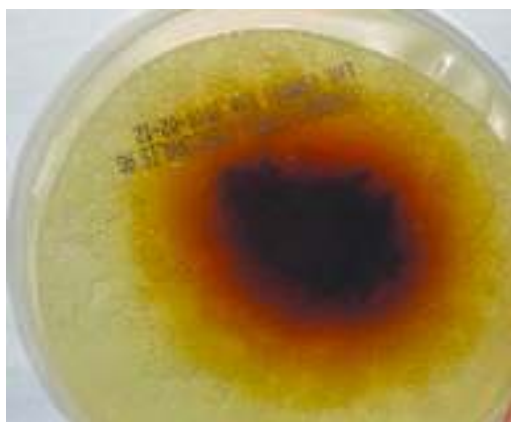


# STRONGYLOIDES STERCORALIS AGAR

## Ready-to-use plates



Strongyloides Stercoralis Agar: colonies formed as a result of larval migration from the center toward the periphery of the plate

### 1 - INTENDED USE

*In vitro* diagnostic device. General-purpose culture medium for the detection of *Strongyloides stercoralis* larvae and other intestinal nematodes from faecal specimens.

### 2 - COMPOSITION - TYPICAL FORMULATION \*

Peptone	10 g
Meat extract	5 g
Sodium chloride	5 g
Agar	15 g
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

Strongyloidiasis is widespread in tropical and subtropical regions and in some temperate areas, including Italy. The parasite has a very peculiar life cycle. Humans become infected through skin penetration by L3 larvae (infective stage) of *Strongyloides stercoralis*. Symptoms may go unnoticed, but generally include abdominal pain, asthmatic crises, wasting, generalized itching, and various skin lesions. <sup>1</sup> The culture method tends to be more sensitive than other diagnostic methods and, with the exception of molecular techniques, is currently the method of choice. <sup>2</sup>

Strongyloides Stercoralis Agar is a general-purpose nutritive medium containing peptones, sodium chloride, and agar. If larvae are present in the faecal specimen, they crawl in a serpentine motion over the agar surface toward the periphery in search of nutrients. In doing so, they carry faecal bacteria with them, creating visible tracks on the agar surface (microbial colonies). <sup>2</sup>

Plates are examined microscopically to confirm the presence of larvae. The agar surface is then washed with 10% formalin, and final confirmation of larval identification is performed by microscopic examination of the sediment obtained from the formalin wash. <sup>1,2</sup>

### 4 - PHYSICAL CHARACTERISTICS

Medium appearance	yellow, clear
Final pH at 25 °C	7.2 ± 0.2

### 5 - MATERIALS PROVIDED

Product	Type	REF	Pack
Strongyloides Stercoralis Agar	Ready-to-use plates	546550	2 x 10 plates ø 90 mm primary packaging: 2 cellophane sachets secondary packaging: cardboard box

### 6 - MATERIALS REQUIRED BUT NOT PROVIDED

Incubator and other laboratory equipment, loops, needles, sterile microbiological swabs, 10% formalin, optical microscope.

### 7 - SPECIMENS

The medium can be directly inoculated with faeces collected from the patient. Faeces must be fresh and stored at room temperature without preservatives for a maximum of 24 hours. For correct diagnosis, it may be necessary to analyse multiple faecal samples (on average 3), preferably collected on alternate days. <sup>3</sup>

Whenever possible, collect the specimen before starting antimicrobial or antiparasitic therapy. Apply good laboratory practice standards for specimen collection, storage, and transport to the laboratory. <sup>4,5</sup>

### 8 - TEST PROCEDURE

- Remove a plate from refrigeration and allow it to reach room temperature.
- Allow the surface of the medium to dry; if necessary, evaporate excess surface moisture by placing the plate slightly open in an incubator.
- Place approximately 3–5 g of faeces in the centre of the agar. If the faeces are liquid, mix them (1:1) with activated charcoal.
- Seal the plate with adhesive tape.
- Incubate the plate for 2–5 days at 26–33 °C, protected from light.
- Examine the plate using an optical microscope (preferably inverted under a stereomicroscope), using a green filter if possible (objectives 3.2×, 10×, and optionally 40×).
- If larvae (and possibly adults) or their tracks are observed, pierce the lid of the plate using the heated tips of forceps.
- Through the hole, irrigate the agar surface with 5–10 mL of 10% formalin (larvae are infective). With extreme caution, the procedure may also be performed with the plate open to facilitate collection of the wash liquid (which also inactivates nematodes).
- Transfer the formalin wash to a 12 or 15 mL conical-bottom tube, centrifuge (2 minutes at 550 g), discard the supernatant, and examine the sediment microscopically (10× and 40×).

### 9 - READING AND INTERPRETATION

Suspected presence of nematodes is indicated by the appearance of tracks of bacterial colonies radiating from the fecal specimen toward the periphery of the plate.

### IDENTIFICATION OF LARVAE



**A – Characteristics of helminth larvae: *S. stercoralis* and hookworms**
**RHABDITIFORM LARVAE**

Feature	<i>Strongyloides</i>	<i>Ancylostoma / Necator</i>
Size	200–300 × 15–18 µm	100–150 × 15–17 µm
Buccal cavity	Short (4 µm)	Long (15 µm)
Oesophagus	1/3 of body length, with two constrictions	1/3 of body length, with two constrictions
Genital primordium	Large (22 µm)	Small (7 µm)
Anal pore	50 µm from the tail	80 µm from the tail


**FILARIFORM LARVAE**

Feature	<i>Strongyloides</i>	<i>Ancylostoma / Necator</i>
Size	500 × 14–20 µm	500 × 14–20 µm
Sheath	Absent	Present
Tail	Bifid (2–3 tips) or blunt	Pointed
Oesophagus	1/2 of body length, without constrictions	1/3 of body length, without constrictions


**B – Characteristics of helminth larvae: *Necator americanus*, *Ancylostoma duodenale*, and *Trichostrongylus* spp.**
**Rhabditoid larvae**

Practically indistinguishable

**Filariform larvae**

Feature	<i>N. americanus</i>	<i>A. duodenale</i>	<i>Trichostrongylus</i> spp.
Cuticle	Extends well beyond larval body, fine transverse striations	Slightly exceeds body, smooth with faint striations	Variable
Anterior end	Oval	Flat	Variable
Oesophagus	With oral cavity, long (¼ body length)	Long (¼ body length)	Short
Tail	Not sharp, conical pointed	Very sharp with rounded tip	Usually very long and progressively thinner

**C – “In vitro” developmental sequence**

Time	Observation
Fresh faeces	Rhabditoid larva L1
2 days	Filariform larva L2
3–5 days	Filariform larva L3
> 7 days	Adults (M and F), second-generation larvae

Hookworms: eggs with blastomeres → rhabditoid larva L1 → filariform larva L2 → encapsulated filariform larva L3

**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 its own Quality Control 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.<sup>9</sup>

CONTROL STRAINS	INCUBATION T° / T / ATM	EXPECTED RESULTS
<i>S. aureus</i> ATCC 25923	28–32 °C / 18–24 h / A	good growth
<i>E. coli</i> ATCC 8739	28–32 °C / 18–24 h / A	good growth

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection



**11- PERFORMANCES CHARACTERISTICS**

Before release, representative samples of all batches of Strongyloides Stercoralis Agar plates are tested for productivity using a semi-quantitative ecometric method with *E. coli* ATCC 8739 and *S. aureus* ATCC 25923. After incubation at 28–32 °C for 18–24 hours, all strains show good growth.

**12 - LIMITATIONS OF THE METHOD**

- Specimen collection and storage methods, as well as the number of faecal samples examined, are critical factors for obtaining reliable results.<sup>4, 6, 7</sup>
- The culture medium described herein is intended as an aid in the diagnosis of parasitic infections. Interpretation of results must take into account the patient's clinical history, the origin of the specimen, and the results of other diagnostic tests (e.g., microscopy).

**13 - PRECAUTIONS AND WARNINGS**

- This product is a qualitative *in vitro* diagnostic device intended for professional use only, is not automated and is not a companion diagnostic tool. It must be used by adequately trained and qualified laboratory personnel, observing 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. 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 allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website [www.biolifeitaliana.it](http://www.biolifeitaliana.it), describing the measures implemented 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 of 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](http://www.biolifeitaliana.it).
- Notify the Manufacturer ([complaint@biolifeitaliana.it](mailto:complaint@biolifeitaliana.it)) and the relevant Authorities of any serious incident occurring in connection with the use of the *in vitro* diagnostics.
- The Manufacturer may not be held responsible for any loss or damage in any way resulting from or related to use of the product in manners not compliant with the instructions provided.

**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**

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**TABLE OF APPLICABLE SYMBOLS**

REF Catalogue number	LOT Batch code	IVD <i>In vitro</i> diagnostic medical device	Manufacturer	This way up	For single use only	CE European conformity mark
Temperature limitations	Contents sufficient for <n> tests	Consult electronic instructions for use	Use by	Keep away from sunlight	Fragile, handle with care	UDI Unique device identifier

**REVISION HISTORY**

Version	Description of changes	Date
Revision 0	First issue	2026/01

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

