

Technical Data Sheet

Reference: 45000S4018

CHALLENGE TEST (PCD) WITH BIOLOGICAL INDICATOR RAPID ONE 1 H

Disposable Test Pack with Biological Indicator and Type 5 Indicator (Integrator)



Product description

The challenge test is composed of an external cardboard die cut envelope, an external label with a chemical process indicator, a standardized barrier of porous paper with a die containing a biological indicator and a load record card that has a type 5 chemical indicator inserted.

Presentation

128 x 98 x 18 mm test package, boxes x 20 units. Instructions and biological indicator certificate. Lot and expiration date printed on the outer packaging.

Classification

Biological sterilization indicator according with ISO 11138. Type 5 chemical sterilization indicator according with ISO 11140.

Shelf-life

24 months from the date of manufacture

Quality control

Control system according to ISO 9001: 2015, ISO 13485: 2016 and GMP (Good Manufacturing Practices) standards.

∫tability

Stability has been verified from manufacture to expiration date, 24 months after date of manufacture.

Authorization and habilitation

ANMAT: PM 1454-44

Test Features

Package that allows detect the efficiency of steam sterilization, by double turning test of the type 5 indicator and the cultivation of the biological indicator. Reactive agents in this test are completely lead free.

Utilization

Place the test package as the only load in a previously heated autoclave. Carry out the cycle you want to evaluate. Once finished, check the turning of the external indicator from blue to black, open the package, remove the load register and check the turn of the type 5 indicator from red to yellow. Remove the biological indicator and proceed to cultivation according to its instructions. Record the results in the load log and file it.

Cautions and warnings

Keep stored at a temperature between 5 and 50 ° C, especially high relative humidity conditions should be avoided. It should not be kept in a refrigerator. The presence of volatile chemicals should be avoided in storage spaces, such as those that tend to give off cleaning products, washes or ammonia cleaners. Specially avoid contact with adhesives, as some aggressive substances that can alter the indicator. Once the test is done, handle carefully to avoid burns and let it cool before opening it. The filling paper must be discarded because during the sterilization process it suffers a loss of air in its fibers and is not reusable. The filler paper is recyclable.

Challenge tests

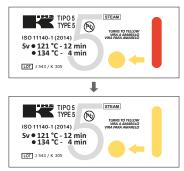
Challenge tests, generically called PCD (Process Challenge Devices) are packages specially designed to detect the effectiveness of sterilization processes in steam autoclaves. They have a biological indicator housed inside a porous cardboard package, which hinders the entry of steam. They are calibrated so that this barrier represents a challenge to the steam entry and thus indicates, if the test is successful, that the operation of the autoclave is efficient enough to overcome the barrier offered by the materials and achieve a correct sterilization in the entire volume of the autoclave. PCDs also have a type 5 indicator inside and a load log to record the results and be used as a file. To use a PCD, the test must be carried out in an empty chamber, preheating and using the process parameters that will be used in the usual cycles. There are challenge trials with 24-hour biological indicators and also with 3 hours, 1 hour or 20 minutes rapid indicators.

Results guide

The internal biological indicator must be evaluated according to instructions attached.



External label turn



Type 5 indicator turn





Technical Data Sheet

Reference: 45000S4017

CHALLENGE TEST (PCD) WITH BIOLOGICAL INDICATOR RAPID 3 HS

Disposable Test Pack with Biological Indicator and Type 5 Indicator (Integrator)



Product description

The challenge test is composed of an external cardboard die cut envelope, an external label with a chemical process indicator, a standardized barrier of porous paper with a die containing a biological indicator and a load record card that has a type 5 chemical indicator inserted.

Presentation

128 x 98 x 18 mm test package, boxes x 20 units. Instructions and biological indicator certificate. Lot and expiration date printed on the outer packaging

Classification

Biological sterilization indicator according with ISO 11138. Type 5 chemical sterilization indicator according with ISO 11140.

Shelf-life

24 months from the date of manufacture

Quality control

Control system according to ISO 9001: 2015, ISO 13485: 2016 and GMP (Good Manufacturing Practices) standards.

Stability

Stability has been verified from manufacture to expiration date, 24 months after date of manufacture.

Authorization and habilitation

ANMAT: PM 1454-44

Test Features

Package that allows detect the efficiency of steam sterilization, by double turning test of the type 5 indicator and the cultivation of the biological indicator. Reactive agents in this test are completely lead free.

Directions for use

Place the test package as the only load in a previously heated autoclave. Carry out the cycle you want to evaluate. Once finished, check the turning of the external indicator from blue to black, open the package, remove the load register and check the turn of the type 5 indicator from red to yellow. Remove the biological indicator and proceed to cultivation according to its instructions. Record the results in the load log and file it.

Cautions and warnings

Keep stored at a temperature between 5 and 50 $^{\circ}$ C, especially high relative humidity conditions should be avoided. It should not be kept in a refrigerator. The presence of vola le chemicals should be avoided in storage spaces, such as those that tend to give off cleaning products, washes or ammonia cleaners. Specially avoid contact with adhesives, as some aggressive substances that can alter the indicator. Once the test is done, handle carefully to avoid burns and let it cool before opening it. The filling paper must be discarded because during the sterilization process it suffers a loss of air in its fibers and is not reusable. The filler paper is recyclable.

Challenge tests

Challenge tests, generically called PCD (Process Challenge Devices) are packages specially designed to detect the effectiveness of sterilization processes in steam autoclaves. They have a biological indicator housed inside a porous cardboard package, which hinders the entry of steam. They are calibrated so that this barrier represents a challenge to the steam entry and thus indicates, if the test is successful, that the operation of the autoclave is efficient enough to overcome the barrier offered by the materials and achieve a correct sterilization in the entire volume of the autoclave. PCDs also have a type 5 indicator inside and a load log to record the results and be used as a file. To use a PCD, the test must be carried out in an empty chamber, preheating and using the process parameters that will be used in the usual cycles. There are challenge trials with 24-hour biological indicators and also with 3 hours, 1 hour or 20 minutes rapid indicators.

Results guide

The internal biological indicator must be evaluated according to instructions attached.





Viraje de la etiqueta externa





Viraje del indicador tipo 5





Technical Data Sheet

Reference: 45000S4016

CHALLENGE TEST (PCD) WITH BIOLOGICAL INDICATOR 24HS

Disposable Test Pack with Biological Indicator and Type 5 Indicator (Integrator)



Product description

The challenge test is composed of an external cardboard die cut envelope, an external label with a chemical process indicator, a standardized barrier of porous paper with a die containing a biological indicator and a load record card that has a type 5 chemical indicator inserted.

Presentation

128 x 98 x 18 mm test package, boxes x 20 units. Instructions and biological indicator certificate. Lot and expiration date printed on the outer packaging.

Classification

Biological sterilization indicator according with ISO 11138. Type 5 chemical sterilization indicator according with ISO 11140.

Shelf-life

24 months from the date of manufacture

Quality control

Control system according to ISO 9001: 2015, ISO 13485: 2016 and GMP (Good Manufacturing Practices) standards.

Stability

Stability has been verified from manufacture to expiration date, 24 months after date of manufacture.

Authorization and habilitation

ANMAT: PM 1454-44

Test Features

Package that allows detect the efficiency of steam sterilization, by double turning test of the type 5 indicator and the cultivation of the biological indicator. Reactive agents in this test are completely lead free.

Utilization

Place the test package as the only load in a previously heated autoclave. Carry out the cycle you want to evaluate. Once finished, check the turning of the external indicator from blue to black, open the package, remove the load register and check the turn of the type 5 indicator from red to yellow. Remove the biological indicator and proceed to cultivation according to its instructions. Record the results in the load log and file it.

Cautions and warnings

Keep stored at a temperature between 5 and 50 $^{\circ}$ C, especially high relative humidity condi ons should be avoided. It should not be kept in a refrigerator. The presence of vola le chemicals should be avoided in storage spaces, such as those that tend to give off cleaning products, washes or ammonia cleaners. Specially avoid contact with adhesives, as some aggressive substances that can alter the indicator. Once the test is done, handle carefully to avoid burns and let it cool before opening it. The filling paper must be discarded because during the sterilization process it suffers a loss of air in its fibers and is not reusable. The filler paper is recyclable.

Challenge tests

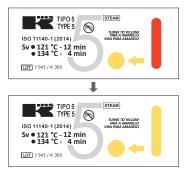
Challenge tests, generically called PCD (Process Challenge Devices) are packages specially designed to detect the effectiveness of sterilization processes in steam autoclaves. They have a biological indicator housed inside a porous cardboard package, which hinders the entry of steam. They are calibrated so that this barrier represents a challenge to the steam entry and thus indicates, if the test is successful, that the operation of the autoclave is efficient enough to overcome the barrier offered by the materials and achieve a correct sterilization in the entire volume of the autoclave. PCDs also have a type 5 indicator inside and a load log to record the results and be used as a file. To use a PCD, the test must be carried out in an empty chamber, preheating and using the process parameters that will be used in the usual cycles. There are challenge trials with 24-hour biological indicators and also with 3 hours, 1 hour or 20 minutes rapid indicators.

Results guide

The internal biological indicator must be evaluated according to instructions attached.



External label turn



Type 5 indicator turn

