

Nissui Compact Dry X-SA Granted PTM Status

Nissui Pharmaceutical Co., Ltd.

Compact Dry X-SA

PTM Status: August 9, 2010

Certificate No.: 081001

Cat. Nos.: 067292 (40 plates) and

067302 (240 plates)

Staphylococcus aureus is a major foodborne pathogen that produces several kinds of heat-stable enterotoxins. Thus, it causes health problems worldwide, and patients experience nausea, vomiting, diarrhea, and abdominal pains after the consumption of contaminated foods. The control of contamination by *S. aureus* is an important issue for manufacturers in food processing and distribution facilities. Several new techniques for enumeration of *S. aureus* have been developed and validated as a suitable alternative to conventional methods. In daily hygiene control, troublesome operations, including preparation of the media, require time and thereby raises labor costs. Consequently, the Compact Dry X-SA (Figure 1), a ready-to-use and self-diffusible dry medium sheet culture system, has been developed by Nissui Pharmaceutical Co., Ltd., for enumerating *S. aureus* in food.

Summary of Validated Claims

The validation studies were conducted under the AOAC Research Institute (RI)-MicroVal joint validation program. The Compact Dry X-SA plates were validated as an analytical tool for determining the colony-forming unit (CFU) of *S. aureus* from a variety of foods. Therefore, the method was compared with EN ISO 6888-1:1999 in cooked sliced ham (meat products), frozen prawns (fish and seafood), raw cow's milk (dairy products), cakes and pastries made with fresh cream (bakery products), and chilled fresh pasta



Figure 1. Compact Dry X-SA.

(other products) by Campden BRI in the United Kingdom under the direction of the AOACRI. For Compact Dry X-SA, $37 \pm 1^\circ\text{C}$ is the recommended temperature and also the standard method for the defined conditions. Thus, the performance tests were conducted at 37°C . In all studies, no apparent differences between the Compact Dry X-SA method and EN ISO 6888-1:1999 results were observed. For the claim of inclusivity and exclusivity, the results observed were 100% (32 *S. aureus* strains) and 100% (23 non-*S. aureus* strains), respectively. For the accuracy claim, correlation of the enumeration method was confirmed. For each food matrix sample data, a correlation factor of $r^2 = 0.993$ (cooked sliced ham), 0.987 (frozen prawns), 0.993 (raw cow's milk), 0.994 (cakes and pastries made with fresh cream), and 0.986 (chilled fresh pasta) could be assigned respectively, as stated in the application for the Performance Tested MethodSM (PTM) program (Table 1). The Compact Dry X-SA plate can be used for the enumeration of *S. aureus* counts for a broad spectrum of foods, but due to microbial physiology, the recommended optimized incubation parameters of fixed temperature and a period of 24 hours should be

kept constant. The consistency in quality and storage robustness of the dehydrated film plates was demonstrated by Nissui Pharmaceutical Co., Ltd., according to the validation program. No significant differences in *S. aureus* counts were observed with different production lots or plates of diverse storage age (three lots; expiry before 17, 6, and 0 months). A sample volume deviation from 0.95 to 1.05 mL and an incubation temperature deviation from 33 to 37°C can be tolerated. The colony counts were equivalent between the whole plate count and the grid-based count (1×1 cm count $\times 20$ and 0.5×0.5 cm count $\times 80$).

Features of Compact Dry X-SA

The Compact Dry X-SA is designed to be a compact plate that needs only a small physical space for storing, testing, and incubating. The Compact Dry X-SA is portable, presterilized, and ready to use; there is no need to prepare medium, which also reduces labor and waste of the medium. In particular, the Compact Dry X-SA is good for emergencies and field tests. The system of Compact Dry X-SA makes liquid samples spread automatically and evenly into the plate (there is no need to spread the sample onto the medium after sampling). The Compact Dry X-SA has 1 1/2 years of shelf life at room temperature. Once a liquid sample is inoculated, the dry coated medium transforms into a gel, and the plate is ready to incubate immediately. After incubation for 24 hours at 37°C , the colonies on the Compact Dry X-SA are visible so the results are easy to read because of

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TABLE 1. RELATIVE ACCURACY RELATIONSHIP BETWEEN THE COMPACT DRY X-SA METHOD AND EN ISO 6888-1:1999

Sample	Regression equation	Correlation coefficient (r^2)
Cooked ham (meat products)	$y = 0.552 + 1.085x$	0.993
Prawns (fish and seafood)	$y = 0.103 + 0.990x$	0.987
Milk (dairy products)	$y = 0.129 + 0.955x$	0.993
Cake (bakery products)	$y = 0.310 + 1.039x$	0.994
Pasta (other products)	$y = 0.723 + 1.112x$	0.986

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the light blue/blue color development by the specific enzyme substrate. Isolated colonies on the Compact Dry X-SA can be subcultured individually to other media for confirmation or preservation. No apparent differences between the Compact Dry X-SA and EN ISO 6888-1:1999 method led to certification by the AOACRI.

Conclusions

The Compact Dry X-SA received AOACRI PTM certification on August 9, 2010. The AOAC RI-MicroVal joint validation program proposed Campden BRI as the expert laboratory for comparison of the performance of the Compact Dry X-SA to that of the EN ISO 6888-1:1999 method for the enumeration of *S. aureus* colony counts. The data showed that these two methods performed equally well. Therefore, the Compact Dry X-SA

is a convenient alternative method for daily *S. aureus* control of foods.

The major advantages of the Compact Dry X-SA system are the reduced operation time and economical use, as confirmed by an independent laboratory. In terms of plate preparation, inoculation, and reading of the results, the Compact Dry X-SA system was easier and quicker than the conventional spread plate technique. The specific enzyme substrate containing the Compact Dry X-SA makes reading the plate easier because of the light blue/blue color development. In case food debris mixes into the Compact Dry X-SA, it could be distinguished from *S. aureus* colonies. Instructions on the use of the Compact Dry X-SA are clear and unambiguous. The Compact Dry X-SA system also has the advantages of reducing the storage space, waste dis-

posal, and required incubator space. The long shelf life of the Compact Dry X-SA also has benefits compared to ready-prepared agar, which has a limited shelf life and needs refrigeration.

This test kit method was reviewed under the AOACRI's PTM-MicroVal joint validation program and found to perform as stated by the manufacturer. ■

—Hajime Teramura
Contributing Writer
h-teramura@yki.nissui-pharm.jp

Mention of trade names or commercial products is for identification only and does not constitute preference over similar ones not mentioned. If you are interested in submitting an article regarding a test kit that has been granted Performance Tested MethodSM status, contact Zerlinde Johnson at zjohnson@aoac.org.