

Biological indicator ACE test®

Produced on ISO 9001:2000 certified factory
Produced on ISO 13485:2003 certified factory
JP, USP, ISO11138 standard

For Validation and Monitoring of Sterilization Processes

ACE test is a biological indicator which can confirm whether sterilization has been carried out properly after autoclave, EO Gas, H₂O₂, LTSF, formalin, and steam sterilization at 115°C

- Features**
- ◆ Highly reliable sterilization results obtained after 24 hours, 48 hours or 7 days culturing
 - ◆ Built-in chemical indicator provides quick identification of processed BIs
 - ◆ Potency and stability retained for 18 months after production
 - ◆ Fits competitor's incubators
 - ◆ Matches criteria required as a biological indicator for JP, USP, EN866, and ISO11138 Sterilization methods

Surface Sterilization



Component: Spore strip bag, Medium (screw cap tube)

How to test:

1. Put a bag in the objective point and sterilize it.
2. After sterilization, take a strip out of a bag under germfree environment and put it in an attached nutrient medium.
3. Culture it together with the positive control by an exclusive incubator (Cat. No. FUK-H8200).

Color change	H ₂ O ₂		ClO ₂	
	After 24 hours	After 48 hours	After 24 hours	After 48 hours
Complete				
Incomplete				

Other Sterilizations



Component: Spore strip, Medium (self-contained)

How to test:

1. Put a bottle in the objective point and sterilize it.
2. After sterilization, confirm whether indicator label has changed.
3. Break an ampoule according to protocol and make a sporule filter paper and a nutrient medium touch and culture it.

* Regarding dry heat test, protocol is different from others. Please see protocol for dry heat test.

Color change	Autoclave		EO gas	
	After 24 hours	After 48 hours	After 24 hours	After 48 hours
Complete				
Incomplete				

Change	ACE test®		ACE test®		ACE test®		ACE test®	
	Before	After	Before	After	Before	After	Before	After
B.I. Steam								
B.I. Steam								
B.I. EO								
B.I. EO								

► Dry Heat Sterilization

Please note that dry sterilization test component is divided to culture medium (Cat. No. FUK-H6302M) and indicator (Cat. No. FUK-H6302). We also offer the set of indicator and medium (Cat. No. FUK-H6302K). Put a bacteria ampoule (Cat. No. FUK-H6302) in an objective container and perform dry heat sterilization. Take the spore strip out of an ampoule and put it in an exclusive nutrient medium (Cat. No. FUK-H6302M), and culture it.

Color change	Dry Heat	
	After 24 hours	After 48 hours
Complete		
Incomplete		



Indicator bacterium for Dry heat sterilization (Cat. No. H6302)



Medium for exclusive use (Cat. No. H6302M)

Type	Indicator bacterium	Label color change after sterilization	Color change of vial when sterilization is incomplete
Hydrogen Peroxide Vapor Sterilization	<i>Geobacillus stearothermophilus</i>	-	
Chlorine dioxide Sterilization	<i>Bacillus atrophaeus</i>	-	
Autoclave	<i>Geobacillus stearothermophilus</i>		
EO gas sterilization	<i>Bacillus atrophaeus</i>		
Dry heat sterilization	<i>Bacillus atrophaeus</i>	-	
Hydrogen peroxide sterilization	<i>Geobacillus stearothermophilus</i>		
Steam sterilization at 115°C	<i>Bacillus subtilis</i> "5230"		
LTSF sterilization	<i>Geobacillus stearothermophilus</i>		
Formalin sterilization	<i>Bacillus atrophaeus</i>		



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ACE test® Product list

Description	Cat. No.	Number of spores	Purpose of use	Package
ACE test (Hydrogen Peroxide Vapor Sterilization) for air sterilization	FUK-H3726-2	Over 1×10^2	Sterilization in the isolator, Sterilization of sickroom environment Sterilization, Decontamination in the pharmaceutical factory	1 pack
	FUK-H3726-3	Over 1×10^3		1 pack (100 bags / 100 bottles)
	FUK-H3726-4	Over 1×10^4		1 pack (100 bags / 100 bottles)
	FUK-H3726-5	Over 1×10^5		1 pack (100 bags / 100 bottles)
	FUK-H3726T	Over 1×10^6		1 pack (100 bags / 100 bottles)
ACE test (Chlorine dioxide Sterilization) for air sterilization	FUK-H6306	Over 1×10^6		1 pack (100 bags / 100 bottles)
ACE test (Autoclave)	FUK-H3723	Over 1×10^5	121°C /132°C steam sterilization	1 pack (100 bottles)
	FUK-H3723T	Over 1×10^6	121°C /132°C steam sterilization	1 pack (100 bottles)
ACE test (EO Gas)	FUK-H3724	Over 1×10^6	EO gas sterilization	1 pack (100 bottles)
ACE test (Dry Heat)	FUK-H6302	Over 1×10^6	160-350°C dry-heat sterilization	1 pack (100 bottles)
ACE test (Medium for <i>B. atrophaeus</i>)	FUK-H6302M	Over 1×10^6	160-350°C dry-heat sterilization	1 pack (100 bottles)
ACE test (Dry Heat Kit)	FUK-H6302K	Over 1×10^6	160-350°C dry-heat sterilization	1 pack (100 bottles of sporule strip and medium)
ACE test (H ₂ O ₂)	FUK-H3725T	Over 1×10^6	hydrogen peroxide low temperature plasma sterilization	1 pack (100 bottles)
ACE test (Steam Sterilizer 115°C)	FUK-H6301	Over 1×10^6	115°C steam sterilization	1 pack (100 bottles)
ACE test (LTSF)	FUK-H6303T	Over 1×10^6	LTSF sterilization	1 pack (100 bottles)
ACE test (formalin)	FUK-H6305	Over 1×10^6	Formalin sterilization	1 pack (100 bottles)

* Exclusive medium is not included. The exclusive medium is FUK- H6302M.

* Biological indicator is not included.

* Set of biological indicator and exclusive medium

Exclusive use for biological indicator

ACE mini INCUBATOR

Block incubator with microprocessor

- ◆ Compact size. Machine fits onto the palm of your hand.
- ◆ Easy-to-read display.
- ◆ Built-in program function allows 9 possible combinations of temperature and time.
- ◆ Accurate and uniform temperature control. Temperature calibration function.
- ◆ Timer function of 1 minute to 99 hours 59 minutes. Alarm buzzer indicates end of incubation.
- ◆ Alarm buzzer when failure is detected in the machine.
- ◆ Complies with safety provisions of CE regulations.
- ◆ CE mark certified
- ◆ Corrosion resistant aluminum block
- ◆ Temperature calibration function



Cat. No.
FUK-H8100



Cat. No.
FUK-H8200

Specifications

Cat. No.	FUK-H8100	FUK-H8200
Operating temperature range	RT + 5°C - 80°C	
Temperature rise time	Within 6 minutes (20°C-56°C)	
Accuracy of temperature	±0.5°C	
Setting time	1 minute – 99 hours 59 minutes	
Unit of display	0.1°C	
Material of thermo block	Aluminum	
Operating environment	5°C - 35°C	
Dimension	W110 mm × D150 mm × H80 mm	
Weight (contains block)	0.5 kg	
Electricity consumption	Mximum 35 W, Average 5 W	
Power source	AC100-240 V, 50/60 Hz, 80 VA	
Ampoule crush device	○	×
Number of apertures	22	15

Correspondence table

Cat. No.	FUK-H8100	FUK-H8200
Hydrogen Peroxide Vapor Sterilization	×	●
Chlorine dioxide Sterilization	×	●
Autoclave	●	●
EO gas sterilization	●	●
Dry heat sterilization	×	●
Hydrogen peroxide sterilization	●	●
Steam sterilization at 115°C	●	●
LTSF sterilization	●	●
Formalin sterilization	●	●

Description	Cat. No.	Size
ACE mini INCUBATOR	FUK-H8100	1 unit
ACE mini INCUBATOR	FUK-H8200	1 unit

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COSMO BIO Co., LTD.

TOYO EKIMAE BLDG. 2-20, TOYO 2-CHOME,
KOTO-KU, TOKYO 135-0016, JAPAN
TEL : (81)3-5632-9617
FAX : (81)3-5632-9618
e-mail : export@cosmobio.co.jp
URL : www.cosmobio.com



www.cosmobio.com