Why the Expiry Date of IVDs Can Be Extended?

The expiry date of *In Vitro* Diagnostics (IVD) products is determined based on stability testing under specified storage conditions. Stability data in the context of IVD refers to information collected during studies that assess the performance, quality, and characteristics of diagnostic products over time and under various storage conditions. Stability data is the foundation for determining the expiry date of IVD products. Stability testing, on the other hand, involves systematic studies that provide insights into the product's stability over time, helping manufacturers set an appropriate shelf life that ensures the product's reliability and accuracy for end-users.

However, under certain circumstances like disease outbreak, the expiry date of an IVD product may be extended to save lives. Nevertheless, it typically involves a rigorous assessment and validation process. There are several reasons why the expiry date of an IVD might be extended: -

a) Stability data verification by the manufacturer to obtain additional stability data that supports the continued performance and stability of the product beyond the initially determined shelf life. As such, a request for extension of the expiry data can be made. This data could be generated through on-going stability testing, accelerated stability studies, or other relevant studies.

b) Real-time stability studies involve monitoring of the products under actual storage conditions for an extended period. If these studies consistently demonstrate that the product remains stable and meets its specifications, regulatory authorities may consider extending the expiry date.

c) Regulatory approval from the regulatory authorities for any extension of the expiry date request submitted by manufacturers by providing robust scientific and stability data. Regulatory bodies will review the data and decide based on the product’s performance, safety and stability.

It is important to note that extending the expiry date of an IVD product is a regulated process, and any changes must be communicated and approved by relevant regulatory authorities. This ensures that the extended shelf life is supported by scientific evidence and that the product's safety and performance are maintained.

Medical Innovation Ventures Sdn. Bhd.(MEDIVEN) follow regulatory guidelines, consult with regulatory authorities and adhere to manufacturing standards of ISO 13485 when seeking an extension of the expiry date for ProDetect products. Additionally, MEDIVEN’s application specialists regularly communicate with healthcare professionals and end-users to ensure that the products are used within the revised expiry date for optimal performance, reliability and accuracy.