SGTi-flex COVID-19 Ag Control

LOT No: CAGC001E



▶ INTENDED USE

SGTi-flex COVID-19 Ag Control is intended to be used for *in vitro* diagnostic use in the quality control of SGTi-flex COVID-19 Ag kit. **For** *in vitro* **diagnostic use**.

▶ SUMMARY

The controls in this kit are to be used as quality control for SGTi-flex COVID-19 Ag assay. The purpose of quality control is to ensure proper performance of the SGTi-flex COVID-19 Ag test.

▶ SAFETY PRECAUTIONS AND WARNINGS

- √ For *in vitro* diagnostic use.
- $\sqrt{\text{For laboratory/ professional use only.}}$
- √ SGTi-flex COVID-19 Ag Control is only available for use with the SGTi-flex COVID-19 Ag Kit.
- √ This control is provided for quality assurance only and must not be used for calibration.
- $\sqrt{\mbox{ This control should not be used past the expiration}}$ date.
- $\sqrt{}$ It should be used and discarded according to your own laboratory's safety procedures.

▶ STORAGE AND STABILITY

- $\sqrt{}$ Store at at +2 to +30 °C. Stable until expiration date on the label.
- \sqrt{After} opening aluminum pouch, used immediately.

▶ MATERIALS SUPPLIED

√SGTi-flex COVID-19 Ag Positive Control swab ·······	1
$\sqrt{\text{SGTi-flex COVID-19}}$ Ag Negative Control swab $\cdots\cdots$	1
Instructions for Use	1

▶ PREPARATION FOR USE

- The control swabs should be used according to the instruction for use for the SGTi-flex COVID-19 Ag test kit.
- Prior to use, allow this product to reach room temperature and stayed homogenous 15~30 minutes.

▶ EXPECTED RESULTS

- √ The result for the control should show the expected results when tested using SGTi-flex COVID-19 Ag. If they do not, the assay should be repeated and checking control solution or assay kit.
- $\sqrt{}$ If test is invalid, both controls must be retested with another device.

	Expected Results		
	C Line	T Line	Result
Negative	+		Non-
control		-	Reactive
Positive	+	1	Reactive
control		T	ixeactive

▶ EXPLANATION OF SYMBOLS USED ON

PACKAGE

	In vitro diagnostic medical		
IVD	_		
	device		
\sum_{i}	Contains sufficient for 1 pcs		
	Do not reuse		
	Do not reuse		
1777	Consult		
	instructions for use.		
1 30℃	Store between		
2℃ - 🚺	2°C and 30°C		
A	Caution, consult accompanying		
<u> </u>	documents		
LOT	Batch code		
\square	Use by		
REF	Catalogue number		
***	Manufacturer		
	Biological Risks		



SUGENTECH, INC.

721-26 JeongJungyeonje-ro,Osong-eup, Heyngdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea

Made in Korea

www.sugentech.com

Rev.No. IS311E-00/2020.10.26