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Wellcolex Colour Salmonella

REF R30858301 ..... Σ 50 **EN**
REF R30858302 ..... Σ 200

1. INTENDED USE

Wellcolex™ Colour Salmonella provides a simple, rapid qualitative latex test procedure for the screening, detection and presumptive serogroup identification of Salmonella from Selenite F broth and on solid media. The Wellcolex Colour Salmonella test has been categorised as highly complex under CLIA.

2. SUMMARY AND EXPLANATION OF THE TEST

The genus Salmonella is responsible for a wide spectrum of human disease ranging from mild forms of gastroenteritis to severe, life-threatening enteric fever and, in addition, asymptomatic carriage can occur. Early, reliable identification is important to the provision of appropriate therapy and to control outbreaks. Minimal identification of the organisms involves both biochemical and serological procedures. Definitive serological testing requires a large number of antisera to both cell-associated 'O' antigens and flagellar 'H' antigens, and ideally this process is performed in reference centres. It is useful for the clinical laboratory to identify the isolate to the 'O' serogroup level prior to submitting it to a reference laboratory[4].

3. PRINCIPLE OF THE PROCEDURE

To perform Wellcolex Colour Salmonella, a sample from a Selenite F broth culture (18 to 24 hours incubation) or a suspension of bacteria from solid agar is reacted with two test reagents, consisting of a mixture of suspensions of red, blue and green latex particles, each of which is coated with antibody specific for different Salmonella serogroups. In the presence of homologous antigen one of the colours in the mixture will agglutinate, and the identity of the antigen is indicated by the colour of the aggregated particles with a contrasting change in the colour of the background. Each combination is easily distinguished from the others and from a negative result in which the particles remain in smooth grey-brown suspension, and the occasional non-specific result in which all the particles agglutinate into grey-brown aggregates against a cleared background.

4. REAGENTS

KIT CONTENTS

	Wellcolex Colour Salmonella	Σ 50 (ZC50/R30858301)	Σ 200 (ZC52/R30858302)
1.	Latex reagent 1	1 dropper bottle (white cap)	4 dropper bottles (white caps)
2.	Latex reagent 2	1 dropper bottle (white cap)	4 dropper bottles (white caps)
3.	Red Positive Control	1 dropper bottle (red cap)	1 dropper bottle (red cap)
4.	Blue Positive Control	1 dropper bottle (blue cap)	1 dropper bottle (blue cap)
5.	Green Positive Control	1 dropper bottle (green cap)	1 dropper bottle (green cap)
6.	Disposable Mixing Sticks	2 bundles	5 bundles
7.	Disposable Reaction Cards	1 pack	4 packs
8.	Disposable Sample Dispensers	2 packs	8 packs
9.	Disposable Suspension Tubes	1 pack	NONE
10.	Instructions for Use	1	1
11.	Reading Guide	1	1

5. DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

See also **Warnings and Precautions**.

8°C
2°C

Unless otherwise stated, all components should be stored at 2 to 8°C, under which condition they will retain activity until the expiry date of the kit.

Once opened, reaction cards should be stored at room temperature (18 to 30°C)

LATEX REAGENT 1

Latex Reagent 1

One (ZC50/R30858301) or four (ZC52/R30858302) dropper bottles of a grey-brown suspension of polystyrene latex particles in buffer containing 0.05% Bronidox® preservative. The latex particles are coated with rabbit antibody with the following specificity:

Red latex	Salmonella group B
Blue latex	Salmonella group C
Green latex	Salmonella group D_1

LATEX REAGENT 2

Latex Reagent 2

One (ZC50/R30858301) or four (ZC52/R30858302) dropper bottles of a grey-brown suspension of polystyrene latex particles in buffer containing 0.05% Bronidox® preservative. The latex particles are coated with rabbit antibody with the following specificity:

Red latex	Vi
Blue latex	Salmonella groups E and G
Green latex	Salmonella group A

RED CONTROL + **Red Positive Control**

Killed bacterial suspension of organisms with Salmonella group B and Vi antigens containing 0.05% Bronidox® and 0.5% formalin as preservative.

BLUE CONTROL + **Blue Positive Control**

Killed bacterial suspension of organisms with Salmonella groups C and E antigens containing 0.05% Bronidox® and 0.5% formalin as preservative.

GREEN CONTROL + **Green Positive Control**

Killed bacterial suspension of organisms with Salmonella group A and D_1 antigens containing 0.05% Bronidox® and 0.5% formalin as preservative.

6. WARNINGS AND PRECAUTIONS

IVD

For *in vitro* diagnostic use only.

For professional use only.

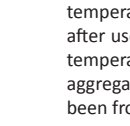
Please refer to the manufacturer's safety data sheet and the product labelling for information on potentially hazardous components.

6.1. HEALTH AND SAFETY INFORMATION

6.1.1 The Red, Blue, and Green Positive Controls contain 0.5% formalin which is classified per applicable European Economic Community (EEC) Regulations as a sensitizer. The following are the appropriate Hazard (H) and Precautionary (P) statements.

RED CONTROL + BLUE CONTROL + GREEN CONTROL +

DANGER



H350	May cause cancer
EUH208	Contains formaldehyde. May produce an allergic reaction
P201	Obtain special instructions before use
P281	Use personal protective equipment as required
P308+P313	IF exposed or concerned: Get medical advice/ attention
	Restricted to professional users

6.1.2 In accordance with the principles of Good Laboratory Practice, it is strongly recommended that all clinical specimens and materials should be handled as potentially infectious and used with all necessary precautions. Ideally, the procedure should be performed in a suitable microbiological safety cabinet[1].

6.1.3 Non-disposable apparatus should be sterilised by any appropriate procedure after use, although the preferred method is to autoclave for 15 minutes at 121°C; disposables should be autoclaved or incinerated. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a disinfectant or 70% alcohol. Materials used to clean spills, including gloves, should be disposed of as potentially biohazardous waste. Do not autoclave materials containing sodium hypochlorite.

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

6.1.5 If any of the reagents come into contact with the skin or eyes, wash the area extensively by immediately rinsing with plenty of water.

6.1.6 Avoid ingestion of the reagents.

6.2. ANALYTICAL PRECAUTIONS

6.2.1 Do not use the reagents beyond the stated expiry date.

6.2.2 Microbiological contamination of reagents must be avoided as this may reduce the life of the product and cause erroneous results.

6.2.3 Allow all reagents and samples to come to room temperature (18 to 30°C) before use. Immediately after use return reagents to the recommended storage temperature. Latex reagents which show signs of aggregation when dispensed for the first time may have been frozen and should not be used.

6.2.4 Store Latex Reagents upright at 2 to 8°C. After prolonged storage some aggregation or drying around the top of the bottle may have occurred with the Latex Reagents. Under these circumstances the Latex Reagents should be shaken vigorously for a few seconds until resuspension is complete.

6.2.5 Personnel with colour vision defects should be able to see agglutination but may experience difficulty in differentiating the colour reactions; if a problem is encountered, reactions should be referred to someone with normal colour vision.

6.2.6 The quality of the Selenite F broth used for the enrichment of Salmonella is important as broth which has been overheated, contains a red precipitate, has been stored for long periods of time or kept above 8°C may give unsatisfactory results and should not be used[5].

6.2.7 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.

6.2.8 Use of a flat-bed rotator is essential. For optimum performance ensure that the rotator is level and has been calibrated to run at 150 ± 5 rpm.

6.2.9 Do not touch the reaction areas on the cards. It is important to ensure that the Reaction Cards lie completely flat on the rotator otherwise clear agglutination patterns will not be seen.

6.2.10 Ensure that the Positive Controls are resuspended by shaking or vortexing vigorously for ten seconds. DO NOT vortex the Latex Reagents.

7. SPECIMEN COLLECTION AND PREPARATION OF CULTURES

The test may be performed directly on Selenite F broth after 18 to 24 hours incubation. The quality of Selenite F broth is important (see **Analytical Precautions**).

The test may also be performed on non-lactose-fermenting colonies growing in primary culture on selective media (for example MacConkey Agar, Hektoen Enteric Agar or Xylose Lysine Desoxycholate Agar), in subculture from enrichment broth on these media or in pure culture (for example Nutrient Agar plates or slopes (slants)).

If it is necessary to confirm the results of the test, the bacterial suspension used for the colour test may be subcultured subsequently for further identification, the same suspension may also be used for testing with Wellcolex Colour Shigella (ZC51/R30858401).

For details of specimen collection and preparation of cultures a standard textbook should be consulted[2,3,4].

8. PROCEDURE

MATERIALS PROVIDED

Wellcolex Colour Salmonella contains sufficient materials for 50 tests (ZC50/R30858301) or 200 tests (ZC52/R30858302), see **Kit Contents**.

Materials Required but not Provided

1. 0.85% sterile saline.
2. The test should be performed on a flat bed rotator with an orbital diameter of 1.25 inches (32 mm)/1.5 inches (38 mm) operating at approximately 150 rpm. **The speed and orbital diameter are critical to the performance of the assay.**
3. Small glass tube or bottle for boiling a sample of Selenite F broth when positive for the Vi antigen.
4. Boiling water bath.
5. Sterile saline containing 0.5 ml of 35% formaldehyde per 100 ml for use when Vi antigen is detected from a colony suspension.
6. Disposable Suspension Tubes are not supplied with ZC52/R30858302. Colony identification can be performed with this kit by using a suitable inert glass or plastic (polystyrene) tube. No other materials or equipment are needed.

PREPARATION OF ENRICHMENT BROTH

1. Ensure that the Selenite F broths are brought to room temperature (18 to 30°C) before inoculation.
2. Inoculate a pea sized sample of faeces or 0.5 ml of liquid faeces into 3 ml of sterile saline or Selenite F broth in a screw capped container. Emulsify by shaking vigorously or by vortexing, ensuring that solid samples are broken up before emulsification.
3. Leave to stand for a few minutes to reduce the risk of aerosol release. Inoculate the broth in a ratio of 1 volume of emulsion to 10 volumes of broth and incubate for 18 to 24 hours at 37°C. Ensure that the lids of the bottles and tubes are loose to allow air to circulate.

NOTE: Successful evaluations have been performed using direct inoculation of the Selenite F broths[9]. It is essential that the pea sized sample of faeces is broken up and emulsified in the broth before incubation.

TEST PROCEDURE

CAUTION: Precautions appropriate to the handling of live cultures should be taken while performing the test.

Broth Testing

NOTE: DO NOT MIX THE SELENITE F BROTHS BEFORE TESTING

Step 1 Resuspend Latex Reagents 1 and 2 by shaking vigorously for a few seconds. Hold the bottles vertically and dispense **one free-falling drop** of each Latex Reagent into a separate circle on a flat Reaction Card. Burst any air bubbles with the end of a Sampling Stick.

Step 2 Using a Disposable Sample Dispenser held vertically, transfer **one free-falling drop** (40 µl) of inoculated Selenite F broth to **each of the two circles**, ensure that the broth is not shaken when they are removed from the incubator. It is important that the sample of broth is taken from just above the faecal debris, ensuring that no debris is taken with the sample. Take care not to dispense air bubbles. Discard the dispenser for safe disposal.

Step 3 Using a Sampling Stick, mix the contents of each circle and spread to cover the whole area of the circle. The same stick may be used for both circles and then discarded for safe disposal.

Step 4 Place the card on a suitable flat-bed rotator and run at **150 ± 5 rpm for 2 minutes** (see **Analytical Precautions**). Switch off and observe for agglutination **without removing the card from the rotator**. The card should be viewed from directly above at a normal reading distance (25 to 35 cm). **Do not use a magnifying lens.** The patterns obtained are clear cut and can be recognised easily under any normal lighting conditions.

If there is any doubt about whether agglutination has occurred the test should be repeated using a 40 µl drop of a negative broth. There should be no visible agglutination. This result should be used as a basis for comparison.

Step 5 Discard the used reaction circles for safe disposal. Ensure that the Latex Reagents are returned to the refrigerator (2 to 8°C).

Colony Identification

Step 1 Dispense approximately 200 µl of saline into a Suspension Tube. The Disposable Sample Dispenser which is graduated at approximately 200 µl may be used.

Step 2 From an overnight culture pick one or two average-sized (1 to 2 mm) suspected Salmonella colonies from the culture plate using the flat end of a Sampling Stick and carefully emulsify the bacteria in the saline. With small colonies more will need to be picked; the end of the Sampling Stick should be covered. Discard the Sampling Stick for safe disposal.

Step 3 Resuspend Latex Reagents 1 and 2 by shaking vigorously for a few seconds. Hold the bottle vertically and dispense one free-falling drop of each Latex Reagent into a separate circle on a flat Reaction Card. Burst any air bubbles with the end of a Sampling Stick.

Step 4 Using a Disposable Sample Dispenser held vertically, transfer **one free-falling drop** (40 µl) of bacterial suspension to **each of the two circles**. Take care not to dispense air bubbles. Discard the Dispenser for safe disposal.

Step 5 Using a Sampling Stick, mix the contents of each circle and spread to cover the whole area of the circle. The same stick may be used for both circles and then discarded for safe disposal.

Step 6 Place the card on a suitable flat-bed rotator and run at **150 ± 5 rpm for 2 minutes** (see **Analytical Precautions**). Switch off and observe for agglutination **without removing the card from the rotator**. The card should be viewed from directly above at a normal reading distance (25 to 35 cm). **Do not use a magnifying lens.** The patterns obtained are clear cut and can be recognised easily under any normal lighting conditions. If there is any doubt about whether agglutination has occurred the test should be repeated using a 40 µl drop of saline. There should be no visible agglutination. This result should be used as a basis for comparison.

Step 7 Discard the used reaction circles for safe disposal. Ensure that the Latex Reagents are returned to the refrigerator (2 to 8°C).

9. RESULTS

READING OF RESULTS

Refer to Wellcolex Colour Salmonella Reading Guide

Negative

Neither Latex Reagent agglutinates and the smooth grey-brown appearance remains substantially unchanged throughout the test (Figure 1). Note, however, that faint traces of granularity may be detected in negative patterns, depending on the visual acuity of the operator.

Positive

A colour change occurs in the reaction due to agglutination of one of the coloured latex suspensions in the mixture, with a contrasting change in the colour of the background. (Figures 3 to 5). Usually a single colour will agglutinate in one Latex Reagent, but with a mixed Salmonella culture, two colours may agglutinate in one Latex Reagent (Figures 6 to 8), or a single colour in both Reagents. These possibilities are easily discriminated. If the pattern of reaction differs from that shown in Figures 3 to 8, the speed and the operation of the rotator should be checked and adjusted accordingly.

Non-specific

All the particles agglutinate giving rise to grey-brown clumps against a cleared background (Figure 9). It is possible that some grey-brown clumps may develop in the presence of a positive reaction. If there has been a distinct colour change in the test, these grey-brown clumps should be ignored.

Debris

On some occasions, particularly when broth cultures are tested, lumps may be apparent in the reaction mixture (Figure 2). These are readily differentiated from a positive or negative reaction and are usually caused by debris in the broth sample. If there is any confusion, the sample should be re-tested after allowing the debris to settle.

NOTE: Selenite F broths giving a presumptive positive or a non-interpretable result should be confirmed or further investigated using conventional procedures[2,3,4].

10. QUALITY CONTROL

Visual Inspection

The Latex Reagents should always be inspected for aggregation as they are dropped onto the Reaction Card and if there is evidence of clumping before addition of the broth sample or bacterial suspension, that Reagent should not be used.

Control Procedures

Quality control testing should be run with each shipment and new kit lot number received. Each laboratory should follow their state and local requirements.

Positive Control Procedure

Confirm the performance of the Latex Reagents using the Positive Controls provided.

Step 1 Into 6 separate Reaction Circles, dispense 3 drops of Latex Reagent 1 and 3 drops of Latex Reagent 2 (one drop per circle).

Step 2 Add one drop of **each** Positive Control to 2 of the Reaction Circles (one containing Latex Reagent 1 and one containing Latex Reagent 2).

Step 3 Mix the reagents using a separate Disposable Sampling Stick for each Positive Control.

Step 4 Rotate the card at **150 ± 5 rpm for 2 minutes** on a mechanical rotator. After this time definitive agglutination should be visible in all 6 Reaction Circles.

Step 5 Discard the used Reaction Card for safe disposal.

The colour of the agglutinated latex in Reagent 1 and Reagent 2 should correspond to the colour of the Positive Control (Blue, Red or Green).

Stock cultures of known Salmonella serogroups may be used in place of the Positive Control.

Negative Control Procedure

Repeat the test procedure using saline or enrichment broth instead of the test sample. There should be no significant agglutination.

11. INTERPRETATION OF RESULTS

A positive result (coloured agglutination) indicates the presence and at the same time identifies the serogroup of Salmonella in the sample (or the presence of Vi antigen), as follows:

REACTION	BACKGROUND	REAGENT		COMMENTS FOR SELENITE TESTING
		1	2	
		SEROGROUP IDENTIFIED		
Green or olive agglutination in one reagent.	Purple/pink	D	A	The colours may vary depending on the colour of the Selenite broth. A positive reaction may be partially masked by red/ brown clumping
Blue agglutination in one reagent	Orange/pink	C	E or G	
Red agglutination in one reagent	Blue/ turquoise	B	Vi	
Irregular dark red/brown specks in both Reagents 1 and 2	Smooth grey/ brown	Negative		This is due to debris (if one reagent has significantly more clumping than the other look carefully for positives – see below).
No agglutination	Smooth grey/ brown	Negative		
Fine, grainy, dark red/ brown agglutination usually occurring equally in both reagents	Clear or light grey/brown	Non-specific		If the reaction stronger in one reagent this may be a positive reaction. Check colour carefully. Boil a 0.5 ml sample as described below
Turquoise agglutination in one reagent	Pink	C and D	A and E or G	Look carefully for colour.
Orange agglutination in one reagent	Blue	B and D	A and Vi	
Purple agglutination in one reagent	Green	B and C	E or G and Vi	

NOTE: When using Selenite F broth the background colour shown above may be masked and appear as a pink or red/brown colour. In such a case identification is made using the colour of the agglutinated latex particles only.

If Vi antigen is detected (red agglutination with Latex Reagent 2), take a fresh sample of Selenite F broth or make a fresh suspension of the culture in saline containing 0.5% formalin in a suitable tube or bottle to kill the bacteria. Immerse in a boiling water bath for 5 minutes, cool and retest with Latex Reagent 1. Alternatively, make at least 400 µl of a fresh suspension of the culture in saline or distilled water. Immerse in a boiling water bath for 30 minutes, cool and re-test with Latex Reagent 1. Agglutination will identify the serogroup of a Salmonella; if there is no agglutination with Latex Reagent 1 the culture is not Salmonella. Note that boiled Vi antigen will still react with Latex Reagent 2.

A negative result indicates that the sample under test does not contain antigens belonging to the Salmonella serogroups covered by the reagents. Mixed growths of non-lactose fermenters are frequently present in stool cultures, and if a negative result is obtained when testing colonies it may be necessary to repeat the test on other selected colonies before discarding the culture as negative.

If a non-specific reaction is obtained the result is not interpretable, and conventional procedures for identification should be followed[2,3,4].

In enrichment broths, non-specific reactions may be caused by heavily mucoid faecal samples. Transfer 0.5 ml or more of the broth to a suitable glass tube or bottle, loosen the cap and place in a boiling water bath for 5 minutes. Cool to room temperature (18 to 30°C) and repeat the test procedure. A sample of the enrichment broth should be processed in the same way for use as a negative control.

12. LIMITATIONS OF THE PROCEDURE

Wellcolex Colour Salmonella is designed as a screening procedure for salmonellae from Selenite F broths and from solid media as a culture identification test. The test will identify Salmonella isolates to serogroup level, which is satisfactory for most purposes when full identification can be performed by a reference laboratory[4]. Definitive identification requires conventional biochemical and serological procedures[2,3,4]; selection of appropriate antisera may be guided by the results of Wellcolex Colour Salmonella.

Occasional false-positive reactions might be encountered due to the presence of shared antigens in heterologous species or genera such as Citrobacter; these may be differentiated using conventional biochemical test procedures. Also Vi antigen may be found on bacteria other than Salmonella[2]; these may be differentiated by retesting a broth sample or colony suspension after boiling to remove the Vi antigen; if no agglutination is seen other than with red latex in Latex Reagent 2 the organism is not Salmonella. Particular caution should be exercised in case one of these organisms is present in an enrichment broth as well as Salmonella; it is wise to confirm the result on a subculture of the broth before reporting.

A negative result does not confirm the absence of Salmonella. For example, the test does not cover the full range of Salmonella serogroups, but will, for example, detect the serogroup present in over 99% of strains encountered in human infection in the UK[6] and over 98% in the USA[7]. In addition the level of Salmonella in some broth cultures may be insufficient to give a positive result. For example this may occur with broths which have not been incubated for a full 18 to 24 hours.

Some sub-optimal preparations of Selenite F broth contain a brick-red precipitate and caution should be exercised in interpreting results obtained in tests with this medium.

13. EXPECTED RESULTS

Strains belonging to serogroups A, B, C, D, E or G, or which possess Vi antigen will give a red, blue or green agglutination with the corresponding component of Latex Reagent 1 or 2.

SPECIFIC PERFORMANCE CHARACTERISTICS

External Evaluation

Two studies have been performed to evaluate Wellcolex Colour Salmonella:

(a) A multicentre study involving five Public Health Laboratories in the UK and three hospital laboratories in the USA on routine cultures for Salmonella.

Each laboratory performed tests on one or more of the following samples from each faecal specimen:

1) Selenite enrichment broths (Selenite F).
2) Lactose negative colonies direct from enrichment broth subcultures on selective-differential agar plates.
3) Lactose negative colonies direct from primary selective-differential agar plates (MacConkey, XLD, DCA, SS and Hektoen).
4) Pure subcultures of lactose negative colonies on nutrient agar.

A rotator was used throughout.

The results are shown in Tables 1 and 2.

The performance of Wellcolex Colour Salmonella was determined by comparison with results of traditional bacteriological methods on the samples.

In this study the sensitivity and specificity of Wellcolex Colour Salmonella (see Tables 1 and 2) were:

	Sensitivity		Specificity	
Primary plate cultures	100%	(65/65)	99.2%	(127/128)
Enrichment broth subcultures	100%	(176/176)	100%	(147/147)
Pure cultures	99.5%	(191/192)	98.0%	(100/102)
Selenite broths	94.2%	(114/121)	99.7%	(305/306)

Nine non-Salmonella cultures were encountered which carried Vi antigen: none of these reacted with group-specific components in the test.

The predictive value of a positive result was 99.3% (432/435) from plate culture, and 99.1% (114/115) from Selenite broth. Negative predictive values were 99.7% (374/375) and 97.8% (305/312) respectively.

The prevalence of Salmonella in the samples studied was 44.8% (554/1237).

The occurrence of non-interpretable reactions with Wellcolex Colour Salmonella was 4.5% (9/202) for primary plate cultures, 6.1% (21/344) for enrichment broth subcultures, 3.6% (11/305) for pure cultures and 2.1% (9/436) from Selenite broth. These samples have been excluded from Tables 1 and 2.

(b) An independent study on fresh isolates and reference cultures.

In this study[8], Wellcolex Colour Salmonella correctly identified 267 of 268 fresh isolates and reference cultures of Salmonellae. These included : ten isolates from each of the ten most common Salmonella serotypes, *(S. typhimurium, S. enteritidis, S. virchow, S. stanley, S. hadar, S. agona, S. heidelberg, S. infantis, S. newport* and *S. braenderup)*, ten strains of *S. typhi* Vi+ and ten Vi-, ten different phagetypes each of *S. paratyphi* A and *S. paratyphi* B and seventy five additional strains from the groups C, D, E and G. No cross reaction was found with Groups F and H. Among the other groups up to and including O-67 tested, a weak reaction with the Group D latex in Reagent 1 was seen with an O-52 *(S. utrecht)* culture; this reaction was not seen with another O-52 *(S. flottbek)*. *S. uccle* (O-3, 54) reacted as expected with the group E reagent.

NOTE: Further details of serological and biochemical test procedures for the identification of Salmonella may be obtained from Ewing (1986)[2].

Table 1

Identification of Salmonella from Plate Cultures

	Wellcolex Colour Salmonella	Routine Result		
	Test Result	POSITIVE[a]	NEGATIVE	TOTAL
PRIMARY CULTURE	POSITIVE	65	1[b]	66
	NEGATIVE	0	127	127
SUBCULTURE FROM BROTH	POSITIVE	176	0	176
	NEGATIVE	0	147	147
PURE SUBCULTURE	POSITIVE	191	2[b,c]	193
	NEGATIVE	1[d]	100[e]	101
	TOTAL	433	377	810

[a] 199 group B, 116 group C, 91 group D, 23 group E, 2 group G and 2 group D / Vi.
[b] unidentified non-lactose fermenter (group E / G reaction).
[c] *Citrobacter freundii* (group E / G reaction).
[d] Group D which had been identified correctly by Wellcolex Colour Salmonella from the broth subculture.
[e] Includes *Escherichia coli, Proteus mirabilis, Campylobacter jejuni, Citrobacter freundii, Enterobacter* spp., *Klebsiella aerogenes* and unspecified coliforms.

Table 2

Identification of Salmonella from Selenite broth

Routine Culture Method

		POSITIVE	NEGATIVE	TOTAL
Wellcolex Colour Salmonella	POSITIVE	114[a]	1[c]	115
	NEGATIVE	7[b]	305[d]	312
	TOTAL	121	306	427

[a] 57 group B, 27 group C, 19 group D, 8 group E, 1 group G, 1 group D/Vi and 1 mixed C/E from which both were isolated.
[b] 1 group B, 2 group C and 4 group D, all identified by Wellcolex Colour Salmonella after further subculture.
[c] *Citrobacter freundii* (group E/G reaction); same reaction seen in plate culture.
[d] Includes *Proteus spp., Citrobacter freundii, Escherichia coli, Klebsiella aerogenes, Enterobacter spp*., *Shigella sonnei* and unspecified coliforms.

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PACKAGING

REF ZC50/R30858301..... Σ 50

REF ZC52/R30858302..... Σ 200

Symbol legend

REF	Catalogue Number
IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
Σ N	Contains sufficient for <N> tests
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

CE

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