

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-13-2

February 11, 2013

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Charm Sciences, Inc. EZ Reader

Charm Sciences has developed a new lateral flow test reader, the EZ Reader, to eventually replace the Charm Pearl Reader. However, Charm Sciences, Inc. will continue sales and support for the Pearl Reader for a period of time. The EZ Reader can be used in a “read only” mode using a separate heater block(s), or in an “incubate and read” mode using a built in heater block. In either mode, it recognizes the test being read and in the “incubate and read” mode it automatically adjusts to the correct temperature and incubation time. The EZ Reader uses the same optic system and line integration as the existing Pearl Reader.

Charm Sciences, Inc. has validated the EZ Reader and has demonstrated that its performance is equivalent to the current Pearl Reader. In their study, full dose response curves were developed in a blinded study for all drugs measured using the Charm SL Beta-Lactam Test (9C13). Thirty (30) tests were conducted at each concentration, 20, 40, 60, 80, and 100% of tolerance/safe level and concurrently tested using a Pearl Reader. Additional experiments were conducted comparing the results of other National Conference on Interstate Milk Shipments (NCIMS) approved tests read by the Pearl Reader in the “read only” mode, including the Charm 3 SL3 Beta-Lactam Test (9C15) and the Charm FLUSLBL Flunixin and Beta-Lactam Test (9C16). All three (3) NCIMS approved tests were also tested using the EZ Reader “incubate and read” mode and then measured using a Pearl Reader.

In this study, the performance of the EZ Reader was equivalent to that of the Pearl Reader. In all tests, the two (2) readers produced equivalent results. Significant differences were not observed in any of the comparison tests between the two (2) readers. The data generated by Charm Sciences, Inc. demonstrate that the two (2) readers both produce acceptable results.

The EZ Reader was also evaluated by FDA, Center for Food Safety and Applied Nutrition's (CFSAN) Laboratory Proficiency and Evaluation Team (LPET), and the performance was determined to be acceptable. The printout of the new EZ Reader meets NCIMS guidelines.

Charm Sciences, Inc. has demonstrated that the EZ Reader is an acceptable substitute for the Pearl Reader. Based upon our review of the EZ Reader, FDA recommends that the EZ Reader can be used in place of the Pearl Reader for use with the NCIMS approved Charm SL Beta-Lactam Test (9C13), Charm 3 SL3 Beta-Lactam Test (9C15) and the Charm FLUSLBL Flunixin and Beta-Lactam Test (9C16) for regulatory testing.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Milk Regulatory Agencies, Milk Rating Agencies, Laboratory Evaluation Officers and Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to robert.hennes@fda.hhs.gov.

A handwritten signature in black ink, appearing to read "Robert Hennes", is centered on the page.

Robert F. Hennes, RS, MPH
CAPT U.S. Public Health Service
Dairy and Egg Branch