SERANA [®] Science for Life

	Title:	TECHNICAL DATA SHEET			
A°	Review Date:	10-JAN-2023	Signature:	itter	
	Date of Issue:	21-DEC-2021	Approved by:	Dr. Iman Kamranfar	
	Document ID:	TDS-S-FBS-US-035	Version:	005	

SPECIMEN

		SPECIMEN	1		
Product Name	Foetal Bovine Serum				
Filtration/Treatment	Gamma irradiated – 25kGy to 50kGy				
Origin	United States				
Product Codes	S-FBS-US-035				
Shelf Life	5 Years from DOM				
Storage Temperature	<-15°C				
Shipping Temperature	dry ice				
Physical and Chemical Analysis	Method	Specifications	Units		
Identity	Internally Validated	Bovine	n/a		
Appearance	Visual	Clear yellow-amber to dark amber liquid	n/a		
Specific Gravity	Mass Balance	> 1.01	g/ml		
рН	Electronic pH Meter	6.8 - 8.2	n/a		
Osmolality	Osmometer	260 - 340	mOsm/kg		
Endotoxin	LAL Kinetic	< 10	EU/ml		
Free Hemoglobin	Colorimetric	< 25	mg/dl		
Protein Profile			<i></i>		
Total Protein	IDEXX Catalyst One	3.0 - 4.5	g/dl		
Albumin	IDEXX Catalyst One	1.4 - 3.4	g/dl		
Globulin	IDEXX Catalyst One	0.4 - 2.4	g/dl		
lgG	ELISA	< 400	μg/ml		
Electrophoretic Pattern	Capillary Electrophoresis	Normal	n/a		
Sterility					
Sterility	Internally Validated	Pass			
Mycoplasma	qPCR	Not detected	n/a		
Wycopiusinu			iiyu		
Antibiotic Testing					
Tetracycline	IDEXX Snap Test	Test and report	n/a		
Oxytetracycline	IDEXX Snap Test	Test and report	n/a		
Chlortetracycline	IDEXX Snap Test	Test and report	n/a		
Virus Testing					
BVDV/BHV-1/PI-3 (CPE)	Cell Culture	Not detected	n/a		
Rabies Virus	qPCR	Not detected	n/a		
Bluetongue Virus (BTV)	qPCR	Not detected	n/a		
BRSV	qPCR	Not detected	n/a		
Reo Virus	qPCR	Not detected	n/a		
BAV	qPCR	Not detected	n/a		
BoPV-1, -2	qPCR	Not detected	n/a		
A stills of the st					
Antibody Testing	Sorum Noutralization Test (Call Culture)				
BVDV - Antibody Type 1	Serum Neutralization Test (Cell Culture) or Detection of Antibodies (ELISA)	Test and report	n/a		
BVDV - Antibody Type 2	Serum Neutralization Test (Cell Culture) or	Test and report	n/a		
BHV-1	Detection of Antibodies (ELISA) Detection of Antibodies (ELISA)	Test and report	n/a		
PI-3	Detection of Antibodies (ELISA)	Test and report	n/a		

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TECHNICAL DATA SHEET

Biochemistry			
Aspartate Aminotransferase (AST)	IDEXX Catalyst One	Record	U/L
Alanine Aminotransferase (ALT)	IDEXX Catalyst One	Record	U/L
Lactate Dehydrogenase (LDH)	IDEXX Catalyst One	Record	U/L
Alkaline Phosphatase (ALKP)	IDEXX Catalyst One Record		U/L
Gamma-Glutamyl Trans.(GGT)			U/L
Cholesterol (CHOL)	IDEXX Catalyst One	Record	mmol/L
Glucose (GLU)	IDEXX Catalyst One	Record	mmol/L
Urea (BUN)	IDEXX Catalyst One	Record	mmol/L
Creatinine (CREA)	IDEXX Catalyst One	Record	µmol/L
Uric Acid (URIC)	IDEXX Catalyst One	Record	µmol/L
Calcium (Ca)	IDEXX Catalyst One	Record	mmol/L
Phosphorus (PHOS)	IDEXX Catalyst One	Record	mmol/L
Total Bilirubin (TBIL)			
Magnesium (Mg) IDEXX Catalyst One Record			mmol/L
dium (Na) IDEXX Catalyst One Record Record			mmol/L
Potassium (K)	IDEXX Catalyst One	Record	mmol/L
Chloride (CL)	IDEXX Catalyst One	Record	mmol/L
Cell Culture Testing - Option 1			
Cell Line	Method	Specifications	Results
L-929, HELA, MRC-5	Morphology Tested vs. Control Serum		Scoring System 1
L-929, HELA, MRC-5	Density Tested vs. Control Serum		Scoring System 2
L-929, HELA, MRC-5	Cell Count	Cell count [log10/ml]/dead cells vs. Control	Record
Scoring system	Meaning		Results
1 - Morphology	Dead Cells		0
	Many Cells degenerate and many dead cells		1
	Cells partially degenerate and many dead cells		2
	Few cells degenerate and few dead cells		3
	Without pathological findings		4
2 - Density	Single cells/cell aggregates		0
	< 50% confluency		1
	50 - 90% confluency		2
	confluency		3
	overly confluent		4
Cell Culture Testing - Option 2			
Cell Line	Method	Specifications	Units
BHK-21, MRC-5	21, MRC-5Multiple Passage - Records results vs. control at day: 0, 3, 6, 12>75% of control growth		%
HK-21, MRC-5 Plating Efficiency - Records results vs. control at day: 0, 3, 6, 12 >75% PE vs. control PE			%
BHK-21, MRC-5 Cloning Efficiency - Records results vs. control at day: 0, 3, 6, 12 >75% CE vs. control CE		>75% CE vs. control CE	%



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EFFECTS OF GAMMA IRRADIATION:

Decline in Viral Titre

A gamma irradiation dose-dependent reduction in survival for enveloped and non-enveloped viruses will be detected. Viruses will show a significant reduction in titre at 25kGy and will be below the level of detection (0.5 TCID50 / ml) at 35kGy. For each batch the irradiation parameters must be in accordance with the with the guidelines of the International Standard ISO 11137-1.

Other Effects

- Reduction of haemoglobin levels with a decrease in serum metabolites.
- Minor discoloration of the product and bottle.
- Possible decrease in growth promotion, plating/cloning efficiency with certain cell lines.

RECOMMENDED USE:

Storage

To effectively preserve the integrity of animal serum, it should be stored frozen and protected from light. The recommended storage temperature is <-15°C.

Multiple thaw/freeze cycles should be avoided, as they will accelerate the degradation of serum nutrients and can encourage the formation of insoluble precipitates. For this reason, serum should never be stored in "frost-free" freezers. These types of freezers periodically warm themselves to avoid internal ice deposits and are detrimental to the stability of frozen serum products.

Suggested Thawing Procedure

- 1. Remove the serum bottles from the freezer and allow them to adjust to room temperature for approximately 10 minutes.
- 2. Place each container in a 30 to 37 °C water bath or incubator. Excessive temperatures will degrade heat labile nutrients. If using a water bath, prevent the bottle caps from being submerged.
- 3. Gently agitate the bottles every 10 15 minutes until the serum is completely thawed.

Efficient and Effective Usage

After thawing, use the serum promptly. Liquid serum may be stored refrigerated (2 to 8 °C) up to four weeks. To avoid thaw/freeze cycles or long periods of refrigeration, it is recommended that any unused serum be immediately dispensed into small, useful aliquots and refrozen for future use.

THIS PRODUCT IS NOT INTENDED FOR HUMAN OR ANIMAL CONSUMPTION OR THERAPEUTIC USE.



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