PRODUCT DESCRIPTION

TET-System Approved FBS is tested to ensure it does not activate tetracycline-regulated gene expression systems. To assess this, highly sensitive reporter cells engineered to express firefly luciferase in response to tetracycline are incubated with the FBS for 24 hours. Only batches that exhibit luciferase activity at or below baseline levels (in the absence of tetracycline) and allow for full induction in the presence of tetracycline are approved for use.

COUNTRY OF ORIGIN

Biowest USA ensures full traceability of the FBS, with the country of origin specified in the Certificate of Analysis (CoA). For more detailed information, please refer to the technical data sheet for standard Fetal Bovine Serum (Ref. TDS-001).

Catalog Number	Description	Origin(s)
TSA1620	Fetal Bovine Serum	Refer to Certificate of Analysis
TSA1480		

INTENDED USE

This product is for in vitro research or further manufacturing only. It is not for human or animal consumption or use as an Active Pharmaceutical Ingredient (API). TET-System Approved FBS is used to prevent interference in tetracycline-regulated gene expression systems by ensuring that the serum is tetracycline approved.

COLLECTION SOURCE

Fetal Bovine Serum is derived from clotted whole blood, aseptically collected from the fetus via cardiac puncture. The serum is collected and treated in compliance with USDA regulations. Our vertical integration system ensures full traceability of the serum throughout all stages—from collection to production and final packaging.

QUALITY CONTROL PARAMETERS

1.1	pH: monitored and reported for each batch, with specifications provided in the Certificate of Analysis (CoA).
1.2	Osmolality: determined by the lowering of the freezing temperature, calibrated against standard solutions. Osmolality specifications are provided in the Certificate of Analysis.
1.3	Endotoxin: tested using USP 85 Photometric Quantitative Techniques. Test results are reported in the Certificate of Analysis.
1.4	Hemoglobin: measured by spectrophotometry. Results are provided in the Certificate of Analysis.
1.5	Total Protein: determined using a colorimetric assay. Results are reported in the Certificate of Analysis.
1.6	Sterility Testing: tested for the absence of aerobic and anaerobic bacteria, fungi, and yeast in compliance with 9CFR regulations. 9CFR regulations ensure that FBS is free from harmful microbial contamination, making it safe for use in sensitive cell culture applications.
1.7	Mycoplasma: tested via culture-based methods or PCR (Polymerase Chain Reaction), depending on customer requirements. Tested for the absence of Mycoplasma.
1.8	Virus Testing: Testing is performed by inoculating permissive cell cultures and following the 9CFR 113.53c, 113.46, and 113.47 requirements. Each batch undergoes virus testing for the following pathogens: • Bovine Viral Diarrhea (BVD) • Infectious Bovine Rhinotracheitis (IBR) / BHV-1 • Parainfluenza Type 3 (PI3)

	• Bluetongue virus • Bovine Respiratory Syncytial Virus (BRSV) • Reovirus & Rabies virus
1.9	Tetracycline: tested via TET ON *invitro* induction. Results are reported in the Certificate of Analysis.
1.10	Other Testing: Additional testing may be available upon request, depending on customer needs.

FILTRATION

Final Filter Size: 0.1µm × 3

TREATMENT PROCESS- Heat Inactivation (Optional Treatment)

Heat inactivation deactivates certain Fetal Bovine Serum (FBS) components that can interfere with cell culture. This process involves heating the serum to 56°C for 30 minutes. Heat treatment can affect serum proteins, which influence the performance of the serum in certain applications.

Heat-inactivated FBS meets the same quality standards as non-heat-treated FBS. The process is carefully controlled to preserve the serum's essential nutrients and growth factors. A color change in the serum, which typically ranges from a yellowish to an opaque appearance, will occur. Color change does not indicate a loss of quality or effectiveness.

Note: Heat inactivation is an optional service that must be specifically requested when ordering. Before using it, be sure to verify whether it is suitable for your particular cell culture requirements.

STORAGE CONDITIONS

Store at ≤ -10°C, protected from light to maintain the serum's integrity.

SHELF LIFE

5 years from the date of manufacture when stored under the recommended conditions.

HANDLING INSTRUCTIONS

2.1	Thawing: Thaw the serum in a refrigerator (2°C to 8°C) or at room temperature. Avoid rapid thawing methods to preserve protein integrity.
2.2	Aliquoting: For optimal preservation, aliquot the serum after thawing using aseptic techniques.
2.3	Storage after Thawing: The serum is recommended for use immediately after thawing. If not all the serum is used, it can be stored at +2°C to +8°C for up to 26 weeks without a significant decrease in cell culture performance, provided sterility is maintained.
2.4	Repeated Freeze/Thaw Cycles: To maintain serum quality, avoid repeated freeze/thaw cycles. Always refreeze aliquots, not the entire bottle.

PRECAUTIONS AND SAFETY

3.1	For Research Use Only: Not for human or animal consumption.
3.2	Protective Equipment: Always wear appropriate PPE, such as gloves, lab coats, and face protection, when handling the serum.
3.3	Aseptic Handling: Ensure that serum is handled under aseptic conditions (e.g., laminar flow hood) to prevent contamination.

REGULATORY INFORMATION

Fetal Bovine Serum complies with relevant regulations set by the USDA and other international bodies for collection, processing, and use.

DISPOSAL INSTRUCTIONS
Dispose of unused serum and packaging according to local regulations for biological materials and hazardous waste.
CERTIFICATE OF ANALYSIS (CoA)
A Certificate of Analysis is provided with each batch and contains detailed specifications, including test results for sterility, endotoxin levels, and other quality control parameters.
DISCLAIMER
This product is intended for research or further manufacturing only. Not for use as an Active Pharmaceutical Ingredient (API) or food or animal feed. Before use, users should refer to the Certificate of Analysis (CoA) for specific details.

For further information or inquiries, please contact Biowest USA Customer Service.