



# Technical Data

## Sterile Fluid Thioglycollate Medium, Double Wrap Pack LQ026CDS DW

### Intended use

Recommended as sterility test medium prepared in accordance with USP, EP, BP, IP.

### Composition\*\*

Ingredients	g / L
Tryptone #	15.000
Yeast extract	5.000
Glucose monohydrate	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500
Resazurin sodium	0.001
Agar	0.750
pH after sterilization ( at 25°C)	7.1±0.2

\*\*Formula adjusted, standardized to suit performance parameters

# - Equivalent to Pancreatic digest of casein

### Directions

Label the ready to use LQ026CDS DW bottle. Inoculate  $\leq 100$  cfu sample and incubate at specified temperature and time.

Note: *If more than upper one-third of the medium has acquired a pink-purple colour, the medium may be restored once by heating in a water bath or in free flowing steam until the pink-purple colour disappears.*

### Principle And Interpretation

Brewer (1) formulated Fluid Thioglycollate Medium for rapid cultivation of aerobes as well as anaerobes including microaerophiles by adding a reducing agent and small amount of agar. The USP (2), BP (3), EP (4), IP (5), AOAC (6) and ISO (7) have recommended the media for sterility testing of antibiotics, biologicals and foods and for determining the phenol coefficient and sporicidal effect of disinfectants. However, it is intended for the examination of clear liquid or water-soluble materials. Fluid Thioglycollate Medium is also routinely used to check the sterility of stored blood in blood banks (8). Tryptone, yeast extract, glucose provide carbon, nitrogen compounds, long chain amino acids, vitamin B complex growth factors necessary for bacterial multiplication. L-cystine and sodium thioglycollate allows *Clostridium* to grow in this medium even under aerobic conditions. Also the small amount of agar used in the medium favors the growth of aerobes as well as anaerobes in the medium by maintaining low redox potential for stabilizing the medium (1). Sodium thioglycollate act as a reducing agent and neutralizes the toxic effects of mercurial preservatives and peroxides formed in the medium, thereby promoting anaerobiosis, and making the medium suitable to test materials containing heavy metals (9). Any increase in the oxygen content is indicated by a colour change of redox indicator, resazurin to red (8,10,11).

### Type of specimen

Pharmaceutical samples for sterility testing

### Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines (2-5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

### Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

### Limitations

1. It is intended for the examination of clear liquid or water-soluble materials.
2. Further biochemical and serological testing must be carried out for complete identification.

## Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

### Quality Control

#### Appearance

Sterile Fluid Thioglycollate Medium in glass bottle (Double Wrap Pack)

#### Colour

Light yellow to pink coloured clear to slightly opalescent solution with upper 10% or less medium will form pink-purple ring on twisting the screw cap

Note: During transportation the medium may appear pink -purple colour due to presence of redox indicator.

#### Quantity of Medium

400 ml of medium in glass bottle

#### pH

6.90- 7.30

#### Sterility Check

Passes release criteria

#### Growth Promotion Test

As per USP/EP/BP/IP

#### Growth promoting properties

Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating  $\leq 100$  cfu at 30-35°C for or not more than 3 days for aerobes and anaerobes.

#### Sterility Testing + Validation

The medium is tested with suitable strains of microorganisms inoculating  $\leq 100$ cfu and incubating at 20-25°C for not more than 3 days in case of bacteria and not more than 5 days in case of fungi.

Organism	Inoculum (CFU)	Growth	Incubation at
<b>Growth promoting</b>			
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	$\leq 100$	luxuriant	30-35°C
# <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	$\leq 100$	luxuriant	30-35°C
^ <i>Pseudomonas paraeruginosa</i> ATCC 9027 (00026*)	$\leq 100$	luxuriant	30-35°C
## <i>Kocuria rhizophila</i> ATCC 9341	$\leq 100$	luxuriant	30-35°C
<i>Clostridium sporogenes</i> ATCC 19404 (00008*)	$\leq 100$	luxuriant	30-35°C
<i>Clostridium sporogenes</i> ATCC 11437	$\leq 100$	luxuriant	30-35°C
** <i>Phocaeicola vulgatus</i> ATCC 8482	$\leq 100$	luxuriant	30-35°C

#### Sterility Testing- Growth promotion+Validation

<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	$\leq 100$	luxuriant	20-25°C
# <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	$\leq 100$	luxuriant	20-25°C
^ <i>Pseudomonas paraeruginosa</i> ATCC 9027 (00026*)	$\leq 100$	luxuriant	20-25°C
## <i>Kocuria rhizophila</i> ATCC 9341	$\leq 100$	luxuriant	20-25°C
<i>Candida albicans</i> ATCC 10231 (00054*)	$\leq 100$	luxuriant	20-25°C
\$ <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	$\leq 100$	luxuriant	20-25°C

**Testing in accordance with EN ISO 11133:2014/Amd.1:2018(E) (10)**

Cultural characteristics observed after an incubation at 36-38°C for 18-24 hours

*Clostridium perfringens* 50 -100 luxuriant 36-38°C  
ATCC 13124 (00007\*)

Key : (\*) Corresponding WDCM numbers,

## Formerly known as *Micrococcus luteus*

§ Formerly known as *Aspergillus niger*

# Formerly known as *Bacillus subtilis* subsp. *spizizenii*

^ Formerly known as *Pseudomonas aeruginosa*

\*\* Formerly known as *Bacteroides vulgatus*

**Storage and Shelf Life**

Store between 15-30°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

**Disposal**

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (12,13).

**Reference**

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