

KN95 MASKS



Mask Specifications					
Outer Layer Dark PP non-woven fabric					
Middle Layer	PP anti-sticking melt blown fabric				
Inner Layer	PP non-woven fabric				
BFE	≥ 95%				
Style	Ear Loop				

Product	SKU	UPC	Product Dimensions	Packaging	Pieces Per Carton	Carton Dimensions	Carton Weight	Price	Remarks
KN95 Masks	KN95	860003871529	10.5 cm x 16.8 cm	400 pc/ctn (10 pc/box & 40 boxes/ctn)	400 pcs	32.5 cm x 44.5 cm x 30.5 cm	9 kg	\$1,320/carton (\$3.30/mask) MRLA Special Pricing \$780/carton (\$1.95/mask)	-FDA Registered -EN 149:2001 -FFP2 -GB 2626-2006

GenLife, LLC 16000 N 80th St, Suite C Scottsdale, AZ 85260

Payments Accepted Via – Credit Card (3% fee), Wire Transfer, ACH

Contact: Terry Dean <u>tdean@gbstumpp.com</u> 315-729-3525

GENLIFE does not directly or indirectly practice medicine or dispense medical services. GENLIFE assumes no liability for data contained or not contained herein.

The Centers for Medicare & Medicaid Services (CMS) is providing guidance to surveyors in regards to the authorization for emergency use of the Centers for Disease Control (CDC)'s 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel assay and the deployment into CDC qualified, and, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests). • Assays that have been issued an Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) remain subject CLIA regulations. • The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and the corresponding protocols have been developed by the CDC for use by CDC qualified laboratories and the assay has been issued an EUA from the FDA. • Upon receipt of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and corresponding Manufacturer's Instructions (MI), CDC qualified laboratories will verify assay performance specifications in their laboratory using an assay without an EUA that is testing for the same agent for which the emergency has been declared, or a modified EUA assay. The CMS Location will notify CMS Baltimore.



LEVEL II MASK



Mask Specifications						
Filter Layer	≥ 98% BFE					
Main Material	Non-woven fabric, melt-blown fabric, nore wire, earloops					
Moderate Fluid Resistance	120 mmHG					

Product	SKU	UPC	Product Dimensions	Packaging	Pieces Per Carton	Carton Dimensions	Carton Weight	Price	Remarks
Level II Mask	LVL2	860003871577	17.5 cm x 9.5 cm	50 pcs/box 20 boxes/ctn	1,000 pcs	53 cm x 40 cm x 44 cm	Gross: 11.48 kg Net: 9.75 kg	MRLA Special Pricing \$380/carton (\$0.38/mask)	-FDA Registered -ASTM Level II -Performance Standard: GB/T32610-2016

GenLife, LLC

16000 N 80th St, Suite C

Scottsdale, AZ 85260

Payments Accepted Via - Credit Card (3% fee), Wire Transfer, ACH

Contact: Terry Dean <u>tdean@gbstumpp.com</u> 315-729-3525

GENLIFE does not directly or indirectly practice medicine or dispense medical services. GENLIFE assumes no liability for data contained or not contained herein.

The Centers for Medicare & Medicaid Services (CMS) is providing guidance to surveyors in regards to the authorization for emergency use of the Centers for Disease Control (CDC)'s 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel assay and the deployment into CDC qualified, and, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests). • Assays that have been issued an Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) remain subject CLIA regulations. • The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and the corresponding protocols have been developed by the CDC for use by CDC qualified laboratories and the assay has been issued an EUA from the FDA. • Upon receipt of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and corresponding Manufacturer's Instructions (MI), CDC qualified laboratories will verify assay performance specifications in their laboratory per the manufacturer's instructions. • CMS is also providing guidance for surveyors to notify their CMS Location if they discover a laboratory using an assay without an EUA that is testing for the same agent for which the emergency has been declared, or a modified EUA assay. The CMS Location will notify CMS Baltimore.