Use of archived specimens in biomarker studies

October 8 2009

Researchers propose a more efficient system using archived specimens for the evaluation of prognostic and predictive biomarkers in a new commentary published online October 8 in the *Journal of the National Cancer Institute*.

The introduction of new biomarkers into routine use in clinical laboratories has been limited partly because of a shortage of prospective studies of marker utility, a lack of reproducibility and reliability among retrospective studies, and low insurance reimbursements for tumor marker tests. In the case of biomarkers for guiding the use of already approved drugs, new prospective studies are sometimes not possible.

Richard M. Simon, DSc, of the Biometric Research Branch at the National Cancer Institute in Bethesda, Md., and colleagues discuss more efficient ways for indirectly testing biomarkers using archived patient tissue specimens, arguing they can be of "great importance for establishing a medical utility of a prognostic or predictive biomarker."

The researchers discuss four conditions that are necessary for this procedure to be useful, which include that representative and sufficient patient samples be available from pivotal clinical trials; biomarker assays be previously validated for use with archived specimens; the strategy for focused analysis of a single marker be fully planned before biomarker evaluation begins; and that results are validated using patient samples from at least one additional clinical trial.

"It is essential to ensure that cancer patients are offered the ben¬efits of valuable prognostic and predictive tests as soon as they are rigorously and reliably evaluated," the authors write. "In this article, we have tried to…propose an update of a level of evidence schema that has been widely used for evalu¬ating… biomarkers in oncology."

Source: Journal of the National Cancer Institute (news : web)