

## Certification of Non-Infectious Clinical Diagnostic Sample

This human, clinical specimen is being imported to benefit from unique laboratory testing available in the U.S. at Progene DX (CLIA License: 22D2259522). It does not require a CDC import permit as per CDC Import Permit Program (<https://www.cdc.gov/cpr/ipp/index.htm>) guidance with the following certification.

- 1 The material contained herein is human whole blood drawn into a PAXgene RNA blood tube. The PAXgene tube contains a chemical preservative/fixative to stabilize RNA to allow for subsequent analysis. The sample is drawn from a subject with an inflammatory disorder. The blood sample is then incubated in the preservative for a total of 4 hours, then its stored in a freezer until transported on dry ice to the Progene DX lab.
  - 2 This material is not known or suspected to contain an infectious biological agent. In addition, the PAXgene preservative has been shown to render viruses inactive after only 15 minutes incubation<sup>1</sup>, and also a 4 to 5 orders of magnitude reduction in bacteria after two hours<sup>2</sup>. This sample has been incubated for 4 hours with the fixative as well as subsequently frozen on dry ice. All viral and/or bacterial contamination would be rendered non-infectious. See references below.
- 1) Inactivation of Influenza A virus, Adenovirus, and Cytomegalovirus with PAXgene Tissue Fixative and Formalin. Marcel Kap, et al. *Biopreservation and Biobanking* 11(4):229-34. August 2013
  - 2) Pathogen Inactivating Properties and Increased Sensitivity in Molecular Diagnostics by PAXgene, a Novel Non-Crosslinking Tissue Fixative. Martina Loibner et al. *PLoS ONE* 11(3). March 2016.