HIMEDIA®

Sterilization Indicators

HiMediaLaboratories™

HiMedia Laboratories Pvt. Limited
www.himedialabs.com

HIMEDIA®

For life is precious

Quality Objectives

- Continually assess and enhance customer satisfaction by constant interaction with the customers to achieve a minimum customer satisfaction index of 80%.

- Make constant efforts for innovation through Research and Development activity for increasing the range of HiMedia products by developing 15 new products and up-gradation of products every year.

- To develop culture of commitment to quality by up-gradation of skills and improvement in work methods to restrict the rejection level below 0.5%.

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Issue Date	Revision
25/2/09	02

Quality Policy

HiMedia are firmly committed to continually enhance total customer satisfaction by consistent provision of superior products, supported with technical service worldwide, through constant innovation in technology and ensuring that customer as well as statutory regulatory requirements are met.

We shall strive to achieve this by fully conforming to the Quality Management System, with the establishment and periodic review of our quality objectives realized through the involvement of our dedicated employees.

Managing Director

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25/2/09	02

Sterilization Indicators

Sterilization (or sterilisation) is a term referring to any process that eliminates (remove) or kills all forms of microbial life, including transmissible agents (such as fungi, bacteria, viruses, spore forms etc.) present on a surface, contained in a fluid, in medication, or in a compound such as biological culture media. Sterilization can be achieved by applying the proper combinations of heat, chemicals, irradiation high pressure and filtrations.

Each of these processes are monitored using some sort of indicators and these indicators are called as sterilization indicators.

A specimen or a batch of a product can be called sterile only when there is complete absence of viable microorganisms from it. However, practical demonstration of this is literally impossible because of its destructive nature. Thus sterility of a specimen is represented in probabilistic terms, where in the chance of a contaminated unit or article is acceptably remote. This can be achieved through heat sterilization through single or multiple cycles followed by aseptic processing. "Good Manufacturing Practices", suggested by various organizations such as ANSI, AAMI, ISO etc., recommends various guidelines for the validation of these processes. An important aspect of these validation programs are that, they involve the usage of chemical or biological indicators of thermal processing. A biological indicator is a characterized preparation of a specific microorganism, mostly spore forming bacteria that provides a defined and stable resistance to a specific sterilization process where as a chemical indicator show colour change on completion of the process. These indicators have been extensively used in hospitals, clinical laboratories, microbiological laboratories, biotechnology laboratories, and in various industries, where in the sterilization processes are monitored and documented frequently.

Product Index

Classification

The process of sterilization and indicators used for this sterilization are classified as follows:

Class	ANSI/AAMI/ISO 11140:2005 Definition	Practical Application
Class 1 : Process Indicators	Process indicators are intended for use with individual units (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designated to react to one or more of critical process variables.	Indicator tapes, indicator labels and load cards are examples of externally visible chemical indicators that are process indicators used for exposure control.
Class 2: Indicators for use in Specific Tests	Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer / sterilization standards	Bowie-Dick Type test are specific tests used for equipment control to evaluate the sterilizer performance
Class 3: Single Variable Indicators	A Single variable indicator shall be designed to reach to one of the critical variables and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable	An example of Single variable indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature. Single variable indicators may be used for pack control monitoring but would not provide as much information as a Class 4 or Class 5 Chemical Indicator. Single Variable indicators may also be use for exposure control monitoring. This temperature tube would be used to determine that a specific temperate was reached at a specific location in the sterilizer chamber.
Class 4: Multi-variable Indicators	A Multi-variable indicator shall be designed to reach to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle as SVs of the chosen variable	Multi- variable Chemical indicators are used for a pack control. These internal chemical indicators are usually paper strips printed with a chemical indicator.
Class 5: Integrating Indicators	Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO11138 series for Bis	Integrating Indicators are the most accurate of the internal Chemical Indicators. Integrating Indicators are control monitoring. They can also be used as an additional monitoring tool to release loads that do not contain implants. For this additional monitoring the Class 5 Integrating Indicator must be used in the appropriate challenge test pack or Process Challenge Device. These indicators must now have SVs at 121del Cel / 250 del F, 135 del Cel / 267 del F and at least one more temperature in between. Also the SV at 121 deg cel must be greater than 16.5 minutes to ensure performance is comparable to BIs in saturated steam.
Class 6: Emulating Indicators	Emulating indicators are cycle verification indicators which shall be designed to reach to all critical variables for specified sterilization cycles. The SVs are generated from the critical Variables of the specified sterilization process.	Emulating Indicators can be used as internal Chemical Indicators for pack control. Emulating Indicators are specified for specific sterilization cycles which means an end user will need to inventory a different Class 6 Emulating Indicator for each sterilization cycle time and temperature (i.e., 3 min, 5 min, 10 min, 18 min, 40 min, etc.) run in the facility. The response of a Class 6 Emulating Indicator does not necessarily correlate to a Biological Indicator so the indicator cannot be used as an additional Monitoring tool to release loads that do not contain implants.

New Codes

List of New equivalent codes of Sterilization Indicators for the earlier codes which have been discontinued

Sr.No.	Previous Code	Equivalent Code	Name	
			Chemical Indicator Strips	**Class**
1	LA757,LA381 to LA384(OK indicator/ Strate-line indicator strips)	LA811-1x250No	Steam indicator Strip	4
2	LA758	LA812-1x250No	Dry Heat indicator Strip	4
			Biological Indicator-Spore Strips	Population
1	LA415	LA922-1x25No, & 1x100No	Geobacillus stearothermophilus Strip	**10^6**
2	LA414	LA923-1x25No, & 1x100No	Geobacillus stearothermophilus Strip	**10^5**
3	LA416	LA924-1x25No, & 1x100No	Bacillus atrophaeus Strip (formerly B.subtilis)	**10^6**
4	LA417	LA925-1x25No, & 1x100No	Bacillus pumilus Strip	**10^6**
			Spore Ampoule	
1	LA840	LA926- 1x50No	Geobacillus stearothermophilus Ampoule	**10^5**
2	LA867	LA927-1x50No	Geobacillus stearothermophilus Ampoule	**10^6**
3	NA	LA928- 1x50No	BRIGHT-CHEQ Geobacillus stearothermophilus Ampoule	**10^6**
4	LA841	LA929-1x50No	Bacillus atrophaeusAmpoule (formerly B.subtilis)	**10^6**

Product Portfolio

HiMedia brings you the following types of Sterilization Indicators

Sr. No.	Product Code	Product Name		
		Chemical Indicator- Strips	**Class**	**ATCC No.**
1	LA811	Steam indicator Strip	4	NA
2	LA812	Dry Heat indicator Strip	4	NA
		Biological Indicator-Spore Strips	**Population**	
1	LA922	Geobacillus stearothermophilus Strip	10^6	7953
2	LA923	Geobacillus stearothermophilus Strip	10^5	7953
3	LA924	Bacillus atrophaeus Strip(formerly B.subtilis)	10^6	9372
4	LA925	Bacillus pumilus Strip	10^6	27142
		Biological Indicator -Spore Ampoule	**Population**	
1	LA926	Geobacillus stearothermophilus Ampoule	10^5	7953
2	LA927	Geobacillus stearothermophilus Ampoule	10^6	7953
3	LA928	BRIGHT-CHEQ Geobacillus stearothermophilus Ampoule	10^6	7953
4	LA929	Bacillus atrophaeus Ampoule (formerly B.subtilis)	10^6	9372
		Chemical Indicator Circular Dots	**Class**	
1	LA921	Radiation chemical process indicator	1	NA
2	LA930	Steam chemical process indicator	1	NA
3	LA931	Eo chemical process indicator	1	NA
4	LA932	Dry Heat chemical process indicator	1	NA
5	LA933	Dry Heat chemical process indicator	1	NA
6	LA934	Hydrogen peroxide chemical process indicator	1	NA

Self Adhesive Tapes

Self Adhesive Sterilization Indicator Tapes LA409/LA411/LA412/LA413
Self Adhesive Neutral Tape

Cream coloured indicator tape having good adhesion to woven and non-woven fabrics with a process indicator printed on tape.

Chemical Indicator

Product Code	Product Name	Size
LA409	Self Adhesive Autoclave Tape [S]	18 mm
LA412	Self Adhesive Dry Heat Tape	19mm
LA413	Self Adhesive ETO Tape [S]	18mm
*LA411	Self Adhesive Neutral Tape (Masking Tape)	18 mm

Recommended Use :

1) Suitable for monitoring sterilization process.

Product Code	Sterilization Process	Process Parameter and Temperature conditions	Colour change
LA409	Autoclave	121°C/15 mins	White strips change to dark brown/black
LA412	Dry Heat	160°C /10 mins	Green coloured strips changes from green to brown colour in 10 minutes at 160°C.
LA413	ETO	On exposure to 600 mg /L EO gas at 50% ± 10% RH, 54.4°C for 45 mins or longer.	gas word on the strips changes from brown to green.

*2) Suitable for sealing materials while autoclaving

LA411	Autoclave	121°C / 15 mins	-

[S] : Material available till stock lasts

Steam Indicator Strip

Steam Indicator Strip	LA811

Recommended as monitoring aid for steam sterilization process.

Application

1. Steam indicator strips can be used in hospitals, clinical laboratories, microbiological laboratories, Biotechnology laboratories, molecular laboratories or wherever steam sterilization is desired.
2. These strips are useful for steam sterilization at 251°F (121°C) or 273°F (134°C).

Principle:

Steam indicator strip is a class 4 chemical indicator strip which provides distinct color change when exposed to steam sterilization process.

Square mark on the strip changes during exposure to steam sterilization. The correct end point is indicated when the square mark on the strip is equal or darker in colour than reference arrow. Such rapid change can be easily visualized.

Dimensions: 112 x 20mm strips

Directions for use :

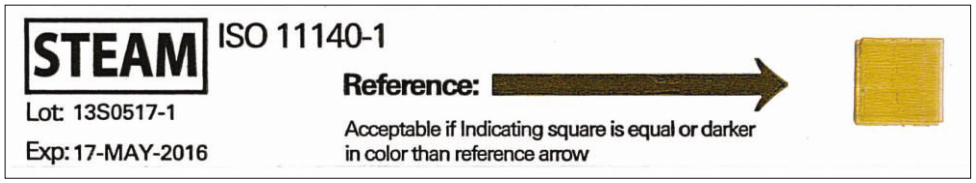
1. Place a indicator strip into each pack of material to be sterilized.
2. Sterilize the material for the desired time and temperature.
3. After completing the process, examine the square mark on the strip.

Interpretation:

Acceptable if indicating square is equal or darker in colour than reference arrow (shade of colour is dependent on exposure parameters and may vary).

Storage :

At or below room temperature (15-30°C), keep dry. Keep away from high temperature, high humidity sterilizing agent and direct sunlight.



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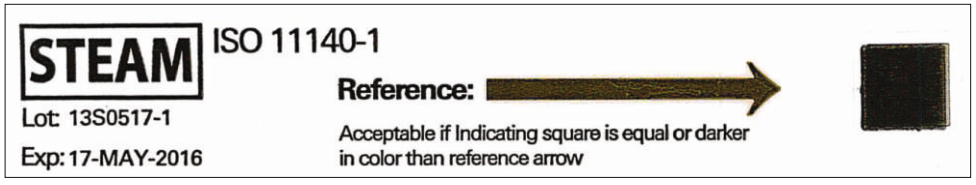


Processed

Dry Heat Indicator Strip

Dry Heat Indicator Strip	LA812

Recommended as monitoring aid for dry heat sterilization process.

Application:

1. Dry heat indicator strips can be used in hospitals, clinical laboratories, microbiological laboratories, Biotechnology laboratories, molecular laboratories or wherever dry heat sterilization is desired.
2. These strips are useful for dry heat sterilization over temperature ranging from 160 -180°C.

Principle:

Dry heat indicator strip is a class 4 chemical indicator strip which provides distinct color change when exposed to dry heat sterilization process.

Orange coloured square mark on the strip changes during exposure to dry heat sterilization. The correct end point is indicated when the orange square mark on the strip is equal or darker in colour than reference arrow. Such rapid change can be easily visualized.

Dimensions: 112 x 20mm strips

Directions for use :

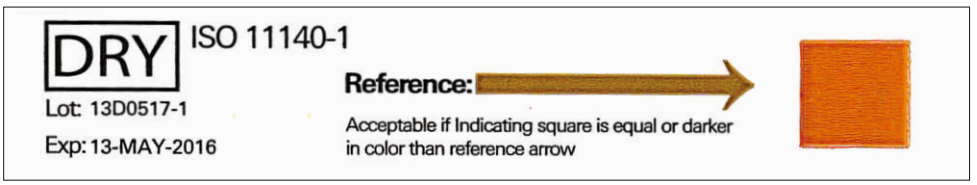
1. Place an indicator strip into each pack of material to be sterilized.
2. Sterilize the material for the desired time and temperature (160°C for 40 minutes).
3. After completing the process, examine the orange square mark on the strip.

Interpretation:

Acceptable if indicating square is equal or darker in colour than reference arrow (shade of colour is dependent on exposure parameters and may vary).

Storage :

At or below room temperature (15-30°C), keep dry. Keep away from high temperature, high humidity sterilizing agent and direct sunlight.



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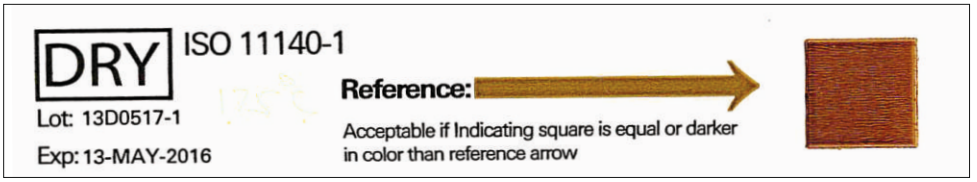

Processed

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Spore Strips - Biological Indicator

Spore Strips - Biological Indicator LA922 / LA923

Spore strips for sterility testing in steam sterilization environment for both Healthcare and Industrial applications. The spore strips consist of inoculated filter paper, 6mm x 30mm, packaged in glassine peel pouches or envelopes which provides protection from environmental contaminants during transport after exposure. The spore strips can be easily removed from the glassine pouch by peeling the pouch open for transfer to culture medium.

Product Name	Product Code	Description	No. of Spores per strips	Strip Size	Pack Size (nos/pack)
Spore Strips-Biological Indicator	LA922	Geobacillus stearothermophilus	10^6	6mm x 30mm	1x100 No. 1 x 25 No.
	LA923	Geobacillus stearothermophilus	10^5	6mm x 30mm	1x100 No. 1 x 25 No.

Geobacillus stearothermophilus ATCC 7953-*(B.stearothermophilus)* For use in monitoring steam sterilization.

Principle :

Each Spore Strips contains a population of $1x10^5$(LA923) / $1x10^6$(LA922) of B. *stearothermophilus spores*. Each spore strips as recommended for steam sterilization act as sterilization indicators. The spores after exposure as specified use, gets killed indicating the efficiency of sterilization process. This is determined by studying the growth of treated spore strips in nutrient media like Soyabean casein digest medium.

Directions for use :

1. Place the spore strips while sterilization to check efficiency of the process (Steam sterilization).
2. Inoculate the treated spore strips in Soyabean casein digest medium at 55°- 57°C. Observe for growth after every 24 hours till 7 days and record the results.
3. Check for presence/ absence of growth. Growth is indicated by turbidity.

Interpretation:

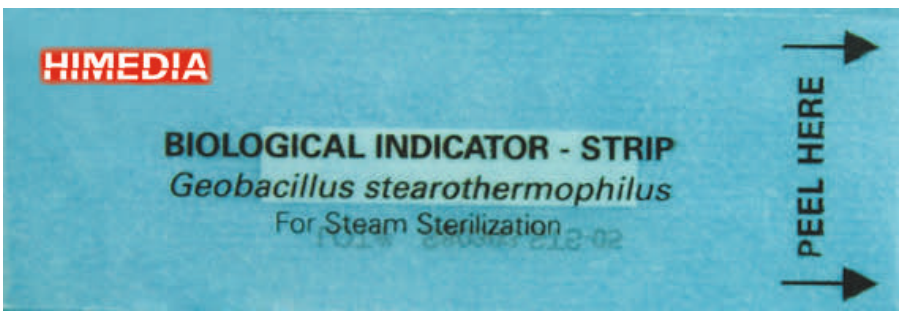
Turbidity - Improper sterilization
No turbidity - Proper sterilization

Storage:

Store the strips under room temperature preferably between 15-30° C. Keep away from high temperature, humidity and sterilants.

Disposal:

Autoclave, steam at 121°C for not less than 30 minutes or incinerate.



Bacillus atrophaeus Spore strip

Bacillus atrophaeus Spore strip	LA924

Spore strips used for monitoring Ethylene oxide (ETO) and dry heat sterilization environment for both Healthcare and Industrial applications. The spore strips consist of inoculated filter paper, 6mm x 30mm, packaged in glassine peel pouches or envelopes which provides protection from environmental contaminants during transport after exposure. The spore strips can be easily removed from the glassine pouch by peeling the pouch open for transfer to culture medium.

Principle:

Each Spore Strips contains a population of $1x10^6$ of B. atrophaeus ATCC 9372 (formerly B. subtilis). Each spore strips as recommended for Ethylene oxide (ETO) and dry heat sterilization act as sterilization indicators. The spores after exposure as specified use, gets killed indicating the efficiency of sterilization process. This is determined by studying the growth of treated spore strips in nutrient media like Soyabean casein digest medium.

Directions for use :

1. Place the spore strips during sterilization to check efficiency of the process (ETO sterilization).
2. Inoculate the treated spore strips in Soyabean casein digest medium at 30 - 35°C. Observe for growth after every 24 hours till 7 days and record the results.
3. Check for presence/ absence of growth. Growth is indicated by turbidity.

Interpretation:

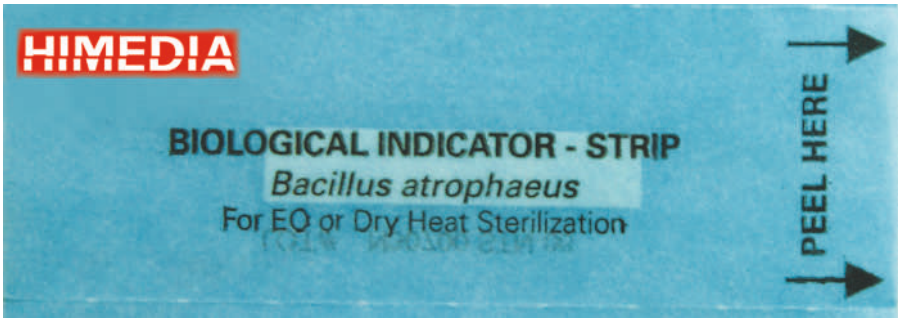
Turbidity - Improper sterilization
No turbidity - Proper sterilization

Storage:

Store the strips under room temperature preferably between 15-30°C. Keep away from high temperature, humidity and sterilants.

Disposal:

Autoclave, steam at 121°C for not less than 30 minutes or incinerate.



Bacillus pumilus Spore Strip

Bacillus Pumilus Spore Strip	LA925

Spore strips used for monitoring radiation sterilization for both Healthcare and Industrial applications. The spore strips consist of inoculated filter paper, 6mm x 30mm, packaged in glassine peel pouches or envelopes which provides protection from environmental contaminants during transport after exposure. The spore strips can be easily removed from the glassine pouch by peeling the pouch open for transfer to culture medium.

Principle:

Each Spore Strips contains a population of $1x10^6$ of *Bacillus pumilus* (ATCC 27142). Each spore strips as recommended for radiation sterilization act as sterilization indicators. The spores after exposure as specified use, gets killed indicating the efficiency of sterilization process. This is determined by studying the growth of treated spore strips in nutrient media like Soyabean casein digest medium.

Directions for use :

1. Place the spore strips during sterilization to check efficiency of the process (Radiation sterilization).
2. Inoculate the treated spore strips in Soyabean casein digest medium at 30-35°C upto 7 days. Observe for growth after every 24 hours till 7 days and record the results.
3. Check for presence/ absence of growth. Growth is indicated by turbidity.

Interpretation:

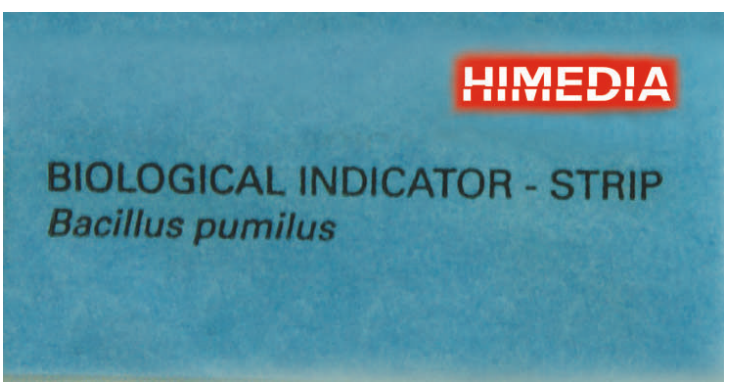
Turbidity - Improper sterilization
No turbidity - Proper sterilization

Storage:

Store the strips under room temperature preferably between 15-30°C. Keep away from high temperature, humidity and sterilants.

Disposal:

Autoclave, steam at 121°C for not less than 30 minutes or incinerate.



Geobacillus Stearothermophilus Ampoule
No. of spores per ampoule = 10^5

Geobacillus stearothermophilus Ampoule LA926
No. of spores per ampoule = 10^5

Spore ampoule is a self-contained Biological Indicator. It is used for monitoring steam sterilization processes.

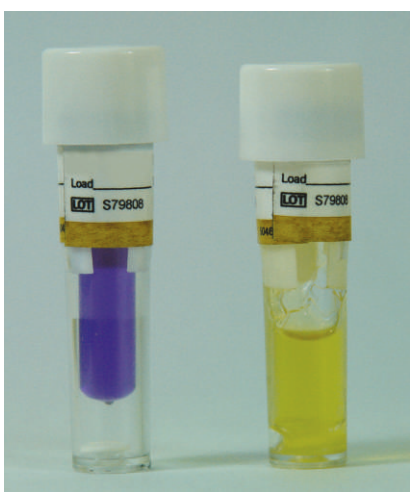
Principle:

Biological Indicator is made up of an external plastic vial with a cap, a crushable glass ampoule with recovery media and a disc inoculated with spores of *Geobacillus stearothermophilus* ATCC 7953. The recovery medium consists of an adequate culture medium with a pH indicator. Spores get killed when exposed to 121°C for 15 minutes in autoclave. On incubation growth is evident by either turbidity and/or a color change from Purple to Yellow. Presence of growth on incubation is indicative of improper sterilization.

Directions for use :

1. Place the ampoule with the material to be sterilized in the most difficult location to sterilize. After sterilization to 121°C for 15 minutes, remove the ampoule.

2 Activate for incubation by depressing the cap completely and crushing the ampoule carefully and incubate at 55-57°C for 48 hours.



w/o growth **w/ growth**

3. Check for presence/ absence of growth. Growth is indicated by turbidity and/ or color change from Purple to Yellow.

Interpretation:

Turbidity or color change from Purple to Yellow - Improper sterilization

No turbidity or color change - Proper sterilization

Storage :

Store the ampoule at 15 - 30°C. Keep away from freezing, sterilizing agents, direct sunlight and UV light Do not refrigerate.

Disposal:

Autoclave, steam at 121°C for not less than 30 minutes or incinerate.

*If desired LA862
HiIncubator can be used

Mains operated 230V AC Incubator Temperature 37°C and 57°C selectable

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Geobacillus stearothermophilus Ampoule
No. of spores per ampoule = 10^6

Geobacillus stearothermophilus Ampoule **LA927**
No. of spores per ampoule = 10^6

Spore ampoule is a self-contained Biological Indicator. It is used for monitoring steam sterilization processes.

Principle :

Biological Indicator is made up of an external plastic vial with a cap, a crushable glass ampoule with recovery media and a disc inoculated with spores of *Geobacillus stearothermophilus* ATCC 7953. The recovery medium consists of an adequate culture medium with a pH indicator. Spores get killed when exposed to 121°C for 15 minutes in an autoclave. On incubation growth is evident by either turbidity and/or a color change from Purple to Yellow. Presence of growth on incubation is indicative of improper sterilization.

Directions for use :

1. Place the ampoule with the material to be sterilized in the most difficult location to sterilize. After sterilization to 121°C for 15 minutes, remove the ampoule.
2. Activate for incubation by depressing the cap completely and crushing the ampoule carefully and incubate at 55-57°C for 48 hours.
3. Check for presence/ absence of growth. Growth is indicated by turbidity and/ or color change from Purple to Yellow.

Interpretation:

Turbidity or color change from Purple to Yellow - Improper sterilization

No turbidity or color change - Proper sterilization

Storage:

Store the ampoule at 15 - 30°C. Keep away from freezing,sterilizing agents, direct sunlight and UV light. Do not refrigerate .

Disposal:

Autoclave, steam at 121°C for not less than 30 minutes or incinerate.

*If desired LA943 HiIncubator Bright check can be used

Mains operated 230V AC Incubator Temperature 37°C and 60°C selectable.

Note: For data downloading software of temperature logging,installation of operatoring system windows xp is required

BRIGHT-CHEQ

BRIGHT-CHEQ LA928

Geobacillus stearothermophilus Ampoule
No. of spores per ampoule = 10^6

The ETIGAM BRIGHT-CHEQ is a convenient Biological Indicator Monitoring System for steam sterilization processes. The BRIGHT-CHEQ does not rely on degradation of chemical substances or enzyme results to forecast anticipated biological activity, but is a rapid acting true biological indicator.

Principle:

The ETIGAM BRIGHT-CHEQ biological indicator is a self contained unit such that the inoculated spore strip and the recovery medium are housed within the same primary package.

Each unit can be incubated in Hi Incubator Bright check (LA935). It provides optimal recovery conditions for the *Geobacillus stearothermophilus* spores.

One or more BRIGHT-CHEQ indicators are sterilized with the load. Upon removal from the sterilizer, the BRIGHT-CHEQ biological indicator is activated by flexing the culture tube to break the media ampoule inside, allowing the growth medium to mix with the paper spore strip.

The activated indicator is then placed in the HiIncubator (LA935) BRIGHT-CHEQ incubator upto 10 hrs. If any spores have survived the sterilization process, the bacteria will grow during incubation and cause a colour change from purple to yellow.

The recommended incubation time of 10 hours meet the CDRH FDA RIT Protocol.

w/o growth w/ growth

*If desired LA935 HiIncubator Brigth check can be used

Directions for use :

1. Place the ampoule with the material to be sterilized in the most difficult location to sterilize. After sterilization to 121°C for 15 minutes, remove the ampoule.
2. Activate for incubation by depressing the cap completely and crushing the ampoule carefully and incubate at 58-62°C for 10 hours.
3. Check for presence/ absence of growth. Growth is indicated by turbidity and/ or color change from Purple to Yellow. Biological growth from sterilization failure is detected in 3 to 5 hours.

Interpretation:

Turbidity or color change from Purple to Yellow - Improper sterilization

No turbidity or color change - Proper sterilization

Advantages of Bright-Cheq:

- High efficacy
- Failed sterilization cycle detected in 3 to 5 hours
- Results are true biological and final in 10 hours
- Dramatic colour change for positive cultures
- Convenient to culture
- No special laboratory is necessary for culturing

Storage :

Store the ampoule at 15-30°C.

Mains operated 230V AC Incubator Temperature 37°C and 60°C selectable

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Bacillus atrophaeus Ampoule (formerly B. subtilis) No. of spores per ampoule = 10^6

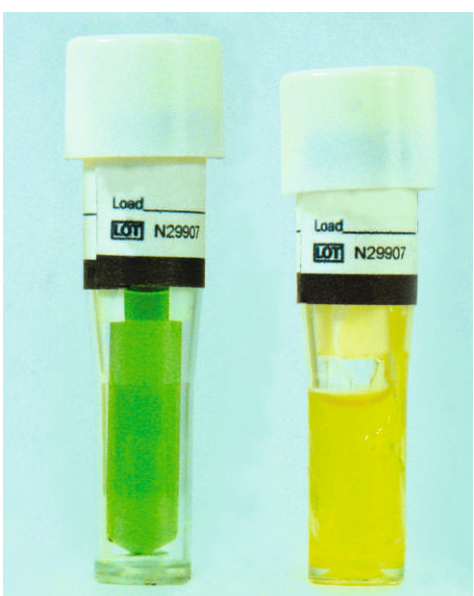
Bacillus atrophaeus Ampoule (formerly B. subtilis) No. of spores per ampoule = 10^6 **LA929**

Spore ampoule is a self-contained Biological Indicator. It is used for ethylene oxide sterilization.

Principle:

Biological Indicator is made up of an external plastic vial with a cap, a crushable glass ampoule with recovery media and a disc inoculated with spores of B. atrophaeus ATCC 9372. The recovery medium consists of an adequate culture medium with a pH indicator. Spores get killed on ethylene oxide sterilization. On incubation growth is evident by either turbidity and/or a color change from Light green to Yellow. Presence of growth on incubation is indicative of improper sterilization.

These spores are the most adequate for this type of process because they are highly resistant to the sterilization agents and they are not pathogenic for the human being.



w/o growth **w/ growth**

Directions for use :

1. Place the ampoule with the material to be sterilized in the most difficult location to sterilize. After sterilization remove the ampoule.
2. Activate for incubation by depressing the cap completely and crushing the ampoule carefully and incubate at 35-37°C for 48 hours.
3. Check for presence/ absence of growth. Growth is indicated by turbidity and/ or color change from Light green to Yellow.

Interpretation:

Turbidity or color change from Light green to Yellow - Improper sterilization

No turbidity or color change - Proper sterilization

Storage :

Store the ampoule at 15 - 30°C. Keep away from freezing, sterilizing agents, direct sunlight and UV light. Do not refrigerate.

Disposal:

Autoclave, steam at 121°C for not less than 30 minutes or incinerate.

Radiation Chemical Process Indicator

Radiation chemical process indicator LA921

Radiation chemical process indicator is designed for use in monitoring sterilization by irradiating with Gamma radiation to a dose of >= 10 kiloGray.

Principle:

Radiation chemical process indicator can distinguish items or packages processed in Radiation from the ones yet to be processed. Initial Yellow colour circular dot (12.7mm) changes to Dark orange/ red (signal colour) after sterilization by irradiating with Gamma radiation to a dose of >= 10 kiloGray. This color change is non-reversible. If circular dot has not completed color change from Yellow to dark orange/ red, investigate as a cycle failure.

Directions for use :

1. All items to be sterilized should be thoroughly cleaned in accordance with standard procedures.
2. Affix Radiation label to each item to be sterilized.
3. Sterilize items as usual in Radiation sterilizer.
4. Examine the color of circular dot of the chemical indicator.

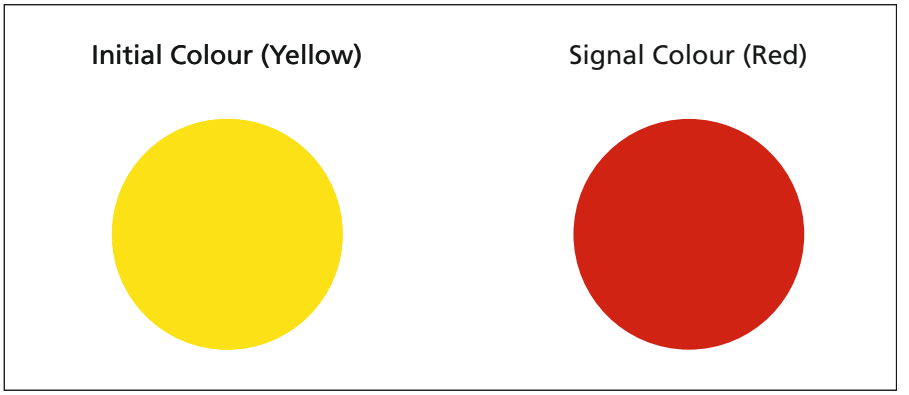
Interpretation:

Yellow chemical indicator turning to Red when sterilized by irradiating with Gamma radiation to a dose of >= 10 kiloGray Proper sterilization.

Note: Labels should be stored at RT (15-30°C) with RH 30-60%.
Protect the labels from moisture and excessive humidity.
Shades of signal colour is dependent on exposure parameters and may vary.
Avoid Storage near fluorescent lighting and direct sunlight.

Storage :

At or below room temperature (15-30°C), keep dry. Keep away from high temperature, high humidity sterilizing agent and direct sunlight.



Steam Chemical Process Indicator

Steam Chemical Process Indicator	LA930

Steam chemical process indicator is used to monitor Steam Sterilization Process.

Principle:

Steam chemical process indicator can distinguish items or packages processed in steam sterilization from the ones yet to be processed. Initial light blue colour circular dot (12.7mm) changes to Mauve (pinkish white) (signal colour) after Steam sterilization at 121°C for 15 min. This color change is non-reversible. If circular dot has not completed color change from light blue to mauve, investigate as a cycle failure

Directions for use :

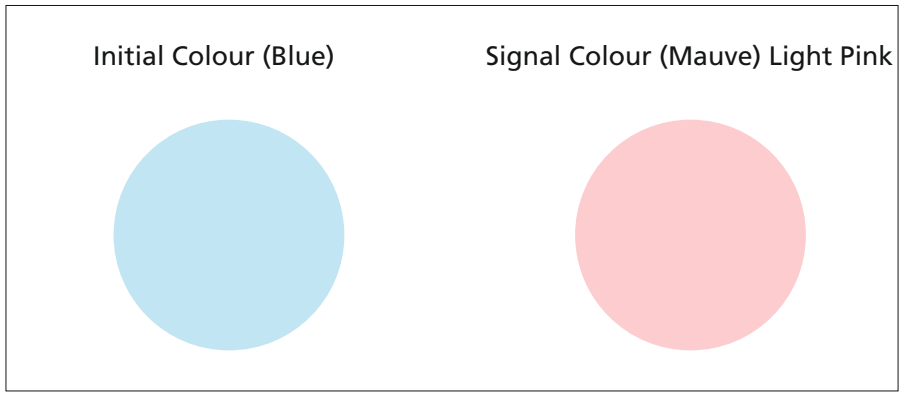
1. All items to be sterilized should be thoroughly cleaned in accordance with standard procedures.
2. Affix steam chemical process indicators to each item to be sterilized.
3. Sterilize items as usual in steam sterilizer.
4. Examine the color of circular dot of the chemical indicator.

Interpretation:

Light blue chemical indicator turning to Mauve (shade of colour is dependent on exposure parameters and may vary) when exposed at 121°C for 15 minutes-Proper sterilization

Storage :

At or below room temperature (15-30°C) keep dry. Keep away from high temperature, high humidity, sterilizing agents and direct sunlight.



Dry Heat Chemical Process Indicator

Dry Heat chemical process indicator — LA932

Dry Heat chemical process indicator is designed for use in dry heat sterilizers operating at <=250°C.

Principle:

Dry heat chemical process indicator can distinguish items or packages processed in dry heat from the ones yet to be processed. Initial pink colour circular dot (12.7mm) changes to Brown (signal colour) after exposure to Dry Heat for >= 1 hour at 250°C. This color change is non-reversible. If circular dot has not completed color change from Pink to Brown, investigate as a cycle failure.

Directions for use :

1. All items to be sterilized should be thoroughly cleaned in accordance with standard procedures.
2. Affix indicator label to each item to be sterilized.
3. Sterilize items as usual in dry heat sterilizer.
4. Examine the color of circular dot of the chemical indicator.

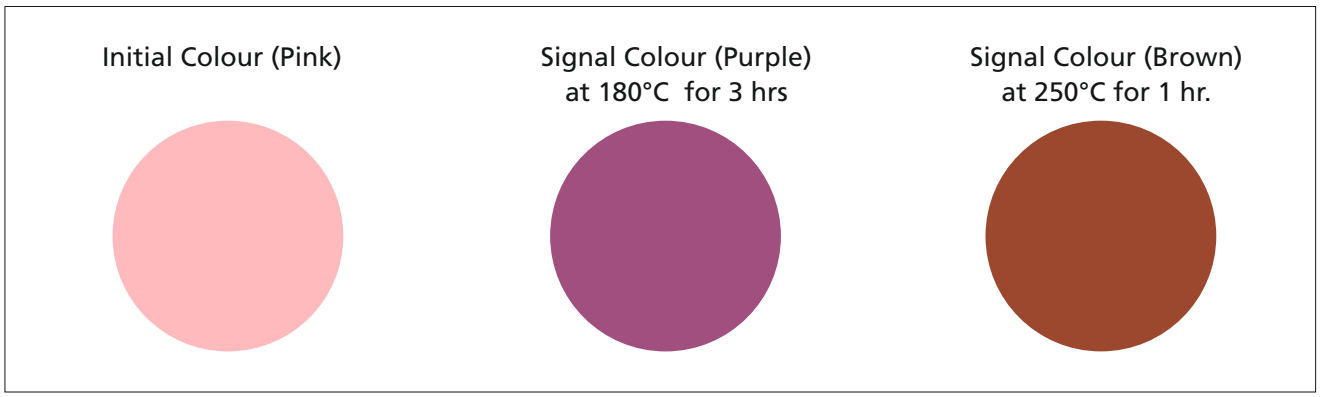
Interpretation:

i) Pink chemical indicator turning to Brown (shade of colour is dependent on exposure parameters and may vary) when exposed at 250°C for 1 hour - Proper sterilization

ii) Pink chemical indicator turning to Purple when exposed at 180°C for 3 hours - Proper sterilization

Storage :

At or below room temperature (15-30°C) keep dry. Keep away from high temperature, high humidity, sterilizing agents and direct sunlight.



HIMEDIA®

Dry Heat Chemical Process Indicator

Dry Heat chemical process indicator LA933

Dry Heat chemical process indicator is designed for use in dry heat sterilizers operating at <=180°C. .

Principle:

Dry heat chemical process indicator can distinguish items or packages processed in dry heat from the ones yet to be processed. Initial orange colour circular dot (12.7mm) changes to Brown (signal colour) after exposure to Dry Heat for >= 10 minutes at 180°C. This color change is non-reversible. If circular dot has not completed color change from Orange to Brown, investigate as a cycle failure.

Directions for use :

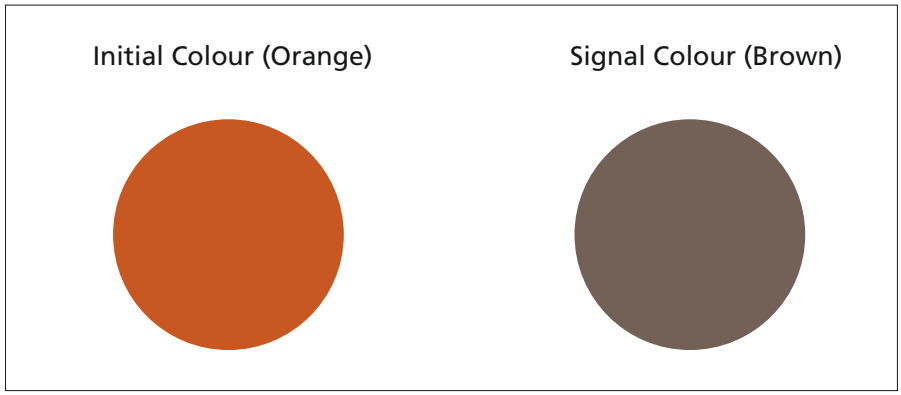
1. All items to be sterilized should be thoroughly cleaned in accordance with standard procedures.
2. Affix dry heat indicator label to each item to be sterilized.
3. Sterilize items as usual in dry heat sterilizer.
4. Examine the color of circular dot of the chemical indicator..

Interpretation:

Orange colour circular chemical indicator turning to Brown (shade of colour is dependent on exposure parameters and may vary) after exposure to Dry Heat for >= 10 minutes at <=180°C - Proper sterilization

Storage :

At or below room temperature (15-30°C) keep dry. Keep away from high temperature, high humidity, sterilizing agents and direct sunlight.



EO Chemical Process Indicator

EO chemical process indicator — LA931

EO chemical process indicator is designed for use in sterilization using Ethylene Oxide.

Principle:

EO chemical process indicator can distinguish items or packages processed in EO from the ones yet to be processed. Initial Violet colour circular dot (12.7mm) changes to Green (signal colour) after EO exposure for 20 minutes at 600 mg/L, 54°C and 60% RH. This color change is non-reversible. If circular dot has not completed color change from Violet to Green, investigate as a cycle failure.

Directions for use :

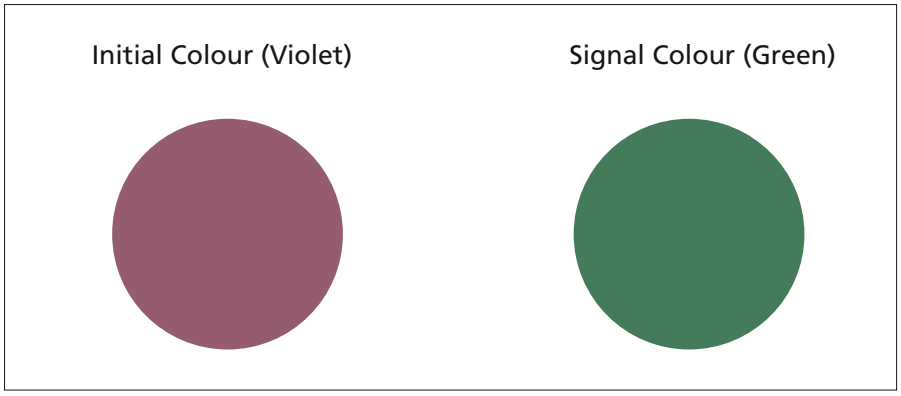
1. All items to be sterilized should be thoroughly cleaned in accordance with standard procedures.
2. Affix EO label to each item to be sterilized.
3. Sterilize items as usual in EO sterilizer.
4. Examine the color of circular dot of the chemical indicator.

Interpretation:

Violet chemical indicator turning to Green (shades of signal colour is dependent on exposure parameters and may vary.) when exposed to ethylene oxide for 20 minutes at 600 mg/l, 54°C and 60% RH - Proper sterilization

Storage :

At or below room temperature (15-30°C) keep dry. Keep away from high temperature, high humidity, sterilizing agents and direct sunlight.



Hydrogen Peroxide Chemical Process Indicator

Hydrogen Peroxide chemical process indicator LA934

Hydrogen Peroxide chemical process indicator is designed for use in monitoring Hydrogen Peroxide sterilizers.

Principle:

Hydrogen Peroxide chemical process indicator can distinguish items or packages exposed to a minimum of 6.0 mg/l of hydrogen peroxide from the ones yet to be processed. Initial Light Yellow colour circular dot (12.7mm) changes to Blue (signal colour) after exposure to hydrogen peroxide for 6 minutes at 50°C. This color change is non-reversible. If circular dot has not completed color change from Light Yellow to Blue, investigate as a cycle failure.

Directions for use :

1. All items to be sterilized should be thoroughly cleaned in accordance with standard procedures.
2. Affix hydrogen peroxide label to each item to be sterilized.
3. Sterilize items by exposing to hydrogen peroxide.
4. Examine the color of circular dot of the chemical indicator.

Interpretation:

Light yellow chemical indicator turning to Blue (shades of signal colour is dependent on exposure parameters and may vary.) when exposed at 50°C for 6 minutes- Proper Sterilization.

Storage :

At or below room temperature (15-30°C) keep dry. Keep away from high temperature, high humidity, sterilizing agents and direct sunlight.

Initial Colour (Yellow)

Signal Colour (Blue)

Bowie and Dick Test Pack

Bowie and Dick Test Pack — [S] LA765

Bowie and Dick Test Packs are used as monitoring aid for steam sterilization process.

Principle:

Bowie and Dick test is a class 2 chemical indicator strip, manufactured by steam detection technology using a chromatic lead free ink detecting the steam presence but not reacting with dry heat. The turning colour is clear and the results interpretation is easy. Besides, this kind of ink allows the detection of non-condensable gases, which, when present, avoid the indicator turning, which remains yellow in such cases.

The Bowie-Dick Test Pack consists of chemical indicators on test sheets positioned inside porous materials and sealed inside a disposable outer wrap.

Bowie-Dick products have yellow chemical indicator that becomes uniform black if the sterilizer is functioning. Any unexpected colour change, such as the center of the test sheet being paler or a different colour edges (i.e. there is a non-uniform colour change) indicates that there was pocket present during the cycle of sterilizer malfunction.

Directions for use :

Test should be carried out daily before beginning the sterilization routine

First of all, a cycle is run with the empty chamber to prepare it and to pick up any possible condensed gases present in the entry tubing.

Then, the test pack is placed inside the sterilizer as an unique load (other material has not to be placed inside the sterilizer), making sure that the upper side of the pack is upwards.

Place the pack on the tray at the coolest zone of the chamber, this is down inside the autoclave, between the drain and the door.

Close the door and run a sterilization cycle (134°C - 3.5min.).

The test is most accurate when nothing else is in the chamber, so do not use this cycle to sterilize items or packs .Other items in this cycle may invalidate the test

After the cycle is complete, remove the pack and open to examine the indicator sheet. CAUTION! Test pack may still be hot so use caution when handling to avoid injury.

Record the necessary information on the sheet (or in a log book) and store for your records.

The filter paper pack can be discarded into a paper recycle bin.

Interpretation:

Indicator colour after sterilization, changes from yellow to black.

If colour change is uniform (black) the autoclave working conditions are satisfactory and correct.

If colour changes is not uniform or by visual examination, different colour shades (yellow or green) are observed among different zones of the indicator, a failure is being detected on the equipment working.

UNPROCESSED

PROCESSED

[S] : Material available till stock lasts

Hi-Indicator See Through Reels

Hi-Indicator See Through Reels — Ⓢ LA834/LA835

See through pouches and reels are the universal packaging solution for sterilization applications and perfectly meet the packaging demands of almost all light and medium weight instruments and sets.

Recommended for sterilizing various materials under varied sterilizing environments.

Product Code	LA834	LA835
Size - Width	150 mm	250 mm
Length	100 meter	100 meter
*Gusset	50 mm	50 mm

Application:

Hi-Indicator see through reels can be used in hospitals, clinical laboratories, Microbiological laboratories, Biotechnology laboratories, Molecular laboratories and healthcare industries using different methods of sterilization as desired.

Principle:

The Hi-Indicator See Through Reels offers to monitor sterilization under different Processes visually. The indicator on the reel detects the sterility by changing the color. The strip is provided with pink and green color which changes to brown, dark yellow and pink as indicated in the table below.

Colour indicator	Steam	ETO	Formaldehyde
Before Process	Pink	Green	Green
After Process	Brown	Dark yellow	Pink

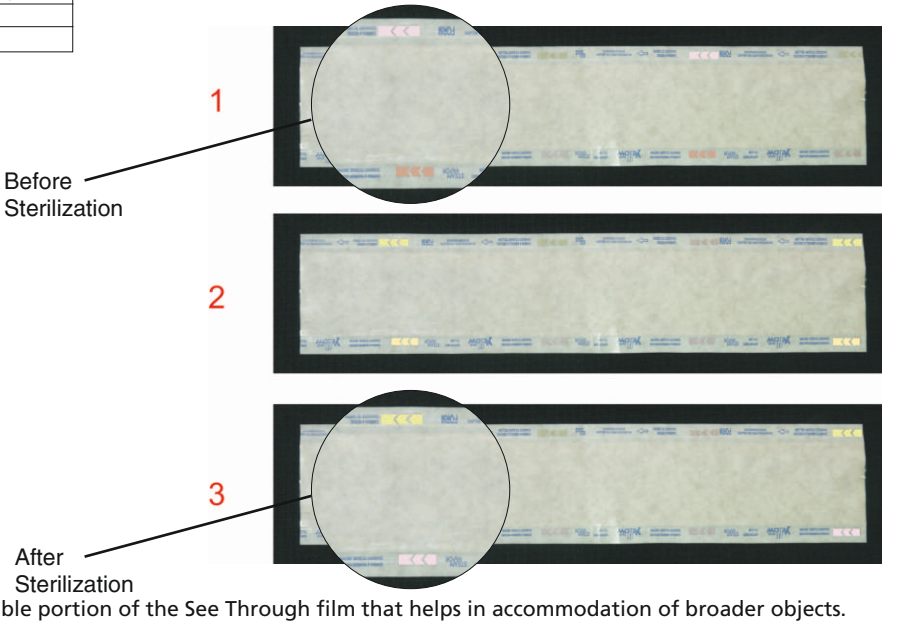
Salient Features:

1. One side clear film for identification of contents through the transparent plastic film.
2. One side medical kraft paper, good wet strength which is excellent for steam sterilization.
3. All imprints are positioned outside the actual packing area to prevent ink contamination reaching the product.
4. Indicator imprints for steam, ETO and formaldehyde sterilization.
5. Lead free.

Direction for use :

1. Place the material to be sterilized inside the reel with the desired length as indicated below.
2. Seal the end and Sterilize the material as per desired procedure of sterilization either by Steam, ETO or Formaldehyde.

Indication of proper sterilization: Change of Pink colour to Brown , Green to Dark Yellow and Green to Pink in cases of Steam, ETO and Formaldehyde respectively (as indicated below).



* Enlargable portion of the See Through film that helps in accommodation of broader objects.

Ⓢ : Material available till stock lasts

Hi-Indicator Paper Bags

Hi-Indicator Paper Bags — Ⓢ LA836 /LA837/LA838

Recommended for sterilizing various materials under steam.

Product code	LA836	LA837	LA838
Width	90mm	125mm	250mm
Length	250mm	250mm	380mm
*Gusset	50mm	50mm	100mm

Application:

Hi-Indicator paper bags can be used in hospitals, clinical laboratories, Microbiological laboratories, Biotechnology laboratories, Molecular laboratories and Healthcare industries using steam sterilization.

Principle:

The Hi-Indicator paper bags offers to monitor steam sterilization visually. The indicator on the bag detects the sterility by changing the color. The bag is provided with pink coloured strip which changes to brown after achieving sterilization.

Direction for Use :

1. Place the material to be sterilized inside the bag.
2. Seal the end and sterilize the material using steam of sterilization.

Indication of proper sterilization: Change of Pink colour to Brown as indicated below confirms the sterilization process to be complete.

* Enlargable portion of the See Through film that helps in accommodation of broader objects.

Ⓢ : Material available till stock lasts

HiMedia Wins India's most Prestigious Rajiv Gandhi National Quality Award Once again

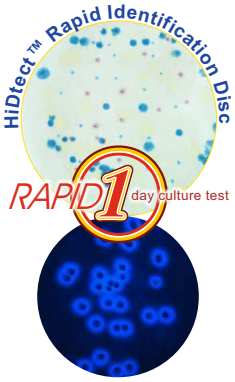
Founded on the culture of uncompromising quality HiMedia have earned a global reputation on Quality and Innovation in BioSciences. With its gun-sight focused on quality, this is the 2nd time HiMedia has received India's most prestigious Rajiv Gandhi National Quality Award. We are happy to announce we have once again established our Excellence in Biotechnology by receiving this award in a glorious ceremony held in April 2013 in New Delhi.

Other Related Products

HiDtect™

Rapid Identification Disc

Revolutionizing microbial detection



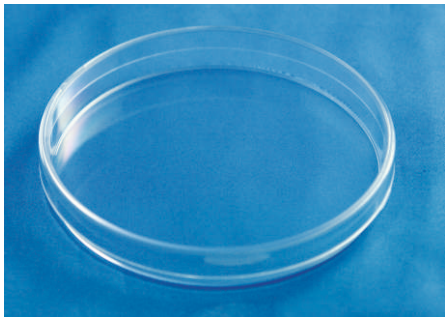
HiDtect™ one day culture test

'Confirmation in just 1 - 4 hours'

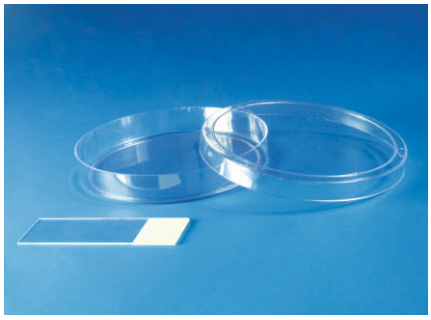
HiCrome™

Comprehensive Range of Chromogenic Media

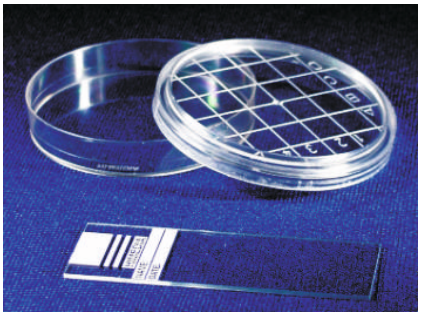
Comprehensives Range of Chromogenic Media



PW001 Petri Plates 90mm



PW002 Petri Plates 100mm



PW007 Petri Plates 65mm

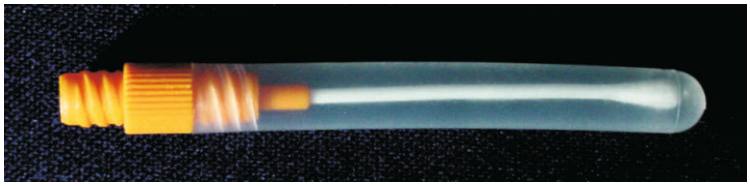
Disposable Plastic FlexiLoops

PW012 PW013 PW014

HiAirflow Economical

LA881

Swabs PW003



HiMediaLaboratories

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Literature Code : TL289_0 /Sterilization Indicators/1213