

ANALYST WORKSHEET	1. PRODUCT: THREELAC DIETARY SUPPLEMENT (LACTIC ACID BACTERIA)		2. SAMPLE NUMBER 285344
	3. SEALS <input type="checkbox"/> INTACT <input checked="" type="checkbox"/> NONE <input type="checkbox"/> BROKEN	4. DATE RECEIVED 6/7/2004	5. RECEIVED FROM Matthew Bernaly

7. DESCRIPTION OF SAMPLE:
 Received one cardboard box, taped shut, and identified, in part, as "Sample#285344 336-2001602-5 05/30/04 RIC Lactobacillus dietary Supplement 03819C" containing 15 subs x 2 (30 subs total) in side brown paper bags folded closed and tied with a rubber band. Subs 1a-15a and 1b-15b identified "Sample# 285344 336-2001602-5 05/27/04 RIC Yogurt Powder 03819C" sub number 1a-15a, 1b-15b. The sample was received at ambient temperature and intact. *Date on cllr is different from date written on cardboard box. See attachment A.*

8. NET CONTENTS	<input checked="" type="checkbox"/> NOT APPLICABLE	DECLARE/UNIT <u>none observed</u>	9. LABELING	<u>1</u> ORIGINAL(S) SUBMITTED
	<input checked="" type="checkbox"/> NOT DETERMINED <i>not clearly</i>	AMOUNT FOUND _____		<u>1 set</u> COPIES SUBMITTED
	UNITS EXAMINED _____	% OF DECLARED _____		<input type="checkbox"/> NONE

10. SUMMARY OF ANALYSIS:

CONTAINER: Heat sealed foil pouch measuring approximately 10cm (L) X 2.25cm (W), inside a white thin white cardboard box with no top measuring approximately 9.75cm (L) X 5.5cm (W) X 10cm (H).

LABELING: Orange and silver colored labeling commercially printed onto foil pouch. No labeling observed other than "Pure Natural Food" printed onto the foil pouch. No labeling observed on white thin cardboard box. Sample collector submitted labeling provided by repacker (see labeling).

CODE: None observed.

PRODUCT: White granular powder with a lemon like scent.

ANALYSIS: Analyzed two 15-sub composites for the presence of Salmonella spp.
 Composite # 1 from subs 1-15.
 Composite # 2 from subs 16-30.

METHOD: Salmonella. BAM On-line April 2003, <http://vm.cfsan.fda.gov/~ebam/bam-toc.html>, Chapter 5.

RESULTS: No Salmonella spp. detected in 2/2 composites.
 All laboratory controls were satisfactory.

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11. RESERVE SAMPLE:
 None. The remaining portions were disposed by the analyst on 6/7/2004.

12. a. ANALYST SIGNATURE (Broke Seal <input type="checkbox"/>) <i>Marco S. Esteves</i>	13. WORK SHEET CHECK	a. BY <i>Elaine B. Dogdog</i>
b.		b. DATE <i>6/16/04</i>
c.	14. DATE REPORTED: <i>6/21/04 MJE</i>	

GENERAL CONTINUATION SHEET

PRODUCT: THREE LAC DIETARY SUPPLEMENT (LACTIC ACID BACTERIA)

SAMPLE NO: 285344

Substrate	Enrichment				TSB (NFDM)				UPB				BG			
	SC	XLD	BS	HE	SC	XLD	BS	HE	SC	XLD	BS	HE	SC	XLD	BS	HE
TSI (K, A)																
LIA (R, A)																
H ₂ S (-,+)																
Gas (-,+)																
Urea (-,+)																
Oxidase (-,+)																
API																
VITEK																
Serology																
Results																

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(+) Control OK @ 37°C
(-) Control OK @ 42°C

no salmonella spp. detected

no salmonella spp. detected

16-30
SC 1 (RV) (T)
RESULTS (Circle One): POSITIVE NEGATIVE

1-15
SC 1 (RV) (T)
TIME INCUBATED: 11:30 am
DATE/TIME TRANSFERRED TO LAB: 11:30 am
RESULTS (Circle One): POSITIVE NEGATIVE

MICROBIOLOGICAL CONTROLS

Growth (G)/No Growth (NG) in
Any Enrichment Medium*

Initials
(Analyst
Partnered)

Date
(Date checked)

Page(s) for
Results
(NA if No Growth)

Check all that apply:

Environmental Controls:

<input checked="" type="checkbox"/>	Air plate(s) type: (HE)	NS	MS	6/18/09	NA
<input type="checkbox"/>	Air plate(s) type: ()				
<input type="checkbox"/>	Air plate(s) type: ()				
<input type="checkbox"/>	2 nd Stage Air plate(s): ()				
<input checked="" type="checkbox"/>	Bench Swab: N/A	NS	MS	6/18/09	NA

Uninoculated Media Controls:

<input checked="" type="checkbox"/>	Enrichment Media type: (N/A)	NS	MS	6/18/09	NA
<input type="checkbox"/>	Phosphate Buffer:				
<input type="checkbox"/>	Other:				

Systems Controls:

<input type="checkbox"/>	Knives(s):				
<input checked="" type="checkbox"/>	Tray:	NS	MS	6/18/09	NA
<input type="checkbox"/>	Forcep:				
<input type="checkbox"/>	Chisel:				
<input type="checkbox"/>	Drill bit:				
<input type="checkbox"/>	Spoon/Scoop:				
<input type="checkbox"/>	Container (jars/bag):				
<input type="checkbox"/>	Blender:				
<input type="checkbox"/>	Test tube:				
<input checked="" type="checkbox"/>	Scissor:	NS	MS	6/18/09	NA
<input type="checkbox"/>	Other:				

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* If turbidity/growth is observed, control will be treated as subsample and analyzed accordingly. See appropriate page for analytical results.

MICROBIOLOGY ANALYSIS EQUIPMENT LIST

Equipment ID	Name Of Equipment Used	Equipment Type	Comments
MIC-817	Champ SQ -scale base	BALANCES	
MIC-153	Precision 30M Convention (I-3J)	INCUBATOR	
MIC-898	Circulating (WB-32)	Waterbath	
MIC-138	Circulating (WB-35)	Waterbath	

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SALMONELLA MEDIA CONTROL SHEET

<u>MEDIUM</u>	<u>MANUF. #</u>	<u>BATCH #</u>	<u>EXPIRATION</u> (mm/dd/yyyy)
<u>Isolation</u>			
Air Plate (<u>1/5</u>)	<u>In-house</u>	<u>040602-991</u>	<u>6/16/2004</u>
Lactose Broth (LB) ^{4/1/2004}			
Lactose Broth (LB) (Swab) ^{4/1/2004}	<u>In-house</u>	<u>040410-689</u>	<u>8/8/2004</u>
Butterfield's Phosphate (Bulk)			
Butterfield's Phosphate (controls)			
Tryptic Soy Broth (TSB)			
Non-fat Dried Milk	<u>In-house</u>	<u>040410-689</u>	<u>8/8/2004</u>
1% Brilliant Green	<u>In-house</u>	<u>040204-172</u>	<u>2/2/2004</u> ^{4/1/2004} <u>2/3/2005</u>
Univ. Preenrich Broth (UPB)			
Rappaport-Vassiliadis (RV)	<u>In-house</u>	<u>040502-821</u>	<u>1/11/2004</u>
Selenite-Cystine (SC)	<u>In-house</u>	<u>040601-827</u>	<u>6/8/2004</u>
Tetrathionate (TT)		<u>040603-999</u>	<u>7/3/2004</u>
0.1% Brilliant Green		<u>030919-2</u>	<u>7/19/2004</u>
I:KI		<u>030918-4</u>	<u>7/12/2004</u>
M Broth			
VIDAS	<u>bioMerieux</u>		
HE Agar	<u>In-house</u>	<u>040608-916</u>	<u>6/12/2004</u>
XLD Agar		<u>040608-917</u>	<u>6/12/2004</u>
BS Agar		<u>040608-918</u>	<u>6/13/2004</u>
TSI			
LIA			
Rapid Urea Broth			
TSA (for oxidase only)			
Oxidase Reagent			
Tryptone Broth			
KCN Broth			
<u>IDENTIFICATION</u>			
MacConkey Agar			
0.85% Saline			
API 20E	<u>bioMerieux</u>		
Mineral Oil			
Ferric Chloride			
Indole Kovacs			
Voges-Proskauer A			
Voges-Proskauer B			
0.45% Saline			
Vitek	<u>bioMerieux</u>		
<u>CONTROL CULTURES</u>			
<i>S. gaminara</i> (Pos. Control)	<u>SEA2575</u>	<u>03/2004 - 3 mls</u>	<u>09/2004</u>
<i>K. pneumoniae</i> (Neg. Control)	<u>ATCC # 13883</u>	<u>07/2004 - 3 mls</u>	<u>09/2004</u>
<i>P. aeruginosa</i> (Pos. ctrl for Oxidase Test)	<u>ATCC # 27853</u>		
<i>E. coli</i> (Neg. ctrl for Oxidase Test)	<u>ATCC # 25922</u>		

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