

# Gamma-Globulin T Aptitud Assay Verification †

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**Abstract:** Gammaglobulin T has in its formulation thimerosal, an organo-mercurial compound, which hinders the growth of Microorganisms in the aptitude assay, which validates the ability to recover a small amount of Microorganisms in the product in question. To inhibit the antimicrobial power of Thimerosal, three methodologies were tested: dilution with 500 milliliters of 0.1% Peptone (Sterility Assay wash solution), washing with 0.5% Sodium thiosulfate (known to neutralize mercury compounds), and washes with Engley / Day Broth (culture broth with a wide range of Microorganisms that neutralizes various antimicrobial and disinfectant agents). Through Membrane Filtration of solutions containing known concentrations of specific microorganisms, the different possible neutralizers mentioned above, and gamma globulin T, it was concluded that the best way to neutralize the antimicrobial was to wash with Engley/Day broth because it was the methodology with which higher counts of colony-forming units were obtained and better maintaining their morphological integrity. Thanks to the study, the Sterility assay Method for this product was defined as a Membrane Filtration together with washing 500 milliliters of Engley/Day broth as thimerosal neutralizer.

**Keywords:** Gammaglobulin T; Thimerosal; Membrane Filtration; Engley/Day Broth.

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## Conflicts of Interest

The authors declare no conflict of interest.