

SERUM INDICES (SERUM INDICES)

Cat. No. SII0448

Lot No. 8543MS, 8544MS, 8545MS & 8546MS

Size: 4 x 5 ml

Expiry: 2025-06-28

GTIN: 05055273217025

INTENDED USE

Intended for *in vitro* diagnostic (IVD) use to monitor the instrument's response in detecting haemolyzed, icteric and lipemic samples. For use in a clinical laboratory setting by trained personnel.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human serum, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), Hepatitis C Virus (HCV) antibody and Anti-Treponema (Syphilis) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Please dispose of all biological and chemical materials according to local guidelines.

STORAGE AND STABILITY

UNOPENED: Store refrigerated at +2°C to +8°C. Stable to expiration date printed on individual vials.

OPENED: Once reconstituted, serum is stable for 14 days at +2°C to +8°C. After use, any residual product should NOT BE RETURNED to the original vial.

Bilirubin in the serum is light sensitive and it is therefore recommended that the serum is stored in the dark.

PREPARATION

Carefully reconstitute each vial with exactly **5 ml** of distilled water. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Invert bottle to ensure that all traces of dry material are dissolved. Avoid the formation of foam by shaking.

MATERIALS PROVIDED

Serum Indices - 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Not applicable.

METHOD AND LIMITATIONS

This product should be treated in the same manner as patient samples. Check that the automatic HIL detection function is active on the instrument. It is recommended to use sodium as the trigger assay. This product should not be used past the expiration date. Discard the vial if there is evidence of microbial contamination.

REPRESENTATIVE INDICES RESULTS

	Haemolysis (H)		Icterus (I)		Lipemia (L)	
	Appearance scale	mg/dl	Appearance scale	mg/dl	Appearance scale	mg/dl
Level 1	-	<30	-	<2	-	<50
Level 2	+	30 - 100	+	2 - 4	+	50 - 100
Level 3	++	100 - 200	++	4 - 10	++	100 - 150
Level 4	+++	200 - 500	+++	10 - 20	+++	150 - 200

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

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