

Product Name: SputEm™ Collection System

Catalogue No.: C200G

This document replaces any previous version

1. Product Description:

- **SputEm™ Collection System:** Disposable, sterile, use to collect, carry and process samples. Base and funnel assembled with a removable sterile 50ml graduated tube with lip seal cap and patient ID label.

2. Packaging:

- **Case:** 72 units per case (individually wrapped)

3. Product Specifications:

- **Material:**
 - Tube: Polypropylene
 - Collection Unit: Polypropylene
 - Cap: Polyethylene
 - Color: Green
- Gamma radiation sterilized at a SAL of 10^{-3} ; specified dose between 6.5 kGy and 13.5 kGy
- Patient label affixed on top of the snap cap
- Temperature range: -90°C to +100°C
- Tube is centrifuge resistant at up to 3 000 g

4. Standards and Conformity:

- **ISO 2859-1:** Sampling and inspection procedures
- **FDA:** Resins conform to FDA 21 CFR 177.1520
- **CONEG / RoHS:** Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals

5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes
- Dimension and volume measurements
- Closure verification
- Leak proof testing in vacuum at 71.3cm Hg

6. Traceability:

- **Lot No. Composition:** 8 or 9 digits

- **The lot number can be found in one or all of these locations:**
 1. On exterior case label
 2. On inserted label inside the master case
 3. On the inner bag

7. Storage Conditions:

- Store at room temperature in normal warehouse conditions
- Protect from any possible contamination
- Protect from any damage to the packaging which could compromise the product sterility

8. Recommended Use:

- Verify proper cap closure when using biohazard material and / or chemical reagents
- Follow chemical resistance chart recommendations

OWNERSHIP OF MATERIALS:

*Materials and information contained in this document are **Simport Scientific's** copyrighted and are protected by worldwide copyright laws and treaty provisions. They may not be copied, reproduced, modified, published, uploaded, posted, transmitted or distributed in any way.*