

Intended Use:

PyroTest #PT6000 is intended to validate dry heat depyrogenation cycles for glassware and non heat-labile materials. The United States Pharmacopeia (USP) recommends that in order for a depyrogenation process to be valid, the endotoxin content of a challenge vial must be reduced at least 1000 fold (>3 log reduction).

Materials Supplied in PyroTest Kit:

- 2 EACH ASSAY VIALS with 0.125 EU/mL sensitivity
- 2 EACH ENDOTOXIN CHALLENGE VIALS containing >1000 EU of E. coli endotoxin
- 2 EACH 30 ML VIALS of endotoxin-free diluent
- 2 EACH 1 CC SYRINGES
- 1 EACH DIRECTIONS FOR USE
- 1 LOG SHEET

Materials Supplied by User:

- PYROTEST ALUMINUM VIRAL HOLDER, #INC004
- INCUBATOR PREHEATED TO 37° C
- APPROPRIATE CONVECTION OVEN

Procedure:

1. Fill oven with a worst case load of glassware to be depyrogenated.
2. Place one (1) of the Endotoxin Challenge vials (red cap) in the oven at the hardest to heat location. Set the other, "Control", Endotoxin Challenge vial aside for later use. Do NOT expose the Control Endotoxin Challenge vial to heat.
3. Do NOT remove the red crimp seal, stopper, or heat resistant label on Endotoxin Challenge vials.
4. Bake glassware and Endotoxin Challenge vial in convection according to parameters used in a standard, predetermined cycle.
5. After the cycle is complete, remove baked Endotoxin Challenge vial from oven.
6. Confirm that incubator and aluminum vial holder #INC004 are heated to 37° C.
7. Reconstitute baked Endotoxin Challenge vial and "Control" Endotoxin Challenge vial with 1.0 mL each of provided diluent water from one of the diluent vials. Set this diluent vial aside for use in Step #9.
8. Flick each vial rapidly with finger to dissolve endotoxin dried on the vial surfaces.
9. Transfer 0.4 mL from the UNBAKED Challenge vial to the 28 mL diluent vial. Shake diluent vial to disburse sample solution.
10. Transfer 0.3 mL from this dilution vial into the second 30 mL vial of diluent. Shake diluent vial to disburse sample solution.
11. Transfer 0.25 mL from the second diluent vial into one the Assay vials (white cap). Flick Assay vial to dissolve LAL reagent.
12. Mark this vial's label with an "X" using indelible ink. X = UNBAKED. Gently place this marked Assay vial in aluminum vial holder, #INC004.
13. Transfer 0.25 mL from Baked Endotoxin Challenge vial into the second Assay vial. Flick this Assay vial to dissolve LAL reagent. Gently place this unmarked Assay vial in aluminum vial holder, #INC004.
14. Quickly return aluminum vial holder containing the two Assay vials to the incubator.
15. Incubate both Assay vials UNDISTURBED at 37° C for 60 minutes.
16. Carefully remove the unmarked (Baked) Assay vial and invert 180 degrees. The contents should be a free flowing liquid. No gel clot indicates that the depyrogenation process was successful. A firm gel clot indicates that endotoxin is still present and the depyrogenation process failed.
17. Carefully remove the marked (Control) Assay vial and invert 180 degrees. The contents should be a firm gel clot.
18. Record results in the PyroTest Depyrogenation Validation Log.
19. Discard used supplies in a safe manner.



PyroTest™

Depyrogenation Validation LOG

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| | | | | | | | RESULTS | | |
|-----------|-----------|------------------|--------|----------------------|------------------|------|----------------|----------|--|
| Test Date | Tested by | Time/Temperature | Oven # | Challenge Vial Lot # | Assay Vial Lot # | PASS | FAIL | Comments | |
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