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M-I-02-3

January 31, 2002

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

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Idexx Snapshot Reader

IDEXX Laboratories, Inc. has developed a new reader, called the Snapshot Reader, for use with the Snap BL test kit. This is a replacement for the current Snap Image Reader, which is no longer being manufactured.

The new Snapshot reader has been validated by IDEXX Laboratories, Inc. to demonstrate that its performance is equivalent to the current image reader. The study protocol was designed with oversight by the Food and Drug Administration (FDA), Center for Veterinary Medicine's Office of Research (CVM OR). In the study, penicillin G was added to milk to give concentrations of one (1), four (4), ten (10), and 100 ppb. Fifteen (15) Snap BL tests were done at each concentration and fifteen (15) tests were done on control milk. Each test was measured using five (5) Snapshot Readers and five (5) Snap Image Readers.

The performance of the Snapshot Reader was equivalent to that of the Snap Image Reader. No statistical difference was observed in the performance of the two (2) readers when measuring the ratios of Snap BL test kit devices exposed to control milk or milk fortified with one (1), four (4), or ten (10) ppb penicillin G. However, the Snapshot Reader gave slightly lower ratios for the milk fortified at 100 ppb. The slight deviation of the performance of the two (2) readers at 100 ppb does not affect the ability of the snapshot reader to distinguish between positive and negative samples. As this difference will not cause erroneous results, it was judged not to be significant by FDA.

The reader was evaluated at FDA, Center for Food Safety and Applied Nutrition's Laboratory Quality Assurance Branch (CFSAN LQAB), and the performance was judged to be acceptable. Both CVM OR and CFSAN LQAB reviewed the manual for the Snapshot Reader and found it acceptable. The printout of the new Snapshot Reader meets the National Conference on Interstate Milk Shipment's (NCIMS) guidelines.

IDEXX Laboratories, Inc. has demonstrated that the Snapshot Reader is an acceptable substitute for the Snap Image Reader. Based upon our review of the Snapshot Reader, FDA recommends that the Snapshot Reader can be used in place of the Snap Image Reader for use with the Snap BL test kit in regulatory testing.

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Milk Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. This memorandum will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date and should be widely distributed to representatives of the dairy industry and other interested parties.

Robert F. Hennes, RS, MPH
Chief, Milk Safety Branch

Attachment (Page 3)

Snapshot™



READER

BETA LACTAM

PENICILLIN G AMOXICILLIN AMPICILLIN CEFTIOFUR CEPHAPIRIN

TETRACYCLINE

TETRACYCLINE CHLORTETRACYCLINE OXYTETRACYCLINE

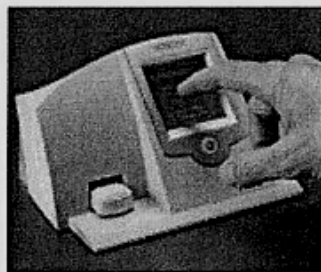
EASY

results at your fingertips

SIMPLE: Touch-screen interface makes data entry fast and easy

CONVENIENT: Smaller foot print frees up bench space

INNOVATIVE: Leading-edge imaging technology ensures easy, accurate reading



TOUCH-SCREEN TECHNOLOGY

The Snapshot Reader is the first residue testing instrument to employ touch-screen technology, which means:

- The easy, self-directing menu guides you through the process step-by-step
- Training time is significantly reduced
- Test results appear within minutes at your fingertips

PRINT OUT

Clear, concise hard-copy results meet regulatory requirements. The Snapshot reader printout displays:

- Name of test kit
- Technician and sample IDs
- Results ratio
- Positive/negative result
- Date and time
- Lot number

IDEXX

INNOVATORS IN RESIDUE TESTING

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