

Product verification documentation.

Mast product name	Mast Assure Shigella sonnei Polyvalent D Antiserum
Mast product code	M10115

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1	General description of the product and intended use
2	Stability data



Section 1 - General description of the product and intended use

Product name	Mast Assure Shigella sonnei Polyvalent D Antiserum
Catalogue number:	M10115
Manufacturer:	Mast Group Ltd., Mast House, Derby Road, Bootle, Liverpool, Merseyside. L20 1EA. UK.
Product description:	 The Mast Assure Shigella sonnei Polyvalent D Antiserum: Ready to use. 2ml of diluted antiserum prepared from rabbits hyperimmunised with standard strains of killed organisms possessing known serotypes or group specific antigens and contain 0.085% sodium azide. Instructions leaflet.
Intended purpose:	Shigella sonnei contains only one distinct serotype that may occur in two forms, phase I (smooth) and phase II (rough). The Mast Assure Shigella sonnei Polyvalent D Antiserum is a liquid stable antiserum for the determination of phase I and phase II forms of Shigella sonnei.
Intended user:	Trained laboratory technical staff.

MAST ASSURE[™]

VERIFICATION DATA



Section 2 - Stability data

Product name

: Polyvalent D antiserum

Storage temperature

: 2~10℃

Test procedure

: The investigation was performed following to operation of product written on

Attachment 6.

Criteria

: 1. Sensitivity test

The agglutination of homologous strains should be 2 + or 3 + in serum dilution of

2. Specificity test

Homologous strains show 3 + agglutination and heterogous strains show no (-)

agglutination.

Rist of strains used on investigation

1) Homologous strain

S. flexneri 6

S. boydii 1

S. boydii 4

S. sonnei phase I S. sonnei phase II Heterogous strain

> S. dysenteriae 1 S. dysenteriae 2 S. dysenteriae 4 S. dysenteriae 5 S. dysenteriae 7 S. dysenteriae 8 S. dysenteriae 11 S. dysenteriae 10

S. flexneri 1a S. flexneri 1b S. flexneri 2b S. flexneri 3a S. flexneri 4a S. flexneri 4b S. flexneri X S. boydii 2 S. boydii 5

S. boydii 7 S. boydii 8 S. boydii 11 S. boydii 10 S. boydii 13 S. boydii 14 S. boydii 16 S. boydii 17 S. boydii 18

S. dysenteriae 3 S. dysenteriae 6 S. dysenteriae 9 S. dysenteriae 12 S. flexneri 2a S. flexneri 3b S. flexneri 5 S. flexneri Y S. boydii 3 S. boydii 6

> S. boydii 9 S. boydii 12 S. boydii 15

Specimen

Product name	Lot No.	MFG. Date
Polyvalent D antiserum	88-905	1989. 5. 25
Polyvalent D antiserum	89-001	1989. 1. 25
Polyvalent D antiserum	90-003	1990. 3. 2



Product name: Polyvalent D antiseum

Lot No. : 88-905

1. Sensitivity test data

Strain		Month after production				
Strain	0	6	12	18	24	30
S. sonnei phase I phase II	3 + 3 +	3+ 3+	3+ 3+	3+ 3+	3+ 3+	3 + 3 +

Samile.			Month after production					
Strain		0	6	12	18	24	30	
S. dysenteriae	1	_ =	_	_	_	_	_	
	2	_	_	-	-	_	- 1	
	3	_	-	_	-	_	-	
	4		_	_	_	_		
	5 6		_		in ita		- 1	
		-	_	_	-	_		
	7	_	_	_	_	_		
	8	_	_	_		_		
	9 10	_	_	_		_		
		_		_			_	
	11 12	_	- - - - - - -	1	_	_		
	12							
S. flexneri	1 a	-	_		_	_		
	1Ъ	_	_ _		_	-	_	
	2a	-	-		_	_	-	
	2b	_	-	-	_	-	_	
	3 a	-	-	_	_	_	_	
	3Ъ	-	-	-	-	_	-	
	4a	-	-		_	_	_	
	4b	_	-	_	-	_	- 1	
	5	_	- - - -		_	_	11111111	
	6		_	-	_	_	_	
	X	_	_	_	_			
	Y	_	_		_			
S. boydii	1	_	_	-	_	_		
·	2	_	_	-	_	-	_	
	3	_	_	-	_		-	
	4	-	_	_	_		_	
	5	_	_	_	- - -	- - -	-	
	6	_	_	_	_	_	_	
	7	_		_		_	_	
	8	_	_		_	_		
	9	_	_	_	_	_	_	
	10	<u>-</u> -			_	_	11111111	
	11	_	_	_	_	_	_	
	12	_			_		_	
	13 14	_			_	_	_	
	15	_	_		_		_	
	16	_	_	_			_	
	17		_	_	_	_	_	
	18	_	_	-	_	_	_	
C compainters ?		3+	٠,	2 .				
S. sonnei phase I phase I	r l	3+	3+	3+	3+	3+	3+	
pnase 1	ı	3+	3+	3+	3+	3+	3+	



Product name: Polyvalent D antiseum Lot No.: 89-001

1. Sensitivity test data

Strain	Month after production					
Strain	0	6	12	18	24	30
S. sonnei phase I phase II	3+ 3+	3 + 3 +	3+ 3+	3+ 3+	3 + 3 +	3 + 3 +

Strain			Month after production					
Strain		0	6	12	18	24	30	
S. dysenteriae	1	_	_	_	_	_	_	
	2	_	_	-	-	_	- 1	
	3	_		_	-	_	-	
i .	4		- - - - - - -	_	_	_	-	
	5		_		111	-	_	
İ	6	-	_	_	_	-	1	
	7	_	_	_	_	_	_	
	8		_	_		_		
	9	_	_	_		_		
	10	_		_			_	
	11 12	_	_	_	_	_	_ :	
	12						_	
S. flexneri	1 a	-	_	-	_	_		
	1 b	_	_	-	_	_	–	
	2a	-	-		_	_	-	
	2b	_	-	-	_	_	-	
	3a	_	- - -	-	_	_ _ _		
	3ъ	-	-	-	_	-	-	
	4a		-		_		_	
	4b	_	_	_	_	_	-	
	5 6	_	_	-	_	_	_	
	X	_	_	_	_	_		
	Ŷ	_	_	_	_	_		
S. boydii	1	_	-	-	_	_	-	
	2	_	_	-	-	-	-	
	3	_	_	-	_	-	-	
	4	_	_	_	-	-	_	
	5 6	-	_	_	_	_	_	
	7		_	_	_			
	8	_		_	_	- - -	_ _ _	
	9	_			_	_	_	
	10		_	_	_	_	_	
	11	- - -	_	_	_	_		
	12	_	_	_	_	_	_	
	13	-	_		_	_		
	14	_	_	_	-	_	_	
	15	_	_	_	_	_		
	16	_	_	_		_		
	17	_	_		_	_	_	
	18	-	-	-	_	-	_	
S. sonnei phase I		3+	3+	3+	2 .	2.	3+	
phase I	r	3+	3+	3+	3 + 3 +	3+ 3+	3+	
pnase 1		3+	3+	3+	0 +	3+	0+	



Product name: Polyvalent D antiseum Lot No.: 90-003

1. Sensitivity test data

Strain	Month after production					
Strain	0	6	12	18	24	30
S. sonnei phase I phase II	3+ 3+	3+ 3+	3+ 3+	3+ 3+	3+ 3+	3 + 3 +

0,-1-	Strain			Month after	production		
Strain		0	6	12	18	24	30
S. dysenteriae	1	_	_	_	_	_	-
	2	-	-	-	-	-	-
	3 4	_	_	_	=	-	_
	5	_	_	_	_	- - - - -	_
	6		_		_	_	_
	7	-	-	-	_	-	-
	8	- - -	-	-		-	- - -
	9	_	_	_		_	_
	10 11	_	_	_	_	_	-
	12	_	_	_	_	_	_
S. flexneri	la 1b	_	_	_	_	_	_
	2a	_	_	_	_	_	_
	2b	_	_		_	_	
	3 a	–	-	_		_	l –
	3 b	_	-	-		_	- -
	4a	-	-	-	_	_	_
	4b 5	- - - - -	- - - -	- - - -	_	- - - -	-
	6		_	_	_	_	- - -
	X	_	_		_	_	_
	Y		_	-	-	_	_
S. boydii	1	_		_			_
o. boyun	2	_	l	_	_		
	3	-	- -	_	_	-	_
	4 5	- - -	-	-	_	-	_
	5	_	-	_	_	_	_
	6 7	_ _	_	_	_	_	_
	8	_	_		_	_	_
	9	_	_	- - -	_	-	_
	10	<u>-</u>	_		-		_
	11		_	_			_
	12	_	_	-	-	_	_
	13	_	_	_	_	_	_
	14 15	_	_			_	_
	16	_	_		_	_	
	17	_	_	_	_	_	_
	18	-	_	_		_	_
S. sonnei phase I	r	3+	3+	3+	3+	3+	3+
phase I	i l	3+	3+	3+	3+	3+	3+
briege n	•	٠,	V T	- V T	o ⊤	U T	0 T



Section 3 - Sensitivity and specificity data

Product name : Polyvalent D antiserum

Storage temperature : 2~10℃

Test procedure : The investigation was performed following to operation of product written on

Attachment 6.

Criteria : 1. Sensitivity test

The agglutination of homologous strains should be 2+ or 3+ in serum dilution of

Specificity test

Homologous strains show 3 + agglutination and heterogous strains show no (-)

agglutination.

Rist of strains used on investigation

Homologous strain

S. sonnei phase I S. sonnei phase II

2) Heterogous strain

weeren all and a commit		
S. dysenteriae 1	S. dysenteriae 2	S. dysenteriae 3
S. dysenteriae 4	S. dysenteriae 5	S. dysenteriae 6
S. dysenteriae 7	S. dysenteriae 8	S. dysenteriae 9
S. dysenteriae 10	S. dysenteriae 11	S. dysenteriae 12
S. flexneri 1a	S. flexneri 1b	S. flexneri 2a
S. flexneri 2b	S. flexneri 3a	S. flexneri 3b
S. flexneri 4a	S. flexneri 4b	S. flexneri 5
S. flexneri 6	S. flexneri X	S. flexneri Y
S. boydii 1	S. boydii 2	S. boydii 3
S. boydii 4	S. boydii 5	S. boydii 6
S. boydii 7	S. boydii 8	S. boydii 9
S. boydii 10	S. boydii 11	S. boydii 12
S. boydii 13	S. boydii 14	S. boydii 15
S. boydii 16	S. boydii 17	-
S. boydii 18	-	

Specimen

Product name	Lot No.	MFG. Date
Polyvalent D antiserum	88-905	1989. 5. 25
Polyvalent D antiserum	89-001	1989. 1. 25
Polyvalent D antiserum	90-003	1990. 3. 2



Sensitivity test data

Strain	Lot No.		
	88-905	89-001	90-003
S. sonnei phase I phase II	3+ 3+	3+ 3+	3 + 3 +

Strain		Lot No.		
		0	6	12
S. dysenteriae	1	_	_	_
	2	_	_	
	3	_	-	
	4 5		_ 	
l	6	_	_	_
	7	_	_	_
	8	-		i –
	9	-		-
	10	-	-	-
	11	_	_	-
	12			
S. flexneri	1a		<u>-</u>	
	1 b	-	-	-
	2 a	-	_	-
	2 b 3 a	_	_	_
	3b			_
	4a	_	_	_
	4 b	–	-	-
	5	_	-	- 1
	6	-		-
	X	_	_	e –
	Y			
S. boydii	1		_	-
	2	_	-	_
	3 4	_	_	-
	5	_	_	-
	6	_	_	i – I
	7	_	_	_
	8	-	-	-
	9	_	_	-
	10	_	_	-
	11 12	_	_	-
	13	_		
	14	_	_	
	15		_	_
	16	-		-
	17	-	-	-
	18	_	-	-
S. sonnei phase I		3+	3+	3+
phase II		3+	3+	3+
P.1200 2				U T