Key Code TSMX7595A

www.oxoid.com/ifu

Europe +800 135 79 135 US 1 855 2360 190

CA 1 855 805 8539 ROW +31 20 794 7071

ProSpecT Campylobacter Microplate Assay

EN

REF R2476096 .....96 Tests

1. INTENDED USE

The ProSpecT™ Campylobacter Microplate Assay is an IN VITRO microplate enzyme immunoassay (EIA) for the qualitative detection of *Campylobacter* Specific Antigen in faecal specimens and broth enriched faecal cultures. ProSpecT Campylobacter Microplate Assay is intended for use as an aid in the diagnosis of *Campylobacter* infections.

2. SUMMARY

The enteropathogenic bacterium *Campylobacter jejuni* is recognized as one of the major etiologic agents of acute diarrhoea in humans[1,2,3]. It is the leading cause of bacterial diarrhoea in the U.S. exceeding both *Salmonella* and *Shigella* combined[4,5]. Although the disease has a worldwide distribution, it is particularly severe in developing countries. *Campylobacter jejuni* infections cause diarrhoea which may be watery and can contain blood, usually occult, and faecal leukocytes[6]. Other symptoms are fever, abdominal pain, nausea, headaches and muscle pain. The illness occurs 2-5 days after ingestion of contaminated food or water and can last 7-10 days. Most infections are self-limiting and antibiotic therapy is not required[9]. Complications are rare, however it has been reported that infections may be concurrent with reactive arthritis, haemolytic uraemic syndrome, meningitis, recurrent colitis, acute cholecystitis and Guillain-Barre syndrome[4]. Children under 5 years and young adults (15-29) are more frequently afflicted with *Campylobacter jejuni* infections than other age groups.

Diagnosis of Campylobacteriosis infections presently rests upon isolation and cultivation of the organism in enrichment broth and selective media containing a variety of antibiotic supplements in a micro-aerophilic atmosphere of 5% oxygen and 10% carbon dioxide. Isolation can take 2 days to a week.

Campylobacter Specific Antigen (SA) is a Campylobacter surface antigen. Western blot analysis reveals 2 bands with molecular weights of approximately 15Kd and 66Kd. Cross reactivity studies indicate this is an antigen shared by *Campylobacter jejuni* and *Campylobacter coli*.

3. PRINCIPLES OF THE TEST

ProSpecT Campylobacter Microplate Assay is a solid phase immunoassay for the detection of *Campylobacter* Specific Antigen (SA). Diluted stool specimens are added to break-away microplate wells on which rabbit polyclonal anti-*Campylobacter* SA antibody is bound. If *Campylobacter* SA is present, it is 'captured' by the bound antibody. The wells are incubated and then washed to remove unbound material. The enzyme conjugate (polyclonal rabbit anti-*Campylobacter* SA labelled with horseradish peroxidase enzyme) is added. The wells are incubated and then washed to remove unbound enzyme conjugate. In a positive reaction, captured Campylobacter Specific Antigen binds the enzyme conjugate to the well. The substrate for the enzyme, 3,3',5,5'-tetramethylbenzidine (TMB), is added. In a positive reaction, the enzyme bound to the well by *Campylobacter* SA converts the substrate to a coloured reaction product. Colour development can be detected visually or spectrophotometrically. In a negative reaction, there is no *Campylobacter* SA or an insufficient level of antigen present to bind the enzyme conjugate and no coloured reaction product develops.

4. SYMBOL DEFINITIONS

REF	Catalogue Number
IVD	In Vitro Diagnostic Medical Device
Σ	Contains sufficient for <n> tests
	Consult Instructions for Use (IFU)
8°C 2°C	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufacturer
DILUTED SAMPLE	Diluted Sample

5. KIT CONTENTS, PREPARATION FOR USE AND STORAGE

The ProSpecT Campylobacter Microplate Assay includes sufficient reagents to perform Σ 96 tests.

See also **Precautions**, section **6**.

The expiration date of each kit is stated on the package label.

Store all components at 2 to 8°C.

Before use, bring all reagents to room temperature (20 - 25°C) and mix gently. Return the unused reagents to the refrigerator after use.

All reagents, except the Wash Buffer, are supplied at working strength. Reagents can be dispensed directly from the dropper bottles or poured out for use with multichannel pipettes. If excess reagent has been poured, the excess should be discarded. Do not pour excess reagent back into the bottle.

Instructions for Use

Transfer pipettes
Microplate Strip Holder and Cover
Procedure Card

MICROTITRATION PLATE

Microplate* (8 wells / strip)

6 strips (R2476048) or 12 strips (R2476096) coated with rabbit polyclonal anti-*Campylobacter* SA antibody. Unused microplate strips should be stored in the foil pouch containing desiccant to exclude moisture.

CONJUGATE

Enzyme Conjugate*

One dropper bottle containing 12 ml (R2476048) or 25 ml (R2476096) of horseradish peroxidase labelled rabbit polyclonal anti-*Campylobacter* SA with antimicrobial agents.

CONTROL +

Positive Control

One dropper bottle containing 4 ml of inactivated *Campylobacter jejuni* culture supernatant suspended in a buffered solution with foetal bovine serum and antimicrobial agents.

CONTROL –

Negative Control

One dropper bottle containing 4 ml of a buffered solution with rabbit serum, a red dye and antimicrobial agents.

SAMPLE DILUENT

Bacterial Specimen Diluent

One bottle containing 120 ml of a buffered solution with rabbit serum, a red dye and antimicrobial agents.

WASH BUFFER (x10)

Wash Buffer

One bottle containing 120 ml of a (x10) concentrated buffered solution with antimicrobial agents.

Dilute (x10) Wash Buffer concentrate to (x1) by adding 1 part concentrate to 9 parts distilled or deionised water. Diluted Wash Buffer is stable for 1 month when stored at 2 - 8°C.

SUBSTRATE TMB

Colour Substrate

One dropper bottle containing 12 ml (R2476048) or 25 ml (R2476096) of 3,3',5,5'-tetramethylbenzidine (TMB) in buffer.

The Colour Substrate should be stored in and used from the light protected bottle in which it is provided. If an aliquot is removed from the original bottle for any reason, do not return unused Colour Substrate to the original bottle.

STOP SOLUTION

Stop Solution

One dropper bottle containing 12 ml of 0.46 mol/l Sulphuric acid.

***Note:** Do not interchange reagents between kits with different lot numbers.

6. PRECAUTIONS

IVD

The reagents are for *in vitro* diagnostic use only.

For professional use only.

Please refer to the Safety Data Sheet (SDS) and product labelling for information on potentially hazardous components.

HEALTH AND SAFETY INFORMATION

6.1. Reagents are prepared from biological materials and should be handled as potentially infectious material. Discard using appropriate biohazard procedures.

6.2. Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

6.3. Specimens may contain potentially infectious agents and should be handled at Biosafety Level 2 as recommended in the CDC/NIH manual, "Biosafety in Microbiological and Biomedical Laboratories", 5th Edition.

6.4. Wash Buffer contains a potential skin sensitiser (< 1% v/v). Avoid skin contact. Wear disposable Vinyl or Nitrile gloves.

6.5. Discard used Wash Buffer in appropriate biohazard containers.

ANALYTICAL PRECAUTIONS

6.6. Carefully read and follow all instructions in this Instruction for Use.

6.7. Reagents are provided at the necessary working strength, with the exception of the Wash Buffer concentrate. Do not dilute reagents, except where instructed.

6.8. Do not use reagents beyond the expiration dates. Expiration dates are printed on each reagent label. Use of reagents beyond the expiration date may affect the accuracy of results.

6.9. The following common reagents may be used across the ProSpecT product range: Wash Buffer, Colour Substrate and Stop Solution.

6.10. Microbial contamination of reagents may decrease the accuracy of the assay. Avoid microbial contamination of reagents by using sterile disposable pipettes when removing aliquots from reagent bottles.

6.11. Allow all reagents and specimens to reach room temperature (20 - 25°C) before use.

6.12. Microplate strips must be stored in the resealable foil pouch, with desiccant, to protect microplate wells from moisture.

6.13. Stool samples must be thoroughly mixed prior to specimen processing to ensure accurate representation of the specimen. DO NOT CONCENTRATE SPECIMENS BEFORE TESTING.

6.14. Colour Substrate is sensitive to light exposure. If the reagent is exposed to light and develops colour, the reagent must be discarded.

6.15. Persons who are colour blind or visually impaired may not be able to read the test visually and should use spectrophotometric readings to interpret results.

6.16. Add reagents to the test wells in the same order throughout the procedure. To avoid contamination do not touch the fluid in the wells with the bottle tips.

6.17. Time each incubation accurately. Start timing after adding reagent to the last well on each microplate being tested. To ensure accurate timing, process no more than three 96 well plates at one time. Deviation from the established procedure may alter the performance of the assay.

6.18. It is important to hold the dropper bottles vertically and that the drop forms at the tip of the nozzle. If the nozzle becomes wet, a drop of incorrect volume will form around the end and not at the tip; if this occurs dry the nozzle before progressing.

7. COLLECTION OF FAECAL SPECIMENS

For direct testing of stool specimens, optimal results will be obtained if stools are tested immediately upon receipt in the laboratory. For broth enriched testing the stool specimen should be added to the enrichment broth immediately upon receipt in the laboratory.

FRESH Unpreserved stool specimens may be stored at 2 - 8°C and tested within 72 hours.

Specimens can be diluted 1:3 in the Bacterial Specimen Diluent and stored refrigerated at 2 - 8°C for up to 72 hours prior to testing.

FROZEN Store stools at -20°C or lower if testing is to be performed later than 72 hours. Avoid repeated freeze-thawing.

CARY BLAIR Stool specimens collected in Cary Blair Transport Media should be refrigerated at 2 - 8°C and tested within 1 week after collection.

8. TEST PROCEDURE

REQUIRED MATERIALS PROVIDED

See **Kit Contents**, section **5**

MATERIALS REQUIRED BUT NOT PROVIDED

Stool specimen collection containers
Timer that measures minutes
Wash bottle for Wash Buffer
Distilled or deionised water

OPTIONAL MATERIALS NOT PROVIDED

Microplate reader capable of reading 450 nm or 450/620 to 650 nm
Cotton or rayon tipped applicator sticks
Micropipette to deliver volumes to 200 µl
Plastic or glass disposable test tubes
Vortex mixer with plate adapter or shaker

PROCEDURE

8.1. **Specimen Preparation for Assay:** Specimens in Cary Blair Transport Media may be added directly to microplate wells for testing (see Step 8.4 below). Be sure to mix the specimens in transport media before transferring to the microplate well.

Fresh stool specimens or broth enriched cultures must be diluted (see Box **A or B** below).

A	**Direct Stool Testing for Fresh, Unpreserved Specimens**
1	Add 0.6 ml Bacterial Specimen Diluent to a clean plastic or glass disposable tube.
2	Mix stool as thoroughly as possible.
3	For liquid stools, semi-solid stools use a transfer pipette to add approximately 0.3 ml (third mark from the tip of the pipette). Expel sample into Bacterial Specimen Diluent and mix by drawing up and down once. Leave the transfer pipette in the tube.
4	For solid stools use an applicator stick to add 0.3 gm (~6 mm diameter). Using the applicator stick, emulsify the stool in the Bacterial Specimen Diluent. Place a transfer pipette in the tube and mix tube contents by drawing up and down once. Leave the transfer pipette in the tube.
5	**PROCEED TO STEP 8.2**

B	**Broth Method for Broth Enrichment Specimens**
1	Inoculate 150 µl or 3 drops of stool into 5 ml GN Broth, Hajna.
2	Incubate at 35 ± 2°C under ambient atmospheric conditions for 18 - 24 hrs.
3	Add 0.6 ml Bacterial Specimen Diluent to a clean 12 x 75 mm tube.
4	Transfer 0.3 ml broth culture into 0.6 ml Bacterial Specimen Diluent using a transfer pipette. Leave the transfer pipette in the tube.
5	**PROCEED TO STEP 8.2**

8.2. Open the foil pouch, remove the required number of microplate strips and place into a microplate strip holder. Use one well for the Negative Control and one well for the Positive Control. If using less than 8 wells, break off the required number of wells from a strip and return the unused wells to the foil pouch with desiccant. RESEAL POUCH TIGHTLY TO EXCLUDE MOISTURE AND RETURN TO THE REFRIGERATOR.

8.3. Add **4 drops** (200 µl) Negative Control to well A1. Add **4 drops** (200 µl) Positive Control to well B1.

8.4. Using a transfer pipette, add **4 drops** of diluted specimen or enriched broth culture, or **4 drops** of specimen in transport medium per well. Note: Place the opening of the transfer pipette just inside the well to avoid splashing into adjacent wells.

8.5. **Cover** microplate and incubate at room temperature (20 - 25°C) for **60 minutes**. Begin timing after the addition of the last specimen.

8.6. Shake out or aspirate the contents of the wells. Wash by completely filling each well with **diluted** Wash Buffer (~350-400 µl/well). Shake out or aspirate all fluid from the wells after each wash. Wash a total of **3 times**. After the last wash remove contents and strike plate on clean paper towels or aspirate. Remove as much Wash Buffer as possible but do not allow the wells to dry out at any time.

8.7. Add **4 drops** (200 µl) of Enzyme Conjugate to each well.

8.8. **Cover** microplate and incubate at room temperature (20 - 25°C) for **30 minutes**.

8.9. Shake out or aspirate and wash each well **5 times** as in step 8.6.

8.10. Add **4 drops** (200 µl) of Colour Substrate to each well.

8.11. **Cover** microplate and incubate at room temperature (20 - 25°C) for **10 minutes**.

8.12. Add **1 drop** (50 µl) Stop Solution to each well. Gently tap or vortex the wells until the yellow colour is uniform. Read reactions within **10 minutes** after adding the Stop Solution.

8.13. Read visually or spectrophotometrically at 450 nm (single wavelength) or 450/620 to 650 nm (dual wavelength).

9. QUALITY CONTROL

Positive and Negative Controls must be included each time the test is performed. The Positive and Negative Controls serve as both reagent and procedural controls. The controls are intended to monitor for substantial reagent failure. The Positive Control will not ensure precision at the assay cut-off.

The optical density (O.D.) of the Negative Control should be < 0.100 at 450 nm or < 0.070 at 450/620 to 650 nm. The Negative Control should be colourless when read visually. If yellow colour equal to 1+ or greater on the Procedure Card is present in the Negative Control, the test should be repeated with careful attention to the wash procedure.

The O.D. of the Positive Control should be > 0.500 at 450 nm or 450/620 to 650 nm. Visually the intensity of colour in the Positive Control should be equal to or greater than the 2+ reaction on the Procedure Card. If there is less colour, call for technical assistance.

10. RESULTS

Refer to enclosed Procedure Card for colour interpretations.

VISUAL

10.1. Read the test results by comparing with the reaction colours on the Procedure Card.

Positive: yellow colour of at least 1+ intensity
Negative: colourless
Indeterminant: faint yellow colour, less than the 1+ reaction

10.2. Interpretation of visual results:

Positive: If yellow colour of at least 1+ intensity develops in the test well, the sample contains *Campylobacter* SA and the test is positive.

Negative: A colourless reaction is a negative result and indicates that no *Campylobacter* SA or an undetectable level of *Campylobacter* SA is present in the sample tested.
Indeterminant: If faint yellow colour that is less than the 1+ reaction develops, the test is indeterminant. Indeterminant results should be repeated. If the repeat test results are positive, the specimen is positive. If the repeat test results are negative, the specimen is negative. If the repeat test results remain indeterminant another specimen should be obtained and tested.

SPECTROPHOTOMETRIC

10.3. Read results at either single (450 nm) or dual (450/620 to 650 nm) wavelength.

10.4. Read the test results:

A. Single Wavelength	Fresh Stool	Transport Media/Broth
Negative:	OD < 0,130	< 0,100
Indeterminant:	OD 0,130 - 0,170	0,100 - 0,130
Positive:	OD > 0,170	> 0,130
B. Dual Wavelength	**Fresh Stool**	**Transport Media/Broth**
Negative:	OD < 0,100	< 0,070
Indeterminant:	OD 0,100 - 0,140	0,070 - 0,100
Positive:	OD > 0,140	> 0.100

10.5. Interpretation of spectrophotometric results:

Positive: An O.D. reading greater than the indicated cut-off for single wavelength or dual wavelength by specimen type is positive and indicates the presence of *Campylobacter* SA.
Negative: An O.D. reading less than the indicated cut-off for single wavelength or dual wavelength by specimen type is a negative result and indicates that no *Campylobacter* SA or an undetectable level of *Campylobacter* SA is present in the sample tested.
Indeterminant: O.D. readings that are in the indicated indeterminant range by specimen type are indeterminant. Indeterminant results should be repeated. If the repeat test results are positive, the specimen is positive. If the repeat test results are negative, the specimen is negative. If the repeat test results remain indeterminant another specimen should be obtained and tested.
An indeterminant result is when both the visual and spectrophotometric reading are in agreement. Indeterminant results should be repeated. If the repeat test results are positive, the specimen is positive. If the repeat test results are negative, the specimen is negative. If the repeat test results remain indeterminant another specimen should be obtained and tested.
Note: Any wells that are clear visually but give an O.D. reading that is inconsistent with the visual interpretation should be considered a discrepant reading and examined for the presence of bubbles, small particles in the wells, or an opaque film on the bottom of the wells. To remove the film, wipe the underside of the wells and read the O.D. again. If the discrepancy between visual and O.D. readings persists, repeat the test.

11. PERFORMANCE LIMITATIONS

The validity of results with the ProSpecT Campylobacter Microplate Assay depends on the control reaction performing as expected. See **Quality Control** section **9**.

A negative test result does not exclude the possibility of the presence of *Campylobacter*, and may occur when the antigen level in the sample is below the detection level of the test. Correlation between the amount of antigen in a sample and clinical presentation has not been established.

As with all IN VITRO diagnostic tests, results should be interpreted by the clinician in conjunction with clinical findings and/or other laboratory results.

Proper specimen collection and processing are essential to achieve optimal performance of the assay. Optimal test results are obtained from specimens tested as soon after collection as possible. See **Collection of Faecal Specimens** section **7**.

The ProSpecT Campylobacter Microplate Assay does not differentiate *C. jejuni* and *C. coli* and there are other serotypes and subspecies that may or may not be detected. It is not known whether *C. upsalensis*, *C. hyointestinalis*, or *C. helviticus* cross-react.

12. EXPECTED VALUES

Campylobacter jejuni is the leading cause of bacterial diarrhoea in the U.S. and infections are highest in the summer to fall period[5]. Infections are usually acquired through the ingestion of contaminated food or water. Testing of commercially frozen poultry samples has shown contamination rates from 30 to 90%[6]. *C. jejuni* is widespread in the animal kingdom and has been isolated from a variety of domestic animals, poultry, and virtually every wild bird species. Transmission by sexual contact or faecal-oral route has also been reported as well as drinking contaminated surface water[5]. Children under 5 years and young adults (15-29) are more frequently afflicted than other age groups. A recent College of American Pathologists study of 601 institutions found that a bacterial pathogen could be identified in 6.4% of the 59,500 specimens submitted[7]. *Campylobacter* was

identified in 1.5% of the specimens, Salmonella in 1.15% and Shigella in 0.9%. Prevalence rates for *C. jejuni* in the United States range from 1.0 to 4.6%[3]. Rates as high as 2.9% were also found in a 4 year study in Switzerland[8].

13. PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

The ProSpecT Campylobacter Microplate Assay was evaluated at three geographically distinct clinical sites in the United States and Canada. The sites were a Metropolitan Hospital in Illinois, a large reference laboratory in New Jersey, and a centralized testing laboratory in Ontario, Canada. All specimens were tested by culture and biochemical assays to confirm a positive isolate of *Campylobacter*. The results at each of the test sites after repeating indeterminant results and discrepant reading results as indicated by the instructions in this Instruction for Use are presented in Table 1.

Table 1. ProSpecT Campylobacter Microplate Assay compared with Culture Assays on direct stool specimens.

SITE 1 CULTURE RESUL

		+	-	
ProSpecT	+	70	6	
Microplate	-	0	337	
Assay		70	343	413

Sensitivity: 100%
Specificity: 98.3%

SITE 2 CULTURE RESULTS

		+	-	
ProSpecT	+	10	0	
Microplate	-	0	214	
Assay		10	214	224

Sensitivity: 100%
Specificity: 100%

SITE 3 CULTURE RESULTS

		+	-	
ProSpecT	+	49	2	
Microplate	-	0	361	
Assay		49	363	412

Sensitivity: 100%
Specificity: 99.4%

Table 2: Results with Combined Data from three Clinical Trial Sites on direct stool specimens.

		Direct +	Direct -	
ProSpecT	+	129	8	
Microplate	-	0	912	
Assay		129	920	1049

Sensitivity: 100% (97.2 - 100%)
Specificity: 99.1% (98.3 - 99.6%)
Correlation: 99.2% (98.5 - 99.7%)

As shown in Table 2 there was 99.2% correlation between the ProSpecT Campylobacter Microplate Assay and culture when the results of all three sites are combined and all indeterminant and discrepant reading results were resolved. All EIA discrepant reading results were resolved as negative after repeat testing. There was one specimen which was initially EIA+, Culture-. Upon repeat testing the culture was positive and was resolved as a true positive. Of the remaining 8 EIA+, Culture- specimens, one was EIA repeat negative. The other 7 were repeatedly positive.

At Trial Site 2 all specimens tested in the direct stool assay were also enriched overnight in GN broth, Hajna @ 35 ± 2°C under ambient atmospheric conditions. The enriched culture was then run in the ProSpecT Campylobacter Microplate Assay and compared to the standard stool culture methodology. The results are presented in Table 3.

Table 3: ProSpecT Campylobacter Microplate Assay compared with Culture Assay on Broth Enriched Stool Cultures.

TRIAL SITE 2 CULTURE RESULTS

		+	-	
ProSpecT	+	9	0	
Microplate	-	1	214	
Assay		10	214	224

Sensitivity: 90.0% (55.5 - 99.9%)
Specificity: 100% (98.3 - 100%)
Correlation: 99.6% (97.5 - 100%)

As shown in table 3 there was 99.6% correlation between the ProSpecT Campylobacter Microplate Assay and culture when the specimens were enriched in GN Broth, Hajna and all discrepant results were resolved. All EIA indeterminant and discrepant results were resolved as negative after repeat testing.

ANALYTICAL SENSITIVITY

The ProSpecT Campylobacter Microplate Assay detects approximately 2.81 ng/ml of *Campylobacter* Specific Antigen and approximately 10^5 CFU/ml.

REPRODUCIBILITY

The inter-assay or run-to-run coefficient of variation (CV) of the ProSpecT Campylobacter Microplate Assay was evaluated by selecting one negative and three positive samples with varying optical density readings. Each specimen was tested in 22-24 wells/run in three consecutive runs. The mean inter-assay CV was 11.4%.

Sample	Mean O.D.	Standard Deviation	% CV
1	1.325	0.033	9.6 %
2	0.535	0.070	13.1 %
3	0.342	0.050	14.6 %
4	0.045	0.004	8.4 %

The intra-assay or within-run CV was evaluated by testing 22-24 wells with each of 4 samples. The mean intra-assay CV was 4.0%.

Sample	Mean O.D.	Standard Deviation	% CV
1	1.268	0.033	2.61 %
2	0.501	0.015	2.95 %
3	0.320	0.009	2.84 %
4	0.047	0.004	7.70 %

CROSS-REACTIVITY

There was no cross reaction when a variety of organisms of the human colonic microflora were tested in the ProSpecT Campylobacter Microplate Assay. Tests were conducted by seeding the organisms listed below into *Campylobacter jejuni* negative and positive stools. Bacteria were seeded at concentrations >1 x 10^7 CFU/ml of stool.

Arcobacter butzleri ATCC® 49616
Campylobacter curvis ATCC® 35224
Campylobacter fetus ATCC® 19438
Campylobacter lari ATCC® 35221
Campylobacter rectus ATCC® 33238
Campylobacter sputorum ATCC® 35980
Citrobacter braakii ATCC® 43162
Escherichia coli, EHEC, ATCC® 43890 (O157:H7)
Escherichia coli, EIEC, ATCC® 43893 (O124:NM)
Escherichia coli, EPEC, ATCC® 12014 (O55:NM)
Escherichia coli, EPEC, ATCC® 33780 (O111:NM)
Escherichia coli, ETEC/EPEC, ATCC® 43887 (O111:NM)
Escherichia coli, Stx negative, ATCC® 25922
Escherichia hermannii ATCC® 33660
Enterobacter cloacae ATCC® 13047
Enterococcus faecalis ATCC® 49149
Helicobacter cinaedi ATCC® 35683
Helicobacter pylori ATCC® 43504
Klebsiella pneumoniae ATCC® 27736
Proteus vulgarus ATCC® 33420
Pseudomonas aeruginosa ATCC® 27853
Salmonella typhimurium SA 972229
Serratia liquefacians ATCC® 27592
Shigella dysenteriae ATCC® 49347

Shigella flexneri ATCC® 25929
Shigella sonnei ATCC® 25931
Staphylococcus aureus ATCC® 25923
Yersinia enterocolitica ATCC® 23715

14. BIBLIOGRAPHY

1. **Guerrant, R.L. and D.A. Bobak. 1991.**
   Review Article, Medical Progress, Bacterial and Protozoal Gastroenteritis. N. Engl. J. Med. 325(5): 327-340.
2. **Mitchell, J.E. and M.M. Skelton. 1988.**
   Diarrhoeal Infections. Am. Fam. Phys. May 37(5): 195-207.
3. **Guerrant, R.L., et al. 1985.**
   Evaluation and Diagnosis of Acute Infectious Diarrhoea. Am. J. Med. 78(6B): 91-98.
4. **Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, *Campylobacter jejuni*. 1992.**
   Bad Bug Book, http://vm.cfsan.fda.gov/-mow/chap4.htm.
5. **Cohen, M.L., 1988.**
   The Epidemiology of Diarrhoeal Disease in the United States Infectious Diarrhoea, Division of Bacterial Disease, CDC, 557-570.
6. **Gilligan, P.H., et al, April 1992.**
   Laboratory Diagnosis of Bacterial Diarrhoea. ASM, Cumitech 12A: 8-10.
7. **Valenstein, P., et al, 1996.**
   The Use and Abuse of Routine Stool Microbiology. Arch. Pathol. Lab. Med., 120: 206-211.
8. **Rohner, P., et al, 1997.**
   Etiological Agents of Infectious Diarrhoea: Implications for Requests for Microbial Culture. J. Clin. Microbiol. 35(6): 1427-1432.
9. **Williams, E.K., 1986.**
   Acute Infectious Diarrhoea. II. Diagnosis, Treatment and Prevention. Pediatr. Infect. Dis. 5(4): 458-465.

CE

Oxoid Ltd Wade Road Basingstoke Hants, RG24 8PW
UK

For technical assistance please contact your local distributor.

IFU X7595A, Revised December 2012
Printed in the UK