

WHO PIP Framework 2016 Review Recommendation

AdvaMedDx recommends that a new system be implemented for diagnostic manufacturers in which a one-time fee is collected at the time of access to PIP biological materials.

Influenza diagnostic manufacturers access and utilize PIP biological materials from the Global Influenza Surveillance and Response System (GISRS) primarily for validation purposes and not in the development of a diagnostic test, which means that the commercial value of access is substantially less than WHO may assume. The PIP Framework should recognize and reflect the differences in how manufacturers use the GISRS. Consideration should be given to the frequency, timing, and method in which the GISRS is used.

Diagnostic tests have been effective in the detection and diagnosis of influenza pathogens. The diagnostics industry is committed to continued investment in improved pandemic influenza diagnostic technologies and supports and contributes to the goal of enhancing global pandemic preparedness and response.