

				10091 / A31609	10099 /A31610	16000 /A31604	10082/ A38400	10093	10094	16141	30044	12664	10100	10101	30048	01190005	10083																
Catalog Number/SKU's (Base number as per COA)																																	
Description				FBS, Qualified		FBS, Qualified		FBS, Certified		Certified Heat-Inactivated		Qualified Heat-Inactivated		Qualified Gamma Irradiated		ES Cell Qualified		ES Cell Qualified		MSC Qualified		Qualified Heat-Inactivated		Qualified Gamma Irradiated		Qualified Gamma Irradiated and Heat Inactivated		Qualified Gamma Irradiated and Heat Inactivated		Certified, Gamma Irradiated			
Country of Origin				New Zealand		Australia		United States		United States		New Zealand		New Zealand		United States		New Zealand		Australia		Australia		Australia		Australia		United States					
Before Change	Units	Test Description	Units	Specification	Method Reference	Before Change	New	Before Change	Before Change ¹	New	Before Change	New	Before Change	New	Before Change	New	Before Change	New	Before Change	New	Before Change	Before Change ¹	New	Before Change	Before Change ¹	New	Before Change	Before Change ¹	New	Before Change	Before Change ¹	New	
Specials(2)ed Testing:																																	
ES Cell Performance Assay		ES Cell Qualification Colony Forming Assay	n/a	Acceptable	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.	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	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
MSC CFU-I Assay		MSC CFU-I Assay	n/a	Acceptable	Thermo Fisher Scientific Specifications: Pooled 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.	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	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Additional testing available on selected lots only:																																	
n/a	n/a	Serology: Anti BVDV Antibody Test	n/a	Check & Record	EMA/CHMP/BWP/457920/2012 Part 7.3.4 and EMEA/CVMP/743/00 4.3.3.3.	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²
n/a	n/a	Virus (EMA): Bluetongue Virus	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	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
n/a	n/a	Virus (EMA): Bovine Adenovirus	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	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
n/a	n/a	Virus (EMA): Bovine Parvovirus	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	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
n/a	n/a	Virus (EMA): Bovine Respiratory Syncytial Virus	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	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
n/a	n/a	Virus (EMA): Bovine Viral Diarrhoea Virus	n/a	Check & Record	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	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²	n/a	Check & Record ²
n/a	n/a	Virus (EMA): Cytopathogenic Agents (Including Bovine Herpesvirus 1 (BHV-1/IBR))	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.	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
n/a	n/a	Virus (EMA): Haemadsorbing Agents (Including Bovine Parainfluenza Virus 3 (PI-3))	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.	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
n/a	n/a	Virus (EMA): Rabies Virus	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	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
n/a	n/a	Virus (EMA): Reovirus	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	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²	n/a	Not Detected ²
USDA Safety Testing																																	
VT- USDA Akabane Virus	n/a	Virus (USDA): Akabane Virus	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	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	n/a	n/a	n/a	n/a	n/a	n/a	n/a
VT- USDA Bluetongue Virus	n/a	Virus (USDA): Bluetongue Virus	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	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	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Tests no longer reported on any SKUs/specifications																																	
Bacteriophage Testing	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	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	n/a	n/a	Check & Record
Sig Performance Assay	%	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	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	n/a	n/a	Check & Record
Tetracycline Determination of % Oxy Hemoglobin	%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record	n/a	None Detected	n/a	None Detected	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	n/a	n/a	n/a	None Detected
Tests to be performed and reported for selected SKUs/specifications only																																	
Biochemical Profile	various	Biochemical Profile	various	Check & Record	Biochemical Profile testing performed by approved contract laboratory.	n/a	Check & Record	n/a	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 and record	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Check & Record
Key																																	
x	Reported on CoA																																
note 1	This current specification applies to selected lots/markets only																																
note 2	Will be reported for selected lots only																																
note 2a	Will continue to be Mycoplasma tested (ES Qualified FBS)																																
note 3	Tested on lots that are distributed within or via the United States only; USDA import requirement.																																
n/a	Not reported on COA																																
Official Document Reference & Title																																	
	Ph. Eur. Bovine Serum Monograph No. 2262																																
	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 medicinal products																																
	USP <1024> Bovine Serum																																
	USP <90> Fetal Bovine Serum																																