

Sterility Sample Collection and Shipping

All samples should be shipped via overnight courier, packed with adequate ice packs to maintain cool temperature and adequate insulation to prevent freezing.

Profile 1 - Direct Inoculation Method

The optimum sample will include both tissue culture media and cellular material (if present) because some micro-organisms are intracellular or highly cell-associated. Any remaining material is held at 4C during the course of incubation as a backup or possible confirmatory testing.

The inoculum size per medium is 100 µL; submitters should submit a sample volume of 1000-1500 µL (1-1.5 mL) so that repeat testing can be performed if deemed advisable (no additional charge). 100 µL is provided to the IDEXX BioResearch PCR laboratory if *Mycoplasma* is requested.

Profile 2F - Membrane Filter Concentration

Complies with FDA Title 21 Code of Federal Regulations 610.12 (**21CFR610.12**)

Profile 2F includes Profile 1 plus a membrane filtration procedure to concentrate potentially low number of contaminating bacteria and to remove anti-bacterial compounds such as antibiotics from the cell culture medium that might inhibit bacterial growth and lead to false negative results. This procedure follows **US CFR 21 CFR 610.12** sterility testing protocol. Submit a sample volume of 5 mL.

Profile 2C – Centrifugation Concentration

Profile 2C also includes Profile 1 but utilizes a centrifugation step instead of filtration for the concentration step. After centrifugation, the supernatant culture fluid, now devoid of cells and potentially contaminating bacteria, is removed and the pellet is re-suspended in sterile PBS and cultured in the same media used in Profile 2F. The advantages of this profile over Profile 2F is that it is a less complex procedure and is therefore less susceptible to potential contamination because manipulation of filter material is not required. Profile 2C is recommended for this reason, but it is **not** US CFR 21 CFR 610.12 compliant. Submit a sample volume of 5 mL. If quantity of material is limited, please contact IDEXX BioResearch at 1-800-669-0825.

The optimum sample will include both tissue culture media and cellular material (if present) because some microorganisms are intracellular or highly cell-associated.

All manipulations are performed in a laminar flow hood for all Sterility profiles.

Identification of Microbial Contaminants

Identification of microbial contaminants is available. Please call Dr. Marcus Crim at 573-499-5776 for details and pricing.

Volume pricing may be available. For more information and pricing, contact IDEXX BioResearch by phone at **1-800-669-0825** or by email at idxxbioresearch@idexx.com.

To submit online, visit: <https://secure.idexxradil.com/onlinesubmission.aspx> To download a fillable PDF submission form, visit: www.idexxbioresearch.com.

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