



CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 15-02

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010
(515) 337-6100

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron Rippke
Director

**BYRON
RIPPKE**

Digitally signed by BYRON RIPPKE
DN: c=US, o=U.S. Government,
ou=Department of Agriculture,
cn=BYRON RIPPKE,
0.9.2342.19200300.100.1.1=12001000
004093
Date: 2015.03.06 07:14:11 -06'00'

SUBJECT: Recognized ISO 15223-1 Symbols on Labeling for Diagnostic Test Kits

I. PURPOSE

This Notice describes symbols that may be used on labeling for diagnostic test kits.

II. BACKGROUND

Requirements for the information that must be included on final container labels, carton labels, and product enclosures are specified in Title 9, *Code of Federal Regulations* (9 CFR), Part 112.2. This regulation does not address the use of symbols, rather than text, in the labeling. Symbols are increasingly used, can be helpful to manufacturers selling kits abroad, and are included in several national and international standards concerning product labeling, including standards endorsed by the United States.

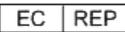
III. POLICY

The Center for Veterinary Biologics has expanded the use of specified ANSI/AAMI/ISO 15223-1:2012 symbols for the labeling of diagnostic test kits in situations where the use of text is not practical. When these symbols are used, an explanatory key must be included in the product enclosure (insert or circular). For multi-language labels, the explanatory key must include all languages that are used in the labeling. The CVB will allow the use of the following symbols:

Symbol	Used for	Reference
	Use by (expiration date)	9 CFR 112.2(a)(9)(i)
	Batch code (component Lot Number); this may be used on kit component containers only	Veterinary Services Memorandum 800.73, Section VII.D

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 15-02

Page 2

Symbol	Used for	Reference
	Serial number; this must be used on the box (carton), not the Lot Number symbol	9 CFR 112.2(a)(9)(iv)
	Authorized representative in the European Community (European distributor)	9 CFR 112.4(c)
	Manufacturer (name and address of licensee and subsidiary or permittee and foreign producer)	9 CFR 112.2(a)(2)
	Date of manufacture (fill date)	
	Temperature limitations (e.g., storage temperature range)	9 CFR 112.(a)(4)
	Upper limit of temperature	
	Lower limit of temperature	
	Consult instructions for use	9 CFR 112.2(a)(5)
	Information added or changed since last version	
	Caution, consult accompanying documents	9 CFR 112.2(a)(5)
	<i>In vitro</i> diagnostic medical device	
	Positive control	
	Negative control	
	Catalog number	
	Contains sufficient for < n > tests	9 CFR 112.2(a)(9)

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 15-02

Page 3

Symbol	Used for	Reference
	Do not reuse	
	Keep away from sunlight	
	This side up	
	Keep dry	

Firms may propose the use of additional symbols, with appropriate justification.

IV. References

ANSI/AAMI/ISO 15223-1:2012, *Symbols to be used with medical device labels, labeling and information to be supplied*

ASTM D5445-11a (ISO 780), *Standard practice for pictorial markings for handling of goods*

V. IMPLEMENTATION/APPLICABILITY

This change is applicable to the labeling of diagnostic test kits only and is effective as of the date of this Notice.