

# Routine Pathological Analysis on PurMa™ Bovine and Horse Serums Analysis of one of our Lots of Ultra-Premium Fetal Bovine Serum

(As an Example)

For Lot specific QC, please login and insert the Lot# to the Quality Control tab



PurMa Biologics, LLC

## Product Identity

Product Category	Cell and Tissue Culture Reagents
Product Name	PurMa™ Bovine & Horse Serums
Catalog Number	
Lot Number	3604102021

## General Policy of QC Analysis for All Types of PurMa™ Fetal and Horse Serums

For each Lot, three set of samples are kept:

1. Three 15 ml aliquots of each lot are kept at -80 °C, the holding is being continued till the expiry date.
2. Three 15ml aliquots of 15 ml are placed at 33 C°, as this temperature accelerates the growth of most of the pathogens. Moreover, the mentioned temperature is the most damaging temperature for cell culture reagents. The holding is being continued for 21 days.
3. Three 15ml aliquots of 15 ml are placed at room temperature. The holding is being continued till the expiry date. Then below mentioned efficacy and pathogenic tests are performed on two sets of the three aliquots:
  - The Samples kept at -80 °C, and.
  - The pathogenic tests are performed on the RT aliquots.

## Mycoplasma Analysis description

1. 50µl of each aliquot is incubated in PurMa™ Mycoplasma Broth LB Medium (P4M010401).
2. 50µg/ml ampicillin and 100µg/ml of Penicillin as well as 25µg/ml Fungicide (Amphotericin) are applied to prevent growth of bacteria and mold/fungus/yeast, respectively.
3. Samples are Shaked at 37°C for three days in aerobic condition.
4. Samples are placed still at room temperature for three days in anaerobic condition to reach the maximum capacity of all variants of mycoplasmas.
5. Egg Fried Structures Evaluation: The presence of “Egg Fried Structures” (mycoplasma colony shape when they are grown on LB-agar), 100 µl of each aliquot is spread on the PurMa™ Mycoplasma LB Agar (P4G010407) and incubated for three days at 37°C. The presence egg fried structure is evaluated.
6. PurMa™ Mycoplasma PCR detection kit (Cat: P4P010404) is used to amplify various mycoplasma species.

7. All the mycoplasma tests described in the table below are performed on the three samples at timepoints mentioned before the expiry date.

### **Mold and Fungus Analysis description**

1. 50µl of each aliquot is incubated in PurMa™ Broth LB Medium (P2U010011).
2. 50µg/ml ampicillin and 100µg/ml of Penicillin is applied to prevent growth of bacteria.
3. Samples are shaken at 33°C for six days (best temperature for growing mold).
4. The appearance turbidity test as well as examination under the inverted microscope are being performed on the three samples at the mentioned timepoints.
5. PurMa™ Mold PCR detection kit (Cat: P4F010410) which is much more sensitive and determines any upcoming mold contamination is used to perform the analysis in molecular level.

### **Bacterial Analysis description**

1. 50µl of each aliquot are incubated in PurMa™ Broth LB Medium (P2U010011).
2. 25µg/ml Fungicide (Amphotericin) was applied to prevent growth of Mold/Yeast and Fungus.
3. Samples shake at 37°C for 48h.
4. The following tests are being performed on the three samples below mentioned timepoints using PurMa™ Bacterial PCR detection kit (Cat: P4B010411).

### **Cell Counting and Growth Analysis**

1. Depending on the cell type, 10, 15 or/and 20% were used to grow NSI as well as COSI cells for three days using DMEM media on the three-aliquot kept at -80°C (see below table).

## **Test specification**

Each test is performed on all three aliquots independently, and the three readings are averaged as one number. The two numbers for each criterion in the below table is an average of three numbers, and each of the two rows is done by independent scientists.

<b>Specifications</b>	<b>After Manufacturing</b>	<b>6 Months Post Manufacturing</b>	<b>18 Months Post Manufacturing</b>	<b>24 Months Post Manufacturing</b>
<b>Morphology &amp; Physical Evaluation</b>				
Appearance (Turbidity) For Mold, Yeast and bacteria (Mycoplasma does not cause turbidity)	Light yellow (transparent)	Light yellow (transparent)	Light yellow (transparent)	Light yellow (transparent)
	Light yellow (transparent)	Light yellow (transparent)	Light yellow (transparent)	Light yellow (transparent)
<b>Pathological Analysis; Non-Molecular Tests</b>				
<b>Mycoplasma Evaluation; Egg Fried Structures Quantification</b>				
100 µ of each aliquot is spread on the PurMa™ Mycoplasma LB Agar (P4G010407) and incubated for three days at 37°C and the number of egg fried structure Counted.	Negative	Negative	Negative	Negative
	Negative	Negative	Negative	Negative

## Mold and Yeast Evaluation

1. Turbidity evaluation. 2. For the common species: Aspergillus Fumigatus, Mucor pusillus, Penicillium Sp, and Candida albicans using microscopic analysis. <b>It proceeds with PCR evaluation (see below).</b>	Negative	Negative	Negative	Negative
	Negative	Negative	Negative	Negative

## Bacterial Evaluation

1. Turbidity evaluation. 2. Microscopic analysis was performed. <b>It proceeds with PCR evaluation (see below).</b>	Negative	Negative	Negative	Negative
	Negative	Negative	Negative	Negative

## Molecular Biology Analysis

### Mycoplasma Evaluation

Using <b>PurMa™ Mycoplasma PCR detection kit (Cat: P4P010404)</b> proven to detect the following species: M. Laidlawi, M. Arginine, M. Boris, M. Fermentans, M. Hominis, M. Hyorhinis and M. Orale.	Negative	Negative	Negative	Negative
	Negative	Negative	Negative	Negative
Using specific primers, the up regulation of mycoplasma promoting proteins are tested: 1. interleukin-1 (IL-1) 2. IL-6, and from Cytokines category CNTF up-regulating cytokine	Negative	Negative	Negative	Negative
	Negative	Negative	Negative	Negative

## Mold and Yeast Analysis

For the common species: Aspergillus Fumigatus, Mucor pusillus, Penicillium Sp, and Candida albicans using microscope analysis as well as <b>PurMa™ Mold PCR Detection Kit (Cat: P4F010410)</b>	Negative	Negative	Negative	Negative
	Negative	Negative	Negative	Negative

## Bacterial Analysis

Common species are being tested by <b>PurMa™ Bacterial PCR Detection Kit (P4B010411)</b> : Staphylococcus pasteurii,	Negative	Negative	Negative	Negative
	Negative	Negative	Negative	Negative

Ecoli and Lactobacillus curvatus.				
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<b>Endotoxin Control Tests</b>				
Endotoxin Level	<= 1 EU/ml	<= 1 EU/ml	<= 1 EU/ml	<= 1 EU/ml
	<= 1 EU/ml	<= 1 EU/ml	<= 1 EU/ml	<= 1 EU/ml

<b>Virus Testing (9 CFR 113.53c)</b>				
Bovine Adenovirus	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Bovine Parvovirus	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Bovine Respiratory Syncytial Virus	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Bovine Viral Diarrhea Virus	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Rabies	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Reovirus	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Cytopathogenic Agents (IBR)	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Hemadsorbing Agents (PI3)	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected
Bluetongue	Not Detected	Not Detected	Not Detected	Not Detected
	Not Detected	Not Detected	Not Detected	Not Detected

<b>Viability Analysis</b>				
Cell Culture Testing – MTT (Cell Proliferation Ability)	Pass Lot 3304102820: 1.2X10 <sup>6</sup>	Pass Lot 3304102820: 1.6X10 <sup>6</sup>	Pass Lot 3304102820: 1.2X10 <sup>6</sup>	Pass Lot 3304102820: 1.6X10 <sup>6</sup>
	Pass Lot 3304102820: 1.8X10 <sup>6</sup>	Pass Lot 3304102820: 1.6X10 <sup>6</sup>	Pass Lot 3304102820: 1.8X10 <sup>6</sup>	Pass Lot 3304102820: 1.6X10 <sup>6</sup>
Cell Types Used	NSI cell (suspension cells)			
	CosI (Adhesive cells)			