Antibody Standardization to Benefit Biomedical Research

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Since the early studies of Emil von Behring and Kitasato Shibasaburo 125 years ago, describing the presence of neutralizing proteins in blood and their effectiveness in controlling infections (which led to the first serum treatment against diphtheria and tetanus), antibodies have been an essential component in biomedical research. Today, antibodies are important probes to identify cellular markers in basic science research, critical components in clinical diagnostics, and therapeutic agents in medicine. The knowledge we have acquired about antibodies over this time and the manufacture of monoclonal antibodies with unique epitope specificity have revolutionized biomedical research.

A recent feature in *Nature* emphasizes the importance of standardizing the use of antibodies to benefit all biomedical research by providing reproducible experimental results *(1)*. The emerging initiative proposing the development of well-defined antibodies for biomedical research is based on recent information regarding the high rate of failed validations for routinely used commercial antibodies and their investment costs across biomedical research, which are estimated to be around $800 million annually worldwide.

The standardization of antibodies that would allow scientists to use the same affinity reagent under identical experimental conditions requires the implementation of 4 crucial steps. (*a*) Phase out polyclonal antibodies, since only 0.5% to 5% bind to their intended target and functionality varies from batch to batch. (*b*) Define all binding antibodies according to their encoding sequence and promote the use of recombinant monoclonal antibodies made from reliable cell lines by isolating and incorporating their sequence genes into plasmid DNA, which are then transferred into cell lines or bacteria for the production of consistent reagents. The use of monoclonal antibodies by their universal sequence information ("bar code"), will allow researchers to use the same reagent for the same target in a standardized format. (*c*) Research publications and antibody manufacturers must provide detailed information regarding the specificity of the antibody as well as the experimental conditions for reproducibility. (*d*) Market forces should combine private and public funding efforts to reduce antibody standardization costs and increase efficiency.

To achieve global standardization of antibodies, scientists are calling for an international collaboration and a funding initiative to guarantee the required characterization. While we wait for these proposals to gain momentum, the important question at this moment is, how can we participate in this initiative from our own biomedical research fields? The answer is very simple: by providing accurate information on commercially used antibodies when publishing biomedical research studies (source of antibody, catalog number, clone, concentration, and experimental conditions) and by separating the good antibodies from the bad ones as the first and critical step toward reproducibility and effectiveness.

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Reference

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