



Client: _____

Test No. (assigned by lab): _____

Test Article: _____

Lot No.: _____

**CLIENT SPECIFICATIONS FOR D VALUE/POPULATION DETERMINATION OF BIOLOGICAL INDICATORS
(Reference M-6 rev _____)**

In the interest of the client, the test cannot proceed without this information provided to Canyon Labs Rochester.

Please check an appropriate box for each item listed below, sign and submit with samples (call with questions)

1. Heat Shock Population Determination Method (M-6):

- Current USP <55>, 4 samples combined (*Note: modified USP methods are used for non-paper strip carriers*)
- Samples tested individually
- Other Method (e.g. Manufacturer's method) _____

(Note: Customer is responsible for providing current revision of procedure)

Specify Population Value for Calculation _____

Note: Using a method that differs from the original manufacturer tested method during dual certification testing may give varying results. For best results, it is advisable to follow the method that the manufacturer uses for determining the labelled population value.

2. D value Determination method:

Fraction Negative Methods

- Current USP <55> (Minimum 300 samples required*)
- Limited Spearman - Karber with Confidence Limits (Minimum 260 samples required*)
- Stumbo, Murphy and Cochran (Minimum 200 samples required*) **

*Note: number of required samples is based on 20 samples per exposure cycle.

**No confidence interval calculated

Other Methods

- Survivor Curve (Minimum 30 samples required-based on 5 samples per exposure cycle)
- Other _____

(Note: Customer is responsible for providing current revision of procedure)

Test: Survival/Kill Analysis (20 samples (USP) or 100 samples (ISO 11138-1)

Exposure Times

- USP formula with Canyon Labs Rochester results
- Manufacturer labeled times
- Other (specify) _____

3. Exposure Temperature(s):

Steam

- 121.1°C ± 0.5°C Qualified Cycle
- 121.0°C ± 0.5°C Qualified Cycle
- Other (**unqualified**) _____

100% EO

- 54 ± 1°C Qualified Cycle
- Other (**unqualified**) _____

4. Interpret population and D value results based on the following requirements:

- Current USP <55>
- Other (**specify**): _____
- None (**results reported as obtained without reference to specifications**)

5. Excess Test Article Disposition

- Return to sponsor via (**Please provide shipper account number**):
 - UPS: Ground, Red, Blue (**circle one**): Account # _____
 - FedEx: Priority, Standard, 2 day (**circle one**): Account # _____
- Discard/Destroy
- Other (**specify**) _____

NOTE: There will be an additional fee for the preparation of up to 200 strips from a spore suspension when required per M-005. Rush service is available at additional charge. Call for quote and turn around time.

Client approval: _____

Date: _____

Canyon approval: _____

Date: _____