

CLIENT INFORMATION

PBL Quote Number:	PO Number: <i>Credit Card to be used for payment</i> <input type="checkbox"/>
Sponsor <i>(send report to):</i>	Invoice To: <i>Check box if same as sponsor</i> <input type="checkbox"/>
Contact Name:	AP Contact Name:
Company Name:	Company Name:
Address:	Address:
City/State/Zip:	City/State/Zip:
Country:	Country:
Phone:	Invoice To Email:
Email:	AP Email:

Regulatory Treatment: <input type="checkbox"/> Non-regulatory <input type="checkbox"/> cGMP <input type="checkbox"/> GLP	Rush Service <i>(will incur a surcharge)</i> : <input type="checkbox"/> YES <input type="checkbox"/> NO
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[illegible]

USP General water testing: cleaning validation extractions, swab samples, tap water

WATER TESTING SAMPLE SUBMISSION PROCEDURE

TOC

Samples for TOC testing should be collected into (2) 40 mL TOC (Special septum cap) glass vials. (1 for test, 1 extra). If the spigot will be cleaned with an organic solvent for micro sampling, make sure that the TOC sample is taken prior to cleaning. Organic solvents may provide out of specification results. Open the tap and allow the interior surface to be cleaned by a flush of water. Fill the sample vial with fluid, then discard; repeating 3 times prior to filling the vial with the water for testing. Document the appropriate sample ID (location), date and time of sampling for your records, on the LSR (Laboratory Service Request) form and on each vial. Maintain samples at 2-8C. Do not freeze.

Pacific BioLabs Sampling Supplies: TOC Sample Vials, 40 mL

CONDUCTIVITY

Submit 1,000 mL per test for water testing. Document the appropriate ID (Location), date, and time of sampling for your records, on the LSR (Laboratory Service Request) form and on each bottle. Indicate specifications (ex, stage the water must pass for USP testing). For solutions testing, submit at least 40mL and indicate specifications, if applicable. These samples do not have to be refrigerated.

Pacific BioLabs Sampling Supplies: Polycarbonate Bottle, 1 Liter or Glass Bottle with Teflon Lined Cap, 1 Liter

MICROBIOLOGICAL ANALYSES

Submit 120 mL per microbiological analysis.

FOR HETEROTROPHIC PLATE COUNT, PER USP <1231>, WATER FOR PHARMACEUTICAL PURPOSES, TESTING MUST BE PERFORMED WITHIN 24 HOURS OF SAMPLE COLLECTION FOR ACCURATE MICROBIAL COUNTS. (Indicate an expiration date/time if this is not applicable for your samples.)

Collect the sample(s) as late in the day as possible. **SHIP THE SAMPLES FOR OVERNIGHT, FIRST MORNING DELIVERY.** This will help to ensure that your samples are received, processed into the lab and the testing performed within the allotted time frame. Document the appropriate ID (location), date and time of sampling for your records, on the LSR (Laboratory Service Request) form and on each specimen cup.

Maintain samples at 2-8C. Do not freeze.

Total Heterotrophic Plate Count - Specify amount of sample submitted that Pacific BioLabs is to test.

BACTERIAL ENDOTOXIN

Samples for particulate are generally stored and shipped at normal storage conditions for the product. Indicate on your paperwork if you would like us to perform the test with the light obscuration or microscopic method. Samples should be taken in precleaned containers for bulk product. All other samples are sent in the regular packaging. For products that are < 25 mL each container, the USP requires a minimum of 10 pooled containers with a total volume of not less than 20 mL. Products that are greater than/equal to 25 mL each may be tested individually but are reported per container as required for small volume samples. If you expect your sample to fail the light obscuration test, please submit double this amount since this method uses 15 mL and we will need to request additional sample in order to perform the microscopic method.

Please note that Pacific BioLabs subcontracts particulate matter testing to a Pacific BioLabs audited facility.

FOR HPC, PER USP <1231>, TESTING MUST BE PERFORMED WITHIN 24 HRS OF SAMPLE COLLECTION FOR ACCURATE MICROBIAL COUNTS. SHIP SAMPLES FOR OVERNIGHT, FIRST MORNING DELIVERY.

OTHER TESTS/SPECIAL INSTRUCTIONS

Note that samples will be reported separately per lot unless otherwise indicated.

TESTING AUTHORIZED BY (please sign):

DATE:

(Signature and date, or electronic signature, is required for testing to begin; unsigned LSR forms will not be processed)