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Date of Issue:	21-DEC-2021
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Version:
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Signature:

005 Dr. Iman Kamranfar

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Title: TECHNICAL DATA SHEET

	SPECIMEN	
Footal Povino Corum		
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Ireland		
S-FBS-IR-035		
5 Years from DOM		
<-15°C		
dry ice		
Method	Specifications	Units
Internally Validated	Bovine	n/a
Visual	Clear yellow-amber to dark amber liquid	n/a
Mass Balance	> 1.01	g/ml
Electronic pH Meter	6.8 - 8.2	n/a
Osmometer	260 - 340	mOsm/kg
LAL Kinetic	< 10	EU/ml
Colorimetric	< 25	mg/dl
IDEXX Catalyst One	3.0 - 4.5	g/dl
IDEXX Catalyst One	1.4 - 3.4	g/dl
IDEXX Catalyst One	0.4 - 2.4	g/dl
ELISA	< 400	μg/ml
Capillary Electrophoresis	Normal	n/a
Internally Validated	Pass	
		n/a
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IDEXX Snap Test	Test and report	n/a
-	·	n/a
	Test and report	n/a
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Cell Culture	Not detected	n/a
qPCR	Not detected	n/a
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Serum Neutralization Test (Cell Culture) or Detection of Antibodies (ELISA)	Test and report	n/a
Serum Neutralization Test (Cell Culture) or Detection of Antibodies (ELISA)	Test and report	n/a
Detection of Antibodies (ELISA)	Test and report	n/a
Detection of Antibodies (ELISA)	Test and report	n/a
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	5 Years from DOM  <-15°C  dry ice  Method  Internally Validated  Visual  Mass Balance  Electronic pH Meter  Osmometer  LAL Kinetic  Colorimetric  IDEXX Catalyst One  IDEXX Catalyst One  IDEXX Catalyst One  ELISA  Capillary Electrophoresis  Internally Validated  qPCR  IDEXX Snap Test  IDEXX Snap	Gamma irradiated – 20kGy to 50kGy Ireland  S-FBS-IR-035  S Years from DOM  <-15°C  dry ice  Method Specifications Internally Validated Bovine Visual Clear yellow-amber to dark amber liquid Mass Balance >1.01 Electronic pH Meter 6.8 - 8.2 Osmometer 260 - 340 LAL Kinetic <10 Colorimetric <25  IDEXX Catalyst One 3.0 - 4.5 IDEXX Catalyst One 1.4 - 3.4 IDEXX Catalyst One 0.4 - 2.4 ELISA <400 Capillary Electrophoresis Normal  Internally Validated Pass QPCR Not detected  QPCR Not detected



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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)	IDEXX Catalyst One	Record	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)	IDEXX Catalyst One	Record	μmol/L
Magnesium (Mg)	IDEXX Catalyst One	Record	mmol/L
Sodium (Na)	IDEXX Catalyst One	Record	mmol/L
Potassium (K)	IDEXX Catalyst One	Record	mmol/L
Chloride (CL)	IDEXX Catalyst One	Record	mmol/L
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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
2 323, 1123 i, Will C 3	Cen count	cen count [rog10/111]/ dedd cens 13. 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	Multiple Passage - Records results vs. control at day: 0, 3, 6, 12	>75% of control growth	%
BHK-21, MRC-5	Plating Efficiency - Records results vs. control at day: 0, 3, 6, 12	>75% PE vs. control PE	%
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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. The irradiation parameters for each batch must be in accordance 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.

