American Diabetes Association.

May 15, 2015

To manufacturers of assays for the quantitation of human C-peptide:

I am writing to inform you that the American Diabetes Association supports the efforts to regulate human C-peptide assays through the C-Peptide Standardization Program. As you know, C-peptide is an important outcome measure used to assess beta cell function and is being used in ongoing trials of subjects with type 1 diabetes designed to assess therapeutic and potential prevention strategies. In this context standardization of C-peptide results is vital to facilitate meta-analyses across multiple trials. A C-peptide measurement is already required by CMS before a patient can be approved for insulin pump therapy. And as we move to greater degrees of personalized medicine, assessment of C-peptide reserve may become a predictor of response to therapy in type 2 diabetes.

Recognizing the increasing importance of C-peptide as a unique clinical tool, the NIDDK established a C-peptide standardization committee in 2002. Since that time international comparison studies have shown the feasibility of standardizing C-peptide assays to a common reference using serum-based materials, two reference laboratories have been established and validated, and a standardization plan has been developed by the Committee. The reference method is now listed in the Joint Committee on Traceability in Laboratory Medicine (JCTLM) database, meaning that manufacturers should now be able to initiate the process of standardizing their C-peptide methods to the established reference method.

Your ongoing cooperation has played a vital role in these efforts to establish the feasibility of assay standardization. We understand that there are internal documentation and validation processes that need to be completed and regulatory issues that need to be addressed. Understanding these constraints, we strongly urge manufacturers to begin that process, with the goal of achieving universal C-peptide standardization as soon as possible. We intend to insist on use of these standardized assays in any research projects we fund moving forward, and critically reviewing submitted manuscripts failing to utilize standardized assays. We greatly appreciate your attention to this matter; if you have any questions or concerns feel free to contact me at any time.

Sincerely yours,

Robert E. Ratner, MD
Chief Scientific and Medical Officer
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