U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

JUL 31 2006

Mr. Nicholas Pagerly
Flight Operations Safety Officer
Manager, Specimen Packaging
Quest Diagnostics
159 Museum Road
Reading, PA 19605

Reference No. 06-0094

Dear Mr. Pagerly:

This is in response to your April 18, 2006 letter concerning how to classify patient specimens offered for transport by aircraft under the International Civil Aviation Organization Technical Instructions for the Transport of Dangerous Goods by Air (ICAO Technical Instructions) and § 171.11 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You state your company may not have the specific information needed to determine if there is a "minimal likelihood" a patient specimen is an infectious substance (Division 6.2). You ask whether your medical experts can assess, based on the types of tests your laboratories perform, if there is a "minimal likelihood" a patient specimen contains a Biological substance, Category A or Category B, or an Exempt human specimen.

The answer is yes. While some tests for the presence of an infectious agent may be requested for patient samples as a routine healthcare practice, a receiver of such a sample in the absence of specific information may use the types of tests requested by a medical professional for a patient sample as an indication of the professional's preliminary judgment of the patient's condition. We have based this opinion on the determination by health care specialists and scientist at the World Health Organization and the U.S. Department of Health and Human Services that the risk of infection during transportation from samples taken from apparently healthy patients and animals and transported for

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routine testing is extremely small. Conversely, if a human or animal sample is transported for other than routine testing when the testing is related to the diagnosis of an infectious disease and if there is reason to suspect that the sample is infectious, that sample is subject to the HMR.

I hope this information is helpful.

Sincerely,

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Edmonson
§ 173.134
Definitions & Exceptions
06-0094

Quest Diagnostics

April 18, 2006

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Manager, Specimen Packaging
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Dear Sirs,

Quest Diagnostics is considering the feasibility of applying the procedures outlined in the ICAO Technical Instructions as they pertain to the transport of infectious specimens pursuant to CFR 49 171.11. Accordingly, Quest Diagnostics is currently examining the possibility of making changes to the way in which it presently classifies patient specimens for transport.

During this examination a question has arisen regarding the definition of the term "minimal likelihood". In the ICAO Guidance Document it states that the determination of 'minimal likelihood" is dependant upon a "professional opinion" which is based upon the patient's medical record, exhibited symptoms and endemic local conditions to name but a few.

As a medical testing facility, we would not necessarily have this specific information when a patient specimen is received at the laboratory to be packaged for further transport. What we do know is what test the patient's physician has ordered. As such, it is our opinion that by having our medical experts examine each of the test types that Quest Diagnostics currently offers; and by building a list of which tests should be classified as Category A, Biological Substance, Category B, and Exempt Human Specimen, this would then constitute a "professional opinion" and thereby comply with the regulatory requirement to determine that a patient specimen has a "minimal likelihood" of harboring a potentially harmful pathogen.

Quest Diagnostics is requesting that the DOT consider our example and comment on the validity of our due diligence.

Sincerely,

Nicholas Pagerly