

MASTASTREP™ VALIDATION



MASTASTREP™ Validation

Mast product name	MASTASTREP
Mast product code	RST 201

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Section 1 - General description of the product and intended use

Product name	MASTASTREP™
Catalogue number:	RST 201
Manufacturer:	Mast Group Ltd., Mast House, Derby Road, Bootle, Liverpool, Merseyside. L20 1EA. UK.
Product description:	<p>The MASTASTREP™ kit contains the following components:</p> <ol style="list-style-type: none">1. Latex Reagents. Ready to use. 6 x 2.5ml of latex particles coated with specific rabbit antibody, for Lancefield groups A, B, C, D, F and G. Contains less than 0.1% sodium azide as preservative.2. Extraction enzyme. 2 x lyophilised reagent. Contains less than 0.01% Thimerosal as preservative.3. Polyvalent Control. Ready to use. 1 x 2.5ml. Contains less than 0.1% sodium azide as preservative.4. 300 single use disposable mixing sticks.5. 50 disposable 6-place test cards.6. Instructions leaflet.
Intended purpose:	The MASTASTREP™ kit is a rapid slide agglutination test for the identification of streptococci of Lancefield groups A, B, C, D, F and G.
Intended user:	Trained laboratory technical staff.

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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	Visible aggregation of latex particles	
	Negative	Milky appearance without any visible aggregation of the latex particles	
	A: <i>Streptococcus pyogenes</i> NCTC 8198 B: <i>Streptococcus agalactiae</i> NCTC 9993 C: <i>Streptococcus equisimilis</i> NCTC 8543 D: <i>Streptococcus durans</i> NCTC 8307 F: <i>Streptococcus</i> spp. NCTC 5389 G: <i>Streptococcus</i> spp. NCTC 9603	Normal Saline solution	
	Aggregation of latex particles with a clear background	Milky appearance without any visible aggregation of the latex particles	

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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 as 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.

MASTASTREP™ stability data from a representative batch

Time from Manufacture (months)	Positive Control						Negative Control	Within Specification
	A	B	C	D	F	G		
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.

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External Evaluations

Third Party Study A

	Number of strains		Total
	Positive	Negative	
Positive	607	55	662
Negative	0	24	24

Sensitivity = 92%
Specificity = 100%