

# Sterilization Procedures for Finetech® Centrifuge Tubes



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# Sterilization Procedures for Finetech® Centrifuge Tubes

## I. Centrifuge tube sterilization procedures:

1. Preparation of the biological indicators (BI)
2. Affixed with sterilization indicator label
3. Sterilization conditions
4. Cultivation of biological indicators after sterilization
5. Sterility results

## II. Description of sterilization procedures

**1. Preparation of the biological indicators (BI):** the BI are placed into centrifuge tubes packed to similar packaging method of the product. The BI is sterilized in the same way as the rest of the products.

\*Using BI can confirm the effects of sterilization 48 hours after sterilization. (Generally, sterility test for sterilization is 7-14 days)



**2. Affixed with sterilization indicator label:** the sterilization indicator labels are placed on the carton of the products to be sterilized. The sterilization labels are "red" before sterilizing by EO and becomes "blue" after sterilization.



## 3. Sterilization conditions

- Sterilization Gas: Ethylene oxide
- Sterilization Temperature:  $40 \pm 3^\circ\text{C}$
- Vacuum Pressure:  $-0.5\text{kg}/\text{cm}^2$
- Sterilization Pressure:  $1.1\text{ kg}/\text{cm}^2$
- Sterilization Time: 10 hours
- Amount of Air Removed After Sterilization: 5 times



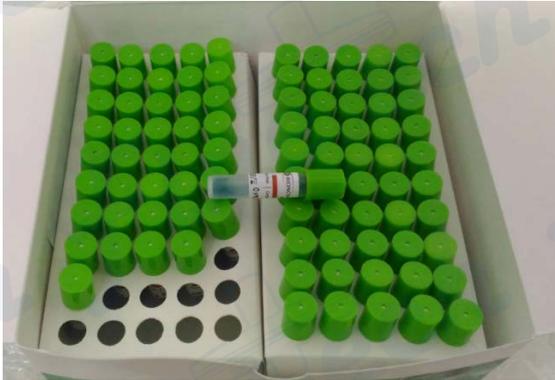
(Sterilization chamber)



(EO sterilization system)

#### 4. Cultivation of biological indicators after sterilization

A. The biological indicators are filled with *Bacillus subtilis*, which is easy to culture and can clearly determine the results of sterilization.



B. Biological indicators' initial color is blue. The bacteria are cultured at 37-40 °C. When there is growth of the bacteria, the color of the BI indicator will turn yellow.

C. Biological indicators are sterilized by Ethylene oxide and then cultured. If the sterilization is complete, the *Bacillus subtilis* will die, resulting in no change to the original color, blue.

#### 5. Sterility results

The centrifuge tubes were sterilized on 2019-07-02 and the BI were placed in the products to be sterilized. After the sterilization process, the BI were removed and an unsterilized BI was added as a control group. Bacteria were cultured at 37-40 °C for 48 hours.

After 48 hours, the BI were taken out and observed for changes in color. The BI subjected to sterilization remained blue while the added unsterilized control changed to yellow.

**The results showed that Finetech's sterile centrifuge tubes were effectively sterilized through E.O. processing.**