
 Miraclean Technology Co.,Ltd.	No.:	2020050928
	Date:	2020-5-9

Title	Certificate Of Analysis
--------------	--------------------------------

Product Name	Virus Transport Medium	Packing Spec.	10ml	Lot.	2020030058
Based on	Product Specificate Requirment of Virus Transport Medium	Batch Quantity	10400	Number of samples	50

No.	Item	Executive Standard / Requirements	Inspection methods	Inspection conclusion
1	Appearance	The sample preservation solution should be clarified without visible suspended impurities or precipitation. The storage liquid shall be red, transparent, and the liquid medium in the container shall be visible. No leakage shall occur.	Visual inspection	pass
2	Volume	The quantity of sample preservation solution shall be no less than the labeled quantity.	Standard weight measurement	pass
3	PH	The PH value of sample preservation solution should be in the range of 7.4 ~ 8.0.	pH test strips	pass
4	Microbial Limit	Bacteria shall not exceed 100cfu, moulds shall not exceed 10cfu, yeasts shall not exceed 10cfu, Staphylococcus aureus and Pseudomonas aeruginosa shall not be detected.	Laboratory testing	pass
5	Labeling	The product logo is clear, intact, neat and without damage.	Visual inspection	pass

Overall test conclusion: Qualified Unqualified

Inspectors	刘文虎	Signature	
Auditor	崔柳		



Miraclean Technology Co.,Ltd.

No.	2020050928
Date	2020-5-9

Title Certificate of Analysis

Item No.	96000	MFG	20200403	Lot	2020040092	Sterilization lot	20200408	
Based on	Guangdong Machinery Note Standard Requirements for 20162411108		Quantity	10400	Number of samples	50	Date	20200509

No.	Item	Executive Standard / Requirements	Test Results
4.1	Appearance and structure	4.1.1 The shape of the swab should be correct	pass
		4.1.2 The product should be clean, odorless, tasteless, and the swab should be soft to the touch. There should be no yellow spots, smudges, foreign objects, and the rod should be smooth.	
		4.1.3 Dimensions in accordance with product specifications	
4.2	Performance	4.2.1 Connection strength When the moving speed of the tensile testing machine fixture is 200mm/min; the pulling force of the sampling head and one end of the connecting rod should be no less than 2N	pass
		4.2.2 When the test span is 6cm, the span should be able to withstand the static pressure of 4N perpendicular to the axial direction for 15S without permanent deformation or breakage.	pass
		4.2.3 The breaking force of the depression at the sampling head end should be no less than 2N.	pass
		4.2.3 The maximum breaking force of the fixed sampling head end vertically downwards in the recess of the post is as follows: <input checked="" type="checkbox"/> 96000 Maximum breaking strength 20N <input type="checkbox"/> 93050 Maximum breaking strength 28N <input type="checkbox"/> 95000 M Maximum breaking strength 30N <input type="checkbox"/> 95000 L Maximum breaking strength 35N <input type="checkbox"/> 95000 LV Maximum breaking strength 20N	20N
		4.2.4 After the glue is applied to the ABS rod, the nylon wool is sprayed, and the rotating friction is 360 degrees not less than 3 times, and the amount of nylon fluff on the surface is not more than 2	pass
4.3	Sterile	It should be sterilized by a confirmed sterilization process.	pass
7.1	Logo, packaging,	It shall comply with the drawings and sample requirements required and confirmed by the Medical Device Manual and Label Management Regulations.	pass

Overall test conclusion Test Result Qualified Unqualified Guangdong Machinery Note Standard Requirements for 20162411108
 Test Result Qualified Unqualified

Inspectors: 刘文虎 Approve: 崔柳
 Date: 2020.05.09 Date: 2020.5.9

