PRODUCT INFORMATION AND QUALITY CONTROL SHEET
CAMPYLOBACTER AGAR

I. INTENDED USE
Campylobacter agar with 5 antimicrobics and 10% Sheep Blood is used for isolating and cultivating *Campylobacter jejuni* from human fecal specimens.

II. SUMMARY AND EXPLANATION
Campylobacter jejuni has been reported to be the causative agent in a number of cases of enteritis, an infection acquired by ingestion of water or food contaminated with the organism.[1] Skirrow isolated *C. jejuni* from fecal specimens by using a selective medium incubated at 42^{0}C in an atmosphere of 5% oxygen, 10% carbon dioxide and 85% nitrogen.

The Skirrow formulation includes blood agar supplemented with vancomycin, polymyxin B and trimethoprim for the selective isolation of *C. fetus* subsp. j*ejuni.*[2] Blaser et al. Further incorporated cephalothin and amphotericin B to improve inhibition of normal enteric flora.

III. PRINCIPLES OF THE PROCEDURE
This medium supports the growth of *Campylobacter* species due to its content of peptones, dextrose, yeast extract and blood. The peptones supply nitrogenous compounds, carbon, sulfur and trace ingredients. Yeast extract is a potent source of the B vitamins. Dextrose is utilized as an energy source. Sheep blood supplies the X factor (heme) and other growth requirements.[3]

The incorporation of the antimicrobial agents amphotericin B, cephalothin, polymyxin B, trimethoprim and vancomycin, suppresses the growth of the normal microbial flora in fecal specimens, thereby facilitating isolation of *C. jejuni*.[3]

IV. TYPICAL FORMULA AND APPEARANCE
Appearance = opaque, cherry red
(Approximate formula* per liter of processed water)

Pancreatic Digest of Casein	10.0g
Peptic Digest of Animal Tissue	10.0
Dextrose	1.0
Sodium Chloride	5.0
Yeast Extract	2.0
Sodium Bisulfite	0.05
Agar	15.0
Defibrinated Sheep Blood	5%

*adjusted and/or supplemented to meet performance criteria.
Final pH: 7.2 ± 0.2 @ 25^{0}C

V. PRECAUTIONS
This product is for *IN VITRO* diagnostic use only. Culture specimens may contain microorganisms that can be potentially infectious to the user. Strict adherence to aseptic techniques and established precautions against microbiological hazards should be followed throughout the procedure. Carefully dispose of all items that contact patient specimens or isolated bacteria.

VI. STORAGE/SHELF LIFE
Plated media should be stored at 2-8^{0}C (36-46^{0}F), media side up, in the unopened or resealed package protected from light. DO NOT FREEZE OR EXPOSE TO HIGH TEMPERATURES. Allow unopened plates to warm to room temperature prior to inoculation. Prior to and during inoculation procedures, plates should be handled in a manner that minimizes product exposure to the environment. Product that has exceeded the assigned expiration date noted on the label should not be used.

Do not use plates that exhibit evidence of drying, cracking, discoloration, microbial contamination or any other signs of deterioration. The presence of excessive condensate may indicate plates that have been damaged by exposure to temperature extremes.

VII. SPECIMEN COLLECTION
The quality of culture results depends primarily on the adequacy and condition of the specimen submitted for examination. Proper specimen collection techniques must be followed to ensure the most accurate culture results. Sterile swabs and
collection containers should be used. Plates should be inoculated promptly after specimen collection. If the specimen cannot be inoculated onto appropriate media within four hours after collection, the specimen should be maintained or transported in Cairy-Blair Transport medium.[1]

Detailed information on proper specimen collection may be obtained from microbiology reference materials.

VIII. MATERIALS PROVIDED
Campylobacter Agar Plates with 5 Antimicrobics & 10% Sheep Blood

IX. MATERIALS REQUIRED BUT NOT PROVIDED
Incubator maintaining 42^{0}C.
Ancillary culture media, reagents and laboratory equipment as required.
Microaerophilic environment system

X. PROCEDURE
Inoculate the specimen as soon as possible after it is received in the laboratory. The streak plate method is used primarily to isolate pure cultures from specimens containing mixed flora. If material is being cultured directly from a swab, roll the swab over a small area of the plate surface at the edge (approximately 1/4 to 1/3 of the plate); then streak in a zig-zag fashion with a sterile loop from this inoculated area in two sections to cover the entire agar surface; flaming or flipping loop between sections. Avoid applying excessive pressure to the agar surface during inoculation to prevent gouging and splitting of the agar media. (Note: Agar surfaces should be smooth and moist but free of excessive moisture that could cause confluent growth patterns.)

Incubate plates at 42^{0}C in a microaerophilic atmosphere containing 5-6% oxygen and 3-10% carbon dioxide. Examine plates at 24, 48 and 72 hours.

XI. EXPECTED RESULTS
NCCLS CONTROL ORGANISMS (ATCC STRAINS)

Campylobacter jenuni (ATCC 33291)	Growth
Escherichia coli (ATCC 25922)	Inhibition (partial)

XII. LABORATORY RESULTS
Colonies of *C. jejuni* appear as non-hemolytic, flat and gray with an irregular edge or raised and round with a mucoid appearance. An alternate colonial morphology which appears to be strain-related consists of round colonies 1 to 2 mm in diameter, which are convex, entire and glistening.[4]

NOTE: If plates are to be examined after 24 hours of incubation, examine plates quickly and place them back into a reduced oxygen atmosphere immediately after examination.[3]

XIII. LIMITATIONS
Due the presence of 15 mg/L of cephalothin, growth of *C. fetus ssp. fetus* will be inhibited. The ability to detect

microorganisms by culture techniques can be affected by the following factors: improper specimen collection, storage and inoculation, initiation of antiinfective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media.

XIV. REFERENCES

1. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Yolken (ed.). Manual of clinical microbiology, 6th ed. American Society for Microbiology, Washington, D.C.
2. Skirrow, M.D. 1977. Campylobacter enteritis: A "new" disease. Br. Med. J. 2:9-11.
3. Manual of BBL products and laboratory procedures. 6th ed.
4. Smibert. 1984. In Krieg and Holt (ed.), Bergey's manual of systematic bacteriology, vol 1 Williams & Wilkins, Baltimore.

USER QUALITY ASSURANCE/ QUALITY CONTROL PROCEDURES AND INFORMATION

HealthLInk recommends that the following quality assurance and quality control procedures be performed on each batch of product.

I. QUALITY ASSURANCE

The following quality assurance procedures must be performed to assure the product will perform according to its intended use within the assigned expiry date:

1. Daily, document that product storage refrigerator maintains temperature within the recommended range: 2-8^{0}C.
2. Daily, document that laboratory incubator maintains recommended temperature: 42^{0}C.

II. QUALITY CONTROL

The following procedures must be performed for each batch (batch = same lot, same shipment) of culture media received in the laboratory:

1. Inoculate two plates with the following NCCLS Quality Control Organisms and compare growth to below:

Campylobacter jejuni (ATCC 33291)	Growth (small, grayish-white to colorless mucoid colonies
Escherichia coli (ATCC 25922)	Inhibition (partial)

2. Inspect plates according to instructions in Section VI "STORAGE/SHELF LIFE"
3. Peel off the portion of a product bag label (Quality Control Certificate) for the lot being accepted into the laboratory and affix it to the 'Peel-and-stick' Quality Control Log Sheet.
4. Initial and date the Quality Control Log Sheet.

Note: Notify Technical Service immediately if media does not meet the inspection criteria.

TECHNICAL SERVICE

HealthLink provides a toll free technical service line (1-800-638-2625) to assist with product usage. To have technical questions answer, please call between the hours of 9:00 am to 5:00 pm EST.

HealthLink
3611 St. Johns Bluff Rd. So. Ste 1
Jacksonville, FL 32224

1-800-638-2625

June, 2001

Product No. 1017 Rev. No. New