

# Wuxi NEST Biotechnology Co., Ltd

## Certificate of Analysis

Product Name	Nest BioFactory 5 Chamber	Product No.	771204	Lot No.	051324KC01	
DOM	2024-05-13	Expiration Date	2027-04			
No.	Item	Inspection items/basis			Result	
1	Appearance	Pull/scratch/flow/release mark: the side pull/scratch/flow/release mark does not exceed 2mm, the bottom culture surface pull scratch flow mark release mark does not exceed 1mm Shrinkage: cultured surface is not allowed. Bubbles: Bubbles are allowed on the side, but the bubbles cannot exceed 1mm <sup>2</sup> , bubbles are not allowed on the bottom culture surface, and bubbles are not allowed on the top box bottle mouth; Bubble at the glue mouth, a single area ≤0.3mm <sup>2</sup> , two bubbles a single area ≤0.2mm <sup>2</sup> Long rubber mouth: the bottom long rubber mouth does not exceed 0.2mm, no wire drawing phenomenon Black spots and impurities: area 0.2mm <sup>2</sup> , distance 100mm or more, ≤2Area 0.1mm <sup>2</sup> , distance 80mm or more, ≤3,Area 0.05mm <sup>2</sup> , distance 50mm or more, ≤5, cannot be moved White spot: not obvious at a distance of 30CM			Pass	
2	Size	Comforming to the blueprint			Pass	
3	Contact angle test	After TC treatment, the contact Angle does not exceed 39 degrees			Pass	
4	Sealing test	Air leakage tester, no air leakage is qualified			Pass	
5	Packaging	Correct packaging materials and quantity; intact packaging			Pass	
6	Sterilization	Red colored irrediration tag with Certificate of Irradiation			Pass	
7	*Sterility testing	No microorganisms can be detected			Pass	
8	*Insoluble particles	Particles 10µm and above ≤25 particles /mL, particles 25µm and above ≤3 particles /mL			Pass	
9	*Endotoxin Detection	≤0.05EU/ml			Pass	
10	*Cell culture test	The cells were evenly distributed and in good condition			Pass	
11	*Rnase and Dnase test	No Rnase detected			Pass	
Conclusion		Pass				
Note: Only Pass or No pass is applicable in filling in 'Result'.						
Items marked with "*" are periodic testing items for representative products.						
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