Certificate of Analysis

JL-8.2.6-C/4-01.22

Product name	Single-use Containers for Human Venous Blood Specimen Collection		Specification	Plain Tube 6ML	
Test basis	Delivery Inspection Procedure and Product Technical Requirement (20192220084)			Material	Plastic
Production batch number	09410176		Altitude information	2500M	
Production quantity(pcs)	3600		Production date	2021-09-16	
Sampling quantity(pcs)	50		Sampling date	2021-09-16	
Test date	2021-09-16		Report date	2021-09-17	

Test item	**Technical Requirement**	**Test result**	**Individual conclusion**
Material	a. During visual inspection, the material of the container shall be free from foreign matter.	Meet the requirement	Pass
Material	b.During visual inspection, the contents shall be clearly observed.	Meet the requirement	Pass
Nominal Liquid Capacity	The draw volume plus the volume of any additive, shall be between 90% and 110% of the nominal capacity.	100%～104.7%	Pass
Graduation and fill lines	For blood collection tubes with a nominal fill line marked on the container or container label, the volume of the filled liquid should not exceed or fall below 10% of the filling capacity.	0%～4.7%	Pass
Design	a.During the leak test, the stopper should be no loose and no fluorescence detected.	Meet the requirement	Pass
Design	b.When the rubber stopper is expected to be removed to facilitate removal of the contents of the blood collection tube, the part of the rubber stopper that is in contact with the sample cannot be touched by fingers or mechanically removing the device.	Meet the requirement	Pass
Construction	a.Blood collection tube should be able to withstand 4 times of removal and installation of the rubber stopper, and the blood collection tube should be free of breaks, collapses, cracks or other visible damage.	Meet the requirement	Pass
Construction	b.The longitudinal axis of the centrifugal blood collection tube could withstand a minimum acceleration of 3000g, and there is no break, collapse, crack or other visible defects.	Meet the requirement	Pass
Construction	c. Observe the blood collection tube with normal vision or corrected vision. There should be no sharp edges, burrs, or rough surfaces that can cause the user's skin or gloves to be accidentally scratched, punctured, or abraded.	Meet the requirement	Pass
Additives	The maximum allowable tolerance of liquid additives should be 90% ~ 110% of the specified volume.	Not applicable	Not applicable
Container identification and specifications	There shall be additive letter code or text description on container or label	Meet the requirement	Pass
Sterility	The interior of blood collection tube shall be sterile if not used.	Not applicable	Not applicable
Bacterial endotoxin	The bacterial endotoxin content of blood collection tube labeled as “Special for G Test” or “Special for GM Test” shall be no more than 0.1EU per piece	Not applicable	Not applicable
Information	a.The label should indicate: manufacturer's name or trademark and address; specification model; production batch number; expiration date; nominal liquid capacity; identification and concentration of additives; instructions or graphical symbols for “single use only” and “in vitro diagnostic medical device”.	Meet the requirement	Pass
Information	b.Identification of the sterilization method used for sterile products.	Not applicable	Not applicable
Information	c.Altitude information of blood collection tubes used in high altitude areas.	Not applicable	Not applicable
Remarks	Single-use Containers for Human Venous Blood Specimen Collection Delivery Inspection procedure is internal control file which is based on products Technical requirement.		
Conclusion	Qualified		

Tested by	Zhang Yuting	Checked by	Pan Xiaohong	Responsible person	Fu Jinping

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