

ANALYST WORKSHEET		1. PRODUCT: THREE LAC DIETARY SUPPLEMENT (LACTIC ACID BACTERIA)		2. SAMPLE NUMBER 285344	
3. SEALS <input checked="" type="checkbox"/> NONE <input type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE RECEIVED 6/7/2004	5. RECEIVED FROM Matthew Benally	6. DISTRICT OR LABORATORY PRL-SW	
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. <i>Date on CLR is different from date written on cardboard box. See attachment A.</i>					
8. NET CONTENTS		<input checked="" type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED UNITS EXAMINED _____		DECLARE/UNIT <u>none observed</u> AMOUNT FOUND _____ % OF DECLARED _____	
		9. LABELING		<input checked="" type="checkbox"/> 1 ORIGINAL(S) SUBMITTED <input checked="" type="checkbox"/> 1 set COPIES SUBMITTED <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.					
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. Dogdoy</i>	
b.				b. DATE 6/16/04	
c.			14. DATE REPORTED: 6/21/04 MGT		

GENERAL CONTINUATION SHEET

PRODUCT: THREELAC DIETARY SUPPLEMENT (LACTIC ACID BACTERIA)

SAMPLE NO: 285344

SUBCOMP	LB				TSB				NFD				UPB				BG			
	HE	XLD	BS	BS	HE	XLD	BS	BS	HE	XLD	BS	BS	HE	XLD	BS	BS	HE	XLD	BS	BS
ENRICHMENT	16-30																			
SELECTIVE ENRICHMENT (Circle Media used)	SC 1 (RV) (TT)																			
VIDAS	RESULTS (Circle One): POSITIVE NEGATIVE																			
STREAK ONTO PLATES	(TT)																			
IDENTIFY ISOLATE	DATE/TIME TRANSFERRED TO M-BROTH: 11:30 am 11:30 am																			
RECORD RESULTS (K, A, NC)	DATE/TIME VIDAS RUN: 11:30 am 11:30 am																			
TSI (If "K, A", Cont.)	RESULTS (Circle One): POSITIVE NEGATIVE																			
LIA (If But is "K", Cont.)	RESULTS (Circle One): POSITIVE NEGATIVE																			
UREA																				
OXIDASE																				
API																				
VITEK																				
Serology	No Salmonella spp. detected																			
Results	No Salmonella spp. detected																			

ANALYST(S) Marco S. Esteves

ANALYST NO. N/A

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(1) Control: OK
(2) Control: OK

MICROBIOLOGICAL CONTROLS

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

Initials
(Analyst
Performed)

Date
(Date checked)

Page(s) for
Results
(N/A if No Growth)

Check all that apply:

Environmental Controls:

<input checked="" type="checkbox"/>	Air plate(s) type: (<u>HE</u>)	<u>NS</u>	<u>MSA</u>	<u>6/18/09</u>	<u>N/A</u>
<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: <u>NFDM</u>	<u>NS</u>	<u>MSA</u>	<u>6/19/09</u>	<u>N/A</u>

Uninoculated Media Controls:

<input checked="" type="checkbox"/>	Enrichment Media type: (<u>NFDM</u>)	<u>NS</u>	<u>MSA</u>	<u>6/19/09</u>	<u>N/A</u>
<input type="checkbox"/>	Phosphate Buffer:	_____	_____	_____	_____
<input type="checkbox"/>	Other:	_____	_____	_____	_____

Systems Controls:

<input type="checkbox"/>	Knives(s):	_____	_____	_____	_____
<input checked="" type="checkbox"/>	Tray:	<u>NS</u>	<u>MSA</u>	<u>6/19/09</u>	<u>N/A</u>
<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:	<u>NS</u>	<u>MSA</u>	<u>6/19/09</u>	<u>N/A</u>
<input type="checkbox"/>	Other:	_____	_____	_____	_____

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

ANALYST(S)

Marco S. Esteves MSA

ANALYST NO:

N/A

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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	

ANALYST(S) *Marco S. Esteves*ANALYST NO. *N/A*PAGE 4 OF 5 PAGES

GENERAL CONTINUATION SHEET	PRODUCT: THREELAC DIETARY SUPPLEMENT (LACTIC ACID BACTERIA)	SAMPLE NO: 285344
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SALMONELLA MEDIA CONTROL SHEET

<u>MEDIUM</u>	<u>MANUF. #</u>	<u>BATCH #</u>	<u>EXPIRATION</u> (mm/dd/yyyy)
Isolation			
Air Plate (<u>1-5</u>)	<u>In-house</u>	<u>040602-991</u>	<u>6/16/2004</u>
Lactose Broth (LB)			
Lactose Broth (LB) (Swab)	<u>In-house</u>	<u>040410-649</u>	<u>8/2/2004</u>
Butterfield's Phosphate (Bulk)			
Butterfield's Phosphate (controls)			
Tryptic Soy Broth (TSB)			
Non-fat Dried Milk	<u>In-house</u>	<u>040410-649</u>	<u>8/2/2004</u>
1% Brilliant Green	<u>In-house</u>	<u>040204-172</u>	<u>2/13/2005</u>
Univ. Preenrich Broth (UPB)			
Rappaport-Vassiliadis (RV)	<u>In-house</u>	<u>040502-821</u>	<u>6/11/2004</u>
Selenite-Cystine (SC)	<u>In-house</u>	<u>040601-887</u>	<u>6/2/2004</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			
IDENTIFICATION			
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>		
CONTROL CULTURES			
<i>S. gaminara</i> (Pos. Control)	<u>SEA2575</u>	<u>03/2004 - 3 ms</u>	<u>09/2004</u>
<i>K. pneumoniae</i> (Neg. Control)	<u>ATCC # 13883</u>	<u>03/2004 - 3 ms</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>		

ANALYST(S) <u>Marco S. Esteves</u> MS 9	ANALYST NO: <u>N/A</u>	PAGE <u>5</u> OF <u>5</u> PAGE(S)
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