The importance of the reproducibility of scientific research cannot be overemphasized. Exact representation of all elements used in experiments is the precondition for reproducibility and is, more often than not, taken for granted by researchers. Misrepresented elements may cause harm by distorting initial research results as well as follow-up research efforts, which may potentially result in long term consequences.

Biowest guarantees compliance with the ethics code established by the serum industry along with all regulatory obligations. By controlling the entire collection and manufacturing processes as well as using state-of-the-art IT software, Biowest guarantees the accuracy of geographic origin and all other data stated on the Certificate of Analysis. Records are maintained on file for five years.

If inadvertently, representation or the description provided for a product turns out to be different than claimed on the COA, customers are promptly informed following ISO, ethical, and regulatory obligations.

Other companies less secure about the integrity of their supply chain resort to using Country of Origin verification by isotope fingerprinting. Biowest welcomes verification of the Country of Origin and all other analysis on the COA. However, verification must be based on samples selected directly from the product received by serum users. If based on supplier samples, then the verification is no more reliable than the representations/assumptions traditionally elaborated by suppliers. There is no substitute for controlling the supply chain.
Biowest was established in 1987 for the harvesting of serum in France. In 2004, when realizing it had been the victim of illegal practices by suppliers, Biowest referred the cases to authorities in the USA and EU. Biowest also took the initiative to promote the foundation of the serum industry association ISIA, which has the objective of promoting ethical behavior in the serum industry.

Biowest’s facility in France is ISO certified, ISO 9001: 2008 and ISO 13485: 2012. Frequently audited by French authorities as well as industrial and OEM customers from around the world, Biowest ensures quality control at every stage of the process and low intra-lot variation. Biowest is committed to the highest standards and guarantees quality, transparency, traceability, and a premium service.

Biowest guarantees the accuracy of geographic origin*, as well as all other data stated on the Certificate of Analysis. The “origin” of serum is defined as the country where the animals were slaughtered and the blood collected. This includes animals born and raised in the country of origin and animals imported for breeding purposes, fattening, or immediate slaughter. For example, “US origin” serum may come from cattle born in the US as well as cattle imported from Canada and Mexico. Similarly, “Mexico origin” serum may come from cattle born in Mexico as well as cattle imported from the US and Guatemala. Therefore, the “geographical purity” of serum coming only from animals born and raised in a specific country cannot be guaranteed. At the same time, there is no evidence that the geographic origin of serum influences the cell culture performance.

Invitation to Customer

Traceability is a component of ISO audits. Each batch of sterile serum is controlled internally beginning with the importation of raw serum through final filtration and labeling. Copies of all documentation are available in paper and electronic formats. Biowest invites customers to follow a bottle and batch of serum back to the abattoirs and countries from where the raw serum was collected, and confirm the harvesting of raw serum forward to the finished batch of sterile serum. We invite you to become familiar with Biowest’s certifications, traceability system, and integrated controls (QA SOPs, SAP) as part of a traceability audit.

*About geographic origin

For a comparison of the virus status of the major countries of origin of FBS, please refer to the attached article (Percy W. Hawkes) or click here.