

# COVID-19 Ag Control

*For in vitro diagnostics use only*

## INTENDED USE

NowCheck COVID-19 Ag Control is intended for use as an external quality control material to monitor the performance of NowCheck COVID-19 Ag Test. It is important to perform control tests with positive and negative control materials to assure your system is working properly.

## PRINCIPLE

This product was designed for use with NowCheck COVID-19 Ag Test for the purpose of monitoring assay performance and maintaining quality assurance. This products should be analyzed in the same manner as unknown specimens according to instructions of the NowCheck COVID-19 Ag Test.

## MATERIALS PROVIDED

	Reagent	10 Tests/Kit
①	Positive control (red colored tube)	10
②	Negative control (Transparent tube)	10
③	Instructions for use	1



## MATERIALS REQUIRED, BUT NOT PROVIDED

- NowCheck COVID-19 Ag Test

## STORAGE AND STABILITY

- Store the NowCheck COVID-19 Ag Control at 2-30°C/36-86°F.
- Kit materials are stable until expiration date printed on the outer box.
- Do not use kit materials, if expiry date has passed.

## PRECAUTIONS

- If there is evidence of microbial contamination in the reconstituted control, discard the control.
- Wear protective clothing and gloves when handling samples or reagents.
- Clean any spillage by immediately and thoroughly wiping up with a suitable disinfectant such as 1% sodium hypochlorite solution.
- Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
- Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

## CONTROL TEST PROCEDURE

This product should be treated the same as patient specimens and run in accordance with instruction accompanying the instrument and kit being used.

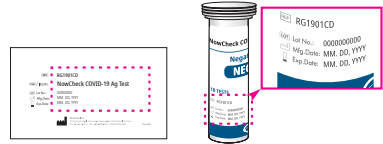
It is recommended that positive and negative controls be run:

- Once for each new lot,
- Once for each untrained operator,
- Once for each new shipments of test kits,
- As required by test procedures in this instructions and in

accordance with local, state and federal regulations of accreditation requirements.

### [Preparation]

- Expose NowCheck COVID-19 Ag Test and NowCheck COVID-19 Ag Control at room temperature (15-30°C/59-86°F) at least 30 minutes prior to the test.
- Carefully read instructions for use.
- Check the expiration date of the control on the bottle and of the test device on the pouch. Do not use expired control and test devices.



### [Preparation of control]

- Open the bottle of NowCheck COVID-19 Ag Control and take a control tube out of the bottle.



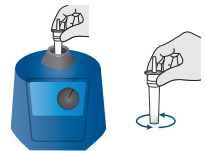
- Insert the positive or negative control tablet into an extraction buffer tube which is in the NowCheck COVID-19 Ag Test.



- Press the nozzle cap tightly onto the tube.



- Mix the control tablet and extraction buffer using vortex or hand swirling.



### [Test procedure]

- Apply 3 drops of the prepared control mixture into the specimen well of the test device.



- Interpreting in accordance with the instructions for use accompanying the NowCheck COVID-19 Ag Test.

## INTERPRETATION OF TEST RESULTS

### [NowCheck COVID-19 Ag Control: Positive]

1. PASS : Positive result for Ag
2. FAIL : Negative result for Ag → Retest
3. Invalid : No Control (C) line → Retest

















### [NowCheck COVID-19 Ag Control: Negative]

1. PASS : Negative result for Ag
2. FAIL : Positive result for Ag → Retest
3. Invalid : No Control (C) line → Retest

## LIMITATIONS

1. This product is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.
2. Adverse storage conditions or use of outdated reagents may produce erroneous results.
3. This product should not be used past the expiration date.
4. Alterations in physical appearance may indicate instability or deterioration of this product. If there is evidence of microbial contamination in this product, discard it.

## SYMBOL

Symbol	Description
	Manufacturer
	Consult instructions for use
	Reference number
	Date of manufacture To indicate the date of analyzer manufacture
	Note
	Contains sufficient for <n> tests
	Do not re-use
	Use by
	Caution! Indicates a situation, which if not avoided could result
	Indicates that you should keep the product dry
	Indicates that the product is fragile and to handle it with care
	Batch code : Indicate the lot number for this analyzer
	Indicates to discard it separately from other household waste
	Keep away from sunlight
	Do not use if packaging is damaged
	Fulfill the requirements of Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices

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