



## **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.: 2601120

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                    |                |        |                                |    |        |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----------------|--------|--------------------------------|----|--------|
| Sample Name                          | Glass Vacuum Tube                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                    | Specification  |        | 16*100mm 10mL                  |    |        |
| Product Description                  | Sodium Fluoride100mg & Potassium Oxalate 20mg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                    | Item No        |        | 1001                           |    |        |
| Lot No.                              | 260101                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                    | Package        |        | 1000pcs/carton                 |    |        |
| Quantity                             | 24000pcs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                    | Source         |        | Warehouse                      |    |        |
| Date of Inspection                   | 2026.01.04                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                    | Date of Report |        | 2026.01.05                     |    |        |
| MFG                                  | 2026.01.01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                    | EXP            |        | 2027.12                        |    |        |
| 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 |     |      |     |      |    |
|                                                       | Pressure resistance testing: The tube can bear 50kpa pressure for 15s, without crack.                                                                                                                         | Physical measure |     |      | 0   | 1    |    |
|                                                       | Mechanical stress testing : After testing, the vacuum blood tube should be no crack, sink or other visible damage.                                                                                            | Physical measure |     |      |     |      |    |
| Bio-load<br>(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<br>(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: /                                  |                                                                                                                                                                                                               |                  |     |      |     |      |    |