

**MASTALEX™**

**VALIDATION**



**MASTALEX™ - MRSA Validation**

<b>Mast product name</b>	MASTALEX™ - MRSA
<b>Mast product code</b>	RST501

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## Section 1 - General description of the product and intended use

Product name	MASTALEX™ MRSA
Catalogue number:	RST501
Manufacturer:	Mast Group Ltd., Mast House, Derby Road, Bootle, Liverpool, Merseyside. L20 1EA. UK.
Product description:	<p>The MASTALEX™ MRSA kit contains the following components:</p> <ol style="list-style-type: none"> <li>1. Extraction Reagent 1 (Green Coloured Cap). Ready to use. 1 x 10ml of 0.1M sodium hydroxide.</li> <li>2. Extraction Reagent 2 (Yellow Coloured Cap). Ready to use. 1 x 2.4ml of 0.5M potassium dihydrogen phosphate.</li> <li>3. Test Latex (Red Coloured Cap). Ready to use. 1 x 1.2ml of latex particles sensitised with anti-PBP2' monoclonal antibodies.</li> <li>4. Control Latex (White Coloured Cap). Ready to use. 1 x 1.2ml of unsensitised latex particles.</li> <li>5. 100 single use disposable mixing sticks.</li> <li>6. 1 pack of 24 four-well reaction cards.</li> <li>7. Instructions leaflet.</li> </ol>
Intended purpose:	The MASTALEX™ MRSA kit is a rapid slide latex test for the detection of penicillin binding protein 2' and the confirmation of Methicillin Resistant <i>Staphylococcus aureus</i> .
Intended user:	Trained laboratory technical staff.
Additional accessories:	Standard microbiological supplies and equipment such as agar plates, standard 5µl loops or sterile disposable microbiological loop (internal volume 1.5µl), boiling water bath or heating block, microfuge or bench centrifuge, small tubes and pipettes.

## Section 2 – Quality Control acceptance criteria

Method:	Quality Control tests performed according to the method given in Mast Instructions for use on the stated organisms.		
Results criteria:	Positive	Agglutination on test latex, no agglutination on control latex	
	Negative	No agglutination on either test or control latex	
	<i>Staphylococcus aureus</i> ATCC® 33591 (MRSA)	<i>Staphylococcus aureus</i> ATCC® 25923	
	Test Latex - Agglutination Control Latex - No agglutination	Test Latex - No agglutination Control Latex - No agglutination	

Note: ATCC® is a trademark of the American Type Culture Collection, Manassas, Virginia, USA.

### Representative batch performance data

Microbiological performance			
Organism	Expected performance	Actual response	
		Lot 960321 Exp. 1997-03	Lot 960318 Exp. 1997-03
<i>Staphylococcus aureus</i> ATCC® 33591 (MRSA)	Test Latex – Agglutination Control Latex - No agglutination	Test Latex – Agglutination Control Latex - No agglutination	Test Latex – Agglutination Control Latex - No agglutination
<i>Staphylococcus aureus</i> ATCC® 25923	Test Latex - No agglutination Control Latex - No agglutination	Test Latex - No agglutination Control Latex - No agglutination	Test Latex - No agglutination Control Latex - No agglutination

### Section 3 - Results of stability and transit studies

#### Stability Protocol

Long term stability tests are undertaken to ensure that the performance of the product remains within specified tolerances, 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 utilised in products supplied to the customer.

Performance tests were carried out on the batches listed below to establish product stability when stored at 2°C to 8°C. Prior to testing each component was allowed to warm up to room temperature and tested in the approved manner.

Mastalex™ MRSA stability data from representative batches

Lot No	Date of Manufacture	Time from Manufacture (months)	MRSA	MSSA	Within Specification
960318	18/03/96	0	+	-	Yes
		12	+	-	Yes
960321	21/03/96	0	+	-	Yes
		12	+	-	Yes
960325	25/03/96	0	+	-	Yes
		12	+	-	Yes

#### Transit studies

Mast Group Limited has undertaken transit validation studies on representative samples of Mast Latex products to establish the effect exposure to adverse, or extreme, temperature has on this product range.

Based on our knowledge of transport conditions that these products may be exposed to, packs of Mast Latex products were subjected to controlled temperature extremes ranging from minus 20°C to 60°C for a period of 14 days (2 weeks) and then tested according to relevant standard quality control tests to determine the effect of simulated transit on their quality.

Over the test period it was established that none of the products tested showed alteration in performance criteria following exposure to ambient temperatures in the range of 20-23.5°C. Thus this data supports our continued use of ambient temperature shipment of Mast Latex products intended for subsequent storage at cold room temperature for up to 1 week without the necessity for employment of insulated temperate shipping containers and associated temperature indicators.