USA CDC Requirements for the import of Biological Substances (human specimen samples)

There are two IATA classifications for human specimen samples

UN2814 Biological Substance Category A - infectious substance as in a form capable of causing permanent disability or life-threatening or fatal disease (Antrax, Ebola, Hendra, etc.) – Q2 Solutions does not meet the BSL requirements to import

UN3373 Biological Substance Category B – Known or reasonably believed to contain infectious substances and which do not meet the criteria for inclusion in Category A – includes non-infectious and infectious samples

A CDC import permit is required for the import of any infectious samples that fall under Category A or Category B

Q2 Solutions holds an import permit for a list of infectious substances/agents that fall under Category B. The CDC import permit is site specific; this means the permit is issued to the receiving lab based on the lab's BSL certification. This means the CDC permit issued to Valencia lab, can only be used to import samples consigned to Valencia. If the samples are consigned to Marietta, Durham, or to a 3rd party lab, the receiving lab must hold a CDC import permit listing the infectious substance/agent

For the import of Biological Substances known to be infectious, the commercial/proforma invoice must declare the name of the infectious substance/pathogen – such HIV, COVID-19, Hepatitis, etc. – and the copy of the CDC import permit should be presented

For the import of Biological Substances not known to be infectious, the commercial/proforma invoice must declare the sample is not known to contain an infectious biological agent and a CDC statement should be included declaring the sample is not known to contain an infectious agent, and it should declare how it is determined the samples are non-infectious