



Sterile Area Sample Identification Checklist

(Ref. MICLAB 095)

Deliver Aseptically Filled samples for the MICRO. LAB.
Complete this Checklist and include with the samples.

PRODUCT NAME:		BPN	
MATERIAL CODE NO.		CONTAINER & FILL SIZE	
FILLING MACHINE NO.		MACHINE STEAMED?	YES / NO
SIGN		START DATE	

<p>All units must be labelled:</p> <ul style="list-style-type: none"> With the time sample taken The Machine No. Sample type (Pyrogen, Bioassay or Sterility) Product description 	<p>NOTE: Minimum of cycles per machine, regardless of filling time, is:</p> <ul style="list-style-type: none"> Sterility 3 Cycles Pyrogen 3 Cycles Bioassay 2 Cycles
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NOTE: IT IS THE OPERATOR'S RESPONSIBILITY TO ENSURE ALL SAMPLES ARE TAKEN.

Starting Shift:

A.	Beginning of the batch:	i) The FIRST full cycle produced (PYROGEN) from each machine. ii) 1 full cycle (STERILITY) from each machine. iii) 1 full cycle (BIOASSAY) from each machine (if necessary)
	Sign (Operator)	Time:.....
B.	Middle of the batch:	i) The FIRST full cycle produced (PYROGEN) from each machine. ii) 1 full cycle (STERILITY) from each machine.
	Sign (Operator)	Time:.....
C.	End of the batch:	i) The FIRST full cycle produced (PYROGEN) from each machine. ii) 1 full cycle (STERILITY) from each machine. iii) 1 full cycle (BIOASSAY) from each machine (if necessary)
	Sign (Operator)	Time:.....
D.	After a STOPPAGE greater than 1 hour:	i) The FIRST full cycle produced (PYROGEN) from each machine. ii) 1 full cycle (STERILITY) from each machine.
	Sign (Operator)	Time:.....

NO. RACKS FOR STERILITY		FINISH DATE	
NO. RACKS FOR PYROGEN		SIGN	
NO. RACKS FOR BIOASSAY			

Comments, (i.e. DR's, water leaks, extra samples, etc.):