Letters to the Editor

The Total Test Approach to Standardization of Immunohistochemistry

To the Editor—We read with great interest the excellent and much needed article by Clive Taylor, MD, PhD, on standardization of immunohistochemistry.1 In several parts of the article, Dr Taylor described the necessity to use immunohistochemistry in a cost-efficient manner, from the selection of antibodies applied to a specific tumor to the choice of an automated system.

With respect to cost-efficiency measures, we would like to add some thoughts concerning the existing guidelines and, more specifically, the potential decision to approve the use of reagents beyond the manufacturers’ recommended expiration dates. A previous study sponsored by the College of American Pathologists Cell Markers Committee, based on results from 221 laboratories performing staining protocols with 4 different antibodies, recommended a ruling on extending the useful reagent shelf life of antibodies.2 Motivated by the same idea, we performed a study evaluating 65 primary antibodies for performance at various times after the manufacturers’ expiration dates. These times ranged from 6 to 131 months postexpiration (mean 32.7 months). Similar to the study reported by Tubbs et al,3 we found overwhelming evidence that “expired” antibodies perform satisfactorily. These results indicate that instead of a mechanical adherence to the manufacturers’ recommendations, a rational quality assurance system would be preferable.

The setting of guidelines by the regulating entities such as the Health Care Financing Administration are absolutely necessary to assure the best possible quality of service by medical laboratories. These regulations are particularly useful in the application of newer methods, and without any doubt have been of crucial importance for the rational development and appropriate use of immunohistochemical stains. On the other hand, with the significant financial strains that medical institutions and particularly academic centers have suffered in recent years due to the reorganization of health care financing and the increasing restrictions for reimbursement from insurance companies, it may be time to re-evaluate some of the established guidelines in order to avoid unnecessary expenses. It is a fact that depending on the size of an immunohistochemistry laboratory, antibodies costing several hundreds or thousands of dollars are discarded unnecessarily every month. The excellent guidelines for quality assurance that have been provided by the regulating organizations, such as the College of American Pathologists, have been generally accepted and are widely practiced in immunohistochemistry laboratories. The application of these guidelines to the issue of expiration dates for primary antibodies could continue to assure the best results while at the same time provide for the rational use of resources.


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In Reply.—The letter by Drachenberg et al is exactly the type of dialogue that pathologists must initiate to ensure proper utilization of immunohistochemical testing. The importance of this issue is emphasized further by the expectation of continuing increases in demand for immunohistochemistry, as well as a rapid growth of in situ hybridization and related molecular methods as applied to tissue sections. These latter methods are directly comparable to immunohistochemistry and will require analogous attention to issues of reproducibility and quality control.

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