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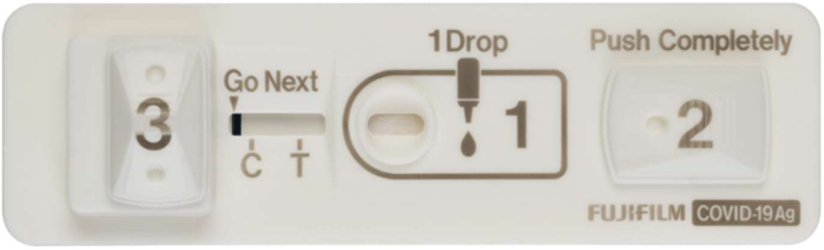
FUJIFILM
Value from Innovation

FUJIFILM COVID-19 Ag Test

IVDD
Technical Documentation File
Results in Performance Evaluation

Version 3



Materials about performance characteristics

for FUJIFILM COVID-19 Ag Test

1. Specimen type

Appropriate specimen type(s)

Nasopharyngeal swabs

Specimen Stability

No data

Freeze/thaw cycle

No data

Preparation of sample

Collected specimen should be prepared as a sample in accordance with the proper method.

2. Performance (TC ST-0202-SIL-COV-001)

(i) Accuracy

1) PROTOCOL

In accordance with Procedure, each specimen was measured for 3 reagent lots.

2) CRITERIA

・Testing an in-house positive control sample[1)] results in a positive result.
・Testing an in-house negative control sample[2)] results in a negative result.

Note 1) A sample made from SARS-CoV-2 recombinant protein diluted to 25 pg/mL in Extraction Reagent Solution R1
Note 2) Extraction Reagent Solution R1.

3) RESULT

Specimen	Lot	Result
in-house negative control	900001	Negative
	900002	Negative
	900003	Negative
in-house positive control	900001	Positive
	900002	Positive
	900003	Positive

4) CONCLUSION

Satisfied criteria and acceptable.

(ii) Precision

1) PROTOCOL

In accordance with Procedure, each specimen was measured 3 times at the same time for 3 reagent lots.

2) CRITERIA

・Testing three in-house positive control samples[1)] at the same time yields all positive results.
・Testing three in-house negative control samples[2)] at the same time yields all negative results.

Note 1) A sample made from SARS-CoV-2 recombinant protein diluted to 25 pg/mL in Extraction Reagent Solution R1
Note 2) Extraction Reagent Solution R1.

3) RESULT

Specimen	Lot	Result
in-house positive control	900001	Positive Positive Positive
	900002	Positive Positive Positive
	900003	Positive Positive Positive
in-house negative control	900001	Negative Negative Negative
	900002	Negative Negative Negative
	900003	Negative Negative Negative

4) CONCLUSION

Satisfied criteria and acceptable.

(iii) Minimum detection sensitivity (Limit of Detection) (Aras No.:001-021101)

1) PROTOCOL

A sample collected from a patient suspected of being infected with SARS-CoV-2 at the Yokohama City University Hospital, and a nasopharyngeal swab storage sample diagnosed as SARS-CoV-2 negative by RT-PCR was used as a pool sample. Inactivated SARS-CoV-2 (JPN / TY / WK-521 strain) was added to this pool sample, and prepared dilution.
In accordance with Procedure, each dilution was measured.

2) RESULT

Lot.900002

Specimen	Lot	Concentration [$TCID_{50}$/mL]	Result
Inactivated SARS-CoV-2 (JPN / TY /WK-521 strain)	900002	2.3×10^2	Positive Positive Positive
		1.1×10^2	Positive Positive Positive
		5.6×10^1	Negative Positive Negative
		2.8×10^1	Negative Negative Negative

3) CONCLUSION

The limit of detection is concentration equivalent to inactivated SARS-CoV-2 (JPN / TY / WK-521 strain) 1.1×10^2 $TCID_{50}$/mL.

3. Correlation (Aras No.:001-021140)

SARS-CoV-2 infection positive / negative of each patient was judged by reference method;
Positive: RT-PCR for nasopharyngeal swabs testing positive.
Negative: RT-PCR for nasopharyngeal swabs testing negative.

1) PROTOCOL

In accordance with Procedure, each nasopharyngeal swabs specimen was measured and compared to the determination result of the reference method.

2) RESULT

Lot.900002 and Lot. 210120

PCR-Positive

		RT-PCR Ct value			
		< 26	< 28	< 30	< 35
FUJIFILM COVID-19 Ag Test	Positive	100	107	110	110
	Negative	0	3	6	11
	Total	100	110	116	121
	Sensitivity (PPA)	100.0%	97.3%	94.8%	90.9%
	95% CI	96.4-100.0%	92.2-99.4%	89.1-98.1%	84.3-95.4%

PCR-Negative

		RT-PCR
		Negative
FUJIFILM COVID-19 Ag Test	Positive	0
	Negative	104
	Total	104
	Specificity (NPA)	100.0%
	95% CI	96.5-100.0%

Overall results of clinical performance

		RT-PCR		
		Positive	Negative	Total
FUJIFILM COVID-19 Ag Test	Positive	110	0	110
	Negative	11	104	115
	Total	121	104	225

Sensitivity (PPA):90.9%(110/121, 95% CI:84.3-95.4%)

Specificity (NPA):100.0%(104/104, 95% CI:96.5-100.0%)

EXPLANATION OF TERMS:

Sensitivity or Positive Percent Agreement (PPA) =

True Positives / (True Positives + False Negatives)

Specificity or Negative Percent Agreement (NPA) =

True Negatives / (True Negatives + False Positives)

3) CONCLUSION

Good correlation result was obtained with the reference method.

4. Interfering substances and medications (TC ST-0206-SIL-COV-001)

1) PROTOCOL

Prepare a sample by adding each interfering substance to in-house negative control, in-house positive control.

In accordance with Procedure, each sample was measured.

2) RESULT

Lot.900003

At the concentrations listed below, the following substances will not invalidate the results given by this product.

・Hemoglobin from hemolysis (450 mg/dL)

・Blood (2%)

5. Cross reactivity (TC ST-0205-SIL-COV-001)

1) PROTOCOL

Prepare a sample by adding each recombinant coronavirus antigens and inactivated influenza virus to in-house negative control, in-house positive control.
In accordance with Procedure, each sample was measured.

2) RESULT

Lot.900003

No cross reactivity was observed with the following virus.

＜Recombinant coronavirus antigens＞

・MERS-CoV
・HCoV-229E,
・HCoV-OC43
・HCoV-NL63
・HCoV-HKU1
・SARS-CoV

＜Inactivated influenza virus＞

・Influenzavirus H1N1
・Influenzavirus H3N2
・Influenzavirus B

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