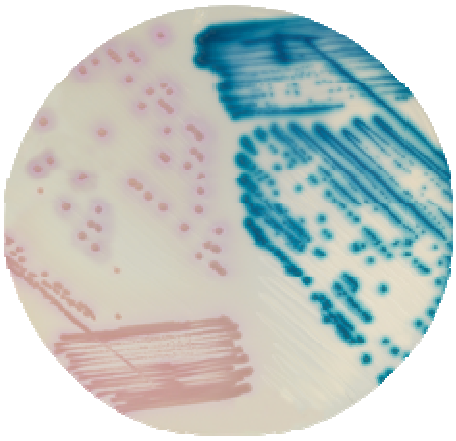
INSTRUCTIONS FOR USE

COLOREX™ LINEZOLID RESISTANCE

Ready for use plates



On the left, in pink, colonies of *S. aureus*/*S. epidermidis*
On the right, in metallic blue, colonies of *Enterococcus*

1 - INTENDED USE

In vitro diagnostic. Chromogenic medium for the detection and differentiation of linezolid-resistant Gram-positive bacteria.

2 - COMPOSITION - TYPICAL FORMULA *

Peptone	20.00 g
Agar	15.00 g
Salts	7.00 g
Mixture of chromogenic and selective compounds	0.40 g
Growth factors	8 mL
Purified water	1000 mL

*The formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Gram-positive cocci pose a threat to human health due to the emergence of antibiotic resistance. Linezolid has a broad spectrum of activity against a variety of Gram-positive pathogens, such as MRSA, RSV, and VRE. However, since its approval for clinical use, the emergence of linezolid-resistant (LIN-R) strains and the horizontal spread of resistance linked to the *cfr* gene have been increasingly reported.
Although the prevalence of linezolid resistance remains low, the emergence of LIN-R strains is of great concern. Today, linezolid susceptibility in clinical specimens from Gram-positive bacteria is primarily monitored by surveillance programs in Europe and the United States. Clinical isolates for surveillance of LIN-R strains include nasal swabs (for screening for *Staphylococcus*) and perianal and rectal areas (for screening for *Enterococcus*).
COLOREX™ Linezolid Resistance is a chromogenic screening medium for the detection, isolation, and differentiation of linezolid-resistant *Staphylococcus* and *Enterococcus* strains.

4 - PHYSICAL CHARACTERISTICS

Medium appearance	pale yellow, clear
Final pH at 20-25 °C	6,9 ± 0,2

5 - MATERIALS PROVIDED - PACKAGING

Product	Tipe	REF	Packaging
Colorex™ Linezolid Resistance	Ready for use plates	54LN76	2 x 10 plates ø 90 mm primary packaging: 2 cellophane sachets secondary packaging: cardboard box

6 - MATERIALS REQUIRED BUT NOT PROVIDED

Sterile loops and swabs, incubator and laboratory equipment as required, ancillary culture media and reagents for the identification of the colonies.

7 - SPECIMENS

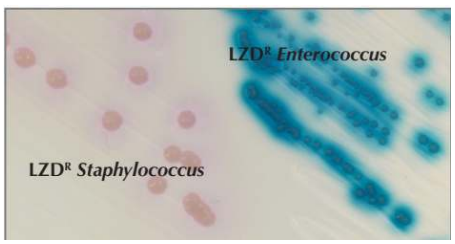
Colorex™ Linezolid Resistance can be used with the following clinical specimens: stool and nasal, perianal, and rectal swabs.
Collect specimens before antimicrobial therapy, whenever possible. Apply good laboratory practice guidelines for specimen collection, transport, and storage.

8 – TEST PROCEDURES

Allow plates to come to room temperature and to dry the surface of the medium.
Inoculate and streak the specimen with a loop over the four quadrants of the plate to obtain well isolated colonies, ensuring that sections 1 and 4 do not overlap. Alternatively, if the material is being cultured directly from a swab, roll the swab over a small area of the surface at the edge; then streak from this inoculated area. Incubate in aerobic atmosphere, at 35-37°C for 36-48 h.

9 - READING AND INTERPRETATION

After incubation, observe the bacterial growth and record the specific morphological and chromatic characteristics of isolated colonies.



Microrganism	Colony appearance
LZD^R *S. aureus*	pink colonies
LZD^R *S. epidermidis*	pink colonies
LZD^R *Enterococcus*	metallic blue colonies
LZD^S Gram (+) bacteria	inhibited or partially inhibited
Gram(-) bacteria	inhibited

LZD^R: linezolid resistant, LZD^S: linezolid not resistant

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10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end-user can perform his own Quality Control testing in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control.

CONTROL STRAINS	INCUBATION (T°/ t / ATM)	EXPECTED RESULTS
S. *epidermidis* LZD^R NCTC 13924	35-37°C/36/48 H/ A	Pink colonies with pink halo
E. faecalis LZD^R NCTC 14360	35-37°C/36/48 H/ A	Metallic blue colonies with blue halo
S. aureus ATCC 25923	35-37°C/36/48 H/ A	inhibited
E. faecalis ATCC 29212	35-37°C/36/48 H/ A	inhibited
E. coli ATCC 8739	35-37°C/36/48 H/ A	inhibited

LZD^R: linezolid resistant; A: aerobic incubation; ATCC is a trademark of American Type Culture Collection. NCTC: National Collection of Type Cultures

11 - PERFORMANCES CHARACTERISTICS

The performance of CHROMagar™ LIN-R medium was evaluated on 134 pure strains (*Enterococcus* spp., *S. aureus, S. epidermidis*, etc.) examined after 24-48 hours of incubation at 35-37°C under aerobic conditions with the following results:

	CHROMagar™ LIN-R
Sensitivity [1]	99%
Specificity[1]	100%

Before release for sale, a representative sample of all lots of Colorex™ Linezolid Resistance ready-to-use plates is tested for productivity, specificity, and selectivity.
Productivity and specificity are assessed using semiquantitative ecometric techniques with the strains *S. epidermidis* LZDR NCTC 13924 and *E. faecalis* LZDR NCTC 14360. After incubation at 35-37°C for 36-48 hours, the growth and color characteristics of the colonies are recorded and if they are typical, the results are considered in accordance with specifications. Selectivity is assessed using the modified Miles-Misra method by inoculating the plates with appropriate decimal dilutions in saline of a 0.5 McFarland suspension of the non-target strains *S. aureus* ATCC 25923, *E. faecalis* ATCC 29212, and *E. coli* ATCC 8739. After incubation at 35-37°C for 36-48 hours, the non-target strains are completely inhibited.

12 - LIMITATIONS OF THE METHOD

Linezolid-susceptible bacteria may show slight growth on heavily inoculated plates.
• Linezolid resistance in Gram-positive bacteria must be confirmed.
• Use of this medium may be difficult for people with color recognition problems.
Microbial colonies present on the plate, even if differentiated based on their color and morphological characteristics, must be subjected, after purification, to complete identification using biochemical, immunological, molecular, or mass spectrometric techniques and, if applicable, subjected to antibiotic susceptibility testing.
The culture medium described here is intended as an aid in the diagnosis of microbial infections. Interpretation of results should be made considering the patient's clinical history, the source of the specimen, and the results of other diagnostic tests.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that the product doesn't contain any transmissible pathogen. Therefore, it is recommended that the ready-to-use plates be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or put into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Each plate of this culture medium is for single use only.
- Ready-to-use plates are not to be considered a "sterile product" as they are not subject to terminal sterilization, but a product with controlled bio contamination, within the limits of defined specifications reported on the Quality Control Certificate.
- Sterilize all biohazard waste before disposal and dispose the unused medium and the sterilized plates inoculated with samples or microbial strains, in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store plates in their original pack at 2-8°C away from direct light. If properly stored, the plates may be used up to the expiration date. Do not use the plates beyond this date. Plates from opened plastic sachet can be used for 7 days when stored in a clean area at 2-8°C. Do not use the plates if the plastic sachet is damaged or if the dish is broken. Do not use the plates with signs of deterioration (e.g. microbial contamination, dehydration, shrinking or cracking of the medium, atypical colour, excess of moisture).

15 - REFERENCES

1. F. Layer et al. «Excellent performance of CHROMagar™ LIN-R to selectively screen for linezolid-resistant enterococci and staphylococci» Diagn. Micr. Infect. Dis. 2021

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	IVD *In vitro* Diagnostic Medical Device	 Manufacturer	 Use by
 Temperature limitation	 Contents sufficient for <n> tests	 Consult Instructions for Use	 For single use only	 Fragile, handle with care

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 0	First version	2025/07

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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