USPS shipping solution



Shipping suspected SARS-CoV-2 (COVID-19) specimens for research or clinical testing under **Emergency Use Authorization** (EUA) by the US Food and Drug Administration (FDA) requires compliance with the US Department of Transportation (DOT), International Air Transport Association (IATA) and United States Postal Service (USPS) requirements.

DNA Genotek has a shipping solution that meets the **triple packaging** requirements for UN3373 Category B designated specimens.







Information contained herein is subject to change without notice and is based on guidelines provided from the DOT, IATA and USPS.

Primary receptacle

OMNIgene®•ORAL and ORAcollect®•RNA devices are available for the collection of potential SARS-CoV-2 (COVID-19) specimens. They are leakproof and capable of withstanding 95 kPa of pressure during transport.

Secondary packaging

The bio-specimen bag is leakproof with an absorbent pad and is marked with the universal biohazard symbol.

Rigid outer packaging

The shipping box is designed to withstand normal mailing conditions and contains the required UN3373 markings. Use it to ship a collection device to a patient AND return the specimen to the lab (2-way). Cushioning material included.



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Pre-collection Post-collection: minimum components required to ship SARS-CoV-2 (COVID-19) specimens for return by USPS Rigid outer packaging, bottom labeling: **Documentation for patient:** UN3373 markings on shipper bo plus USPS postal label Collection and return instructions, unique to each shipper. and contact label Primary This document must be provided receptacle: by shipper to USPS for UN3373 Collected shipping approval. specimen **Cushioning:** Bubble envelope Secondary packaging: Bio-specimen bag with absorbent pad Contact person's name Telephone number and biohazard symbol Rigid outer packaging: White shipper box (2-way) Approximate dimensions: 24.6 cm x 11.12 cm x 2.85 cm Person who has knowledge or incident mitigation information on the material being shipped. This information must be included on the waybill **Figure 1.** Representational image only or bill of lading, and on the outer packaging.

Checklist of USPS requirements

Based upon DNA Genotek's pre-approved mailing solution with USPS, the shipper shall provide the following documents to Product Classification, US Postal Service:

1. Patient collection and return instruction document (approved by FDA or IRB)	✓
A physical sample of the complete shipping solution (i.e., all of the components pictured in Figure 1 above)	✓
 CLIA certification and EUA from the FDA for a commercial company, or IRB approval for an academic research project (RUO) 	✓
Photographs of post-collection components for SARS-CoV-2 (COVID-19) suspected sample return	✓
5. Contact person's name and telephone number for UN3373 labeling requirements	✓



(Image for reference, not to scale)





OMNIgene® ORAL and ORAcollect® RNA are available for the collection of suspected SARS-CoV-2 (COVID-19) specimens.

For more information on our products and fulfillment services available to support your sample collection needs, contact your DNA Genotek Account Manager or info@dnagenotek.com.

Some DNA Genotek $\mbox{\em may}$ products may not be available in all geographic regions.

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