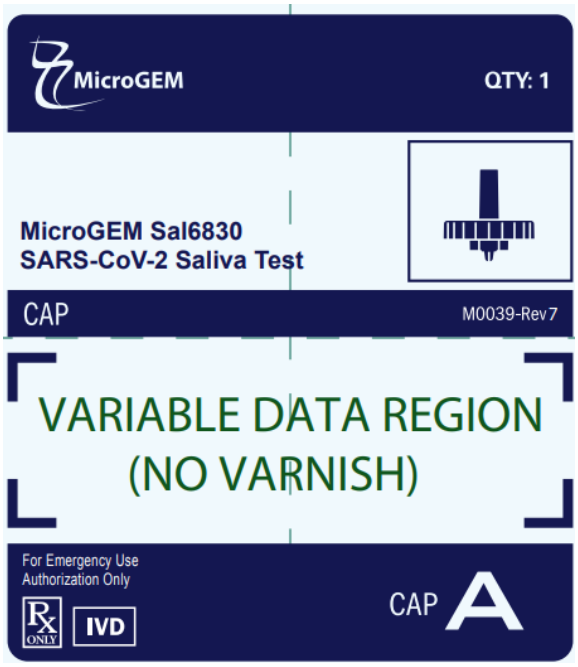
MicroGEM

SAL6830 Label Set

Cap Pouch A



Variable Print

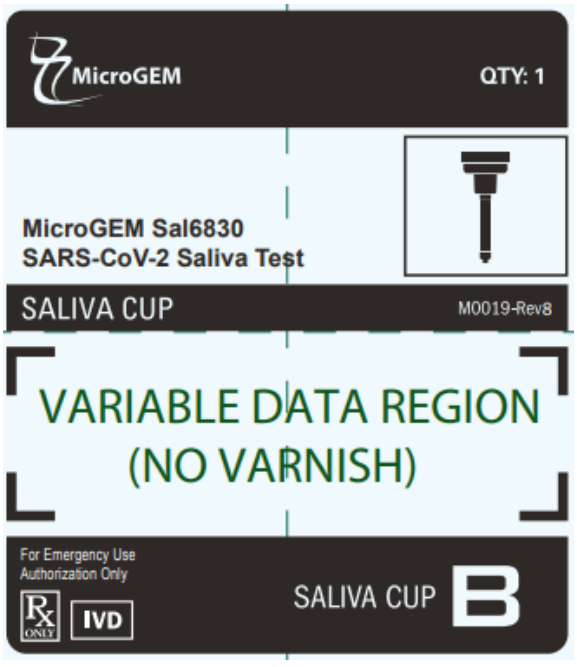
PN M0148

LOT 1V100000

PN: M0161

PN: M0039

Cup Pouch B



Variable Print

PN M0149

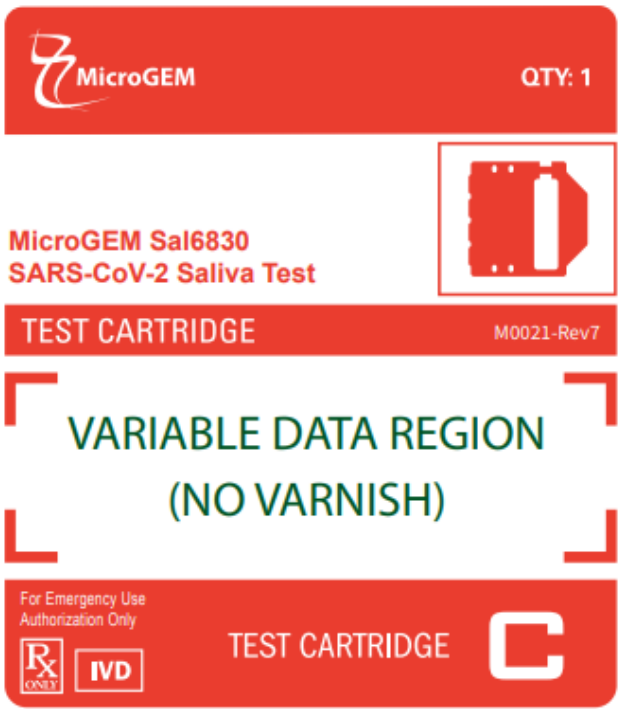
LOT 1V100000

YYYY-MM-DD

PN: M0158

PN: M0019

Cartridge Pouch C



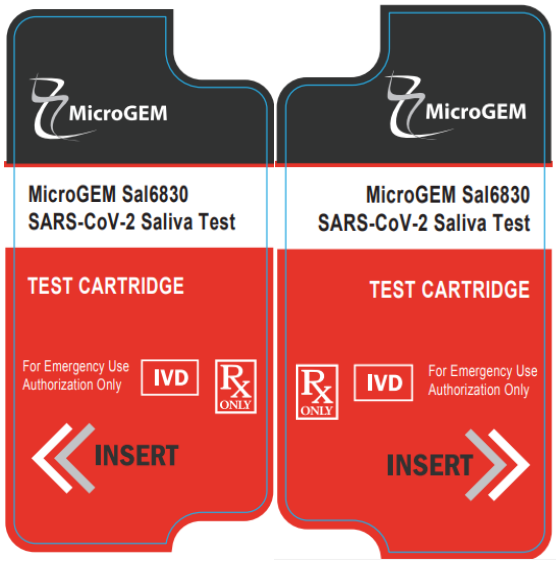
PN: M0021

Variable Print Data:

PN M0150
LOT 1V100000
YYYY-MM-DD

PN: M0159

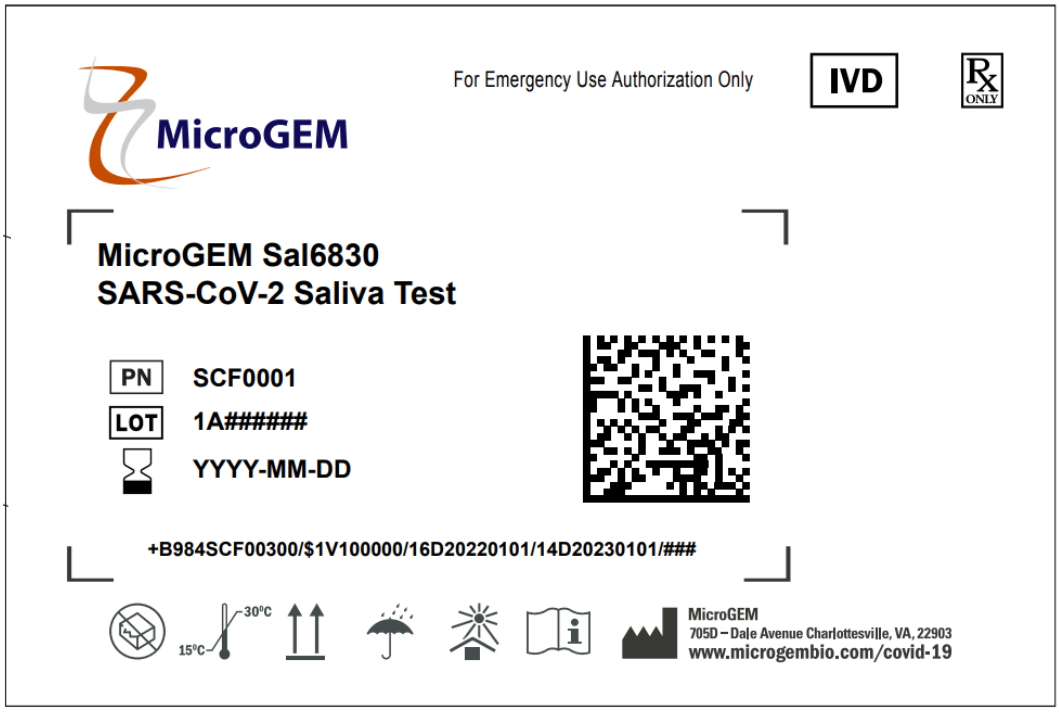
Structural Label



PN: M0235

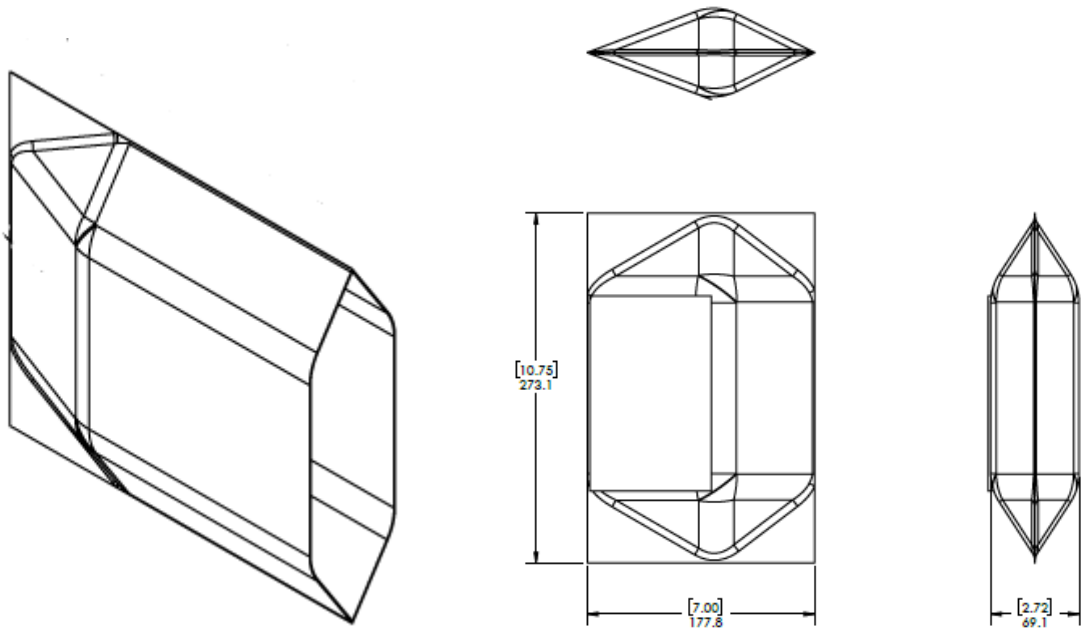
PN: M0236

Kit Pouch D Label



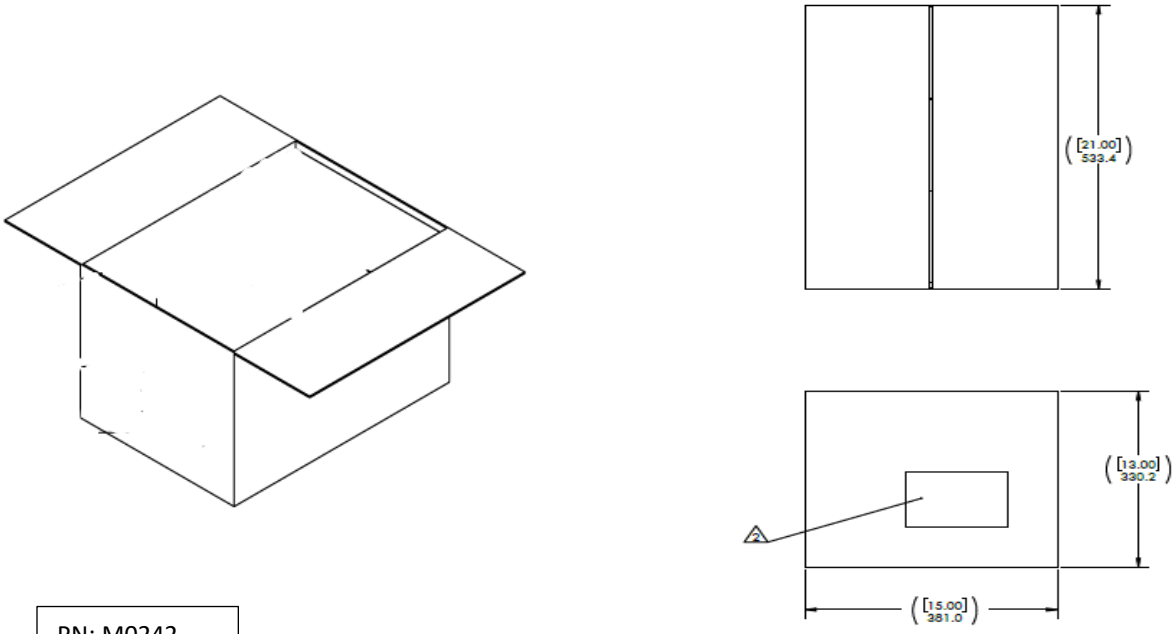
PN: M0205

Kit Pouch D



PN: M0027

Master Shipper

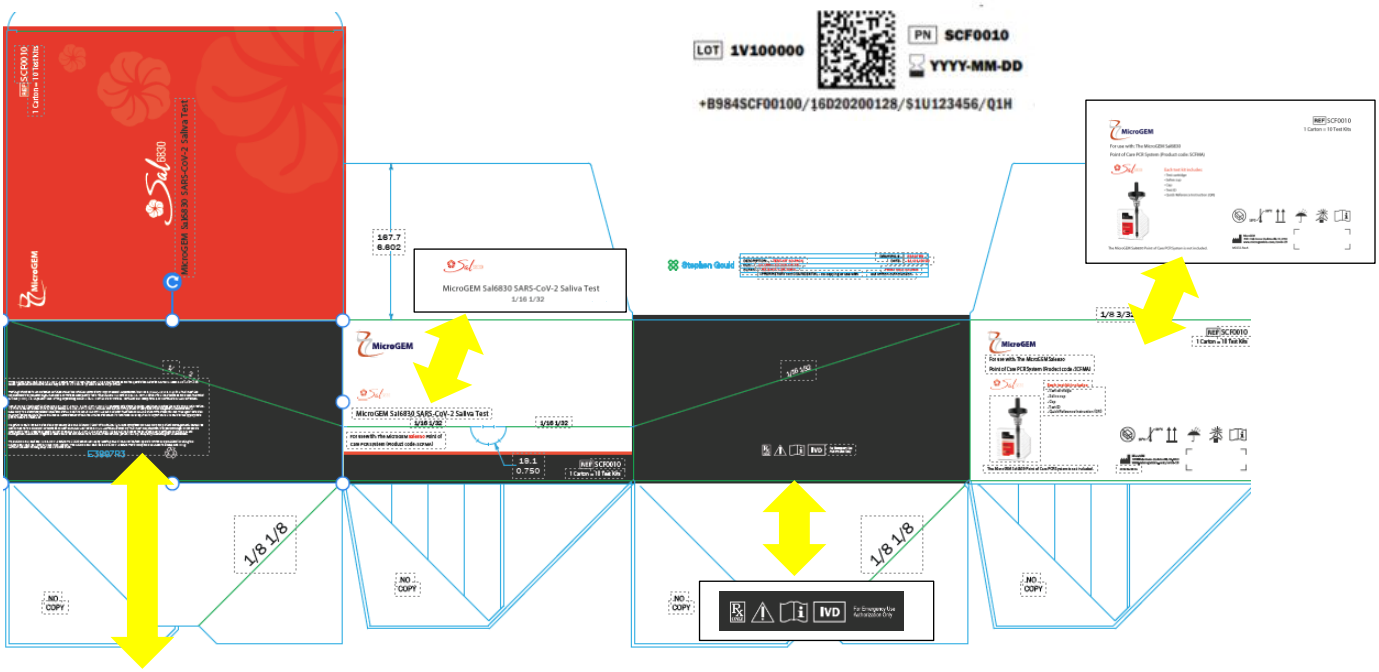


PN: M0242

MicroGEM

SAL6830 Label Set

Kit 10 Pack Box



The MicroGEM *Sal*6830 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.

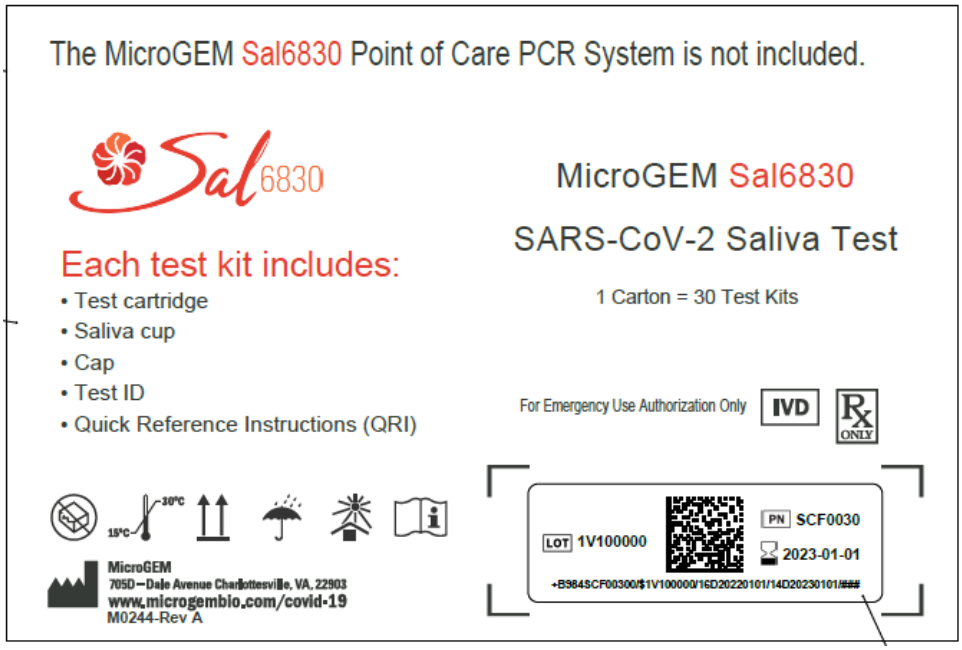
Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity 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



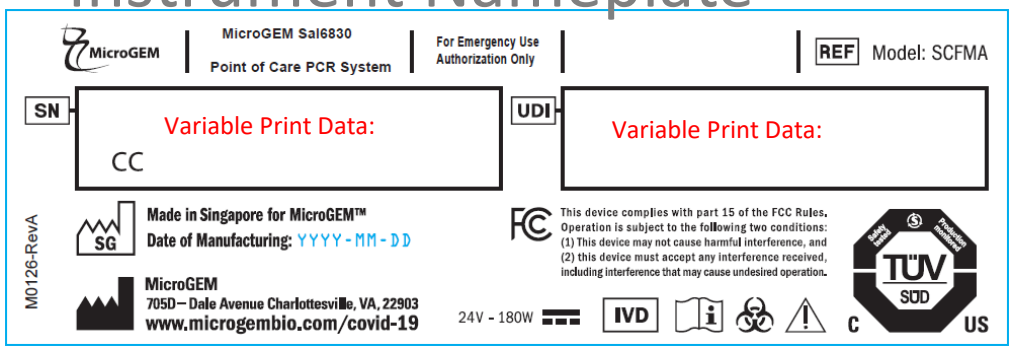
PN: M0243

PIC Card

PN: M0013

SAL6830 Label Set

Instrument Nameplate



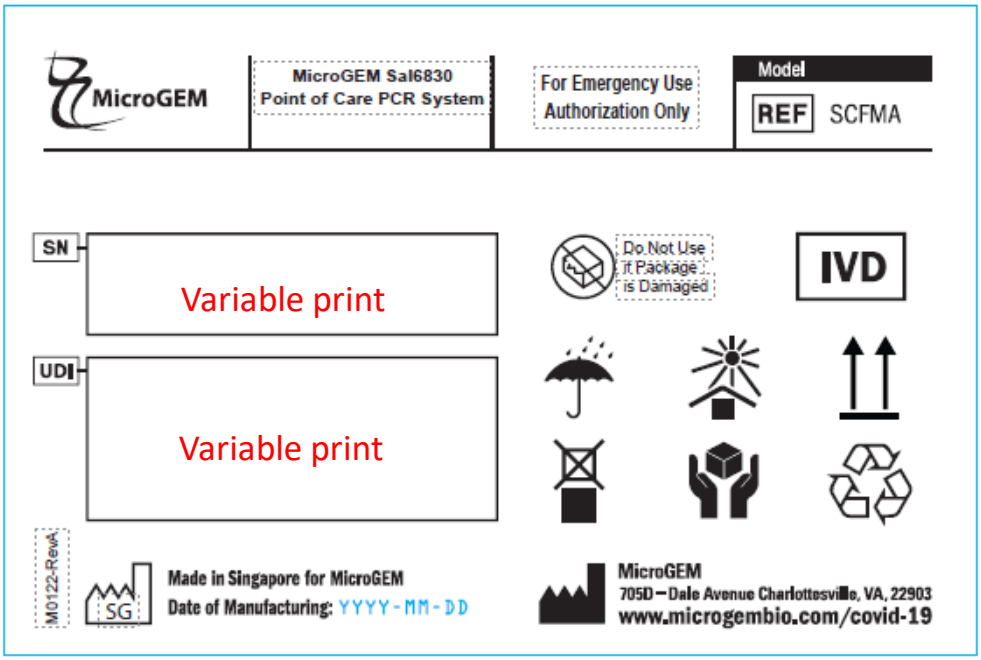
PN: M0126

Variable Print Data:

00874

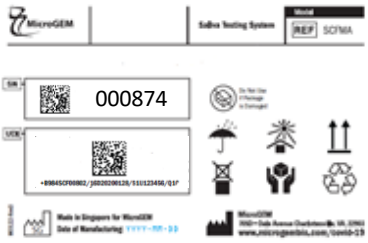
Variable Print Data:

Instrument Carton Label

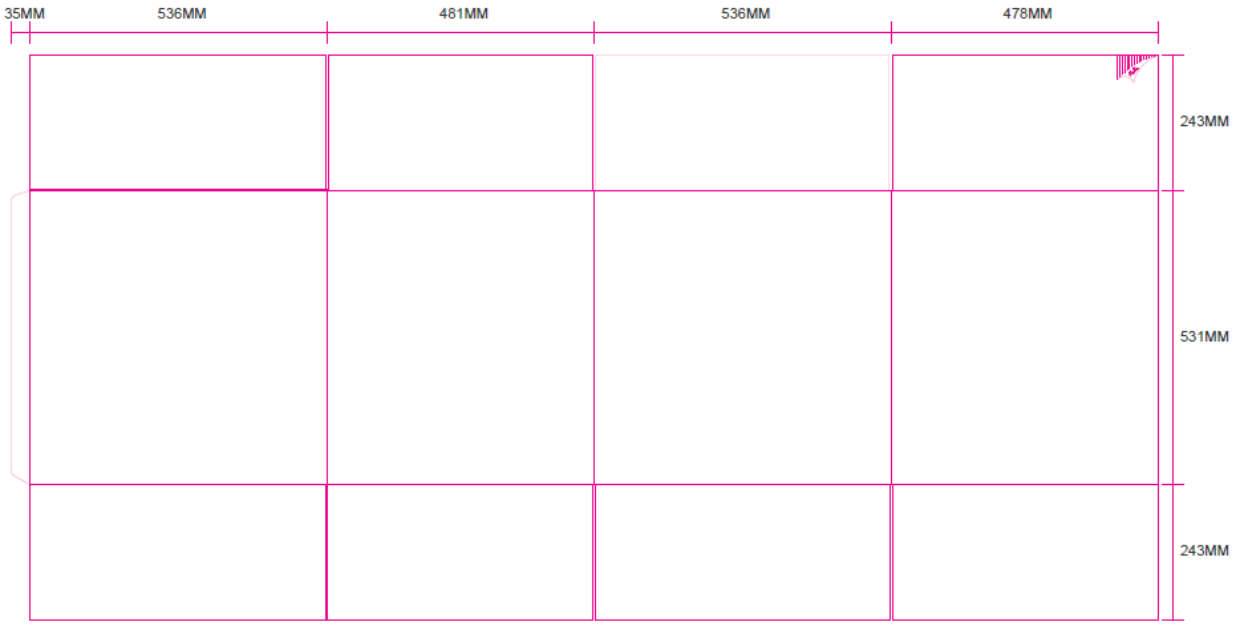


PN: M0122

Variable Print Data:



Instrument Box

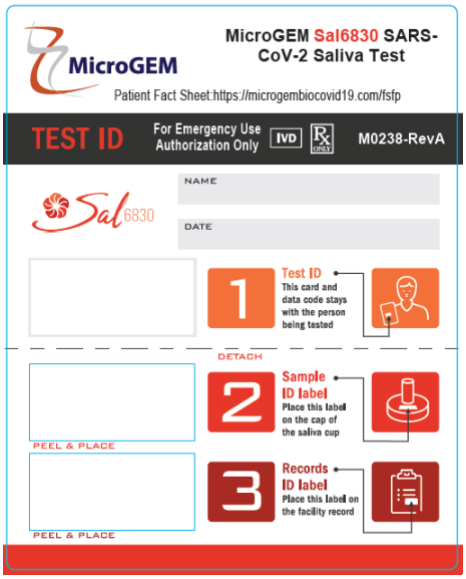


PN: M0110

MicroGEM

SAL6830 Label Set

Test ID Card

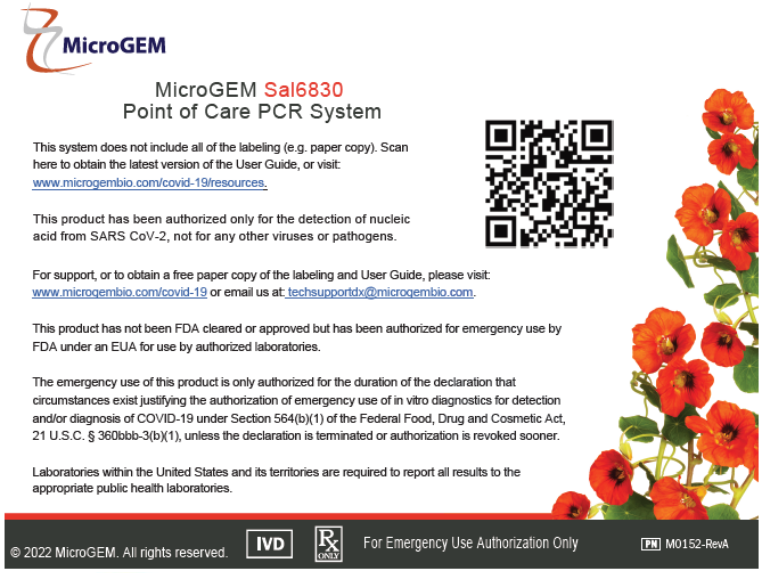


PN: M0238

MicroGEM

SAL6830 Label Set

System Quick Start Card



PN: M0152