		Catalog Number/SKU's (Base not Description			Catalog Number/SKU's (Base number as per COA)				10099 /A31610 FBS, Qualified			/A31604		10082/ A38400		10093 Qualified Heat-Inactivated		10094 Qualified Gamma Irradiated		16141 ES Cell Qualified		044 Qualified	12664 MSC Qualified			Ougli	10100 Qualified Heat-Inactivated		10101 Qualified Gamma Irradiated		Qualifie Irradiate	30048 Qualified Gamma Irradiated and Heat Inactivated		190005 ed Gamma ed and Heat	Certifie	ed, Gamma
					Country of Origin	FB3, G	<u>Qualified</u>		FBS, Qualifie	<u>a</u>	FB3, 0	Certified	Certified He	eat-inactivated	Qualified He	eat-inactivated	i irra	latea	E5 C6	eii Quaimed	E3 Cell C	Qualified		MSC Qualifie	ea	Quai	med Heat-inac	tivated	ırra	diated	inac	tivated	inac	tivated	ırra	diated
Before Chan	ge		Harmonis(z)ed	Specification to be In	mplemented March 1, 2019	New 2	Zealand ————————————————————————————————————	Before	Australia Before		United Before	d States	Unite Before	d States	New Before	Zealand 	New Before	Zealand 	Uni Before	ited States	New Ze	<u>Cealand</u>	Before	Australia Before		Before	Australia Before		Au:	stralia 	<u>Au</u> Before	stralia	Au Before	stralia	Before	ed States
Test Description Tests to be performe	Units	Test Description orted for all SKUs/Specific	Units	Specification	Method Reference	Change	New	Change	Change ¹	New	Change	New	Change	New	Change	New	Change	New	Change	New	Change	New	Change	Change ¹	New	Change	Change ¹	New	Change	New	Change	New	Change	New	Change	New
		Expiration Date	n/a	n/a	n/a	х	х	х	X	х	х	Х	х	х	х	х	х	Х	х	х	x	x	Х	х	х	x	Х	х	х	Х	х	Х	х	х	х	x
Country of Origin	n/a	Country of Origin	n/a	n/a	n/a	x	x	X	x	X	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	х	х	x	X	x	x	x
n/a n/a	n/a n/a	Appearance Batch Volume	n/a	Pass Check & Record	Visual and Physical Inspection. Batch manufacturing record.	n/a	Pass Check & Record	n/a	n/a	Pass Check & Record	n/a	Pass Check &	n/a	Pass Check &	n/a	Pass Check &	n/a	Pass Check & Record	n/a	Pass Check & Record	n/a	Pass Check & Record	n/a	n/a	Pass Check & Record	n/a n/a	n/a	Pass Check & Record	n/a	Pass Check &	n/a	Pass Check & Record	n/a	Pass Check & Record	n/a	Pass Check & Record
TI/A	11/4	Daterr volume		CHECK & NECOID	Dater manufacturing record.	11/4	Necord	Tiva	11/4	Record	11/4	Record		Record	=10 or<br Check &	Record	=10 or<br Check &	record	11/4	Officer & Necola	11/2	record	11/4	11/a	1100014	=10 or<br Check &	11/4	Record	Tira	Record	II/a	record	11/G	Record	Tiva	Record
Haemoglobin or	EU/mL mg/100m	Endotoxin	EU/mL	=5.00</td <td>Current edition of USP <85> and EP 2.6.14. Determined Spectrophotometrically. Current edition</td> <td><!--=10 EU/mL Check &</td--><td></td><td><!--=10 EU/mL</td--><td></td><td><!--=5 EU/mL</td--><td><!--=5 EU/mL</td--><td><!--=5 EU/mL</td--><td><!--=5 EU/mL</td--><td><!--=5 EU/mL</td--><td>Record¹ Check &</td><td><!--=5 EU/mL</td--><td>Record¹ Check &</td><td><!--=5 EU/mL</td--><td><!--=50 EU/mL</td--><td><!--=5 EU/mL</td--><td><!--=10 EU/mL<br-->Check &</td><td><!--=5 EU/mL</td--><td><!--=10 EU/mL<br-->Check &</td><td><!--=10 EU/mL</td--><td></td><td>Record¹ Check &</td><td><!--=10 EU/mL</td--><td><!--=5 EU/mL</td--><td><!--=10<br-->Check &</td><td><!--=5 EU/mL</td--><td><!--=10<br-->Check &</td><td><!--=5 EU/mL</td--><td><!--=10<br-->Check &</td><td><!--=5 EU/mL</td--><td><!--=10</td--><td><!--=5 EU/mL</td--></td></td></td></td></td></td></td></td></td></td></td></td></td></td></td></td></td></td></td></td>	Current edition of USP <85> and EP 2.6.14. Determined Spectrophotometrically. 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Tiornione Fronte		Identification: Bovine Gam	Vallede	CHOOK & ROOGIA	Radial Immunodiffusion. Current edition of USP	11/4	record	Tiva	record	Rooord	record	record	Record	Record	11/4	record	11/4	record	11/4	11/4	11/4	11/4	11/4	Ittooru	11/4	11/4	record	record	11/4	record	11/4	record	11/0	record	Record	INCOCIU
n/a Electrophoretic Pattern		Globulin	n/a	Bovine	<90> modified and EP 2.7.1.	n/a	Bovine	n/a	n/a	Bovine	n/a	Bovine	n/a	Bovine	n/a	Bovine	n/a	Bovine	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Bovine	n/a	Bovine	n/a	Bovine	n/a	Bovine	n/a	Bovine
or Electrophoretic Profile	n/a	Identification: Electrophore Profile	n/a	Normal	Protein Electrophoresis.	Normal	Normal Check &	Normal	Normal	Normal Check &	Normal	Normal Check &	Normal	Normal Check &	Normal	Normal Check &	Normal	Normal Check &	Normal	Normal	Normal	Normal Check &	Normal	Normal	Normal Check &	Normal	Normal	Normal Check &	Normal	Normal Check &	Normal	Normal Check &	Normal	Normal Check &	Normal	Normal Check &
n/a Mycoplasma,	n/a	Manufacturing Date	n/a	Check & Record	Batch manufacturing record.	n/a	Record	n/a	n/a	Record	n/a	Record	n/a	Record	n/a	Record	n/a	Record	n/a	Check & Record		Record	n/a	n/a	Record	n/a	n/a	Record	n/a	Record	n/a	Record	n/a	Record	n/a	Record
Supplemental (H- stain) or Mycoplasma - Supplemental testing(H-Stain)	n/a	Mycoplasma: Supplement Testing (H- Stain)	al n/a	Not Detected	Hoescht Stain. Current edition of USP <63> and EP 2.6.7.(Note: 16141 - on selected Lots)	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected ^{2 &2a}	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
Mycoplasma Testing or Mycoplasma			.,,		Direct Culture. Current edition of USP <63> and EP 2.6.7. (Note: 16141 - on selected Lots)																															3.20.000
Screen Origin Confirmation		Mycoplasma Origin Confirmation	n/a	Not Detected	Acid digestion, ICP-MS and statistical modelling.	Negative	Not Detected		Pass or	Not Detected	Negative Passes Test		Negative	Not Detected	Negative Pass	Not Detected	Negative Pass	Not Detected	Negative	Not Detected ^{2 & 2a}	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Negative Passes Test		Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
Origin Confirmation	mOsm/kg or	J Sagar Commitmentation	II/a	1 433		1 033	1 000						1 433	1 033		1 433		1 000	Π/α	1 000	Iva	1 433	ıva	11/ C	1 033	1 433			1 033	1 433	1 033	1 000	1 433	1 433	TI/ C	7 433
Osmolality	mOsm/kg H2O	Osmolality	mOsm/kg H2O	280-340	Freezing Point Depression, Current edition of USP <785> and EP 2.2.35.		280-340 mOsm/kg H2O	Check & Record	280-340 mOsm/kg	280-340 mOsm/kg H20	280-340 mOsm/kg	280-340 mOsm/kg H2	280-340 O mOsm/kg	280-340 mOsm/kg H20	Check & Record	280-340 mOsm/kg H20	Check & Record	280-340 mOsm/kg H20		280-340 mOsm/k H2O	Check & Record	280-340 mOsm/kg H2O	Check & Record		280-340 mOsm/kg H2O		280-340 mOsm/kg	280-340 mOsm/kg H20		280-340 mOsm/kg H20	Check & Record or		Check & Record or			280-340 MOsm/kg H2O
					Cell Line Used: Sp2/O-Ag14, ATCC No. CRL-1581 or P3 x 63 - Ag8.653, ATCC No. CRL-1580. The cloning efficiency assay analyzes the ability of each																															
Performance Testing: Cloning Assay		Performance: Relative Clo	ning	Check & Record	FBS lot to support cloning and growth of murine myeloma cells and derived hybridomas.			Check & Record		Check &	Check & Record	Check &	Check &	Check &		Check & Record	Check & Record	Check & Record	Check & Record	Check & Record		Check &		Check & Record	Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check & Record	Check &	Check & Record	Check &
Cioning Assay	70	Emoioncy(NOE)	70	CHECK & RECORD	Cell Line Used Human Diploid Lung Fibroplast (MRC-5), ATCC No. CCL171 or Human Diploid Lung Fibroplast (WI-38), ATCC No. CCL-75. The growth promotion assay measures the ability of each FBS lot to support proliferation of fastidious	Necord	Nessia	record	record	record	record	record	record	INCCOIL	record	record	Record	Record	record	CHECK & REGORD	INCCOID	record	Record	Record	INCOORD	record	Record	record	Record	record	record	Record	Record	record	record	Record
Performance Testing: Growth Assay	%	Performance: Relative Gro	owth %	Check & Record	human diploid fibroblasts through multiple subcultures.	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record		Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record	Check & Record		Check & Record
Performance Testing:		Performance: Relative Pla	ting		Cell Line Used: Human Carcinoma (A549), ATCC No. CCL-185. Analysis of cellular attachment and proliferation of a human transformed cell line.	Check &	Check &	Check &	Check &	Check &		Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &			Check &		Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &	Check &
Plating Assay	n/a	Efficiency(RPE)	% 	7.0-8.0	Combined Electrode. Current edition of USP <791>.	Check & Record	7.0-8.0	Check & Record	6.9-7.8	7.0-8.0	Record 6.9-7.8	7.0-8.0	Record 6.9-7.8	7.0-8.0	Check & Record	7.0-8.0	Record Check & Record	7.0-8.0	Record 6.9 - 7.4	7.0-8.0	Record Check & Record	7.0-8.0	Record Check & Record	Record 6.9 - 7.8	7.0-8.0	Check & Record	6.9 - 7.8	7.0-8.0	Check & Record	7.0-8.0	Check & Record	7.0-8.0	Check & Record	7.0-8.0	6.9-7.8	7.0-8.0
Alpha Globulin		Protein: Alpha Globulin	mg/mL	Check & Record	Protein Electrophoresis.	n/a	Check & Record	n/a	Check & Record	Check & Record	n/a	Check & Record	n/a	Check & Record	n/a	Check & Record	n/a	Check & Record	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record	n/a	Check & Record	n/a	Check & Record	n/a	Check & Record	n/a	Check & Record Check &
Beta Globulin Composoition of		Protein: Beta Globulin	mg/mL	Check & Record	Protein Electrophoresis.	n/a	Check & Record Check &	n/a	Check & Record Check &	Check & Record Check &	n/a	Check & Record Check &	n/a	Check & Record Check &	n/a	Check & Record Check &	n/a	Check & Record Check &	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record Check &	n/a	Check & Record Check &	n/a	Check & Record Check &	n/a	Check & Record Check &	n/a	Check & Record Check &
Protein: Albumin Determination of		Protein: Albumin	mg/mL	Check & Record	Protein Electrophoresis.	n/a	Record	n/a	Record	Record	n/a	Record	n/a	Record	n/a	Record	n/a	Record	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Record	n/a	Record	n/a	Record	n/a	Record	n/a	Record
Bovine IgG Elisa Assay	ug/mL	Protein: Gamma Globulin	mg/L	=500</td <td>Radial Immunodiffusion, Current edition of USP <90> modified and EP 2.7.1.</td> <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td>Check & Record</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td></td></td></td></td></td></td></td>	Radial Immunodiffusion, Current edition of USP <90> modified and EP 2.7.1.	n/a	=500 mg/L</td <td>n/a</td> <td>Check & Record</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td></td></td></td></td></td></td>	n/a	Check & Record	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td></td></td></td></td></td>	n/a	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td></td></td></td></td>	n/a	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td></td></td></td>	n/a	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td></td></td>	n/a	=500 mg/L</td <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td></td>	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td></td>	n/a	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td></td>	n/a	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--><td>n/a</td><td><!--=500 mg/L</td--></td></td>	n/a	=500 mg/L</td <td>n/a</td> <td><!--=500 mg/L</td--></td>	n/a	=500 mg/L</td
Total Protein	g/dL or g/L	Protein: Total Protein Serology: BVDV Serum	mg/mL	30-45	Biuret Method, USP <1057> and EP 2.5.33 modified	25-55 g/L	30-45 mg/mL Check &	25-55 g/L	3.0-4.5 g/dL	30-45 mg/mL Check &	3.0-5.0 g/dL	30-45 mg/mL Check &	3.0-5.0 g/dL	30-45 mg/mL Check &	25-55 g/L	30-45 mg/mL Check &	25-55 g/L	30-45 mg/mL Check &	3.0 - 5.0 g/dL	30-45 mg/mL	25-55 g/L	30-45 mg/mL	25-55 g/L	3.0 - 5.0 g/dL	30-45 mg/mL	25-55 g/L	3.0 - 5.0 g/dL	30-45 mg/mL Check &	25-55 g/L	30-45 mg/mL	25-55 g/L	30-45 mg/mL Check &	25-55 g/L	30-45 mg/mL Check &	Check & Record	30-45 mg/mL Check &
n/a Sterility Testing or	n/a	Neutralisation Titre (Antibo Sterility: Bacterial and Fur	Jary 1.17 a.	Check & Record No Growth	Serum Neutralisation / Neutralization Test.	n/a	Record No growth	n/a	n/a	Record No growth	n/a	Record No growth	n/a	Record No growth	n/a	Record No growth	n/a	Record No growth	n/a	n/a		n/a No growth	n/a	n/a	n/a No growth	n/a	n/a	Record No growth	n/a	Record No growth	n/a	Record No growth	n/a	Record No growth	n/a	Record No growth
Sterility VT-Bluetongue Virus	n/a	Testing	n/a	Detected	Current edition of USP <71> and EP 2.6.1. Code of Federal Regulations, (CFR), Title 9, Part	Negative	detected	Negative	Negative	detected	Negative	detected	Negative	detected	Negative	detected	Negative	detected	Negative	n/a	Negative	detected	Negative	Negative	detected	Negative	Negative	detected	Negative	detected	Negative	detected	Negative	detected	Negative	detected
FA or Virus: Bluetongue Virus VT- Bovine	n/a	Virus (9CFR): Bluetongue	Virus n/a	Not Detected		Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	n/a	Negative	Not Detected	Negative	Negative	Not Detected	Negative	n/a	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
Adenovirus FA or Virus: Bovine Adenovirus	n/a	Virus (9CFR): Bovine Adendovirus	n/a	Not Detected	Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	n/a	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
VT- Bovine Parvovirus FA or Virus: Bovine		Virus (9CFR): Bovine	* Is		Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by																															
Parvovirus VT-BRSV Flourescent Antibdody or Virus:	II/d		II/a	Not Detected	fluorescent antibody. Code of Federal Regulations, (CFR), Title 9, Part	Negative	Not Detected	rvegalive	ivegalive	Not Detected	ivegalive	INOT DETECTED	iveyalive	NOT Defected	iveyalive	INOU DETECTED	ivegalive	Not Detected	rvegauve	Not Detected	ivegative	Not Detected	rvegative	ivegalive	NOT Detected	ivegauve	rvegauve	NOT Defected	ivegalive	Not Detected	rvegalive	Not Detected	rvegauve	Not Detected	rvegalive	Not Detected
Bovine Respiratory Syncytial Virus	n/a	Virus (9CFR): Bovine Respiratory Syncytial Viru	s n/a	Not Detected	113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
VT- BVDV Fluorescent Antibody or Virus: Bovine Viral Diarrhea		Virus (9CFR): Bovine Vira Diarrhoea Virus (Non	I		Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by		Check &			Check &		Check &		Check &		Check &		Check &				Check &			Check &			Check &		Check &		Check &		Check &		Check &
Virus VT- Cytopathogenic	n/a	Cytopathogenic)	n/a	Check & Record		Tested	Record	Tested	Tested	Record	Tested	Record	Tested	Record	Tested	Record	Tested	Record	Tested	Check & Record	Tested	Record	Tested	Tested	Record	Tested	Tested	Record	Tested	Record	Tested	Record	Tested	Record	Negative	Record
Agents or Virus: Cytopathogenic Agents	n/a	Virus (9CFR): Cytopathog Agents (Including Bovine Herpesvirus 1 (BHV-1/IBF		Not Detected	Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
VT-Hemadsorbing Agents or Virus:		Virus (9CFR): Haemadsor	bing																				Ü										J			
Haemadsorbing Agents	n/a	Agents (Including Bovine Parainfluenza Virus 3 (Pl-		Not Detected	Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Code of Federal Regulations, (CFR), Title 9, Part	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
VT- Rabies Virus FA or Virus: Rabies Virus	n/a	Virus (9CFR): Rabies Viru	s n/a	Not Detected	113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected	Negative	Not Detected
VT-Reovirus FA or	n/s		2/2	Not Detected	Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by																															Not Detected
Virus: Reovirus	III/d	Virus(9CFR): Reovirus TSE CEP R1 CEP 2000-0)89	INUL Detected	fluorescent antibody. EDQM Certificate of Suitability for Transmissible Spongiform Encephalopathy Risk. Current edition of		Not Detected	rvegativė	inegative	Not Detected	ivegative	Not Detected Check &	rvegative	Not Detected Check &	ivegative	Not Detected	ivegative	Not Detected	ivegative	Not Detected	Negative	Not Detected	rvegative	Negative	Not Detected	inegalive	Negative	Not Detected	ivegative	Not Detected	rvegative	Not Detected	rvegative	Not Detected	ivegalive	Check &
n/a	n/a	Revision	n/a	Check & Record	EP 5.2.8. EDQM Certificate of Suitability for Transmissible	n/a	n/a	n/a	n/a	n/a	n/a	Record	n/a	Record	n/a	n/a	n/a	n/a	n/a	Check & Record		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Record
COS Revision: R1- CEP 2000-155	n/a	TSE CEP R1- CEP 2000- Revision	n/a	Check & Record	Spongiform Encephalopathy Risk. Current edition of EP 5.2.8. EDQM Certificate of Suitability for Transmissible		Check & Record	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record	Check & Record	Check & Record	Check & Record	n/a	n/a	Check & Record	Check & Record	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
n/a	n/a	TSE CEP R1- CEP 2001- Revision	024 n/a	Check & Record	Spongiform Encephalopathy Risk. Current edition of	n/a	n/a	n/a	n/a	Check & Record	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record	n/a	n/a	Check & Record	n/a	Check & Record	n/a	Check & Record	n/a	Check & Record	n/a	n/a
Additional informatio	n reported	d on Gamma Irradiated/He	at Inactivated SI	<u> </u>														Check &											Check &	Check &		Check &	Check &	Check &		
Range	n/a	Irradiation Dose Range	kGy	Check & Record	Original lot number of product pre gamma	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a Check &	n/a	n/a Check &	n/a	Check & Record Check &	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a Check &	Check & Record Check &	Check & Record Check &	n/a	Record	Record	Record Check &	n/a	n/a Check &
Original Lot Number Original Catalogue	n/a	Original Lot Number	n/a	Check & Record	irradiation or heat inactivation. Original catalogue number of product pre gamma	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Record Check &	n/a	Record Check &	n/a	Record Check &	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Record Check &	Record Check &	Record Check &	n/a	Record Check &	Record Check &	Record Check &	n/a	Record Check &
Number	n/a	Original Catalogue Number	er n/a	Check & Record		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Record	n/a	Record	n/a	Record	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Record	Record	Record	n/a	Record	Record	Record	n/a	Record

				10091 / A31609		10099 /A31610		510 16000 /A31604		1	10082/ A38400	1	10093		0094	16	141	30	30044	12664			10			10101		30048	01190005		10083		
				Catalog Number/SKU's (Base number as per COA)																									Qualified Gamma	Qualifi	ed Gamma		
				Description	FBS, Qu	ualified		FBS, Qualified	d	FBS, Certified	Certifi	ed Heat-Inactivate	d Qualified F	leat-Inactiva		ed Gamma diated	ES Cell (Qualified	ES Cell	II Qualified		MSC Qualified	I	Qualific	ed Heat-Inac	tivated	Qualified Ga Irradiate		Irradiated and Heat Inactivated	Irradiate	d and Heat tivated	Certified, Gam Irradiated	
Before Change		Harmonis(z)ed Sp	pecification to be In	Country of Origin nplemented March 1, 2019	New Ze	ealand		<u>Australia</u>		United States		United States	New	v Zealand	New 2	Zealand	United	l States	New	Zealand		Australia			Australia		Australi	ia	Australia	Au	stralia	United States	es
Test Description Units	Test Description	Unite	Specification	Method Reference	Before Change	New	Before Change	Before Change ¹	New	Before Change Ne	Bef	ore	Before Change		Before Change	New	Before Change	New	Before Change	New	Before Change	Before Change ¹	New	Before Change	Before Change ¹	New	Before Change	New	Before Change New	Before Change	New	Before Change	
Specialis(z)ed Testing:	Test Description	Offics	эреспісаціон	Method Reference	Change	inew .	Change	Change	New	Change Ne	W Clia	nge New	Change	New	Change	New	Change	New	Change	New	Change	Change	New	Change	Change	New	Change	New	Change New	Change	New	Change	New
ES Cell Performance	ES Cell Qualification Colony	V		Each lot of serum is qualified by thawing mESCs, culturing them in control media and media supplemented with test lot FBS. After 7 days the cells are stained for the pluripotency marker alkaline phosphatase, then with the non-specific cellular marker Methylene Blue. Pluripotent colonies are counted. Test serum and ES Qualified FBS Control must meet ES Cell Qualification Colony Forming Assay specifications for test serum to be ES Cell Qualified.																													
Assay	Forming Assay	n/a	Acceptable	Thermo Fisher Scientific Specifications: Pooled	n/a r	n/a	n/a	n/a	n/a n	a <mark>n/a</mark>	n/a	n/a	n/a	n/a	n/a	n/a A	Acceptable A	Acceptable	Acceptable	Acceptable	n/a	n/a	n/a	n/a r	n/a	n/a n	/a n/a	a n	/a n/a	n/a	n/a	n/a n/a	
				early passage cryopreserved mesenchymal stem cells were plated at low density. The medium was supplemented with 10% test or control FBS. Plates were incubated for 14 days, stained and colonies enumerated under a dissection microscope. An acceptable result is defined as the ability of the serum to support growth and proliferation of mesenchymal stem cells at clonal densities.																													
MSC CFU-f Assay	MSC CFU-f Assay	n/a	Acceptable		n/a	n/a	n/a	n/a	n/a n	a <mark>n/a</mark>	n/a	n/a	n/a	n/a	n/a	n/a n	n/a <mark>n</mark>	n/a	n/a	n/a	Acceptable	Acceptable	Acceptable	n/a r	n/a	n/a n	/a <mark>n/e</mark>	n,	/a <mark>n/a</mark>	n/a	n/a	n/a <mark>n/a</mark>	
*Additional testing available	on selected lots only: Serology: Anti BVDV Antibo	dy		EMA/CHMP/BWP/457920/2012 Part 7.3.4 and	(Check &			Check &	Check &		Check &		Check &		Check &										Check &	Cr	eck &	Check &		Check &	Chec	ck &
n/a n/a	Test	n/a	Check & Record	EMEA/CVMP/743/00 4.3.3.3. EMA/CHMP/BWP/457920/2012 Part 7.3.1 and	11/4	Record ²	n/a	n/a	Record ² n	a Record ²	n/a	Record ²	n/a	Record ²	n/a	Record ² n	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Record ² n.	/a Re	ecord ²	/a Record ²	n/a	Record ²	n/a Reco	
n/a n/a	Virus (EMA): Bluetongue Vi	rus n/a	Not Detected	7.3.2 and EMEA/CVMP/743/00 part 4.3.3. Detected by fluorescent antibody		Not Detected ²	n/a	n/a	Not Detected ² n	a Not Dete	ected ² n/a	Not Detected	n/a	Not Detecte	ed ² n/a	Not Detected ²	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Not Detected ²	ı/a <mark>N</mark> c	t Detected ² n	/a Not Detected	n/a	Not Detected ²	n/a Not [Detecte
n/a n/a	Virus (EMA): Bovine Adendovirus	n/a	Not Detected	EMA/CHMP/BWP/457920/2012 Part 7.3.1 and 7.3.2 and EMEA/CVMP/743/00 part 4.3.3. Detected by fluorescent antibody		Not Detected ²	n/a	n/a	Not Detected ²	a Not Dete	ected ² n/a	Not Detected	2 n/a	Not Detecte	ed ² n/a	Not Detected ²	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Not Detected ²	n/a No	t Detected ² In	/a Not Detected	n/a	Not Detected ²	un/a Not '	Detected
1,74	, addidovingo	1770	Trot Bottottou	EMA/CHMP/BWP/457920/2012 Part 7.3.1 and 7.3.2 and EMEA/CVMP/743/00 part 4.3.3. Detected		1101 2 0100104	11/4	1774	Trot Bototoa II	1101201	11/4	1101 2 0100100	11/4	THUI DUIGUE	11/4	Not Dottotto		,	11/0	1170	717.0	1170	11/4	11/10	,,,	THE DELECTION IN		A D Stocked		11/4	THE DELECTION		70.00.0
n/a n/a	Virus (EMA): Bovine Parvov	rirus n/a	Not Detected	by fluorescent antibody EMA/CHMP/BWP/457920/2012 Part 7.3.1 and		Not Detected ²	n/a	n/a	Not Detected ² n	a Not Dete	cted ² n/a	Not Detected	n/a	Not Detecte	ed ² n/a	Not Detected ² n	n/a <mark>n</mark>	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Not Detected ² n.	/a No	t Detected ² n	/a Not Detected	n/a	Not Detected ²	<u>n</u> /a Not Γ	Detecte
n/a n/a	Virus (EMA): Bovine Respiratory Syncytial Virus	n/a	Not Detected	7.3.2 and EMEA/CVMP/743/00 part 4.3.3. Detected by fluorescent antibody EMA/CHMP/BWP/457920/2012 Part 7.3.1 and		Not Detected ²	n/a	n/a	Not Detected ² n	a Not Dete	ected ² n/a	Not Detected	n/a	Not Detecte	ed ² n/a	Not Detected ²	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Not Detected ² n	ı/a Nc	t Detected ² n	/a Not Detected	n/a	Not Detected ²	n/a Not Γ	Detecte
n/a n/a	Virus (EMA): Bovine Viral Diarrhoea Virus	n/a	Check & Record	7.3.2 and EMEA/CVMP/743/00 part 4.3.3. Detected by fluorescent antibody	l ,	Check &	n/a	n/a	Check &	Check & Record ²	n/a	Check & Record ²	n/a	Check &	n/a	Not Detected ²	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Check &	Ch n/a	eck &	Check & Record ²	n/a	Check &	n/a Reco	ck &
n/a n/a	Virus (EMA): Cytopathogen Agents (Including Bovine Herpesvirus 1 (BHV-1/IBR))		Not Detected	EMA/CHMP/BWP/457920/2012 Part 7.3.1 and 7.3.2 and EMEA/CVMP/743/00 part 4.3.3.		Not Detected ²	n/a	n/a	Not Detected ² n		octed ² n/a	Not Detected	n/a	Not Detecte		Not Detected ²	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Not Detected ²	n/a No	t Detected ² n		n/a	Not Detected ²	n/a Not	Detecte
2/2	Virus (EMA): Haemadsorbin Agents (Including Bovine Parainfluenza Virus 3 (PI-3)		Not Detected	EMA/CHMP/BWP/457920/2012 Part 7.3.1 and 7.3.2 and EMEA/CVMP/743/00 part 4.3.3.	2/0	Not Detected ²	2/2	2/2	Not Detected ²	a Not Dete	ected ² n/a	Not Detected	2 2	Not Detecte	ad ² n/a	Not Detected ²			2/2	20/0	2/2	n/o	n/o	2/0	2/0	Not Detected ² n	n/o	t Detected ²	/a Not Detected	2 n/a	Not Detected ²	No.	Detecto
iiva iiva	Paramiluenza virus 3 (PI-3)) 1/a	Not Detected	EMA/CHMP/BWP/457920/2012 Part 7.3.1 and 7.3.2 and EMEA/CVMP/743/00 part 4.3.3. Detected		Not Detected	n/a	II/a	Not Detected III	a Not Dete	ected n/a	Not Detected	II/a	Not Detecte	ed II/a	Not Detected III	ıı/a II	1/a	П/а	II/a	n/a	II/a	II/a	n/a i	1/a	Not Detected III	a No	t Detected ² n	a Not Detected	n/a	Not Detected	I/a NOLL	Detecte
n/a n/a	Virus (EMA): Rabies Virus	n/a	Not Detected	by fluorescent antibody EMA/CHMP/BWP/457920/2012 Part 7.3.1 and	n/a I	Not Detected ²	n/a	n/a	Not Detected ²	a Not Dete	octed ² n/a	Not Detected	n/a	Not Detecte	ed ² n/a	Not Detected ²	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Not Detected ² n	/a No	t Detected ² n	/a Not Detected	n/a	Not Detected ²	n/a Not D	Detecte
n/a n/a	Virus (EMA): Reovirus	n/a	Not Detected	7.3.2 and EMEA/CVMP/743/00 part 4.3.3. Detected by fluorescent antibody	n/a I	Not Detected ²	n/a	n/a	Not Detected ² n	a Not Dete	ected ² n/a	Not Detected	n/a	Not Detecte	ed ² n/a	Not Detected ²	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	Not Detected ²	ı/a <mark>N</mark> c	t Detected ² n	/a Not Detected	n/a	Not Detected ²	n/a Not [Detecte
USDA Safety Testing																																	
VT- USDA Akabane	Virus (USDA): Akabane Viru	is n/a	Negative	Virus Testing is performed by the sheep inoculation test by the U.S. Department of Agriculture, Animal and Plant Inspection Service, National Veterinary Services Laboratories, Ames, Iowa.	n/a	n/a	n/a	Negative	Negative ³	20/0	0/0	n/a	n/a	n/a	n/a	n/a	u/a	n/a	n/a	n/a	n/a	Negativo	Negative ³	n/a	Venative	Negative ³	0/2	native ³	Negative ³	n/a	Negativo ³	n/a	
VT- USDA Bluetongue	Virus (USDA): Akabane Virus (USDA): Bluetongue \		Negative	Virus Testing is performed by the sheep inoculation test by the U.S. Department of Agriculture, Animal and Plant Inspection Service, National Veterinary	n/a	n/a	n/a	Nogotive	Negative ³	a jiva	n/a	n/a	n/a	n/a	n/a	n/o	Ma.	n/a	n/o	n/a	n/o	Negative	Negative ³	n/a	Negative	Negative ³		gative ³ n	Negative ³	n/a	Negative ³	n/a 11/d	
Tests no longer reported on	, ,	nius II/a	Negative	Services Laboratories, Ames, Iowa.	ıı/a	ıı/a	IIVa	Inegative	inegalive n	a I <mark>n/a</mark>	II/a	II/a	ıı/a	II/d	II/a	liva n	ıra <mark>N</mark>	ıra	11/a	II/d	II/a	inegative	ivegauve	11/a [vegalive	inegative in	a Ne	gauve n	a INEGATIVE	II/d	ivegative	ıra n/a	
	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record		heck & n/a	Check & Record		n/a	n/a	n/a	n/a n	n/a n	n/a	n/a	n/a	n/a	n/a	n/a		Check & Record	n/a n	n/a n/s	a n	'a n/a	n/a	n/a	Check & n/a	
Bacteriophage Testing n/a Sf9 Performance Assay %	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record		heck & n/a	Check & Record		n/a	n/a	n/a	n/a n	n/a n	n/a	n/a	n/a	n/a	Check and Record	n/a		Check & Record	<mark>n/a</mark> n	n/a <u>n/</u> a	n,	/a <mark>n/a</mark>	n/a		Check & n/a	
Tetracycline n/a	n/a	n/a	n/a	n/a	n/a r	n/a	n/a	n/a	n/a N	one Detected n/a	None D Check &	etected n/a	n/a	n/a	n/a	n/a n	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a r	n/a	n/a n	ı/a <mark>n/</mark> a	a n	/a <mark>n/a</mark>	n/a	n/a	None Detected n/a	
Determination of % Oxy Hemoglobin %	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record	n/a >	/=70% <mark>n/a</mark>	Record ¹	n/a	n/a	n/a	n/a	n/a n	n/a n	n/a	n/a	n/a	n/a	n/a	n/a	n/a F	Check & Record	n/a n	ı/a <mark>n/</mark> a	n,	/a n/a	n/a	n/a	>=70% n/a	
Tests to be performed and r	eported for selected SKUs/Spe	ecifications only		Biochemical Profile testing performed by approved		Check &		Check &	Check & C	heck & Check &	Check &	& Check &		Check &		Check &						Check and			Check &	Check &	C	eck &	Check &		Check &	n/a Reco	ck &
Biochemical Profile variou	s Biochemical Profile	various	Check & Record	contract laboratory.		Record	n/a			ecord Record	Record		n/a	Record	n/a	Record	n/a n	n/a	n/a	n/a	n/a	record	n/a	n/a F	Record	Check & n.	/a Re	eck & n	Check & Record	n/a	Check & Record	n/a Reco	ord
	ted on CoA urrent specification applies to sel	- - - - - -	- anh																														

This current specification applies to selected lots/markets only
Will be reported for selected lots only

Will continued to be Mycoplasma tested (ES Qualified FBS)

Ph. Eur. Bovine Serum Monograph No. 2262□

Not reported on COA

medicinal products

USP <1024> Bovine Serum
USP <90> Fetal Bovine Serum

Offical Document Reference & Title

Tested on lots that are distributed within or via the United States only; USDA import requirement.

EMA/CHMP/BWP/457920/2012 - Guideline on the use of bovine serum in the manufacture of human biological medicinal products

EMEA/CVMP/743/00 Rev2 - Requirements and controls applied to bovine serum used in the production of immunological veterinary