



Manufacturer's Certificate of Analysis

American Toxicology Products is the owner and distributor of the Vacuguard™ collection product line. Vacuguard™ products are manufactured by Zhejiang Gongdong Medical Technology Co., Ltd. The following Manufacturer's Certificate of Analysis is the original manufacturer-issued quality document.

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Certificate of Analysis

(Disposable Vacuum Blood Collection Tube)

Report No.: 2512264

Report No.: 2012204	Sample Name	Glass Vacuum Tube	Specification	16*100mm 10mL				
	Product Description	Sodium Fluoride100mg & Potassium Oxalate 20mg	Item No	GD100SP				
	Lot No.	251204	Package	1000pcs/carton				
	Quantity	30000pcs	Source	Warehouse				
	Date of Inspection	2025.12.10	Date of Report	2025.12.11				
	MFG	2025.12.04	EXP	2027.11				
	Basis of Inspection	JY-058 Disposable Vacuum Blood Collection Tube Inspection Regulation						
	Test Items	Requirements	Inspection Methods	Standards	Sample	Acceptable Quality Level (AQL)		Result
Appearances	The marks and labels on the test tubes shall be clear and right and shall not peel off. The tube shall not be surrounded and covered by the label totally, and it shall be transparent and clean. The blood sample in the test tube shall be clearly seen by normal vision. No distortion, sand hole, impurity or air blister on its outer surface. The test tubes shall be smooth, even and no slitter edge on them and shall be uniform in wall thickness. The bottom of tube shall be smooth and unified in its thickness.	Visual inspection	S-1	5	10		Re	
					Ac	Re	0	
					1	2		
Markings	The cap color, specification and expiration date of the blood tube shall conform to standard, the color of label and cap should be conform..	Visual inspection	S-1	5	2.5		Re	
					Ac	Re	0	
					0	1		
Additive Volume	The additive content of each tube should be controlled within the standard range.	Physical measure	S-1	5	2.5		Re	
					Ac	Re	0	
					0	1		
Graduated Markings and Filling Lines	The volume of liquid filled shall not exceed or fall below 10% of the filling line.	Physical measure	S-1	5	2.5		Re	
					Ac	Re	0	
					0	1		
Nominal Liquid Capacity	Liquid Additive Volume: The sum of the liquid additive volume and the tube suction volume should be 90%-110% of the Nominal liquid capacity as specification. Sufficient free area should be left for the robot or hand operating mixture.	Physical measure	S-1	5	2.5		Re	
					Ac	Re	0	
					0	1		
Composition	The blood collection tubes have built-in negative pressure and consist of test tubes, additives, reagent plugs and/or plastic caps, labels, plastic caps made of polyethylene plastic material; test tube plugs made of butyl rubber plugs; test tubes made of PET plastic, of which the tubes used for non-sterile blood collection tubes can be made of glass.3.2% sodium citrate tubes are available in single-wall and double-wall types, with the inner tube of the double-wall type made of polypropylene and the outer tube of the double-wall type made of PET plastic. The outer tube is made of PET plastic.	Physical measure	S-1	5	10		Re	
					Ac	Re	0	
					1	2		

Physical Property	Leak test: fluorescence should not be detected in water submerged in the blood collection tube.	Physical measure	S-1	5	2.5		Re
					Ac	Re	0
	Strength test: The blood collection tube can withstand centrifugal acceleration of 3000gn in the direction of its longitudinal axis for 10min without any fracture, collapse, crack or other visible defects.	Physical measure			0	1	
	Pressure resistance testing: The tube can bear 50kpa pressure for 15s, without crack.	Physical measure					
	Mechanical stress testing : After testing, the vacuum blood tube should be no crack, sink or other visible damage.	Physical measure					
Bio-load (non-sterile blood collection tube)	The average biological load of one non-sterile blood collection tube should not exceed 10cfu/piece.	Physical measure		PASS		PASS	
Sterilized Testing (sterile blood collection tube)	If the tube request for sterilized, it should be sterile after the availably irradiation sterilization.	Physical measure		PASS			
Conclusion: PASS							
Bad items content: /							

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 QC Dept