



# CERTIFICATE OF COMPLIANCE

BD Diagnostics  
Preanalytical Systems  
150 South 1st Avenue  
Broken Bow NE 68822-2203 US

Page: 1 of 1

**Product Name** : TUBE BAC GC 16X100 10.0 PLBL GR NAF/KOX  
**Catalog Number** : 367001 **Manufacture Date:** 2021/06/10  
**Batch Number** : 1137362  
**Expiration Date** : 2023/05/31

### CERTIFICATION OF COMPLIANCE

This material number is a (TUBE GLU GC 16x100 10.0 PLBL GR NAF/KOX) BD Diagnostics Preanalytical Systems Blood Collection Tube reorder #367001. Manufacturing specification for this tube requires the following amounts of powdered additives in each tube.

Potassium Oxalate 18.0mg. to 23.0mg. (Nominal 20.0mg. )  
Sodium Fluoride 90.0mg. to 115.0mg. (Nominal 100.0mg.)

This tube is manufactured specifically for blood alcohol determination. The chemicals added to this tube will not disturb the integrity of the blood sample relative to the alcohol content.

Vacuum in the tube is set to draw 9.3mL to 10.7mL (Nominal 10.0mL). Using a specific gravity for blood of 1.057 grams the following would be the minimum and maximum percent of additive to blood.

Potassium Oxalate 0.16% to 0.23% (Nominal 0.19%)  
Sodium Fluoride 0.80% to 1.17% (Nominal 0.95%)

#### Sterility Claim:

All products which are labeled as either "Sterile" or "Sterile Interior" and released for sale by BD Diagnostics Preanalytical Systems are certified to be sterile as long as the product package or product is unopened and undamaged. For those products labeled "Sterile Interior" only the product interior is sterile.

#### Manufacturing Claim:

BD Diagnostics Preanalytical Systems products are manufactured in accordance with the medical device regulations (21CFR820) and comply with Medical Device Reporting (MDR) Regulations (21CFR803). All products and manufacturing facilities comply with FDA registration and listing requirements (21CFR807). The released products satisfy BD Diagnostics Preanalytical Systems finished product specifications. The Broken Bow facility is also ISO 13485:2003 certified.

Broken Bow Quality Assurance  
Release date:2021/07/22  
Name:Erlinda Larsen

This certificate is produced and controlled electronically and is valid without handwritten signatures.