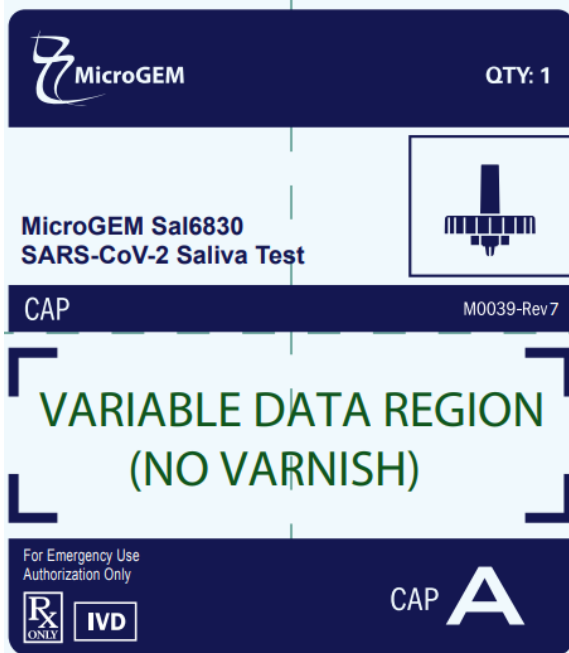


Cap Pouch A



Variable Print

PN M0148

LOT 1V100000

PN: M0161

PN: M0039

Cup Pouch B



Variable Print

PN M0149

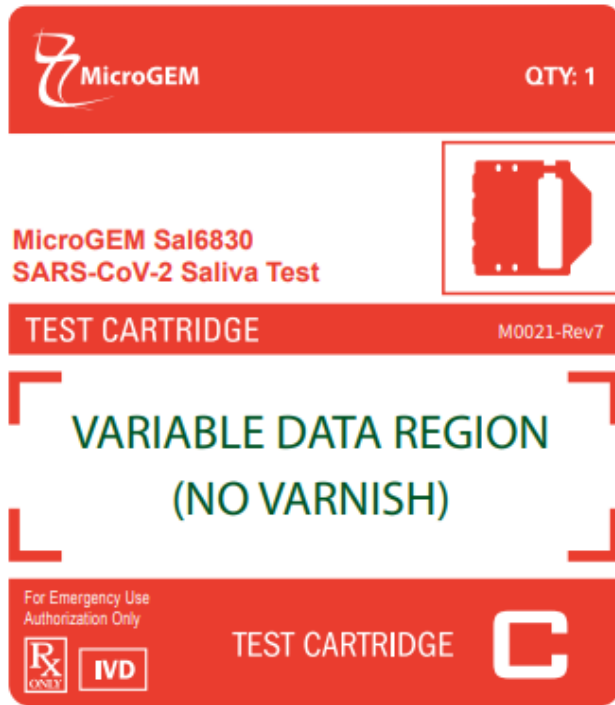
LOT 1V100000

YYMM-DD

PN: M0158

PN: M0019

Cartridge Pouch C



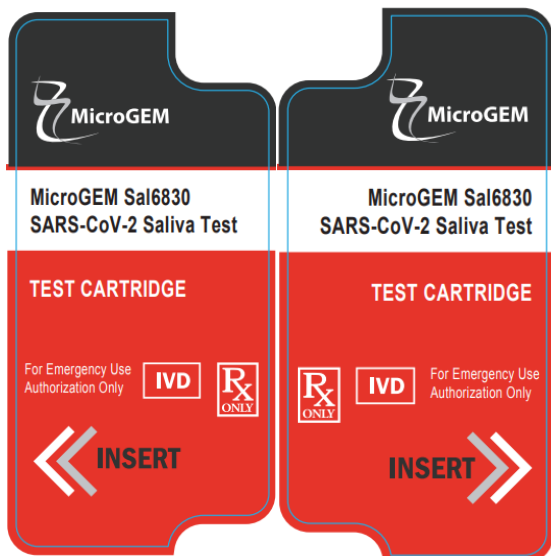
PN: M0021

Variable Print Data:

- PN M0150
- LOT 1V100000
- YYYY-MM-DD

PN: M0159


Structural Label




PN: M0235

PN: M0236


Kit Pouch D Label




For Emergency Use Authorization Only


IVD 

**MicroGEM Sal6830
SARS-CoV-2 Saliva Test**

PN SCF0001
LOT 1A#####
 YYYY-MM-DD

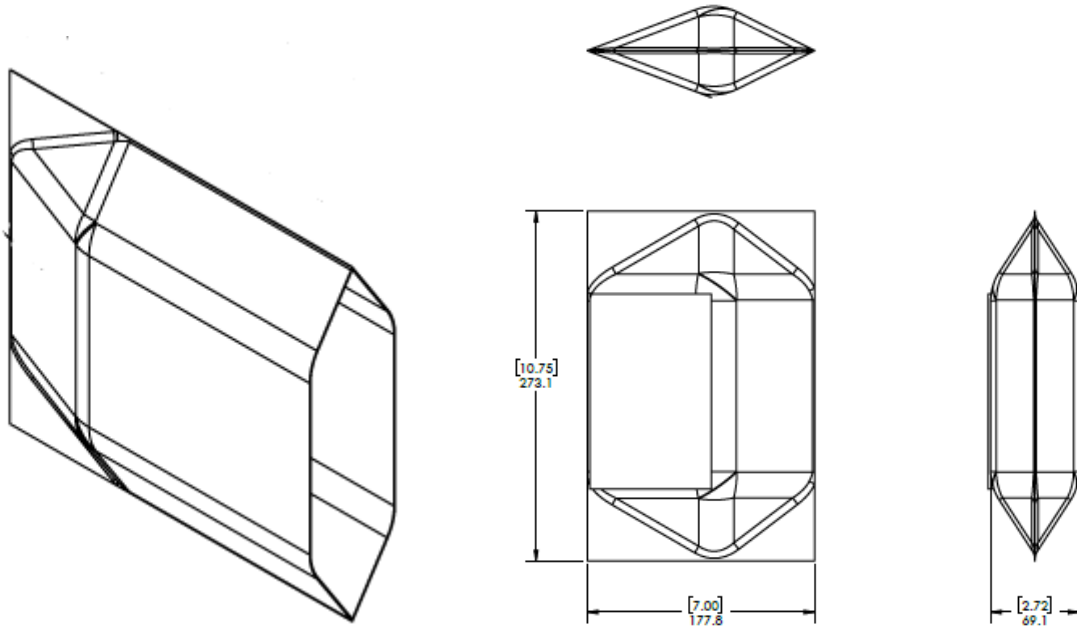


+B984SCF00300/\$1V100000/16D20220101/14D20230101/###

 MicroGEM
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www.microgembio.com/covid-19

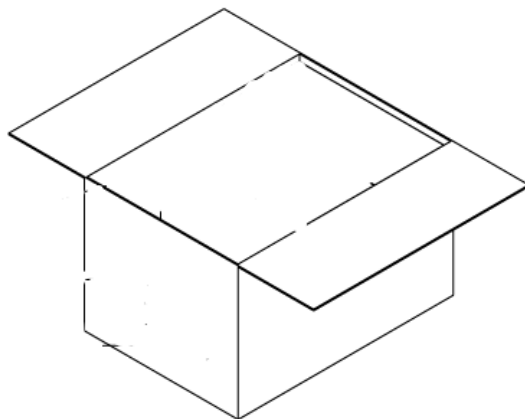
PN: M0205

Kit Pouch D

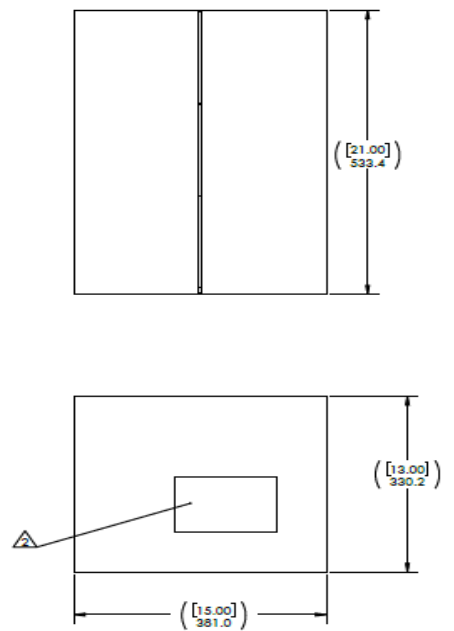


PN: M0027

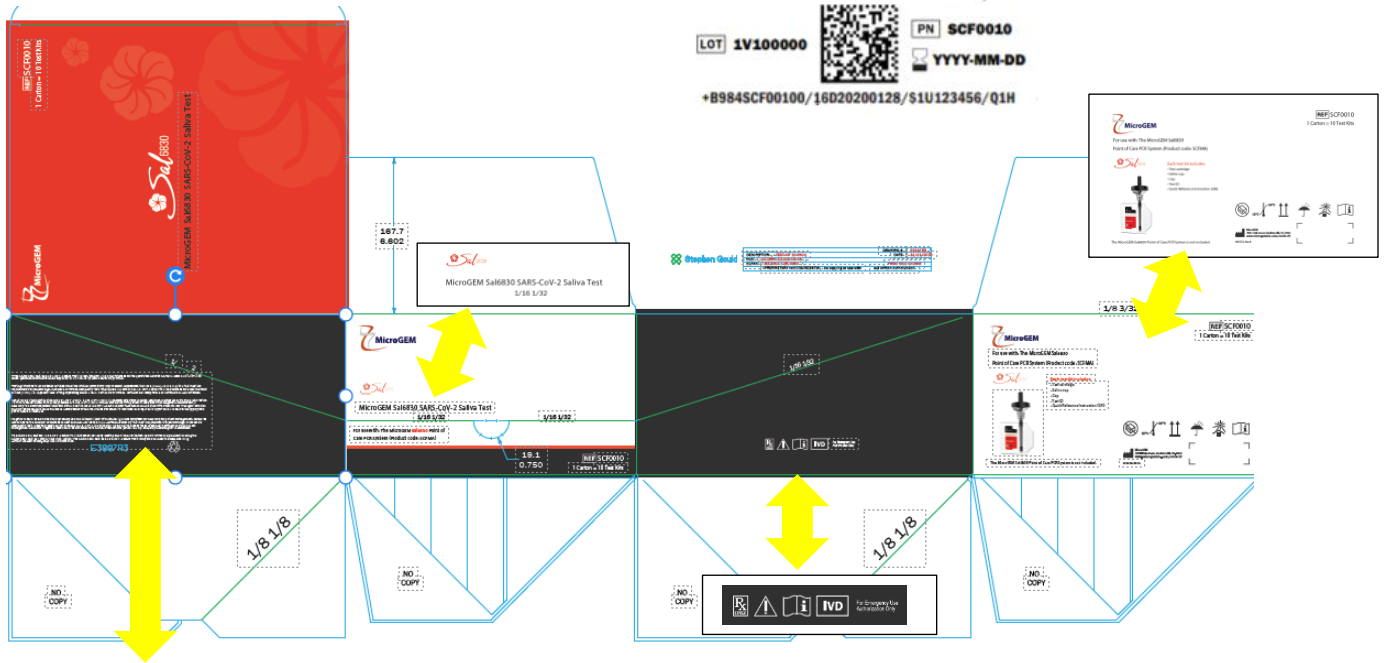
Master Shipper



PN: M0242



Kit 10 Pack Box



The MicroGEM *Sal6830* SARS-CoV-2 Saliva Test is a real-time RT-PCR assay intended for the qualitative detection of RNA from SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by their healthcare provider.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. The MicroGEM *Sal6830* SARS-CoV-2 Saliva Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The MicroGEM *Sal6830* SARS-CoV-2 Saliva Test is intended for use by health professionals or trained operators who are proficient in using the MicroGEM *Sal6830* Point of Care PCR System. The MicroGEM *Sal6830* SARS-CoV-2 Saliva Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Variable Print Data:

PN: M0160



Kit 30 Pack Master Shipper

The MicroGEM Sal6830 Point of Care PCR System is not included.



MicroGEM Sal6830
SARS-CoV-2 Saliva Test

Each test kit includes:

- Test cartridge
- Saliva cup
- Cap
- Test ID
- Quick Reference Instructions (QRI)

1 Carton = 30 Test Kits

For Emergency Use Authorization Only



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www.microgembio.com/covid-19
M0244-Rev A



PN: M0243

PIC Card



MicroGEM Sal6830 SARS-CoV-2 Saliva Test

This kit does not include all of the labeling (e.g. paper copy).
Scan here to obtain the latest version of the Instructions for Use, or visit:
www.microgembio.com/covid-19/resources



or
<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2>

For support, or to obtain a free paper copy of the labeling and Instructions for Use, please visit:
www.microgembio.com/covid-19 or email us at: techsupportdx@microgembio.com.

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.



PN: M0013



SAL6830 Label Set

Instrument Nameplate

	MicroGEM Sal6830 Point of Care PCR System	For Emergency Use Authorization Only	REF Model: SCFMA
SN	Variable Print Data: CC	UDI	Variable Print Data:
M0126-RevA 	Made in Singapore for MicroGEM™ Date of Manufacturing: YYYY-MM-DD	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.	
 MicroGEM 705D - Dale Avenue Charlottesville, VA, 22903 www.microgembio.com/covid-19	24V - 180W	IVD	C

PN: M0126

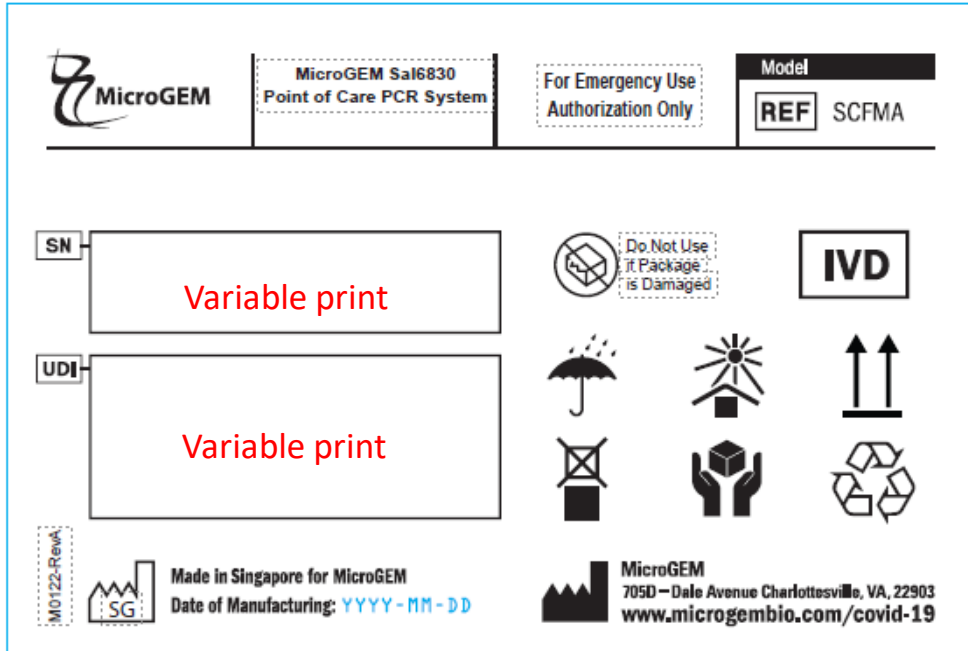
Variable Print Data:

00874

Variable Print Data:

-8845CF88E2-88202612E-110123456-01P

Instrument Carton Label



The label template includes the following elements:

- MicroGEM Logo** and **MicroGEM Sal6830 Point of Care PCR System**
- For Emergency Use Authorization Only** (dashed border)
- Model REF SCFMA**
- SN** (Serial Number) field with **Variable print** text
- UDI** (Unique Device Identifier) field with **Variable print** text
- Do Not Use if Package is Damaged** warning icon
- IVD** (In Vitro Diagnostic) icon
- Handling icons: umbrella (rain), sun (heat), hands holding a box (fragile), and recycling symbol.
- M0122-RevA** and **SG** (Singapore) logo
- Made in Singapore for MicroGEM** and **Date of Manufacturing: YYYY-MM-DD**
- MicroGEM** address: **705D - Dale Avenue Charlottesville, VA, 22903** and **www.microgembio.com/covid-19**

PN: M0122

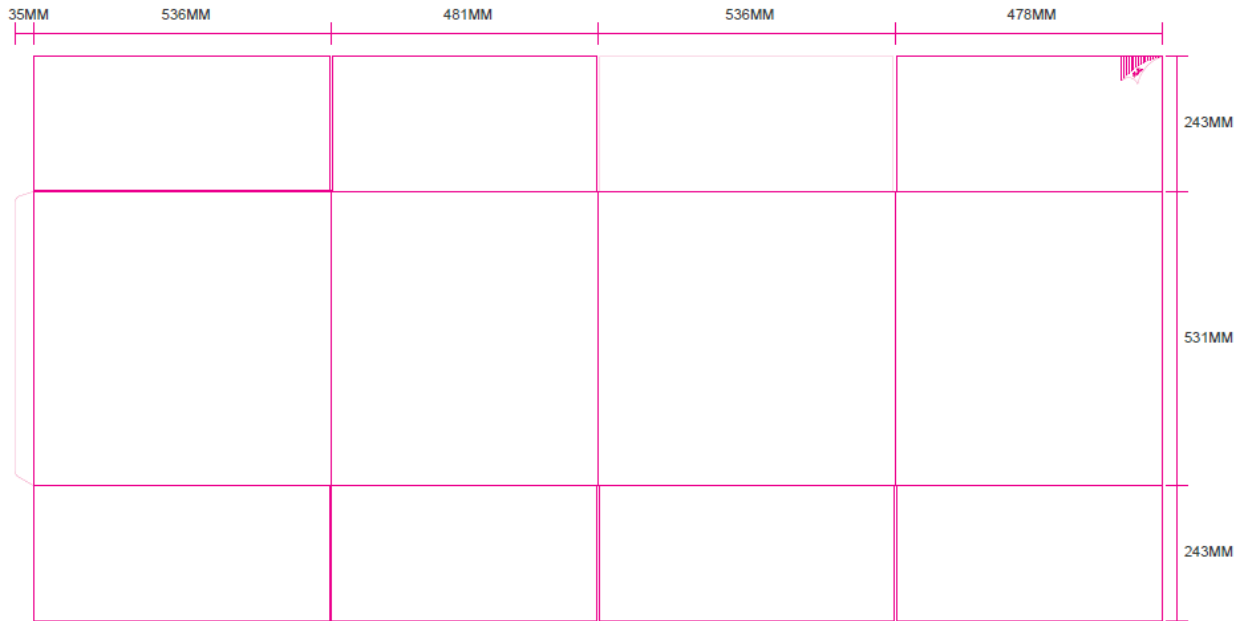
Variable Print Data:



The variable print data example shows the label with the following specific information:


- MicroGEM** logo and **Saliva Testing System**
- Model REF SCFMA**
- SN** field with QR code and value **000874**
- UDI** field with QR code and value ***894CF09802, 202009120, 11112440, 01***
- Do Not Use if Package is Damaged** warning icon
- IVD** icon
- Handling icons: umbrella, sun, hands holding a box, and recycling symbol.
- M0122-RevA** and **SG** logo
- Made in Singapore for MicroGEM** and **Date of Manufacturing: YYYY-MM-DD**
- MicroGEM** address: **705D - Dale Avenue Charlottesville, VA, 22903** and **www.microgembio.com/covid-19**

Instrument Box





PN: M0110

Test ID Card





MicroGEM Sal6830 SARS-CoV-2 Saliva Test
Patient Fact Sheet <https://microgembiocovid19.com/fsfp>

TEST ID For Emergency Use Authorization Only   M0238-RevA


NAME

DATE




1 Test ID
This card and data code stays with the person being tested 

DETACH

2 Sample ID label
Place this label on the cap of the saliva cup 

PEEL & PLACE

3 Records ID label
Place this label on the facility record 

PEEL & PLACE

PN: M0238



SAL6830 Label Set

System Quick Start Card



MicroGEM Sal6830 Point of Care PCR System

This system does not include all of the labeling (e.g. paper copy). Scan here to obtain the latest version of the User Guide, or visit: www.microgenbio.com/covid-19/resources.



This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.

For support, or to obtain a free paper copy of the labeling and User Guide, please visit: www.microgenbio.com/covid-19 or email us at techsupportdx@microgenbio.com.

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.



- 1 Unpack the MicroGEM Sal6830 Point of Care PCR System, taking care when lifting the system. There are carrying features at the front and rear of the system for assistance.
- 2 Place on a clean, flat, level, and stable surface within reach of an electrical outlet.
- 3 Connect the 24V power supply to the system. Plug the adapter into an appropriate electrical outlet.
- 4 Once the power is connected, press the Power Button on the right side of the system to power up and start the system.
- 5 Follow prompts on screen for system set up

SN

For support, please visit: www.microgenbio.com/covid-19
Or email: techsupportdx@microgenbio.com

PN: M0152

