenza A+B		2		
		LumiraDx SARS-CoV-2 & Flu A/B		4		
		Medix Biochemica Actim Influenza A&B		83		
		Meridian Bioscience TruFlu		1		
		nal von minden NADAL Influenza A+B		6		

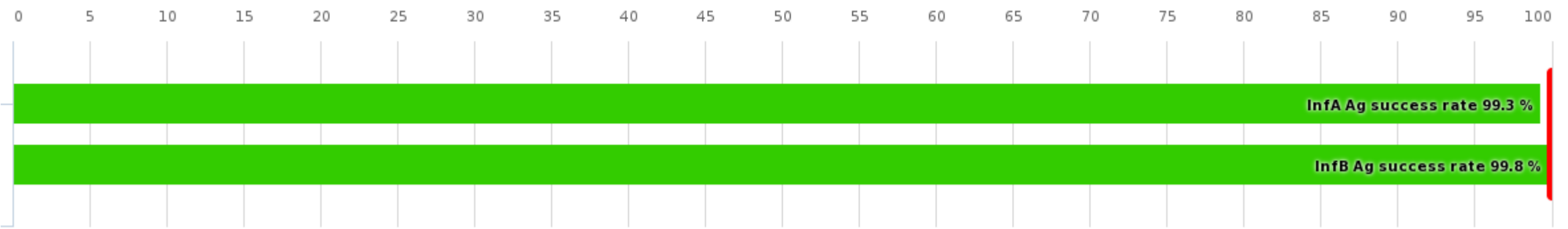
		Quidel Sofia Influenza A+B FIA		30		
		Screen Italia SCREEN TEST FLU A/B		1		
		SD Biosensor STANDARD F Influenza A/B FIA		15		
		SD Biosensor STANDARD Q Influenza A/B Test		2		
		Sekisui Diagnostics OSOM Influenza A&B		1		
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		2		
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		49		
		Servibio Influenza A+B Color		2		
		Standard Diagnostics SD Bioline Influenza Ag		1		
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3		
		Vidia Rapid-VIDITEST Influenza A+B		2		
		Virusys NCP ELISA		2		
		Vitassay Influenza A+ B Double test		2		
		Vitro Bio Chem Vitrotrack Influenza A+B		1		
	Positive		2		0 %	0
		Certest Influenza A+B		1		
		Medix Biochemica Actim Influenza A&B		1		
	Total:		414		99.5 %	

InfB Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		13		0 %	0
		Abbott BinaxNOW Influenza A&B		2		
		ArcDia mariPOC Quick Flu/RSV		4		
		ArcDia mariPOC Respi+		1		
		BD Veritor System Flu A+B Kit		2		
		Certest Influenza A+B		1		
		Medix Biochemica Actim Influenza A&B		2		
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		1		
	Weak positive		4		100 %	2
		Abbott BinaxNOW Influenza A&B		3		
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		1		
	Positive		399		100 %	2
		Abbott BinaxNOW Influenza A&B		22		
		Acro Biotech Influenza A+B Rapid Test Dipstick		3		
		ArcDia mariPOC Quick Flu+		14		
		ArcDia mariPOC Quick Flu/RSV		11		
		ArcDia mariPOC Respi		2		
		ArcDia mariPOC Respi+		17		
		BD Directigen Flu A+B		1		
		BD Veritor System Flu A+B Kit		45		
		Biomaxima Influenza A+B cassettes		2		
		Biosynex COMBO COVID-FLU-RSV BSS		8		
		Biosynex INFLUENZATOP		6		
		Biosynex INFLUENZATOP BSS		38		
		Biotical Health Influenza A+B card		1		
		Certest Influenza A+B		7		
		Coris BioConcept Inlu A+B K-Set		3		
		Hangzhou AllTest Influenza A+B Rapid Test		7		
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
		Humasis Influenza A/B Antigen Test		1		
		Hydrex Influenza A/B Test		1		
		Intermed Diagnostik Nord Influenza A+B		2		
		LumiraDx SARS-CoV-2 & Flu A/B		4		
		Medix Biochemica Actim Influenza A&B		84		
		Meridian Bioscience TruFlu		2		
		nal von minden NADAL Influenza A+B		6		
		Quidel Sofia Influenza A+B FIA		30		
		Screen Italia SCREEN TEST FLU A/B		1		
		SD Biosensor STANDARD F Influenza A/B FIA		15		
		SD Biosensor STANDARD Q Influenza A/B Test		2		
		Sekisui Diagnostics OSOM Influenza A&B		2		
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		3		
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		45		

	Servibio Influenza A+B Color		2		
	Standard Diagnostics SD Bioline Influenza Ag		1		
	Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3		
	Vidia Rapid-VIDITEST Influenza A+B		2		
	Virusys NCP ELISA		1		
	Vitassay Influenza A+ B Double test		2		
	Vitro Bio Chem Vitrotrack Influenza A+B		1		
	Total:		416		96.9 %

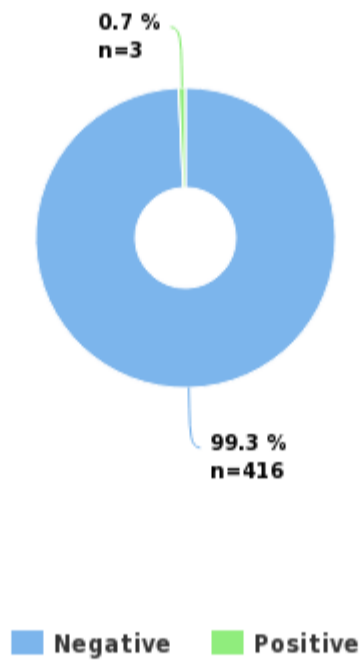
Sample S002

Sample S002 success rate

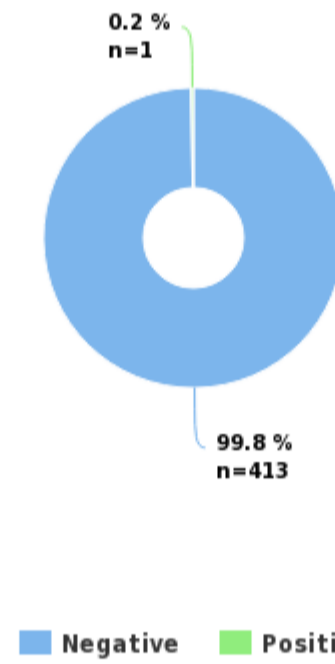


Sample S002 results	Responded	AVR success rate	Count
	InfA Ag	99.3 %	419
	InfB Ag	99.8 %	414
	Total:	99.5 %	833

Sample S002 InfA Ag



Sample S002 InfB Ag



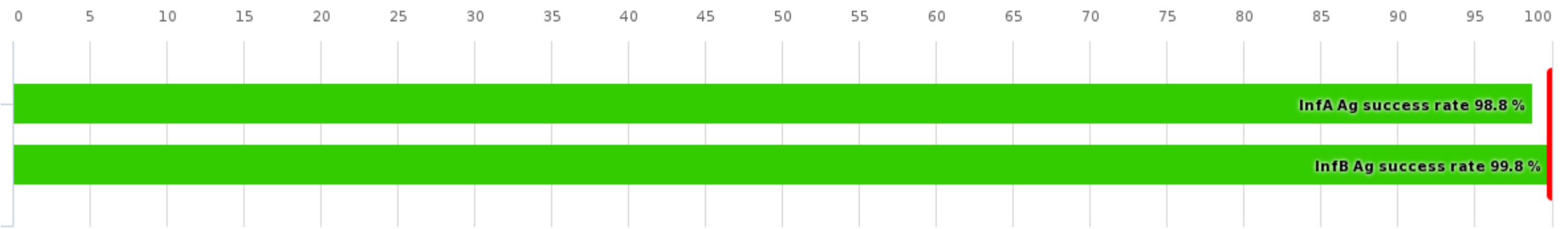
InfA Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		416		100 %	2
		Abbott BinaxNOW Influenza A&B		26		
		Acro Biotech Influenza A+B Rapid Test Dipstick		3		
		ArcDia mariPOC Quick Flu+		15		
		ArcDia mariPOC Quick Flu/RSV		14		
		ArcDia mariPOC Respi		2		
		ArcDia mariPOC Respi+		18		
		BD Veritor System Flu A+B Kit		49		
		Biomaxima Influenza A+B cassettes		2		
		Biosynex COMBO COVID-FLU-RSV BSS		8		
		Biosynex INFLUENZATOP		7		
		Biosynex INFLUENZATOP BSS		38		
		Biotical Health Influenza A+B card		1		
		Certest Influenza A+B		8		
		Coris BioConcept Infla A+B K-SeT		3		
		Hangzhou AllTest Influenza A+B Rapid Test		7		
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
		Humasis Influenza A/B Antigen Test		1		
		Hydrex Influenza A/B Test		1		
		Intermed Diagnostik Nord Influenza A+B		2		
		LumiraDx SARS-CoV-2 & Flu A/B		4		
		Medix Biochemica Actim Influenza A&B		85		
		nal von minden NADAL Influenza A+B		6		
		Quidel QuickVue Influenza A&B		1		

		Quidel Sofia Influenza A+B FIA		31		
		Screen Italia SCREEN TEST FLU A/B		1		
		SD Biosensor STANDARD F Influenza A/B FIA		15		
		SD Biosensor STANDARD Q Influenza A/B Test		2		
		Sekisui Diagnostics OSOM Influenza A&B		1		
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		1		
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		50		
		Servibio Influenza A+B Color		2		
		Standard Diagnostics SD Bioline Influenza Ag		1		
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3		
		Vidia Rapid-VIDITEST Influenza A+B		2		
		Virusys NCP ELISA		1		
		Vitassay Influenza A+ B Double test		2		
		Vitro Bio Chem Vitrotrack Influenza A+B		1		
	Positive		3		0 %	0
		Medix Biochemica Actim Influenza A&B		1		
		Meridian Bioscience TruFlu		1		
		Virusys NCP ELISA		1		
	Total:		419		99.3 %	

InfB Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		413		100 %	2
		Abbott BinaxNOW Influenza A&B		26		
		Acro Biotech Influenza A+B Rapid Test Dipstick		3		
		ArcDia mariPOC Quick Flu+		15		
		ArcDia mariPOC Quick Flu/RSV		14		
		ArcDia mariPOC Respi		2		
		ArcDia mariPOC Respi+		18		
		BD Veritor System Flu A+B Kit		48		
		Biomaxima Influenza A+B cassettes		2		
		Biosynex COMBO COVID-FLU-RSV BSS		8		
		Biosynex INFLUENZATOP		7		
		Biosynex INFLUENZATOP BSS		38		
		Biotical Health Influenza A+B card		1		
		Certest Influenza A+B		7		
		Coris BioConcept Influenza A+B K-Set		3		
		Hangzhou AllTest Influenza A+B Rapid Test		7		
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
		Humasis Influenza A/B Antigen Test		1		
		Hydrex Influenza A/B Test		1		
		Intermed Diagnostik Nord Influenza A+B		2		
		LumiraDx SARS-CoV-2 & Flu A/B		4		
		Medix Biochemica Actim Influenza A&B		83		
		Meridian Bioscience TruFlu		2		
		nal von minden NADAL Influenza A+B		6		
		Quidel Sofia Influenza A+B FIA		32		
		Screen Italia SCREEN TEST FLU A/B		1		
		SD Biosensor STANDARD F Influenza A/B FIA		15		
		SD Biosensor STANDARD Q Influenza A/B Test		2		
		Sekisui Diagnostics OSOM Influenza A&B		2		
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		2		
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		47		
		Servibio Influenza A+B Color		2		
		Standard Diagnostics SD Bioline Influenza Ag		1		
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3		
		Vidia Rapid-VIDITEST Influenza A+B		2		
		Virusys NCP ELISA		1		
		Vitassay Influenza A+ B Double test		2		
		Vitro Bio Chem Vitrotrack Influenza A+B		1		
	Positive		1		0 %	0
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		1		
	Total:		414		99.8 %	

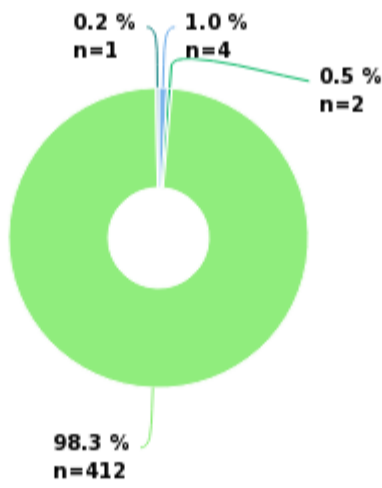
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	InfA Ag	98.8 %	419
	InfB Ag	99.8 %	414
	Total:	99.3 %	833

Sample S003 InfA Ag



Sample S003 InfB Ag



■ Negative ■ Weak positive ■ Positive ■ Invalid result

■ Negative ■ Invalid result

InfA Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		4		0 %	0
		Abbott BinaxNOW Influenza A&B		1		
		BD Veritor System Flu A+B Kit		1		
		Medix Biochemica Actim Influenza A&B		1		
		Meridian Bioscience TruFlu		1		
	Weak positive		2		100 %	2
		Abbott BinaxNOW Influenza A&B		1		
		Medix Biochemica Actim Influenza A&B		1		
	Positive		412		100 %	2
		Abbott BinaxNOW Influenza A&B		23		
		Acro Biotech Influenza A+B Rapid Test Dipstick		3		
		ArcDia mariPOC Quick Flu+		14		
		ArcDia mariPOC Quick Flu/RSV		15		
		ArcDia mariPOC Respi		2		
		ArcDia mariPOC Respi+		18		
		BD Veritor System Flu A+B Kit		48		
		Biomaxima Influenza A+B cassettes		2		
		Biosynex COMBO COVID-FLU-RSV BSS		8		
		Biosynex INFLUENZATOP		7		
		Biosynex INFLUENZATOP BSS		38		
		Biotical Health Influenza A+B card		1		
		Certest Influenza A+B		9		
		Coris BioConcept Influenza A+B K-SeT		3		
		Hangzhou AllTest Influenza A+B Rapid Test		7		

	Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
	Humasis Influenza A/B Antigen Test		1		
	Hydrex Influenza A/B Test		1		
	Intermed Diagnostik Nord Influenza A+B		2		
	LumiraDx SARS-CoV-2 & Flu A/B		4		
	Medix Biochemica Actim Influenza A&B		84		
	nal von minden NADAL Influenza A+B		6		
	Quidel Sofia Influenza A+B FIA		32		
	Screen Italia SCREEN TEST FLU A/B		1		
	SD Biosensor STANDARD F Influenza A/B FIA		14		
	SD Biosensor STANDARD Q Influenza A/B Test		2		
	Sekisui Diagnostics OSOM Influenza A&B		1		
	Sekisui Diagnostics OSOM Ultra Flu A & B Test		2		
	Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		49		
	Servibio Influenza A+B Color		2		
	Standard Diagnostics SD Bioline Influenza Ag		1		
	Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3		
	Vidia Rapid-VIDITEST Influenza A+B		2		
	Virusys NCP ELISA		2		
	Vitassay Influenza A+ B Double test		2		
	Vitro Bio Chem Vitrotrack Influenza A+B		1		
	Invalid result		1	0 %	0
	SD Biosensor STANDARD F Influenza A/B FIA		1		
	Total:		419	98.8 %	

InfB Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		413		100 %	2
		Abbott BinaxNOW Influenza A&B		25		
		Acro Biotech Influenza A+B Rapid Test Dipstick		3		
		ArcDia mariPOC Quick Flu+		14		
		ArcDia mariPOC Quick Flu/RSV		15		
		ArcDia mariPOC Respi		2		
		ArcDia mariPOC Respi+		18		
		BD Veritor System Flu A+B Kit		48		
		Biomaxima Influenza A+B cassettes		2		
		Biosynex COMBO COVID-FLU-RSV BSS		8		
		Biosynex INFLUENZATOP		7		
		Biosynex INFLUENZATOP BSS		38		
		Biotical Health Influenza A+B card		1		
		Certest Influenza A+B		8		
		Coris BioConcept Infla A+B K-SeT		3		
		Hangzhou AllTest Influenza A+B Rapid Test		7		
		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
		Humasis Influenza A/B Antigen Test		1		
		Hydrex Influenza A/B Test		1		
		Intermed Diagnostik Nord Influenza A+B		2		
		LumiraDx SARS-CoV-2 & Flu A/B		4		
		Medix Biochemica Actim Influenza A&B		83		
		Meridian Bioscience TruFlu		2		
		nal von minden NADAL Influenza A+B		6		
		Quidel Sofia Influenza A+B FIA		32		
		Screen Italia SCREEN TEST FLU A/B		1		
		SD Biosensor STANDARD F Influenza A/B FIA		14		
		SD Biosensor STANDARD Q Influenza A/B Test		2		
		Sekisui Diagnostics OSOM Influenza A&B		2		
		Sekisui Diagnostics OSOM Ultra Flu A & B Test		3		
		Sekisui Diagnostics OSOM Ultra Plus Flu A & B Test		47		
		Servibio Influenza A+B Color		2		
		Standard Diagnostics SD Bioline Influenza Ag		1		
		Standard Diagnostics SD Bioline Influenza Ag A/B/A(H1N1) Pandemic		3		
		Vidia Rapid-VIDITEST Influenza A+B		2		
		Virusys NCP ELISA		1		

		Vitassay Influenza A+ B Double test		2		
		Vitro Bio Chem Vitrotrack Influenza A+B		1		
	Invalid result		1		0 %	0
		SD Biosensor STANDARD F Influenza A/B FIA		1		
	Total:		414		99.8 %	

Report Info

PARTICIPANTS

Altogether 390 laboratories from 16 countries participated in this EQA round.

REPORT INFO

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green color and laboratory's own result with a black radio button . In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

SCORING

The round is scored based on test results when 60% or more of the participants report the expected result and when at least three results are reported. The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample success rates.

The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

External Quality Assessment Scheme

Influenza virus A and B, antigen detection Round 1, 2023

Specimens

Samples of this EQA round were artificial nasopharyngeal samples. The samples were suitable for antigen detection methods. Based on the quality controls conducted by the sample material manufacturer, pre-testing and the results obtained in the round, the sample lots are to be considered as homogeneous, stable and suitable for external quality assessment. The materials were sent without temperature control packaging.

The expected results and pre-test laboratory C_t values were as follows:

Sample S001 (LQ774823011)
Influenza B virus (Hong Kong/5/72); positive, C_t 21.4

Sample S002 (LQ774823012)
Negative

Sample S003 (LQ774823013)
Influenza A virus (H1N1); positive, C_t 23.0

Pre-test methods: Seegene Allplex Respiratory Panel 1 (C_t values) and laboratory developed test (RT-PCR).

Report info

Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – Expert

In principle, this was an easy EQA round, but the result of the sample S001 indicated possible test-specific sensitivity issues. The test-specific success rate of influenza B virus in the sample was 79–100%. Based on the C_t value of the sample with whole virus material, it was strong enough for antigen detection. Otherwise, the erroneous results of the round were sporadic.

Exceptions in scoring

No exceptions.

End of report

2023-03-24

FINAL REPORT

Product no. 5671

Subcontracting: Sample pretesting

Samples sent	2023-01-31
Round closed	2023-02-27
Expected results	2023-02-28
Final report	2023-03-24

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

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