

July 3, 2020

Notification RE: Pyrochrome® Kinetic Chromogenic Method with E0005 – Certificate of Analysis

Dear Valued Customer:

You are receiving this notification as a customer of record for one of our Pyrochrome® products. Catalog #'s: C1500-5, C1500-25, CG1500-5, CG1500-25

Last year, Associates of Cape Cod, Inc. (ACC) reformatted our certificates by combining both the Certificate of Analysis (C of A) and the Certificate of Compliance (C of C) into one Certificate of Analysis (C of A) document. A notification regarding this change was sent out March 12, 2019. This change included the addition of Mean onset time (seconds) for the lowest CSE standard concentration. Prior to this change, the Certificate of Compliance (C of C) stated the Onset times for RSE standard series at release and as such was a separate document. The onset time for the lowest standard is typically used to gauge the appropriate runtime for the assay.

After reviewing the practical use and feedback on the reformatted C of A, ACC has decided to modify the C of A even further in an effort to align the information provided on the C of A and to continue to provide information for which customers were already accustomed. The new C of A version, going forward, will list Mean Onset Time (seconds) for the lowest RSE concentration as obtained from the potency assay.

The Mean onset time of the CSE concentration is listed as a reference only for use in determining an appropriate incubation time. The mean onset time for the lowest CSE concentration will be reported for 0.0016 ng/mL concentration from the potency assay which is listed immediately following the Valid range of potency. Valid range of potency describes the RSE standard curve range (i.e. 0.001 - 10 EU/mL or 0.005 – 50 EU/mL) used on the potency assay. Therefore, the CSE concentration in "Mean onset time for the lowest CSE standard concentration" does not equal to the lowest RSE standard concentration listed in the Valid range of potency and as such may be confusing to our customers.

The new version of the C of A aligns the Mean Onset Time value with the Valid range of potency which is also what our customers are accustomed to seeing. There is no impact associated with your use of the CSE due to the fact that the onset time is intended to provide guidance only.

The Certificate of Analysis (C of A) is and will remain available for download from our corporate website utilizing the following link: <http://www.acciusa.com/pageCOA.php>.

We appreciate your business, and will continue to provide you with leading endotoxin and glucan detection products and services to meet your current and future needs.

Sincerely,



Vann Jones
Senior Manager, Marketing