U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

September 25, 2020

Austin Udocor
Senior Manager
DNA Genotek
3000-5000 Palladium Drive
Ottawa, ON Canada K2V 1C2

Reference No. 20-0063

Dear Mr. Udocor:

This letter is in response to your August 13, 2020, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the exception for infectious substances in § 173.134(b)(11). You reference "Scenario 4" on pg. 7 of the Pipeline and Hazardous Materials Safety Administration (PHMSA) guidance document titled, "*Transporting Infectious Substances Safely*," and ask specifically whether saliva samples used for routine direct-to-customer genetic testing or research (e.g., ancestry or pharmacogenomics testing) would apply to the scenario. In addition, you ask whether this guidance is the most current with respect to shipping specimens.

Section 173.134(b) provides a listing of material that is not subject to the HMR as a Division 6.2 infectious substance. The exception provided in § 173.134(b)(11) specifically addresses human or animal samples (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis of an infectious disease. Such routine testing includes those for drug/alcohol, cholesterol, blood glucose level, prostate specific antibody, testing to monitor kidney or liver function, pregnancy, or tests for diagnosis of non-infectious diseases, such as cancer biopsies, and *for which there is a low probability the sample is infectious* (emphasis added). Based on the information you provided, it is our understanding that the saliva samples are transported for routine testing not related to the diagnosis of an infectious disease. However, in accordance with § 173.22 of the HMR, it is the shipper's responsibility to properly classify a material, and therefore, determine if the saliva samples are eligible or not for exception from regulations under the HMR.

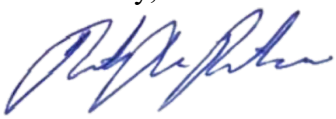
Furthermore, with respect to the guidance document, PHMSA revised and reissued "*Transporting Infectious Substances Safely"* in April 2020. It is our most current general guidance on transporting infectious substances under the HMR that is available on our website.

Please note that PHMSA has other useful information on the transportation of infectious substances at the following web link:

https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-overview

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,



Dirk Der Kinderen
Chief, Standards Development Branch
Standards and Rulemaking Division

Baker

20-0063

From: Foster, Glenn (PHMSA)
To: Dodd, Alice (PHMSA)
Cc: DerKinderen, Dirk (PHMSA); Kelley, Shane (PHMSA); Nickels, Matthew (PHMSA)
Subject: FW: Shipping of Saliva samples
Date: Friday, August 14, 2020 5:41:49 AM
Attachments: Transporting Infectious Substances Safely.pdf
image005.png
image006.png

Alice,

Please have the attached checked in as a request for a Letter of Interpretation and assign it to the next Specialist in the rotation. Please note in the file that John Heneghan would like to be notified when a response is issued.

Thanks,
Glenn

From: Heneghan, John (PHMSA)
Sent: Thursday, August 13, 2020 6:09 PM
To: austin.udocor@dnagenotek.com; INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>
Cc: Quade, William (PHMSA) <william.quade@dot.gov>; Kochman, Benjamin (PHMSA) <benjamin.kochman@dot.gov>; Schoonover, William (PHMSA) <william.schoonover@dot.gov>; Heneghan, John (PHMSA) <John.Heneghan@dot.gov>
Subject: FW: Shipping of Saliva samples

Austin,

As you are asking for a specific interpretation of the regulations, I am forwarding your question to our Office of Standards who will reply back to you in a timely manner.

We will be in touch.

Thanks

John

John P. Heneghan
Director, Southern Region
Office of Hazardous Materials Safety, Field Operations
Pipeline and Hazardous Materials Safety Administration
U.S. Department of Transportation
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Atlanta, Georgia 30303
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Linkedin: www.linkedin.com/in/johnheneghan

From: Austin Udocor [mailto:austin.udocor@dnagenotek.com]
Sent: Thursday, August 13, 2020 3:41 PM
To: Quade, William (PHMSA) <william.quade@dot.gov>; Kochman, Benjamin (PHMSA) <benjamin.kochman@dot.gov>; Schoonover, William (PHMSA) <william.schoonover@dot.gov>; Heneghan, John (PHMSA) <John.Heneghan@dot.gov>
Subject: Shipping of Saliva samples

Dear PHMSA Team,

I hope you are all doing well. Earlier this year, we discussed shipping of saliva samples for COVID-19 testing for a number of customers we were supporting.

We have a question with respect to the attached PHMSA Guidance, Scenario 4 on page 7. Specifically, do saliva samples used for routine direct to consumer genetic testing or research e.g. ancestry or pharmacogenomics testing fall under this category

Secondly, is this the most current guidance with respect to specimen shipping?

Any assistance you can provide will be helpful.

Many thanks for your response.

Austin

Austin Udocor | Senior Manager, Regulatory Affairs
DNA Genotek | **Superior Samples ● Proven Performance**
3000-500 Palladium Drive, Ottawa, ON Canada K2V 1C2
austin.udocor@dnagenotek.com | www.dnagenotek.com |
Toll-Free: 1-866-813-6354 x **2245** | Direct: 613-723-5757 x 2245 | Fax: 1-613-638-4628

From: Quade, William (PHMSA) [mailto:william.quade@dot.gov]
Sent: April 30, 2020 12:20 PM
To: Austin Udocor <austin.udocor@dnagenotek.com>; Kochman, Benjamin (PHMSA) <benjamin.kochman@dot.gov>; Schoonover, William (PHMSA) <william.schoonover@dot.gov>
Cc: tiffany@p23labs.com; Kasia Drozd <kasia.drozd@dnagenotek.com>
Subject: RE: [EUA200403] P23 Labs TaqPath SARS-CoV-2 Assay EUA

Austin,

Thank you for contacting us. We just want to make sure that the transportation requirements are going to be met. I will be forwarding you information to our team who will reach out this afternoon.

Thanks,

Bill Quade
Deputy Associate Administrator for Plans and Policy
USDOT, PHMSA
1200 New Jersey Ave, SE, Washington, DC 20590
Office: 202.366.6873 ⋄ Mobile: 202.510.8276

From: Austin Udocor [mailto:austin.udocor@dnagenotek.com]
Sent: Thursday, April 30, 2020 12:12 PM
To: Kochman, Benjamin (PHMSA) <benjamin.kochman@dot.gov>; Schoonover, William (PHMSA) <william.schoonover@dot.gov>; Quade, William (PHMSA) <william.quade@dot.gov>
Cc: tiffany@p23labs.com; Kasia Drozd <kasia.drozd@dnagenotek.com>
Subject: [EUA200403] P23 Labs TaqPath SARS-CoV-2 Assay EUA
Importance: High

Good Afternoon,

We hope you are doing well.

Our company DNA Genotek is supporting P23 Labs in the above referenced SARS-CoV-2 Assay Emergency Use Authorization application currently in FDA review. DNA Genotek is the manufacturer of the saliva collection devices. A description of the proposed assay is provided below for context. P23 Lab contact Dr. Tiffany Montgomery is copied on the email.

The FDA reviewer included the comments below and asking that we make you all aware. Please let us know if you have any questions or comments.

FDA reviewer comment:

"I wanted to bring the following to your attention. For your home or self collected saliva specimens under the supervision of a HCP that will be shipped to your laboratory for testing, we are now asking that you contact the Department of Transportation Pipeline and Hazardous Materials Safety Administration to make them aware that your product will be shipping coronavirus clinical samples. I am not sure if you or DNA Genotek would be responsible for contacting the Dept of Transportation. Can you please reach out to DNA Genotek and discuss?"
The contact are provided below:
Please email:
Kochman, Benjamin (PHMSA) <benjamin.kochman@dot.gov> Director of Governmental, International and Public Affairs
Schoonover, William (PHMSA) <william.schoonover@dot.gov> William Schoonover (Associate Administrator for Hazardous Materials Safety)
Quade, William (PHMSA) <william.quade@dot.gov> William Quade (Deputy Associate Administrator for Hazardous Materials Safety)."

Description of the proposed assay

The P23 Labs, TaqPath SARS-CoV-2 assay is a RT-PCR detection assay is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab and saliva specimens from individuals suspected of COVID-19 by their healthcare provider. Saliva Specimens have been validated for self-collection under the supervision of a health care professional (HCP) and professional collection by a HCP. Self-collection of saliva, under supervision of a trained HCP, will occur in the home, assisted living setting, at a doctor's office, or drive through collection site. All swab collections will be performed directly by a trained healthcare provider in the doctor's office or other appropriate setting. Specimens will be returned to the laboratory for testing within 24 hours of collection using same-day or overnight logistics services such as courier, FedEx, or UPS. Testing is limited to P23 Labs, LLC (P23), Little Rock, AR, that is Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratories.

The safety data sheet for the saliva collection device OMNIgene·ORAL OM-505 (DNA Genotek Inc) is attached. Please let us know if you have any questions or comments.

Best regards,

Austin

Austin Udocor | Senior Manager, Regulatory Affairs
DNA Genotek | **Superior Samples ● Proven Performance**
3000-500 Palladium Drive, Ottawa, ON Canada K2V 1C2
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Visit our blog, **The Genetic Link** at https://blog.dnagenotek.com