



Stability and Storage of mastdiscs® AST, Supplements and Dehydrated Culture Media

MAST® has been manufacturing antibiotic containing susceptibility test discs (**mast**discs® *AST*), freeze dried supplements (Selectavials and Selectatabs) and dehydrated culture media for many years and shipping them to all parts of the world.

All MAST® products are manufactured in accordance with a certified ISO 13485 quality system that covers design, manufacture and supply of *in vitro* diagnostic laboratory products. MAST® conducts long term stability tests to ensure that the performance of the product remains within specified tolerance, under recommended storage conditions over the period between manufacture and stated expiry date. Studies are based on "Real Time" testing of retained product samples of the same material formulation, container and closure system as utilized in products supplied to the customer.

Product dossiers include evidence of stability testing which indicates that **mast**discs[®] *AST*, freeze dried supplements and dehydrated culture media suffer no significant loss of potency at ambient temperature for short periods.

MAST® has conducted studies as part of the ISO 13485 quality system to determine what length of time, and what shipping conditions must prevail, to verify that product specifications and performance are maintained. This verification is based on both simulated conditions and real shipping conditions. Conditions were selected which would not impose excessive fees for special shipping and handling requirements.

MAST[®]'s policy is based on shipping products at ambient temperature but ensuring they arrive at the destination within a maximum of 7 days. However as stated on MAST[®] delivery notes and company invoices, these products should be stored immediately on arrival at their destination, according to labelled specifications – usually refrigerated at 2-8°C for discs and supplements and room temperature for dehydrated culture media. Provided this happens the products should, if used correctly, perform to specification until their stated expiry date.

MAST[®] can make no warranties, expressed or implied, and assume no liability in connection with shipping conditions, manner of storage and incorrect product usage, which may occur or be outside MAST[®]'s control.

J A HOBSON LABORATORY MANAGER