



21124 Cabot Blvd.
Hayward, California 94545
510-785-2564 Telephone
800-284-4949 Orders
510-782-4639 Fax
www.biolog.com

CERTIFICATE OF PERFORMANCE

Product No.: 72403
Name: Inoculating Fluid -C (IF-C)
Lot No.: 20MAY191
Expiration Date: 19 MAY 2021

QUALITY PROFILE

<u>Challenge organisms</u>	<u>Source</u>	<u>Growth Result</u>
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NO GROWTH PROMOTION REQUIRED

Final pH: 7.1 ± 0.2 @ 25 °C.
Color: Light Green
Unit: tube
Volume: 12 mL

Samples of this lot have met pH, appearance, and performance standards established by Biolog, Inc. Representative samples were incubated for 72 hours at room temperature, membrane filtration processed samples were incubated at 30 °C – 35 °C for 48 hours and found to be acceptable. Results were obtained at time of release. Certification does not exempt the user from his/her responsibility to assure satisfactory performance at the time of use.

INTENDED USE

NOT FOR HUMAN IN VITRO DIAGNOSTIC USE.

APPROVAL: QUALITY ASSURANCE

06 July 2020
DATE

Document Number: QC7240X.F3
 Revision Number: A
 Effective Date: 18 April 2018
 Page: 1 of 1
 Date Printed: Thursday, 12 April 2018



Note: Printed documents are for reference only and may be outdated. Refer to controlled version to verify latest release.

Document Name: IF-C Quality Control Form

Section 1: Product Information

Product Name:	IF-C
Part Number:	72403
Lot Number:	20MAY191
Expiration Date:	19 MAY 2021

Indicate:
<input checked="" type="checkbox"/> Out-Source Manufactured
<input type="checkbox"/> In-House Manufactured

Section 2: Quality Profile

Physical Properties:

	Expected:	Actual:	Result:	Initials / Date
pH:	7.1 ± 0.2	7.18	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	DP 06/22/2020
Color:	Light green	Light green	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	DP 06/22/2020

Contamination Check:

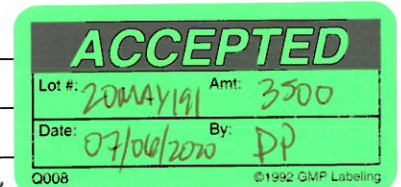
	Plate Type	Result
1	26 °C, GEN III MicroPlate (3x)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
2	30 °C, GEN III MicroPlate (3x)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
3	36 °C, GEN III MicroPlate (3x)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Contamination Check Result:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

Performance Test:

	Strain Name	Protocol	ATCC No.	ID	SIM
1	<i>Aerococcus viridans</i>	C1	11563	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	0.619
2	<i>Streptococcus pneumoniae</i>	C1	6301	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	0.711
3	<i>Neisseria lactamica</i>	C2	23972	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	0.787
4	<i>Moraxella catarrhalis</i>	C2	25238	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	0.566
Performance Test Result:				<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	

Section 3: Final Result

Final Result (Pass / Fail):	Pass
Technician Name:	David Pham
Sign / Date:	David Pham 07/02/2020
QA Approval / Date:	06 July 2020

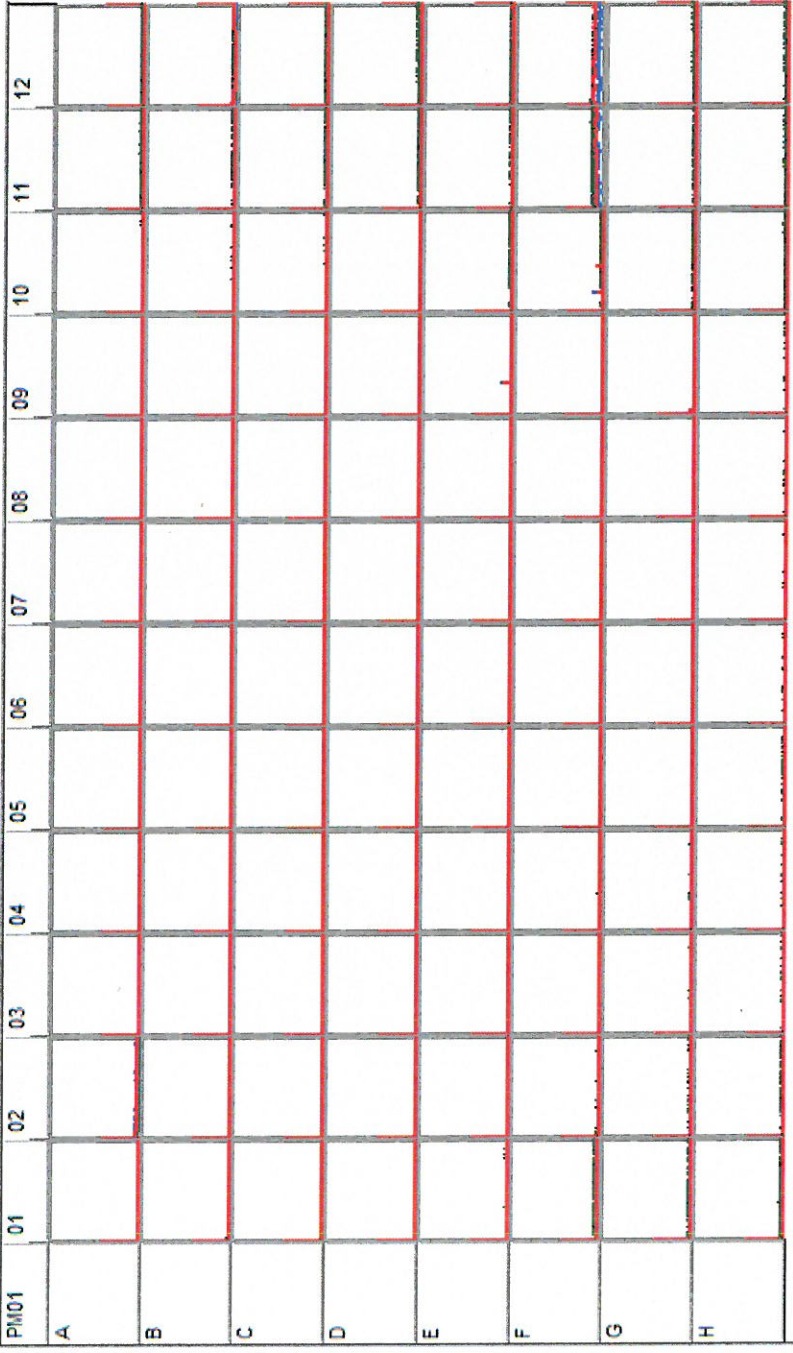


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QC7240X.F3 Rev. A

DEE DP 07/02/2020

Save Graph PM1 / Aggregate Parameter Values: Med



Analysis Parameters

< None > Area
 Average Height Initial Rate

Calculate

Plot Cropping

Apply

First: 0 hours

Last: 95.75 hours

Y Max: 225 units

Kinetic Background Subtraction

Parametric Background Subtraction

Display

X Axis: 24 hours

Y Axis: 24 units

Grid Lines Crop Lines
 Well Outlines Proportional

Apply

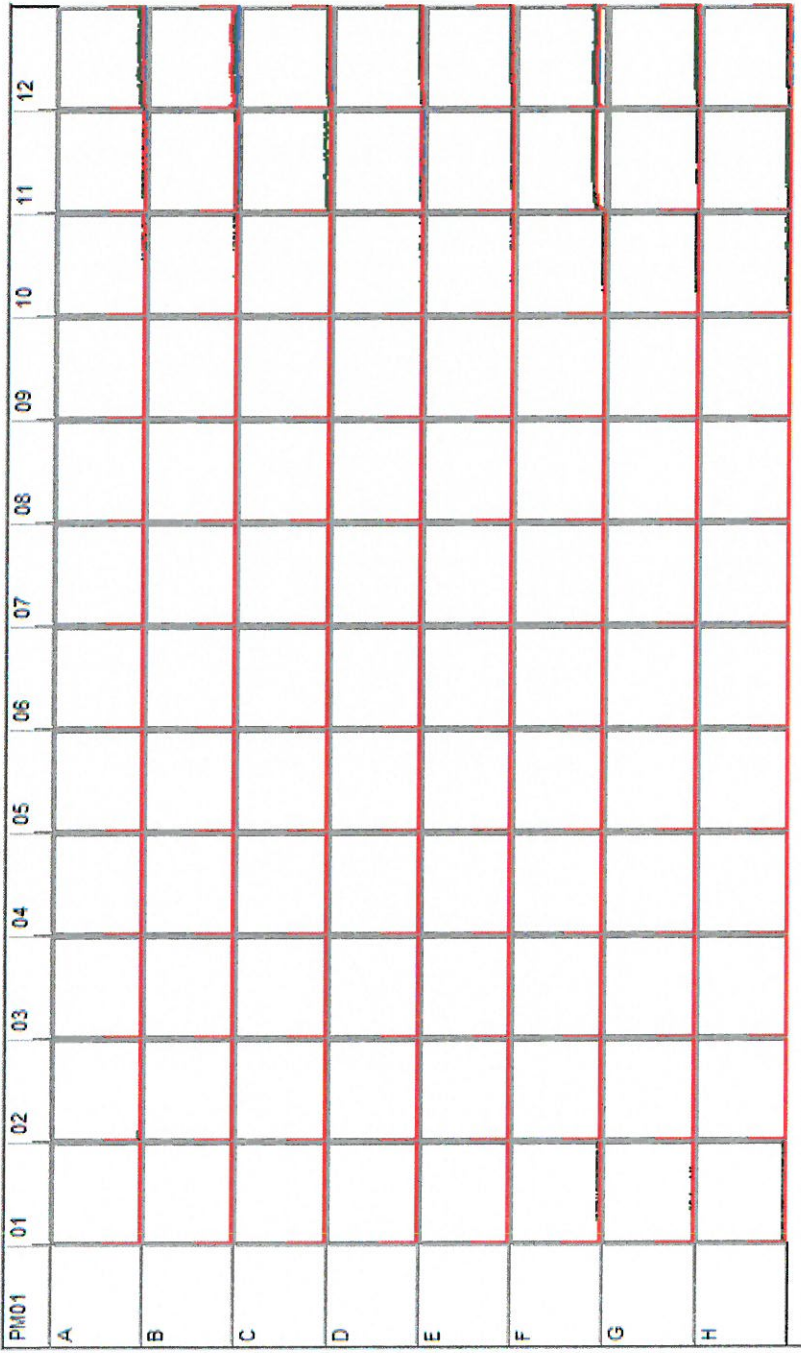


Plate Type Plates

Plate Type	Gene/Cmpd	Organism	Strain	Other	Duration	File Name
1	IFC 20MAY191	CONT CK 26C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 MI\MI Inoculating Fluid\IF B 72402\2020\IF-B C 20MAY\QCP_206_18081
2	IFC 20MAY191	CONT CK 26C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 MI\MI Inoculating Fluid\IF B 72402\2020\IF-B C 20MAY\QCP_206_18081
3	IFC 20MAY191	CONT CK 26C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 MI\MI Inoculating Fluid\IF B 72402\2020\IF-B C 20MAY\QCP_206_18081

DR 07/02/2020

PM1 / Aggregate Parameter Values: Med



Analysis Parameters

< None >
 Area
 Average Height
 Initial Rate

Calculate

Plot Cropping

First: hours
 Last: hours
 Y Max: units

Apply

Kinetic Background Subtraction
 Parametric Background Subtraction

Display

X Axis: hours
 Y Axis: units

Grid Lines
 Crop Lines
 Well Outlines
 Proportional

Apply

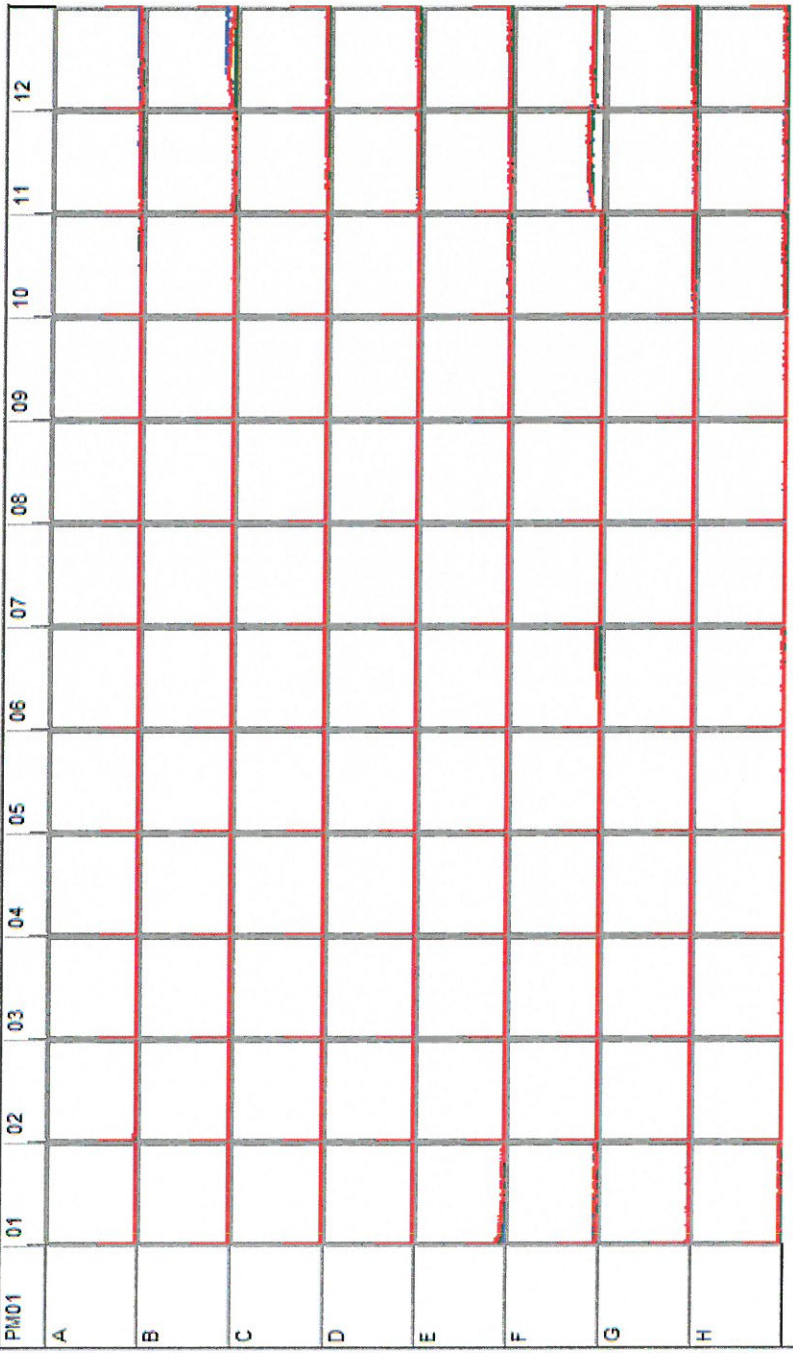


Plate Type Plates

Plate Type	Gene/Cmpd	Organism	Strain	Other	Duration	File Name
1	IFC 20MAY191	CONT CK 30C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 MINMI Inoculating Fluid\IF-B 72402\2020\IF-B C 20MAY\QCP_269_18081
2	IFC 20MAY191	CONT CK 30C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 MINMI Inoculating Fluid\IF-B 72402\2020\IF-B C 20MAY\QCP_269_18081
3	IFC 20MAY191	CONT CK 30C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 MINMI Inoculating Fluid\IF-B 72402\2020\IF-B C 20MAY\QCP_269_18081

Dr 07/02/2020

PM1 / Aggregate Parameter Values: Med



Analysis Parameters

< None >
 Area
 Average Height
 Initial Rate

Calculate

Plot Cropping

Apply

First hours

Last hours

Y Max units

Kinetic Background Subtraction

Parametric Background Subtraction

Display

X Axis hours

Y Axis units

Grid Lines
 Crop Lines
 Well Outlines
 Proportional

Plate Type Plates

Plate Type	Gene/Cmpd	Organism	Strain	Other	Duration	File Name
1	IFC 20MAY191	CONT CK 36C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 M\MI Inoculating Fluid\IF-B C 20MAY\QCP_352_18081
2	IFC 20MAY191	CONT CK 36C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 M\MI Inoculating Fluid\IF-B C 20MAY\QCP_352_18081
3	IFC 20MAY191	CONT CK 36C	GEN III 3312121	DP 06/22/2020	95:45	F:\01 M\MI Inoculating Fluid\IF-B C 20MAY\QCP_352_18081

DR 07/02/2020

Program: OMNILOG 50: 2.4.1.134
 User < unrestricted access >
 Data File QCP_316_200617_A.D5E
 Data Location C:\Program Files (x86)\Biolog\OL50_24\QCP\DATA_2020\06\
 Instrument S/N 316
 Mlid5.dll 2.4.1.72

Plate Data:

Project Type	ID	Read Mode	Normal ID
Project Code	QCP	Setup Time	Jun 17 2020 2:34 PM
Project Name	IFC 20MAY141/191 PERF	Target Incubation	22 Hours
Plate Type	GEN III	Elapsed Incubation	Done Reading
Plate Position	11-A	Plate Temperature	33
Plate Protocol	C1		

User Fields:

Sample No.	11563
Sample Name	AER. VIR
IF Lot No.	IFC 20MAY191
Plate Lot No.	GEN III 3404291
Medium	BUG+B
Transmittance	T 90
Technician	DP 06/17/2020

ID Details:

ID Called At	6 Hours
ID Status	Final ID
Biolog ID-Database	GEN_III_v2.08.00.I5G

ID Result	Species ID: <i>Aerococcus viridans</i>
ID Comment	
ID Notice	

Rank	PROB	SIM	DIST	Organism Type	Species
1	0.729	0.619	2.128	GP-Coccus	<i>Aerococcus viridans</i>
2	0.113	0.082	3.923	GP-Coccus	<i>Streptococcus downei</i>
3	0.083	0.059	4.213	GP-Coccus	<i>Streptococcus sobrinus</i>
4	0.075	0.052	4.317	GP-Coccus	<i>Leuconostoc lactis</i>

Key: <x: positive, x: negative, <x-: mismatched positive, x+: mismatched negative {x: borderline, -x: less than A1 well

OmniLog Values

Data	1	2	3	4	5	6	7	8	9	10	11	12
A	53	< 134	< 134	47	54	38	< 171	46	40	< 119	< 96	{ 56
B	58	< 160	42	37	32	30	41	39	34	< 96	+ { 74	{ 61
C	< 152	< 120	< 172	< 127	47	44	36	38	36	{ 67	{ 69	{ 72
D	66	< 115	47	46	< 96	46	46	48	48	{ 70	{ 54	{ 64
E	71	47	48	45	52	44	35	44	53	{ 68	{ 62	{ 73
F	< 172	51	46	52	58	61	58	48	50	{ 69	< 110	< 110
G	53	45	69	{ 80	60	62	59	69	72	< 116	< 103	< 122
H	< 93	68	66	71	63	< 92	{ 86	{ 84	{ 88	< 149	< 185	< 114 -

Program: OMNILOG 50: 2.4.1.134
 User < unrestricted access >
 Data File QCP_316_200617_A.D5E
 Data Location C:\Program Files (x86)\Biolog\OL50_24\QCP\DATA_2020\06\
 Instrument S/N 316
 Mlid5.dll 2.4.1.72

Plate Data:

Project Type	ID	Read Mode	Normal ID
Project Code	QCP	Setup Time	Jun 17 2020 2:34 PM
Project Name	IFC 20MAY141/191 PERF	Target Incubation	22 Hours
Plate Type	GEN III	Elapsed Incubation	Done Reading
Plate Position	11-B	Plate Temperature	33
Plate Protocol	C1		

User Fields:

Sample No.	6301
Sample Name	STR. PNE
IF Lot No.	IFC 20MAY191
Plate Lot No.	GEN III 3404291
Medium	BUG+B
Transmittance	T 90
Technician	DP 06/17/2020

ID Details:

ID Called At	14 Hours
ID Status	Final ID
Biolog ID-Database	GEN_III_v2.08.00.I5G

ID Result	Species ID: Streptococcus pneumoniae
ID Comment	
ID Notice	

Rank	PROB	SIM	DIST	Organism Type	Species
1	0.845	0.711	2.170	GP-Coccus	Streptococcus pneumoniae
2	0.056	0.040	3.916	GP-Coccus	Streptococcus oralis
3	0.054	0.039	3.932	GP-Coccus	Streptococcus suis serogroup 5
4	0.045	0.032	4.048	GP-Coccus	Streptococcus mitis

Key: <x: positive, x: negative, <x-: mismatched positive, x+: mismatched negative {x: borderline, -x: less than A1 well

OmniLog Values

Data	1	2	3	4	5	6	7	8	9	10	11	12
A	54	< 117	< 154	< 151	{ 77	46	< 167	55	< 131	< 195	< 150	63
B	< 152	< 172	< 138 -	50	50	{ 76	< 87	< 90 +	56	{ 115	61	79
C	< 140	< 152	< 111	{ 81	46	35	38	38	38	{ 95	65	58
D	42	38	33	34	51	34	39	37	37	45	49	61
E	45	38	38	33	34	37	31	33	39	53	46	53
F	< 150	42	40	32	34	36	30	30	33	50	{ 109	{ 100
G	29	32	34	32	34	30	32	34	34	< 141	46	65
H	48	36	31	37	31	67	37	45	36	< 149	{ 117	62

Program: OMNILOG 50: 2.4.1.134
 User < unrestricted access >
 Data File QCP_316_200617_A.D5E
 Data Location C:\Program Files (x86)\Biolog\OL50_24\QCP\DATA_2020\06\
 Instrument S/N 316
 Mlid5.dll 2.4.1.72

Plate Data:

Project Type	ID	Read Mode	Normal ID
Project Code	QCP	Setup Time	Jun 17 2020 2:34 PM
Project Name	IFC 20MAY141/191 PERF	Target Incubation	36 Hours
Plate Type	GEN III	Elapsed Incubation	Done Reading
Plate Position	12-A	Plate Temperature	33
Plate Protocol	C2		

User Fields:

Sample No.	23972
Sample Name	NEI. LAC
IF Lot No.	IFC 20MAY191
Plate Lot No.	GEN III 3404291
Medium	CHOC
Transmittance	T 65
Technician	DP 06/17/2020

ID Details:

ID Called At	
ID Status	Final ID

ID Result	No ID: Insufficient Pattern
ID Comment	
ID Notice	

OmniLog Values

Data	1	2	3	4	5	6	7	8	9	10	11	12
A	48	48	35	33	37	40	33	37	43	78	78	76
B	45	35	34	36	32	31	39	34	40	68	79	73
C	43	43	37	33	31	39	43	40	39	96	84	86
D	45	39	37	36	33	44	52	44	47	81	76	92
E	56	43	37	39	44	66	38	39	47	85	81	86
F	62	40	49	44	53	61	56	43	53	91	{ 104	{ 108
G	50	44	70	{ 73	50	60	59	{ 72	{ 73	< 109	95	< 114
H	61	58	< 94	{ 66	{ 63	< 80	< 73	< 80	< 83	< 118	< 126	< 127

Program: OMNILOG 50: 2.4.1.134
 User < unrestricted access >
 Data File QCP_316_200624_A.D5E
 Data Location C:\Program Files (x86)\Biolog\OL50_24\QCP\DATA_2020\06\
 Instrument S/N 316
 Mlid5.dll 2.4.1.72

Plate Data:

Project Type	ID	Read Mode	Single Read ID
Project Code	QCP	Setup Time	Jun 23 2020 3:11 PM
Project Name	IFC 20MAY141/171 2X	Target Incubation	22 Hours
Plate Type	GEN III	Elapsed Incubation	Done Reading
Plate Position	18-B	Plate Temperature	33
Plate Protocol	C2		

User Fields:

Sample No.	23972
Sample Name	NEI. LAC
IF Lot No.	IFC 20MAY141/171 EE DP 07/02/2020
Plate Lot No.	GEN III 3312121
Medium	CHOC
Transmittance	T 65
Technician	DP

ID Details:

ID Called At	22 Hours
ID Status	Final ID
Biolog ID-Database	GEN_III_v2.08.00.15G

ID Result	Species ID: Neisseria lactamica
ID Comment	
ID Notice	

Rank	PROB	SIM	DIST	Organism Type	Species
1	0.918	0.787	1.958	GN-Fas	Neisseria lactamica
2	0.065	0.048	3.652	GN-Fas	Neisseria meningitidis
3	0.009	0.006	4.917	GN-Fas	Neisseria cinerea
4	0.007	0.005	5.063	GN-Fas	Neisseria animaloris

Key: <x: positive, x: negative, <x-: mismatched positive, x+: mismatched negative {x: borderline, -x: less than A1 well

OmniLog Values

Data	1	2	3	4	5	6	7	8	9	10	11	12	
A	47	52	< 242	38	38	37	41	39	44	< 135	{ 89	{ 70	
B	41	< 196	37	39	32	37	34	36	37	{ 67	{ 78	{ 81	
C	< 229	36	36	31	33	36	36	35	35	< 218	{ 75	{ 82	
D	39	33	33	32	32	{ 77	< 81	33	31	{ 64	{ 74	{ 81	
E	38	59	34	30	< 116	- < 236	33	27	31	{ 69	57	58	
F	53	58	38	35	{ 75	< 84	33	30	32	{ 79	< 127	< 111	
G	34	< 208	39	< 239	28	< 159	32	< 89	+	52	{ 69	57	{ 80
H	46	36	< 82	39	41	41	32	35	32	{ 77	{ 72	{ 61	

Program: OMNILOG 50: 2.4.1.134
 User < unrestricted access >
 Data File QCP_316_200617_A.D5E
 Data Location C:\Program Files (x86)\Biolog\OL50_24\QCP\DATA_2020\06\
 Instrument S/N 316
 Mlid5.dll 2.4.1.72

Plate Data:

Project Type	ID	Read Mode	Normal ID
Project Code	QCP	Setup Time	Jun 17 2020 2:34 PM
Project Name	IFC 20MAY141/191 PERF	Target Incubation	36 Hours
Plate Type	GEN III	Elapsed Incubation	Done Reading
Plate Position	12-B	Plate Temperature	33
Plate Protocol	C2		

User Fields:

Sample No.	25238
Sample Name	MRX. CAT
IF Lot No.	IFC 20MAY191
Plate Lot No.	GEN III 3404291
Medium	CHOC
Transmittance	T 65
Technician	DP 06/17/2020

ID Details:

ID Called At	26 Hours
ID Status	Final ID
Biolog ID-Database	GEN_III_v2.08.00.I5G

ID Result	Species ID: Moraxella catarrhalis
ID Comment	
ID Notice	

Rank	PROB	SIM	DIST	Organism Type	Species
1	0.620	0.556	1.421	GN-Fas	Moraxella catarrhalis
2	0.138	0.115	2.386	GN-Fas	Moraxella nonliquefaciens
3	0.136	0.112	2.396	GN-Fas	Moraxella ovis
4	0.107	0.087	2.548	GN-Fas	Moraxella bovis

Key: <x: positive, x: negative, <x-: mismatched positive, x+: mismatched negative {x: borderline, -x: less than A1 well

Omnilog Values

Data	1	2	3	4	5	6	7	8	9	10	11	12
A	60	56	46	45	48	48	48	48	55	< 185	79	82
B	49	45	42	45	42	47	42	39	48	{ 125 -	66	67
C	46	40	41	40	39	43	45	45	39	80	64	71
D	44	36	38	36	39	49	43	40	37	62	61	74
E	50	67	35	39	45	< 105	54	41	45	61	58	61
F	54	43	40	42	35	44	40	43	48	63	{ 99	{ 100
G	41	33	44	< 137	30	< 188	35	< 117	40	61	53	73
H	< 80	46	48	51	43	49	36	{ 101	38	75	68	75

Northeast Laboratory Services

P.O. Box 788
 Westbrook, ME 04093 USA
 (207) 873-7711
 (207) 873-7022 (Fax)

Order # CN137530
 Shipment # 199037
 Page: 1 of 1
 Date: 5/29/2020
 Cust PO # 44737



Please report any discrepancies to NEL within 48 hours of receipt. Any unauthorized returns will not be accepted.

Packing List

Each lot of NEL product in this shipment meets NEL and applicable CLSI (M22-A3) and CLIA 88 Mfg. Quality Control requirements.

Sold To: 525963
 BIOLOG
 21124 CABOT BOULEVARD
 HAYWARD, CA 94545

Transport Via:
 FDX 3-DAY SAVER
 FOB Point:

Ship To: 000000
 BIOLOG
 ATTN INVENTORY
 21124 CABOT BOULEVARD
 HAYWARD, CA 94545

"EMAIL COPY OF PACKING SLIP TO ALEX & SHAWN FOR ALL SHIPMENTS SENT TO DEAN'S SERVICES"

Item / Lot# Description	UM	Order Quantity	Quantity Due	Shipped Quantity
002 72403 INOCULATING FLUID(IF)C 12.5ML,20/BX	BX	352	352	352 x 10 = 7040
FG-WI Lot# 20MAY141		Expires: 14 May 2021	Quantity: 177 x 20 = 3540	
FG-WI Lot# 20MAY191		Expires: 19 May 2021	Quantity: 175 x 20 = 3500	

Packed by: DN Packages: 19 Freight Charges: 2706.50 Value: 58,052.80

Dept: MEDN
 Ref: CN137530
 Bill to: BILL SENDEL
 Service: EXPRESS SAVER

Trk: 1400000000

Rec'd by [Signature]
 06-08-20

HOLD

Lot #:	Amt:
Date:	By:

Q012 ©1998 GMP Labeling