

TABLE 10* - United States

Inv Name	Patient ID	Treat Group	Study Visit	Study Day	Targeted Organism Isolated	Azithromycin		Clarithromycin		Clinical Zone	Pathogen Outcome	Sputum Taken	Local		Central				
						S/I/R	MIC	Zone	S/I/R				MIC	MIC*	SEC*	Bac*	Grn*	MIC*	SEC*
	1	AZITH	BL	1	H.influenzae								Yes	>25	<10	Yes	No	NA	NA
	1	AZITH	BOT	10	H.influenzae						IMP	PE	Yes	<=25	<10			NA	NA
	1	AZITH	TOC	26	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	2	CLARI	BL	1	H.influenzae	S	0.5	22	8	2	16		Yes	>25	<10	Yes	Yes	NA	>=10
	2	CLARI	BOT	12	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	19	AZITH	BL	1	H.influenzae								Yes	>25	<10	Yes	Yes	NA	>=10
	19	AZITH	BOT	1	H.influenzae							NA	NA	NA	NA			NA	NA
	19	AZITH	TOC	1	H.influenzae							NA	NA	NA	NA			NA	NA
	69	CLARI	BL	1	H.influenzae	S	0.5	20	6	8	16		Yes	>25	<10	Yes	Yes	>25	<10
	69	CLARI	BOT	12	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	69	CLARI	TOC	22	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	78	CLARI	BL	0	H.influenzae	S	4	20	1	16	12		Yes	>25	<10	Yes	Yes	NA	NA
	78	CLARI	BOT	11	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	78	CLARI	TOC	24	H.influenzae						FAIL	F	Yes	>25	<10			>25	<10
	87	CLARI	BL	1	H.influenzae								Yes	>25	<10	Yes	Yes	>25	<10
	87	CLARI	BOT	12	H.influenzae						IMP	PE	UTE	NA	NA			NA	NA
	87	CLARI	TOC	25	H.influenzae						FAIL	PF	UTE	NA	NA			NA	NA
	88	AZITH	BL	1	H.influenzae	S	1	18	5	8	13		Yes	>25	<10	Yes	Yes	>25	<10
	88	AZITH	BOT	10	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	88	AZITH	TOC	23	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	90	CLARI	BL	1	H.influenzae								Yes	>25	<10	No	Yes	>25	<10
	90	CLARI	BOT	13	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	90	CLARI	TOC	22	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	100	AZITH	BL	1	H.influenzae								Yes	>25	<10	ND	Yes	NA	NA
	100	AZITH	BOT	13	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	100	AZITH	TOC	27	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	105	AZITH	BL	1	H.influenzae								Yes	>25	<10	Yes	Yes	>25	<10
	105	AZITH	BOT	11	H.influenzae						IMP	PE	UTE	NA	NA			NA	NA
	105	AZITH	TOC	22	H.influenzae						CURE	P	UTE	NA	NA			NA	NA
	126	CLARI	BL	1	H.influenzae								Yes	>25	<10	Yes	Yes	>25	<10
	126	CLARI	BOT	11	H.influenzae						IMP	PE	UTE	NA	NA			NA	NA
	126	CLARI	TOC	28	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	149	CLARI	BL	1	H.influenzae	S	1	24	8	8	16		Yes	>25	<10	Yes	Yes	>25	<10
	149	CLARI	BOT	10	H.influenzae						CURE	E	Yes	>25	>=10			<=25	NA
	149	CLARI	TOC	24	H.influenzae						CURE	E	Yes	>25	>=10			<=25	NA
	222	AZITH	BL	1	H.influenzae	S	2	20	1	16	12		Yes	>25	<10	Yes	Yes	>25	<10
	222	AZITH	BOT	14	H.influenzae						IMP	PE	UTE	NA	NA			NA	NA
	222	AZITH	TOC	32	H.influenzae						CURE	PE	UTE	NA	NA			NA	NA
	270	CLARI	TOC	24	H.influenzae	S	1	25	5	4	19	FAIL	Yes	>25	<10			>25	<10
	289	AZITH	BL	1	H.influenzae	S	1	25	8	8	15		Yes	>25	<10		Yes	>25	<10
	289	AZITH	BOT	8	H.influenzae						FAIL	PP	Yes	<=25	<10			NA	NA
	289	AZITH	TOC		H.influenzae						FAIL	PP	NA	NA			NA	NA	
	26	CLARI	BL	1	M.catarrhalis								Yes	>25	<10	Yes	Yes	>25	<10
	26	CLARI	BOT	13	M.catarrhalis						CURE	PE	UTE	NA	NA			NA	NA
	26	CLARI	TOC	22	M.catarrhalis						CURE	PE	UTE	NA	NA			NA	NA
	37	CLARI	BL	1	M.catarrhalis	S	0.06	38	5	0.12	33		Yes	>25	<10	Yes	Yes	>25	<10
	37	CLARI	BOT	12	M.catarrhalis						CURE	PE	UTE	NA	NA			NA	NA
	37	CLARI	TOC	22	M.catarrhalis						CURE	PE	UTE	NA	NA			NA	NA
	81	AZITH	BL	1	M.catarrhalis								Yes	>25	<10	Yes	Yes	>25	<10
	81	AZITH	BOT	11	M.catarrhalis						CURE	E	Yes	>25	<10			NA	NA
	81	AZITH	TOC	22	M.catarrhalis						CURE	E	Yes	>25	<10			NA	NA
	106	CLARI	BL	1	M.catarrhalis	S	<=0.06	36	5	<=0.06	33		Yes	>25	<10	Yes	Yes	>25	<10

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TABLE 10* – United States (con't)

Protocol: A0661013 – Modified-to-Treat (MITT): A Randomized, Multicenter, Double-Blind, Double-Dummy Trial Comparing Azithromycin 500 mg Daily for 3 Days with Clarithromycin 1 Gram Daily for 10 Days for the Treatment of Acute Bacterial Exacerbation of Chronic Bronchitis

Inv Name	Patient ID	Treat Group	Study Visit	Study Day	Targeted Organism Isolated	Azithromycin			Clarithromycin			Clinical Outcome	Pathogen Outcome	Sputum Taken	Local			Central		
						S/1/R	MIC	Zone	S/1/R	MIC	Zone				WBC*	SBC*	Bac*	Grm*	WBC*	SBC*
	106	CLARI	BOT	11	M.catarrhalis							CURE	PE	UTE	NA	NA			NA	NA
	106	CLARI	TOC	22	M.catarrhalis							CURE	PE	UTE	NA	NA			NA	NA
	151	AZITH	BL	1	M.catarrhalis	S	0.06	32	S	0.06	30			Yes	>25	<10	Yes	Yes	<=25	<10
	151	AZITH	BOT	12	M.catarrhalis							IMP	E	Yes	>25	<10			<=25	NA
	151	AZITH	TOC	22	M.catarrhalis							CURE	PE	UTE	NA	NA			NA	>=10
	152	AZITH	BL	1	M.catarrhalis	S	0.06	31	S	0.06	30			Yes	>25	<10	Yes	Yes	>25	<10
	152	AZITH	BOT	11	M.catarrhalis							IMP	E	Yes	>25	<10			>25	<10
	152	AZITH	TOC	22	M.catarrhalis							FAIL	E	Yes	>25	<10			>25	<10
	473	CLARI	BL	1	M.catarrhalis	S	<=0.06	38	S	0.12	32			Yes	>25	<10	No	Yes	>25	<10
	473	CLARI	BOT	11	M.catarrhalis							CURE	PE	UTE	NA	NA			NA	NA
	473	CLARI	TOC	22	M.catarrhalis							CURE	PE	UTE	NA	NA			NA	NA
	87	CLARI	BL	1	S.pneumoniae	S	0.12	27	S	0.03	31			Yes	>25	<10	Yes	Yes	>25	<10
	87	CLARI	BOT	12	S.pneumoniae							IMP	PE	UTE	NA	NA			NA	NA
	87	CLARI	TOC	25	S.pneumoniae							FAIL	PP	UTE	NA	NA			NA	NA
	88	AZITH	BL	1	S.pneumoniae									Yes	>25	<10	Yes	Yes	>25	<10
	88	AZITH	BOT	10	S.pneumoniae							CURE	PE	UTE	NA	NA			NA	NA
	88	AZITH	TOC	23	S.pneumoniae							CURE	PE	UTE	NA	NA			NA	NA
	270	CLARI	BL	1	S.pneumoniae	R	8	10	R	2	14			Yes	>25	<10	No	Yes	>25	<10
	270	CLARI	BOT	11	S.pneumoniae							IMP	E	Yes	>25	<10			>25	<10
	270	CLARI	TOC	24	S.pneumoniae	R	8	10	R	2	13	FAIL	P	Yes	>25	<10			>25	<10
	87	CLARI	BL	1	H.paraeinfluenzae									Yes	>25	<10	Yes	Yes	>25	<10
	87	CLARI	BOT	12	H.paraeinfluenzae							IMP	PE	UTE	NA	NA			NA	NA
	87	CLARI	TOC	25	H.paraeinfluenzae							FAIL	PP	UTE	NA	NA			NA	NA
	105	AZITH	BL	1	H.paraeinfluenzae									Yes	>25	<10	Yes	Yes	>25	<10
	105	AZITH	BOT	11	H.paraeinfluenzae							IMP	PE	UTE	NA	NA			NA	NA
	105	AZITH	TOC	22	H.paraeinfluenzae							CURE		UTE	NA	NA			NA	NA

* Adopted from NDA 50-784, Letter Date: 01/18/02, Enclosure 2, FDA Query #15.

Treatment Group: Azith = Azithromycin, Clari = Clarithromycin
 Pathogen Outcome: E = Eradication, P = Persistence, SI = Superinfection, PE = Presumed Eradication, and PP = Presumed Persistence
 Clinical Outcome: C = Cure, Imp = Improved, and F = Fail. UTE: Unable to Expectorate
 * WBC = Gram Stain: WBC PER LPF (10X), SEC = Gram Stain: SQUAM EPITHELIAL CELLS/LPF (10X)
 * Bac = BACTERIAL ORGANISM PRESENT, Grm = GRAM STAIN SENT TO CENTRAL LAB

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Clinical Outcome and Bacteriological Outcome Results at TOC

Protocol: A0661013 -- Modified-To-Treat (MITT) Population – United States

1. Number of Patients isolated with *Haemophilus influenzae* at Baseline = 7

Clinical Outcome:

Patients Cured = 5/7 (71.4%)
Patients Failures = 1/7 (14.3%)
Result Not Given = 1/7 (14.3%)

Bacteriological Outcome:

Presumed Eradicated = 4/7 (57.1%)
Result Not Available = 1/7 (14.3%)

2. Number of Patients isolated with *Moraxella catarrhalis* at Baseline = 3

Clinical Outcome:

Patients Cured = 2/3 (66.7%)
Patient Failures = 1/3 (33.3%)

Bacteriological Outcome:

Eradicated = 2/3 (66.7%)
Presumed Eradicated = 1/3 (33.3%)
Eradicated + Presumed Eradicated = 3/3 (100%)

3. Number of patients isolated with *Streptococcus pneumoniae* at baseline = 1

Clinical Outcome:

Patients Cured = 1/1 (100%)

Bacteriological Outcome:

Presumed Eradicated = 1/1 (100%)

4. Number of patients isolated with *Haemophilus parainfluenzae* at baseline = 1

Clinical Outcome:

Patients Cured = 1/1 (100%)

Bacteriological Outcome:

Result Not Given = 1/1 (100%)

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Protocol: A0661013 (MITT) -- Summary Tables

TABLE 11: Clinical Outcome and Bacteriological Outcome Results at TOC

Haemophilus influenzae

<u>Country</u>	<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
Argentina: Number of Patients isolated with <i>Haemophilus influenzae</i> at Baseline = 2		
	Patients Cured = 1/2 (50%)	Presumed Eradicated = 1/2 (50%)
	Patient Failures = 1/2 (50%)	
Brazil: Number of Patients isolated with <i>Haemophilus influenzae</i> at Baseline = 2		
	Patients Cured = 2/2 (100%)	Eradicated = 1/2 (50%)
		Presumed Eradicated = 1/2 (50%)
		Eradicated + Presumed Eradicated = 2/2 (100%)
Chile: Number of Patients isolated with <i>Haemophilus influenzae</i> at Baseline = 2		
	Patients Cured = 2/2 (100%)	Presumed Eradicated = 2/2 (100%)
Costa Rica: Number of Patients isolated with <i>Haemophilus influenzae</i> at Baseline = 1		
	Patients Cured = 1/1 (100%)	Presumed Eradicated = 1/1 (100%)
South Africa: Number of Patients isolated with <i>Haemophilus influenzae</i> at Baseline = 1		
	Patients Cured = 1/1 (100%)	----
United States: Number of Patients isolated with <i>Haemophilus influenzae</i> at Baseline = 7		
	Patients Cured = 5/7 (71.4%)	Presumed Eradicated = 4/7 (57.1%)
	Patients Failures = 1/7 (14.3%)	Result Not Available = 1/7 (14.3%)
	Result Not Given = 1/7 (14.3%)	

Combined Total Number of Patients isolated with *Haemophilus influenzae* at Baseline = 15

<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
Patients Cured = 12/15 (80%)	Eradicated = 1/15 (6.67%)
Patients Failures = 2/15 (13.3%)	Presumed Eradicated = 9/15 (60%)
Result Not Given = 1/15 (6.67%)	Eradicated + Presumed Eradicated = 10/15 (66.7%)
	Result Not Available = 1/15 (6.67%)

TABLE 12: Clinical Outcome and Bacteriological Outcome Results at TOC

Moraxella Catarrhalis

<u>Country</u>	<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
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Argentina: Number of Patients isolated with *Moraxella catarrhalis* at Baseline = 6

Patients Cured = 5/6 (83.3%) Presumed Eradicated = 4/6 (66.7%)
 Result Not Given = 1/6 (16.7%) Result Not Available = 2/6 (33.3%)

Brazil: Number of Patients isolated with *Moraxella catarrhalis* at Baseline = 2

Patients Cured = 2/2 (100%) Presumed Eradicated = 2/2 (100%)

Chile: Number of Patients isolated with *Moraxella catarrhalis* at Baseline = 1

Patients Cured = 1/1 (100%) Presumed Eradicated = 1/1 (100%)

United States: Number of Patients isolated with *Moraxella catarrhalis* at Baseline = 3

Patients Cured = 2/3 (66.7%) Eradicated = 2/3 (66.7%)
 Patient Failures = 1/3 (33.3%) Presumed Eradicated = 1/3 (33.3%)
 Eradicated + Presumed Eradicated = 3/3 (100%)

Combined Total Number of Patients isolated with *Moraxella catarrhalis* at Baseline = 12

<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
Patients Cured = 10/12 (83.3%)	Eradicated = 2/12 (16.7%)
Patients Failures = 2/12 (16.7%)	Presumed Eradicated = 8/12 (66.7%)
Result Not Given = 1/12 (8.3%)	Eradicated + Presumed Eradicated = 10/12 (83.3%)
	Result Not Available = 2/12 (16.7%)

TABLE 13: Clinical Outcome and Bacteriological Outcome Results at TOC

Streptococcus pneumoniae

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<u>Country</u>	<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
Argentina: Number of patients isolated with <i>Streptococcus pneumoniae</i> at baseline = 7		
	Patients Cured = 6/7 (85.7%)	Eradicated = 1/7 (14.3%)
	Patient Failures = 1/7 (14.3%)	Presumed Eradicated = 5/7 (71.4%)
Brazil: Number of patients isolated with <i>Streptococcus pneumoniae</i> at baseline = 5		
	Patients Cured = 5/5 (100%)	Eradicated = 2/5 (40%)
		Presumed Eradicated = 3/5 (60%)
Canada: Number of patients isolated with <i>Streptococcus pneumoniae</i> at baseline = 1		
	Patients Cured = 1/1 (100%)	
	Presumed Eradicated = 1/1 (100%)	
Chile: Number of patients isolated with <i>Streptococcus pneumoniae</i> at baseline = 3		
	Patients Cured = 3/3 (100%)	Eradicated = 1/3 (33.3%)
		Presumed Eradicated = 2/3 (66.7%)
Costa Rica: Number of patients isolated with <i>Streptococcus pneumoniae</i> at baseline = 15		
	Patients Cured = 13/15 (86.7%)	Presumed Eradicated = 13/15 (86.7%)
	Patients Failures = 2/15 (13.3%)	
India: Number of patients isolated with <i>Streptococcus pneumoniae</i> at baseline = 1		
	Patients Cured = 1/1 (100%)	Eradicated = 1/1 (100%)
United States: Number of patients isolated with <i>Streptococcus pneumoniae</i> at baseline = 1		
	Patients Cured = 1/1 (100%)	Presumed Eradicated = 1/1 (100%)
Combined Total Number of Patients isolated with <i>Streptococcus pneumoniae</i> at Baseline = 33		
	<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
	Patients Cured = 30/33 (90.9%)	Eradicated = 5/33 (15.2%)
	Patients Failures = 3/33 (9.1%)	Presumed Eradicated = 25/33 (75.8%)
		Eradicated + Presumed Eradicated = 30/33 (90.9%)

TABLE 14: Clinical Outcome and Bacteriological Outcome Results at TOC

Haemophilus parainfluenzae

<u>Country</u>	<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
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India: Number of patients isolated with *Haemophilus parainfluenzae* at baseline = 2

Patients Cured = 2/2 (100%) Eradicated = 1/2 (50%)

South Africa: Number of patients isolated with *Haemophilus parainfluenzae* at baseline = 1

Patients Cured = 1/1 (100%) Presumed Eradicated = 1/1 (100%)

United States: Number of patients isolated with *Haemophilus parainfluenzae* at baseline = 1

Patients Cured = 1/1 (100%) Result Not Given = 1/1 (100%)

Combined Total Number of Patients isolated with *Haemophilus parainfluenzae* at Baseline = 4

<u>Clinical Outcome</u>	<u>Bacteriological Outcome</u>
Patients Cured = 4/4 (100%)	Eradicated = 1/4 (25%) Presumed Eradicated = 1/4 (25%) Eradicated + Presumed Eradicated = 2/4 (50%) Result Not Given = 1/4 (25%)

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Protocol: A0661013 -- MITT Summary Analyses

TABLE 15: Combined Clinical Outcome and Bacteriological Outcome Results at TOC

	<i>Haemophilus influenzae</i>	<i>Moraxella catarrhalis</i>	<i>Streptococcus pneumoniae</i>	<i>Haemophilus parainfluenzae</i>
Patients with Isolates	15	13	33	4
Patients Cured	12/15 (80%)	10/12 (83.3%)	30/33 (90.9%)	4/4 (100%)
Patient Failures	2/15 (13.3%)	2/12 (16.7%)	3/33 (9.1%)	None
Clinical Outcome Result Not Given	1/15 (6.67%)	1/12 (8.3%)	None	None
Microorganisms Eradicated	1/15 (6.67%)	2/12 (16.7%)	5/33 (15.2%)	1/4 (25%)
Microorganisms Presumed Eradicated	9/15 (60%)	8/12 (66.7%)	25/33 (75.8%)	1/4 (25%)
Microorganisms (Eradicated + Presumed Eradicated)	10/15 (66.7%)	10/12 (83.3%)	30/33 (90.9%)	2/4 (50%)
Bacteriological Outcome Not Given	None	None	None	None
Bacteriological Outcome Not Available	1/15 (6.67%)	2/12 (16.7%)	None	1/4 (25%)

Microbiologist's Comments

The clinical cure outcome rate and bacteriological (i.e., eradication + presumed eradication) outcome rate for the aforementioned microorganisms in the Modified-to-Treat (MITT) population are summarized as follows:

Clinical Outcome Rate (MITT)

Bacteriological Outcome Rate (MITT)

(Cure)		(Eradication and Presumed Eradication)	
<i>Haemophilus influenzae</i> =	12/15 (80%)	<i>Haemophilus influenzae</i> =	10/15 (66.7%)
<i>Moraxella catarrhalis</i> =	10/12 (83.3%)	<i>Moraxella catarrhalis</i> =	10/12 (83.3%)
<i>Streptococcus pneumoniae</i> =	30/33 (90.9%)	<i>Streptococcus pneumoniae</i> =	30/33 (90.9%)
<i>Haemophilus parainfluenzae</i> =	4/4 (100%)	<i>Haemophilus parainfluenzae</i> =	2/4 (50%)

The bacteriological (i.e., eradication + presumed eradication) rates for the Applicant's targeted microorganisms (*Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pneumoniae*) in the Modified-to-Treat (MITT) population are acceptable. Although the *Haemophilus influenzae* number of isolates and corresponding bacteriological outcome rate are seen low, 10/16 (62.5%), the bacteriological outcome rate is of azithromycin versus the bacteriological outcome rate of azithromycin versus *Haemophilus influenzae* is within the expected percentage rate range.

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3. . Protocol A0661013: Acute Exacerbation of Chronic Bronchitis (AECB)

TABLE 16 show the results of Protocol A0661013: "A Randomized, Multicenter, Double-Blind, Double-Dummy Trial Comparing Azithromycin 500 mg Daily for 3 Days with Clarithromycin 1 Gram Daily for 10 Days for the Treatment of Acute Bacterial Exacerbation of Chronic Bronchitis" for the Modified-to-Treat (MITT) and the Per Protocol (PP) Populations.

Comment: Only the Per Protocol (PP) bacteriological evaluable populations will be essentially analyzed.

TABLE 16*

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NDA 50-784
 PFIZER INC.
 ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

PAGE 44 of 69

TRT SUBJECT	Visit	Day	MITT		Sputum Taken?*	Gram Stain				Pathogen Isolated &		Pathogen Analyzed	Response**		CLIN ANALY
			BACT EVAL	FP BACT EVAL		Local WBC	Local Rpt	Central WBC	Central Rpt	Local	Central		PATH	BACT	
AZITH 0001	BL	1	Y		Yes	>25	<10	NA	NA	H. INFLUENZAE		H. INFLUENZAE			
	NOT	10	Y	Y	Yes	<=25	<10	NA	NA				PE	PE	Imp
	TOC	26	Y	Y	UTE	NA	NA	NA	NA						C
0007	BL	1	N		Yes	>25	<10	<=25	>=10						
	NOT	11	N	N	Yes	<=25	>=10	NA	NA						F
	TOC				NA	NA	NA	NA	NA						F
0008	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	13	N	N	UTE	NA	NA	NA	NA						Imp
	TOC	21	N	N	UTE	NA	NA	NA	NA						F
0014	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	10	N	N	UTE	NA	NA	NA	NA						C
	TOC	24	N	N	UTE	NA	NA	NA	NA						C
0016	BL	1	N		Yes	>25	<10	<=25	>=10						
	NOT	10	N		UTE	NA	NA	NA	NA						
	TOC	22	N		UTE	NA	NA	NA	NA						
0019	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	13	N	N	Yes	>25	<10	>25	<10						Imp
	TOC	22	N	N	Yes	>25	<10	>25	<10						F
0019	BL	1	Y		Yes	>25	<10	NA	>=10	H. INFLUENZAE	S. INFLUENZAE	H. INFLUENZAE			
	NOT	1	Y	N	NA	NA	NA	NA	NA						
	NOT	1	Y	N	NA	NA	NA	NA	NA			S. INFLUENZAE	NA	NA	
	TOC	1	Y	N	NA	NA	NA	NA	NA			H. INFLUENZAE	NA	NA	
0021	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	13	N	N	Yes	>25	<10	>25	<10						Imp
	TOC	22	N	N	Yes	>25	>=10	NA	NA						F
0024	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	11	N	N	Yes	>25	>=10	NA	NA						Imp
	TOC	21	N	N	Yes	<=25	>=10	NA	NA						C
0028	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	10	N	N	UTE	NA	NA	NA	NA						Imp
	TOC	23	N	N	UTE	NA	NA	NA	NA						C
AZITH 0049	BL	1	N		Yes	<=25	<10	<=25	>=10						
	NOT	13	N	N	UTE	NA	NA	NA	NA						Imp
	TOC	23	N	N	UTE	NA	NA	NA	NA						C
0050	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	11	N	N	Yes	>25	>=10	NA	NA						Imp
	TOC	22	N	N	UTE	NA	NA	NA	NA						C
0053	BL	1	N		Yes	>25	<10	<=25	>=10						
	NOT	13	N	N	Yes	>25	>=10	NA	NA						C
	TOC	23	N	N	Yes	>25	>=10	NA	NA						N
0054	BL	1	N		Yes	>25	>=10	<=25	>=10						
	NOT	11	N	N	Yes	>25	>=10	NA	NA						Imp
	TOC	13	N	N	NA	NA	NA	NA	NA						
0067	BL	1	N		Yes	>25	<10	NA	NA						
	NOT	11	N	N	UTE	NA	NA	NA	NA						C
	TOC	21	N	N	UTE	NA	NA	NA	NA						C
0068	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	11	N	N	UTE	NA	NA	NA	NA						C
	TOC	22	N	N	UTE	NA	NA	NA	NA						C
0072	BL	1	N		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			
	NOT	10	N	N	Yes	>25	<10	>25	<10						Imp
	TOC	23	N	N	Yes	<=25	>=10	NA	NA						C
0074	BL	1	N		Yes	>25	<10	>25	<10						
	NOT	13	N	N	Yes	>25	<10	>25	<10						F
	TOC				NA	NA	NA	NA	NA			PS. AERUGINOSA			F
0081	BL	1	Y		Yes	>25	<10	>25	<10	H. CATABRALLIS	H. CATABRALLIS	H. CATABRALLIS			
	NOT	11	Y	Y	Yes	>25	<10	NA	NA						C
	NOT	11	Y	Y	Yes	>25	<10	NA	NA			H. CATABRALLIS	R	R	C
	TOC	22	Y	Y	Yes	>25	<10	NA	NA			H. CATABRALLIS	R	R	C
0083	BL	1	N		Yes	>25	<10	NA	NA						
	NOT	12	N	N	UTE	NA	NA	NA	NA						C
	TOC	21	N	N	Yes	<=27	<10	NA	NA	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			C
0085	BL	1	N		Yes	>25	<10	>25	<10						

TABLE 16 (con't)

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NDA 50-784
PFIZER INC.
ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

PAGE 45 of 89

STY SUBJECT	Visit Day	NITT		Sputum Taken?*	Gram Stain				Pathogen Isolated #		Response**		CLIA ANALY	
		BACT EVAL	FP EVAL		Local WBC	Local Epi	Control WBC	Control Epi	Local	Control	Pathogen Analyzed	PATN		BACT
ALITH 0085	BL 1	H	H	YFE	NA	NA	NA	NA					Imp	
	TOC 23	H	H	YFE	NA	NA	NA	NA					C	
	0088	BL 1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	M. INFLUENZAE	M. INFLUENZAE		
		BL 1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		
	ROT 10	Y	Y	YFE	NA	NA	NA	NA				DE	DE	C
	ROT 10	Y	Y	YFE	NA	NA	NA	NA			M. INFLUENZAE			C
	ROT 10	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE			C
TOC 22	Y	Y	YFE	NA	NA	NA	NA						C	
TOC 23	Y	Y	YFE	NA	NA	NA	NA			M. INFLUENZAE		DE	DE	C
TOC 23	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE		DE	DE	C
0089	BL 1	H		Yes	>25	<10	NA	NA			SERRATIA MARCESCENS			
	ROT 11	H	H	YFE	NA	NA	NA	NA					Imp	
TOC 22	H	H	YFE	NA	NA	NA	NA						C	
0082	BL 1	H		Yes	>25	<10	>25	<10						
	ROT 10	H	H	YFE	NA	NA	NA	NA					C	
TOC 22	H	H	YFE	NA	NA	NA	NA						C	
0097	BL 1	H		Yes	>25	<10	>25	<10						
	ROT 15	H	H	YFE	NA	NA	NA	NA					C	
TOC 23	H	H	YFE	NA	NA	NA	NA						C	
0100	BL 1	Y		Yes	>25	<10	NA	NA	H. INFLUENZAE		M. INFLUENZAE			
	ROT 13	Y	Y	YFE	NA	NA	NA	NA					C	
	ROT 13	Y	Y	YFE	NA	NA	NA	NA			M. INFLUENZAE	DE	DE	C
	TOC 27	Y	Y	YFE	NA	NA	NA	NA			M. INFLUENZAE	DE	DE	C
0105	BL 1	Y		Yes	>25	<10	>25	<10			SERRATIA MARCESCENS			
	BL 1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE		M. INFLUENZAE			
	BL 3	Y		Yes	>25	<10	>25	<10			M. PARAINFLUENZAE			
	ROT 11	Y	Y	YFE	NA	NA	NA	NA					Imp	
	ROT 11	Y	Y	YFE	NA	NA	NA	NA			M. INFLUENZAE	DE	DE	Imp
	ROT 11	Y	Y	YFE	NA	NA	NA	NA			M. PARAINFLUENZAE	D	DE	C
	TOC 22	Y	Y	YFE	NA	NA	NA	NA	H. INFLUENZAE				C	
TOC 22	Y	Y	YFE	NA	NA	NA	NA	H. INFLUENZAE				C		
0113	BL 1	H		Yes	>25	<10	>25	<10			STREPT. MALTOPHILIA			
	ROT 12	H	H	Yes	>25	<10	>25	<10					F	
	TOC 23	H	H	Yes	>25	<10	>25	<10					F	
ALITH 0114	BL 1	H		Yes	>25	<10	>25	<10			S. AERUUS			
	ROT 13	H	H	YFE	NA	NA	NA	NA					C	
	TOC 22	H	H	YFE	NA	NA	NA	NA					C	
0117	BL 1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			
	ROT 12	Y	Y	Yes	<=25	<10	NA	NA			S. PNEUMONIAE	DE	DE	C
	ROT 12	Y	Y	Yes	<=25	<10	NA	NA			S. PNEUMONIAE			C
	TOC 21	Y	Y	Yes	<=25	<10	NA	NA			S. PNEUMONIAE	DE	DE	C
0120	BL 1	Y		Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	M. PARAINFLUENZAE			
	ROT 12	Y	Y	YFE	NA	NA	NA	NA					C	
	ROT 12	Y	Y	YFE	NA	NA	NA	NA			H. PARAINFLUENZAE	DE	DE	C
	TOC 21	Y	Y	Yes	<=25	<10	NA	NA			H. PARAINFLUENZAE	DE	DE	C
0125	BL 1	H		Yes	>25	<10	>25	<10					Imp	
	ROT 11	H	H	YFE	NA	NA	NA	NA					C	
TOC 23	H	H	YFE	NA	NA	NA	NA							
0137	BL 1	H		Yes	>25	<10	>25	<10						
	ROT 10	H	H	YFE	NA	NA	NA	NA					C	
TOC 22	H	H	YFE	NA	NA	NA	NA					C		
0151	BL 1	Y		Yes	>25	<10	>25	<10	M. CATARRHALIS	M. CATARRHALIS	M. CATARRHALIS			
	ROT 12	Y	Y	Yes	>25	<10	<=25	NA					Imp	
	ROT 12	Y	Y	Yes	>25	<10	<=25	NA			M. CATARRHALIS	E	E	Imp
	TOC 22	Y	Y	YFE	NA	NA	NA	>=10					C	
0152	BL 1	Y		Yes	>25	<10	>25	<10	M. CATARRHALIS	M. CATARRHALIS	M. CATARRHALIS			
	ROT 11	Y	Y	Yes	>25	<10	>25	<10					Imp	
	ROT 11	Y	Y	Yes	>25	<10	>25	<10			M. CATARRHALIS	E	E	Imp
	TOC 22	Y	Y	Yes	>25	<10	>25	<10					F	
0159	BL 1	H		Yes	>25	<10	>25	<10					Imp	
	ROT 12	H	H	Yes	>25	<10	NA	NA					C	
	ROT 12	H	H	Yes	>25	<10	NA	NA					C	
	TOC 26	H	H	Yes	>25	<10	NA	NA					C	
0160	BL 0	H		Yes	>25	<10	NA	NA					C	
	ROT 14	H	H	YFE	NA	NA	NA	NA					C	
	TOC 31	H	H	YFE	NA	NA	NA	NA					C	

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NDA 50-784

PAGE 46 of 69

PFIZER INC.

ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

TABLE 16 (con't)

STY SUBJECT	Visit	Day	MTT		Sputum Taken**	Gram Stain				Pathogen Isolated *		Response**			CLIN ABLY	
			REAL	ANCT		Local	Central	Local	Central	Local	Central	Pathogen Analyzed	PAIN	SACT		
ASTM 0162	BL	1	H		Yes	>25	<10	>25	<10							
	ROT	10	H	H	Yes	<=25	>=10	NA	NA							C
	TOC	22	H	H	Yes	<=25	>=10	NA	NA							C
0164	BL	1	H		Yes	<=25	>=10	NA	>=10							
	ROT	11	H	H	Yes	<=25	>=10	NA	NA							C
	TOC	23	H	H	Yes	<=25	>=10	NA	NA							C
0170	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	11	Y	Y	UTE	NA	NA	NA	NA							C
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
0172	BL	1	H		Yes	>25	<10	>25	<10			A. HAEMOLYTIC STREP				
	BL	1	H		Yes	>25	<10	>25	<10	STREP. GROUP A						
	ROT	10	H	H	Yes	<=25	>=10	NA	NA							Imp
	TOC	24	H	H	UTE	NA	NA	NA	NA							C
0173	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	10	Y	Y	UTE	NA	NA	NA	NA							C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
	TOC	22	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
0174	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	10	Y	Y	UTE	NA	NA	NA	NA							C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
	TOC	24	Y	H	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
0177	BL	1	Y		Yes	>25	<10	<=25	NA	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	11	Y	Y	UTE	NA	NA	NA	NA							C
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
	TOC	22	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
0179	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	10	Y	Y	Yes	<=25	>=10	NA	NA							Imp
	ROT	10	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DR	DR		Imp
	TOC	22	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DR	DR		C
ASTM 0181	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	12	Y	Y	Yes	<=25	>=10	NA	NA							Imp
	ROT	12	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DR	DR		Imp
	TOC	21	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DR	DR		C
0183	BL	1	Y		Yes	>25	<10	<=25	>=10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	10	Y	Y	UTE	NA	NA	NA	NA							C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
0185	BL	1	Y		Yes	>25	<10	NA	NA	N. CATARRHALIS		N. CATARRHALIS				
	ROT	13	Y	Y	UTE	NA	NA	NA	NA							C
	ROT	13	Y	Y	UTE	NA	NA	NA	NA			N. CATARRHALIS	DR	DR		C
	TOC	23	Y	Y	ED	NA	NA	NA	NA			N. CATARRHALIS	NA	NA		C
0187	BL	1	Y		Yes	>25	<10	>25	<10	MORAXELLA SP.		M. CATARRHALIS				
	BL	1	Y		Yes	>25	<10	>25	<10							
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			M. CATARRHALIS	DR	DR		C
	TOC	19	Y	Y	Yes	<=25	>=10	NA	NA			M. CATARRHALIS	DR	DR		C
0189	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	11	Y	Y	UTE	NA	NA	NA	NA							Imp
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		Imp
	TOC	21	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
0182	BL	9	H		Yes	>25	<10	>25	<10	N. CATARRHALIS						
	ROT	13	H	H	Yes	>25	<10	NA	NA							C
	TOC	20	H	H	Yes	>25	<10	NA	NA			NEISSERIA SP.				C
0193	BL	1	Y		Yes	>25	<10	<=25	NA	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE				
	ROT	14	Y	Y	Yes	<=25	>=10	NA	NA							Imp
	ROT	14	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DR	DR		Imp
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DR	DR		C
0195	BL	1	H		Yes	<=25	>=10	>25	<10							
	ROT	10	H	H	UTE	NA	NA	NA	NA							Imp

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NDA 50-784
 PFIZER INC.
 ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

PAGE 47 of 69

TABLE 16¹ (con't)

SITE SUBJECT	Visit Day	NFTY BACT KUAL	SP BACT KUAL	Specimen Taken**	Gram Stain				Pathogen Isolated &		Pathogen Analyzed	Response**		CLIN ABALY
					Local WBC	Spd	Control WBC	Spd	Local	Control		PATN	EMCT	
ALITE 0194	TOC 29	H	H	HEE	NA	NA	NA	NA						F
0197	BL 1	H	H	Yes	>25	<10	>25	<10						
	BL 1	H	H	Yes	>25	<10	>25	<10	S. RUBROUS	COAGULASE NEG STAPH				
	ROT 15	H	H	HEE	NA	NA	NA	NA						Imp
0208	BL 1	H	H	Yes	>25	<10	>25	<10						
	BL 1	H	H	Yes	>25	<10	>25	<10	MORAXELLA SP.	A. HAEMOLYTIC STREP				
	ROT 13	H	H	UFE	NA	NA	NA	NA						C
0203	BL 1	H	H	Yes	>25	<10	<=25	NA						
	ROT 11	H	H	UFE	NA	NA	NA	NA						C
	TOC 25	H	H	UFE	NA	NA	NA	NA						C
0204	BL 1	H	H	Yes	>25	<10	<=25	>=10						
	BL 1	H	H	Yes	>25	<10	<=25	>=10	M. CATARRHALIS	WEISSERIA SP.				
	ROT 11	H	H	Yes	>25	>=10	<=25	>=10	M. CATARRHALIS	WEISSERIA SP.				Imp
	ROT 11	H	H	Yes	>25	>=10	<=25	>=10	M. CATARRHALIS	WEISSERIA SP.				Imp
0206	BL 1	H	H	Yes	>25	<10	<=25	>=10						
	BL 1	H	H	Yes	>25	<10	<=25	>=10	M. CATARRHALIS	WEISSERIA SP.				
	ROT 12	H	H	UFE	NA	NA	NA	NA						Imp
	TOC 22	H	H	UFE	NA	NA	NA	NA						F
0208	BL 1	Y	Y	Yes	>25	<10	NA	>=10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			
	ROT 14	Y	Y	Yes	>25	<10	NA	NA	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE	E	H	Imp
	ROT 14	Y	Y	Yes	>25	<10	NA	NA	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE	P	F	Imp
	TOC 18	Y	Y	Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			F
0210	BL 1	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			
	ROT 12	Y	Y	HEE	NA	NA	NA	NA						C
	ROT 12	Y	Y	UFE	NA	NA	NA	NA						C
	TOC 21	Y	Y	UFE	NA	NA	NA	NA						C
0211	BL 1	Y	Y	Yes	>25	<10	>25	<10	MORAXELLA SP.					
	BL 1	Y	Y	Yes	>25	<10	>25	<10	MORAXELLA SP.	M. CATARRHALIS	M. CATARRHALIS			
	ROT 12	Y	Y	UFE	NA	NA	NA	NA						C
	ROT 12	Y	Y	UFE	NA	NA	NA	NA						C
0215	BL 1	H	H	Yes	>25	<10	>25	<10						
	ROT 11	H	H	Yes	>25	<10	>25	<10						
	TOC 29	H	H	HEE	NA	NA	NA	NA						F
	TOC 29	H	H	HEE	NA	NA	NA	NA						F
0222	BL 1	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			
	ROT 14	Y	Y	UFE	NA	NA	NA	NA						Imp
	ROT 14	Y	Y	UFE	NA	NA	NA	NA						Imp
	TOC 32	Y	Y	UFE	NA	NA	NA	NA						C
0225	BL 1	H	H	Yes	>25	<10	>25	<10						
	ROT 11	H	H	UFE	NA	NA	NA	NA						Imp
	ROT 11	H	H	UFE	NA	NA	NA	NA						Imp
	TOC 22	H	H	Yes	<=25	>=10	NA	NA						C
0244	BL 1	H	H	Yes	>25	<10	>25	<10						
	ROT 11	H	H	Yes	<=25	<10	NA	NA						Imp
	TOC 22	H	H	Yes	<=25	<10	NA	NA						C
0247	BL 1	H	H	Yes	>25	<10	>25	<10						
	ROT 12	H	H	Yes	<=25	>=10	NA	NA						C
	TOC 26	H	H	Yes	<=25	>=10	NA	NA						C
0249	BL 1	Y	Y	Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			
	BL 1	Y	Y	Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE			
	ROT 11	Y	Y	Yes	>25	<10	>25	<10						F
	ROT 11	Y	Y	Yes	>25	<10	>25	<10						F
	ROT 11	Y	Y	Yes	>25	<10	>25	<10						F
	TOC 19	Y	Y	HEE	NA	NA	NA	NA						F
0250	BL 1	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			
	ROT 11	Y	Y	UFE	NA	NA	NA	NA						C
	ROT 11	Y	Y	UFE	NA	NA	NA	NA						C
	TOC 21	Y	Y	UFE	NA	NA	NA	NA						C
0271	BL 1	H	H	Yes	>25	<10	<=25	NA						
	ROT 17	H	H	HEE	NA	NA	NA	NA						C
	TOC 42	H	H	HEE	NA	NA	NA	NA						C

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NDA 50-784
 PFIZER INC.
 ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

PAGE 48 of 69

TABLE 16¹ (con't)

TRT SUBJECT	Visit	Day	BACT		Optim Tskant**	Orms				Dethogen Isolated *		Response**		CLEAR ANALY
			ACT	FWAL		Local NSC	Strain Epi	Control NSC	Epi	Local	Control	Dethogen Analyzed	PATH	
AZITH 0272	BL	1	H		Yes	>25	<10	>25	<10	SERRATIA MARCESCENS	SERRATIA MARCESCENS			Imp
	ROT	10	H	H	Yes	NA	NA	NA	NA					C
	TOC	24	H	H	Yes	NA	NA	NA	NA					C
0274	BL	1	H		Yes	>25	>10	>25	<10					C
	ROT	10	H	H	Yes	>25	<10	>25	<10					C
	TOC	22	H	H	Yes	<=25	>=10	NA	NA					C
0276	BL	1	H		Yes	>25	<10	>25	<10					Imp
	ROT	11	H	H	Yes	>25	<10	>25	<10					C
	TOC	23	H	H	Yes	>25	<10	>25	<10					C
0281	BL	1	H		Yes	>25	<10	>25	<10					Imp
	ROT	11	H	H	Yes	NA	NA	NA	NA					C
	TOC	24	H	H	Yes	NA	NA	NA	NA					C
0284	BL	1	H		Yes	>25	<10	<=25	>=10					C
	ROT	8	H	H	Yes	NA	NA	NA	NA					C
	TOC	21	H	H	Yes	NA	NA	NA	NA					C
0285	BL	1	H		Yes	>25	<10	>25	<10					Imp
	ROT	14	H	H	Yes	NA	NA	NA	NA					C
	TOC	22	H	H	Yes	NA	NA	NA	NA					C
0289	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE		
	ROT	8	Y	Y	Yes	<=25	<10	NA	NA					F
	ROT	8	Y	Y	Yes	<=25	<10	NA	NA			H. INFLUENZAE	DF	DF
	TOC	Y	Y	NA	NA	NA	NA	NA	NA					F
	TOC	Y	Y	NA	NA	NA	NA	NA	NA			H. INFLUENZAE	DF	DF
0292	BL	8	H		Yes	>25	<10	>25	<10					Imp
	ROT	10	H	H	Yes	NA	NA	NA	NA					C
	TOC	23	H	H	Yes	NA	NA	NA	NA					C
0305	BL	0	H		Yes	>25	<10	>25	<10	S. PNEUMONIAE	A. HAEMOLYTIC STREP			Imp
	ROT	10	H	H	Yes	NA	NA	NA	NA					C
	TOC	24	H	H	Yes	NA	NA	NA	NA					C
0306	BL	-1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		C
	ROT	12	Y	Y	Yes	NA	NA	NA	NA					C
	TOC	23	Y	Y	Yes	NA	NA	NA	NA			S. PNEUMONIAE	DF	DF
AZITH 0308	TOC	21	Y	Y	Yes	NA	NA	NA	NA	S. PNEUMONIAE	M. CATARRHALIS	S. PNEUMONIAE	DF	DF
	BL	1	Y		Yes	>25	<10	<=25	>=10	M. CATARRHALIS	M. CATARRHALIS	M. CATARRHALIS		C
	ROT	12	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
0310	ROT	12	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
	TOC	22	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
	TOC	22	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
	TOC	22	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
	TOC	22	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
0311	BL	1	H		Yes	>25	<10	>25	<10	KLEBSIELLA	KLEBSIELLA			C
	ROT	11	H	H	Yes	NA	NA	NA	NA					C
	TOC	22	H	H	Yes	NA	NA	NA	NA					C
0315	BL	0	H		Yes	>25	<10	>25	<10					C
	ROT	10	H	H	Yes	NA	NA	NA	NA					C
	TOC	23	H	H	Yes	NA	NA	NA	NA					C
0317	BL	1	Y		Yes	>25	<10	>25	<10	M. CATARRHALIS	M. CATARRHALIS	M. CATARRHALIS		C
	ROT	12	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
	ROT	12	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
	TOC	23	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
	TOC	23	Y	Y	Yes	NA	NA	NA	NA			M. CATARRHALIS	DF	DF
0320	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		Imp
	ROT	11	Y	Y	Yes	NA	NA	NA	NA			S. PNEUMONIAE	DF	DF
	ROT	11	Y	Y	Yes	NA	NA	NA	NA			S. PNEUMONIAE	DF	DF
	TOC	21	Y	Y	Yes	NA	NA	NA	NA			S. PNEUMONIAE	DF	DF
	TOC	21	Y	Y	Yes	NA	NA	NA	NA			S. PNEUMONIAE	DF	DF
0321	BL	1	Y		Yes	>25	<10	NA	>=10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		Imp
	ROT	11	Y	Y	Yes	>25	>=10	NA	>=10			S. PNEUMONIAE		Imp
	ROT	11	Y	Y	Yes	>25	>=10	NA	>=10			S. PNEUMONIAE		Imp
	TOC	12	Y	H	Yes	>25	<10	NA	NA			S. PNEUMONIAE		C
	TOC	12	Y	H	Yes	>25	<10	NA	NA			S. PNEUMONIAE		C
0323	BL	1	Y		Yes	>25	<10	>25	<10	M. CATARRHALIS	M. CATARRHALIS	M. CATARRHALIS		C
	ROT	1	Y	H	Yes	NA	NA	NA	NA			M. CATARRHALIS	NA	NA
	ROT	1	Y	H	Yes	NA	NA	NA	NA			M. CATARRHALIS	NA	NA
	TOC	1	Y	H	Yes	NA	NA	NA	NA			M. CATARRHALIS	NA	NA
	TOC	1	Y	H	Yes	NA	NA	NA	NA			M. CATARRHALIS	NA	NA
0327	BL	1	H		Yes	>25	<10	>25	<10	ACTINOBACTER CALC.	ACTINOBACTER CALC.			C
	ROT	11	H	H	Yes	NA	NA	NA	NA					C
	TOC	22	H	H	Yes	NA	NA	NA	NA					C

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 ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

PAGE 49 of 69

TABLE 16⁷ (con't)

VIT SUBJECT	Visit	Day	MTT		Specimen Taken??	Gram Stain				Pathogen Isolated & Confirmed		Response**		CLIN ANALY
			BACT	EMCZ		Local WBC	Unstained WBC	Local WBC	Unstained WBC	Local	Confirmed	Pathogen Analyzed	DAEM	
AZITH 0324	BL	1	M		Yes	>25	<10	NA	>10		A. HAEMOLYTIC STREP			
	BL	1	M		Yes	>25	<10	NA	>10	S. PNEUMONIAE				
	ROT	16	M	M	Yes	<=25	<10	NA	NA					F
	TOC	22	M	M	UTE	NA	NA	NA	NA					F
0326	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		C
	ROT	13	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	ROT	13	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
0332	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE		F
	ROT	11	Y	Y	Yes	>25	<10	NA	NA			H. INFLUENZAE	R	R
	ROT	11	Y	Y	Yes	>25	<10	NA	NA			H. INFLUENZAE	R	R
	TOC	23	Y	Y	NA	NA	NA	NA	NA			H. INFLUENZAE	DD	DD
0338	BL	1	Y		Yes	>25	<10	NA	>10	M. CATARRHALIS	M. CATARRHALIS	M. CATARRHALIS		Imp
	ROT	13	Y	Y	UTE	NA	NA	NA	NA			M. CATARRHALIS	DE	DE
	ROT	13	Y	Y	UTE	NA	NA	NA	NA			M. CATARRHALIS	DE	DE
	TOC	21	Y	Y	UTE	NA	NA	NA	NA			M. CATARRHALIS	DE	DE
0334	BL	1	M		Yes	>25	<10	NA	>10					C
	ROT	12	M	M	UTE	NA	NA	NA	NA					C
	ROT	12	M	M	Yes	>25	<10	NA	NA					C
	TOC	20	M	M	UTE	NA	NA	NA	NA					C
0348	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		Imp
	ROT	10	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	ROT	10	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
0347	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		C
	ROT	12	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	ROT	12	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	21	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DE	DE
0351	BL	1	Y		Yes	>25	<10	NA	>10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		Imp
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
AZITH 0351	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	23	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
0352	BL	1	Y		Yes	>25	<10	<=25	>=10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		F
	ROT	12	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	PP	PP
	ROT	12	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	PP	PP
	TOC	26	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	PP	PP
0353	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		Imp
	ROT	11	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DE	DE
	ROT	11	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	26	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DE	DE
0354	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE		C
	ROT	11	Y	Y	Yes	<=25	>=10	NA	NA			H. INFLUENZAE	DE	DE
	ROT	11	Y	Y	Yes	<=25	>=10	NA	NA			H. INFLUENZAE	DE	DE
	TOC	26	Y	Y	Yes	<=25	>=10	NA	NA			H. INFLUENZAE	DE	DE
0358	BL	1	M		Yes	>25	<10	NA	>10		B. HAEMOLYTIC STREP			
	BL	1	M		Yes	>25	<10	NA	>10	STREP GROUP A				Imp
	ROT	11	M	M	UTE	NA	NA	NA	NA					C
	TOC	25	M	M	UTE	NA	NA	NA	NA					C
0365	BL	1	B		Yes	>25	<10	<=25	>=10	S. AUREUS	S. AUREUS	S. AUREUS		C
	ROT	11	B	M	Yes	<=25	>=10	NA	NA					C
	ROT	11	B	M	UTE	NA	NA	NA	NA					C
	TOC	25	B	M	UTE	NA	NA	NA	NA					C
0361	BL	1	Y		Yes	>25	<10	<=25	>=10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		C
	ROT	16	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	ROT	16	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	21	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DE	DE
0362	BL	1	Y		Yes	>25	<10	<=25	>=10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE		C
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
	TOC	21	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE
0370	BL	1	Y		Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE		C
	ROT	11	Y	Y	UTE	NA	NA	NA	NA			H. PARAINFLUENZAE		C

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 PFIZER INC.
 ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

PAGE 50 of 69

TABLE 16 (con't)

TRF SUBJECT	Visit	Day	MTT RAC1 SVAL	PD RAC2 KVAL	Sputum Taken??	Gross Stain				Pathogen Isolated		Response**			CLIN ABLLV
						local WBC	local Epi	Central WBC	Central Epi	Local	Central	Pathogen Analyzed	BATH	RACT	
AKTH 0376	ROT	11	Y	Y	YFE	NA	NA	NA	NA			N. PARAINFLUENZAE	DE	DE	C
	TDC	21	Y	Y	YFE	NA	NA	NA	NA			N. PARAINFLUENZAE	DE	DE	C
	TDC	21	Y	Y	YFE	NA	NA	NA	NA			N. PARAINFLUENZAE	DE	DE	C
0372	BL	1	Y		Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	N. PARAINFLUENZAE			
	ROT	11	Y	Y	Yes	<=25	<10	NA	NA			H. PARAINFLUENZAE	DE	DE	C
	TDC	22	Y	Y	Yes	<=25	<10	NA	NA			H. PARAINFLUENZAE	DE	DE	C
0374	BL	1	N		Yes	>25	<10	<=25	NA						
	ROT	11	N	N	YFE	NA	NA	NA	NA						C
	TDC	21	N	N	YFE	NA	NA	NA	NA						C
0376	BL	1	N		Yes	>25	<10	<=25	NA						
	ROT	11	N	N	YFE	NA	NA	NA	NA						C
	TDC	22	N	N	YFE	NA	NA	NA	NA						C
0379	BL	1	N		Yes	>25	<10	>25	<10						
	ROT	14	N	N	YFE	NA	NA	NA	NA						C
	TDC	22	N	N	YFE	NA	NA	NA	NA						C
0389	BL	1	N		Yes	>25	<10	>25	<10						
	ROT	12	N	N	YFE	NA	NA	NA	NA	H. CAVARHALIS	WEISSKILIA SP.				C
	TDC	22	N	N	YFE	NA	NA	NA	NA						C
0390	BL	1	N		Yes	>25	<10	>25	<10	SPERMOPHILUS SP.					
	ROT	11	N	N	YFE	NA	NA	NA	NA						Imp
	TDC	22	N	N	YFE	NA	NA	NA	NA						C
0394	BL	1	N		Yes	>25	<10	NA	>=10	PROTEUS SP.	PROTEUS SP.				
	ROT	11	N	N	YFE	NA	NA	NA	NA						C
	TDC	24	N	N	YFE	NA	NA	NA	NA						C
0396	BL	1	N		Yes	>25	<10	>25	<10						
	ROT	11	N	N	YFE	NA	NA	NA	NA						C
	TDC	27	N	N	YFE	NA	NA	NA	NA						C
0397	BL	1	N		Yes	>25	<10	>25	<10	KLEBSIELLA	KLEBSIELLA				
	ROT	13	N	N	YFE	NA	NA	NA	NA						C
	TDC	27	N	N	YFE	NA	NA	NA	NA						C
AKTH 0409	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			Imp
	ROT	12	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE	Imp
	ROT	12	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE	C
	TDC	25	Y	Y	Yes	>25	<10	>25	<10	S. AUREUS		S. AUREUS			C
	TDC	25	Y	Y	Yes	>25	<10	>25	<10	S. AUREUS		S. AUREUS			C
0411	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			
	ROT	10	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE	C
	ROT	10	Y	Y	YFE	NA	NA	NA	NA			H. INFLUENZAE	DE	DE	C
	ROT	10	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE	C
	TDC	22	Y	Y	YFE	NA	NA	NA	NA			H. INFLUENZAE	DE	DE	C
0422	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			Imp
	ROT	10	Y	Y	YFE	NA	NA	NA	NA			H. INFLUENZAE	DE	DE	Imp
	ROT	10	Y	Y	YFE	NA	NA	NA	NA			H. INFLUENZAE	DE	DE	C
	TDC	21	Y	Y	YFE	NA	NA	NA	NA			H. INFLUENZAE	DE	DE	C
	TDC	21	Y	Y	YFE	NA	NA	NA	NA			H. INFLUENZAE	DE	DE	C
0423	BL	1	Y		Yes	>25	<10	>25	<10	H. CAVARHALIS	H. CAVARHALIS	H. CAVARHALIS			
	ROT	11	Y	Y	YFE	NA	NA	NA	NA			H. CAVARHALIS	DE	DE	C
	ROT	11	Y	Y	YFE	NA	NA	NA	NA			H. CAVARHALIS	DE	DE	C
	TDC	23	Y	Y	YFE	NA	NA	NA	NA			H. CAVARHALIS	DE	DE	C
	TDC	23	Y	Y	YFE	NA	NA	NA	NA			H. CAVARHALIS	DE	DE	C
0427	BL	1	N		Yes	>25	<10	>25	<10						
	ROT	11	N	N	YFE	NA	NA	NA	NA						C
	TDC	24	N	N	YFE	NA	NA	NA	NA						C
0428	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			
	ROT	10	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE	C
	ROT	10	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE	C
	TDC	22	Y	Y	YFE	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE	C
0434	BL	1	N		Yes	>25	<10	NA	>=10						
	ROT	11	N	N	YFE	NA	NA	NA	NA						Imp
	TDC	25	N	N	YFE	NA	NA	NA	NA						C
0436	BL	1	N		Yes	>25	<10	>25	<10						
	ROT	13	N	N	YFE	NA	NA	NA	NA						C

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 ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

PAGE 51 of 69

TABLE 16 (con't)

SITE	VISIT	DAY	MITT BACT	PP BACT	Sputum Taken?*	Gram Stain				Pathogen Isolated &		Response**			CLEAN ANALY
						WBC	Local Epi	Control WBC	Control Epi	Local	Control	Pathogen Analyzed	PRM	BACT	
ALITH 0436	TOC	22	N	N	UTE	NA	NA	NA	NA						C
0441	BL	1	N	N	Yes	>25	<10	NA	>=10						C
	ROT	12	N	N	UTE	NA	NA	NA	NA						C
	TOC	22	N	N	Yes	<=25	>=10	<=25	NA						C
0447	BL	1	N	N	Yes	>25	<10	NA	>=10						C
	ROT	1	N	N	UTE	NA	NA	NA	NA						C
	TOC	22	N	N	Yes	>25	<10	NA	>=10						C
0453	BL	1	Y	Y	Yes	>25	<10	>25	<10						C
	BL	3	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	S. AUREUS	H. INFLUENZAE			C
	ROT	11	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	11	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	20	Y	Y	UTE	NA	NA	NA	NA						C
0460	BL	1	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	13	Y	Y	UTE	NA	NA	NA	NA	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE			C
	ROT	13	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	23	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
0463	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
0464	BL	1	Y	Y	Yes	>25	<10	<=25	NA	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE			C
	ROT	12	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	12	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
0466	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			C
	ROT	12	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	12	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
0467	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			C
	BL	1	Y	Y	Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			C
															C
ALITH 0467	ROT	11	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	13	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	11	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	22	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	22	Y	Y	UTE	NA	NA	NA	NA						C
0469	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE			C
	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE			C
	ROT	13	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	13	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	23	Y	Y	UTE	NA	NA	NA	NA						C
0470	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. INFLUENZAE	H. INFLUENZAE	H. INFLUENZAE			C
	ROT	12	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	12	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	23	Y	Y	UTE	NA	NA	NA	NA						C
0474	BL	1	N	N	Yes	>25	<10	NA	>=10						C
	ROT	13	N	N	Yes	>25	<10	NA	NA						C
	TOC	26	N	N	UTE	NA	NA	NA	NA						C
0478	BL	1	Y	Y	Yes	>25	<10	<=25	NA	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			Imp
	ROT	10	Y	Y	Yes	<=25	>=10	NA	NA						C
	ROT	10	Y	Y	Yes	<=25	>=10	NA	NA						C
	TOC	21	Y	Y	Yes	<=25	>=10	>25	<10						C
	TOC	21	Y	Y	Yes	<=25	>=10	>25	<10						C
0479	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE			C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	23	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA						C
0486	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. CATARRHALIS	H. CATARRHALIS	H. CATARRHALIS			C
	BL	1	Y	Y	Yes	>25	<10	>25	<10	H. PARAINFLUENZAE	H. PARAINFLUENZAE	H. PARAINFLUENZAE			C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA						C
	ROT	10	Y	Y	UTE	NA	NA	NA	NA						C
	TOC	23	Y	Y	UTE	NA	NA	NA	NA						C

TABLE 16 (con't)

TRT SUBJECT	Visit	Day	MITT BACT EVAL	PP BACT EVAL	Specimen Taken?*	Gram Stain				Pathogen Isolated &		Response**	CLIN AGLY		
						Local WBC	Local Epi	Control WBC	Control Epi	Local	Control			Pathogen Analyzed	DAY#
0486	TOC	21	Y	Y	UTE	NA	NA	NA	NA			N. PARAINFLUENZAE	DE	PE	C
0488	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	N. INFLUENZAE	N. INFLUENZAE			
	EDT	11	Y	Y	UTE	NA	NA	NA	NA			N. INFLUENZAE	DE	PE	C
	EDT	11	Y	Y	UTE	NA	NA	NA	NA			N. INFLUENZAE	DE	PE	C
	TOC	21	Y	Y	Yes	<=25	<10	NA	NA			N. INFLUENZAE	DE	PE	C
	TOC	21	Y	Y	Yes	<=25	<10	NA	NA			N. INFLUENZAE	DE	PE	C
0490	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	N. INFLUENZAE	N. INFLUENZAE			
	EDT	13	Y	Y	UTE	NA	NA	NA	NA			N. INFLUENZAE	DE	PE	C
	EDT	13	Y	Y	UTE	NA	NA	NA	NA			N. INFLUENZAE	DE	PE	C
0491	BL	1	Y		Yes	>25	<10	>25	<10	HEINSTERIA MEN. S. PNEUMONIAE	HEINSTERIA MEN. S. PNEUMONIAE	S. PNEUMONIAE N. PARAINFLUENZAE			
	BL	1	Y		Yes	>25	<10	>25	<10	S. PNEUMONIAE N. PARAINFLUENZAE	N. PARAINFLUENZAE	N. PARAINFLUENZAE			
	EDT	10	Y	Y	UTE	NA	NA	NA	NA			S. PNEUMONIAE	DE		C
	EDT	10	Y	Y	UTE	NA	NA	NA	NA			N. PARAINFLUENZAE	DE	PE	C
	TOC	21	Y	Y	Yes	<=25	<10	NA	NA			S. PNEUMONIAE	DE		C
	TOC	21	Y	Y	Yes	<=25	<10	NA	NA			S. PNEUMONIAE	DE		C
	TOC	21	Y	Y	Yes	<=25	<10	NA	NA			N. PARAINFLUENZAE	DE	PE	C
	TOC	21	Y	Y	Yes	<=25	<10	NA	NA			N. PARAINFLUENZAE	DE	PE	C
0493	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	N. INFLUENZAE	N. INFLUENZAE			
	EDT	12	Y	Y	Yes	<=25	<10	NA	NA			N. INFLUENZAE	DE	PE	C
	EDT	12	Y	Y	Yes	<=25	<10	NA	NA			N. INFLUENZAE	DE	PE	C
	TOC	21	Y	Y	UTE	NA	NA	NA	NA			N. INFLUENZAE	DE	PE	C
0496	BL	1	Y		Yes	>25	<10	>25	<10	N. CANTABRIGALIS	N. CANTABRIGALIS	N. CANTABRIGALIS			
	EDT	11	Y	Y	UTE	NA	NA	NA	NA			N. CANTABRIGALIS	DE	PE	C
	EDT	11	Y	Y	UTE	NA	NA	NA	NA			N. CANTABRIGALIS	DE	PE	C
	TOC	23	Y	Y	Yes	<=25	<10	NA	NA			N. CANTABRIGALIS	DE	PE	C
0497	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	N. INFLUENZAE	N. INFLUENZAE			
	EDT	1	Y	N	NA	NA	NA	NA	NA			N. INFLUENZAE	NA	NA	
	EDT	1	Y	N	NA	NA	NA	NA	NA			N. INFLUENZAE	NA	NA	
	TOC	1	Y	N	NA	NA	NA	NA	NA			N. INFLUENZAE	NA	NA	
	TOC	1	Y	N	NA	NA	NA	NA	NA			N. INFLUENZAE	NA	NA	
0500	BL	1	Y		Yes	>25	<10	>25	<10	H. INFLUENZAE	N. INFLUENZAE	N. INFLUENZAE			
	EDT	11	Y	Y	Yes	<=25	>=10	NA	NA			N. INFLUENZAE	DE	PE	C
	EDT	11	Y	Y	Yes	<=25	>=10	NA	NA			N. INFLUENZAE	DE	PE	C

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NDA 50-784

Page 54 of 69

PFIZER INC.

ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

ALMTB	0584	BL	1	B	Yes	>25	<10	>25	<10									
		EXT	11	B	B	Yes	>25	<10	NA	NA								C
		TOC	21	B	B	UTZ	NA	NA	NA	NA								C
	0596	BL	1	B	Yes	>25	<10	NA	NA									C
		EXT	12	B	B	Yes	>25	<10	NA	NA								C
		TOC	21	B	D	UTZ	NA	NA	NA	NA								C
	0591	BL	1	B	Yes	>25	<10	>25	<10									F
		EXT	12	B	M	UTZ	NA	NA	NA	NA								F
		TOC	23	B	M	UTZ	NA	NA	NA	NA								F
	0605	BL	1	Y	Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE						
		EXT	13	Y	Y	Yes	<=25	>=10	NA	NA								Imp
		EXT	13	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	DE	DE			Imp
		TOC	24	Y	Y	Yes	>25	<10	<=25	>=10			S. PNEUMONIAE	R	R			C
		TOC	24	Y	Y	Yes	>25	<10	<=25	>=10			S. PNEUMONIAE	R	R			C
	0606	BL	1	B	Yes	>25	<10	>25	<10									C
		EXT	14	B	D	Yes	>25	<10	>25	<10								C
		TOC	23	B	M	UTZ	NA	NA	NA	NA								C
	0609	BL	1	B	Yes	>25	<10	<=25	>=10	SERRATIA MARCESCENS	SERRATIA MARCESCENS	SERRATIA MARCESCENS						Imp
		EXT	11	B	B	Yes	>25	>=10	NA	>=10			SERRATIA MARCESCENS					F
		TOC	24	B	B	Yes	>25	>=10	<=25	NA			SERRATIA MARCESCENS					F
	0610	BL	1	Y	Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE						Imp
		EXT	11	Y	Y	Yes	>25	<10	<=25	NA			S. PNEUMONIAE	R	R			Imp
		EXT	11	Y	Y	Yes	>25	<10	<=25	NA			S. PNEUMONIAE	R	R			Imp
		TOC	20	Y	Y	UTZ	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE			C
		TOC	20	Y	Y	UTZ	NA	NA	NA	NA			S. PNEUMONIAE	DE	DE			C
	0614	BL	1	B	Yes	>25	<10	>25	<10									Imp
		EXT	13	B	B	Yes	>25	<10	>25	<10	S. AUREUS	S. AUREUS						F
		TOC	24	B	B	Yes	>25	<10	>25	<10	STAPH. SPECIES							F
		TOC	24	B	B	ND	NA	NA	>25	<10	H. PARAINFLUENZAE							F
	0615	BL	1	B	Yes	>25	<10	NA	NA	STAPH. SPECIES								Imp
		BL	1	B	Yes	>25	<10	NA	NA	E. COLI								Imp
		EXT	11	B	D	Yes	>25	<10	NA	NA								C
		TOC	21	B	D	UTZ	NA	NA	NA	NA								C
	0619	BL	0	B	Yes	>25	<10	<=25	NA									

TABLE 16* (con't)

PAT SUBJECT	VIAIR	Day	MITT BLCT	SP BVAL	SP BACT	Spusum Taken?*	Gram Stain				Pathogen Isolated w/		Response**		CLIN ANALY				
							Local WBC	Local Epi	Central WBC	Central Epi	Local	Central	Pathogen Analyzed	BATH		BACT			
ALMTB 0619			EXT	10	B		Yes	<=25	>=10	<=25	>=10								
			EXT	10	B		Yes	<=25	>=10	<=25	>=10			ENTEROCOCTER SP.					
			EXT	10	B		Yes	<=25	>=10	<=25	>=10			NEISSERIA SP.					
			TOC	20	B	B	Yes	<=25	>=10	<=25	NA			M. CATARRHALIS				C	
			TOC	20	B	B	Yes	<=25	>=10	<=25	NA			KLEBSIELLA				C	
0620			EXT	12	B	B	Yes	<=25	>=10	<=25	NA			NEISSERIA SP.				C	
			EXT	12	B	B	Yes	<=25	>=10	<=25	NA			NON-HAEMOLYTIC STREP				C	
			TOC	20	B	B	Yes	<=25	>=10	<=25	NA			M. CATARRHALIS				C	
			BL	1	B		Yes	>25	<10	>25	<10								
			EXT	12	B	B	Yes	>25	<10	>25	<10			M. CATARRHALIS				Imp	
0621			EXT	12	B	B	Yes	>25	<10	>25	<10			ENTEROCOCTER SP.				Imp	
			TOC	22	B	B	UTZ	NA	NA	NA	NA			E. COLI				Imp	
			BL	1	B		Yes	>25	<10	<=25	>=10							C	
			EXT	11	B	B	Yes	<=25	>=10	<=25	>=10			ACETABOCTER SP.				Imp	
0624			TOC	21	B	B	Yes	<=25	>=10	<=25	>=10			SERRATIA MARCESCENS				C	
			BL	1	Y		Yes	>25	<10	NA	>=10			ENTEROCOCTER SP.				C	
			BL	1	Y		Yes	>25	<10	NA	>=10			CITROCOCTER SP.				C	
			BL	1	Y		Yes	>25	<10	NA	>=10			OTHER					
			BL	1	Y		Yes	>25	<10	NA	>=10			ENTEROCOCTER SP.				Imp	
			BL	1	Y		Yes	>25	<10	NA	>=10			M. CATARRHALIS				C	
			BL	1	Y		Yes	>25	<10	NA	>=10			S. PNEUMONIAE				C	
			EXT	1	Y	B	NA	NA	NA	NA	NA								
			EXT	1	Y	B	NA	NA	NA	NA	NA								
			TOC	20	Y	Y	Yes	<=25	>=10	NA	>=10			ENTEROCOCTER SP.	ENTEROCOCTER SP.				C
0625			TOC	20	Y	Y	Yes	<=25	>=10	NA	>=10			ENTEROCOCTER SP.	ENTEROCOCTER SP.				C
			TOC	20	Y	Y	Yes	<=25	>=10	NA	>=10			ENTEROCOCTER SP.	ENTEROCOCTER SP.				C
			BL	1	B		Yes	>25	<10	>25	<10			M. CATARRHALIS				Imp	
			EXT	13	B	B	Yes	>25	<10	>25	<10			M. CATARRHALIS				C	
			TOC	22	B	B	Yes	>25	<10	>25	<10			S. PNEUMONIAE				C	
0626			BL	1	Y		Yes	>25	<10	>25	<10								
			BL	1	Y		Yes	>25	<10	>25	<10			RAMNODIPLIN SP.					
			EXT	15	Y	B	UTZ	NA	NA	NA	NA			N. INFLUENZAE				Imp	
			EXT	15	Y	B	UTZ	NA	NA	NA	NA			N. INFLUENZAE				Imp	
			TOC	22	Y	Y	UTZ	NA	NA	NA	NA			N. INFLUENZAE	DE	DE		C	

PFIZER INC.

ZITHROMAX® (azithromycin) 500 mg Film-Coated Tablet

ALTIM	0429	ML	1	B	Yes	>25	<10	>25	<10	CONJUGATE NBC STAPH								
		ROT	12	B	Yes	>25	>10	>25	<10	SARMOVILLUS SP.								Imp
		ROT	12	B	Yes	>25	>10	>25	<10		N. INFLUENZAE	N. INFLUENZAE						Imp
		TOC	23	B	Yes	>25	<10	NA	NA	SARMOVILLUS SP.								C
	0430	ML	1	Y	Yes	>25	<10	NA	>10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE						C
		ROT	15	Y	Yes	<=25	<10	NA	NA									C
		ROT	15	Y	Yes	<=25	<10	NA	NA			S. PNEUMONIAE		DE	DE			C
		TOC	25	Y	Yes	<=25	>=10	NA	NA									C
		TOC	25	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE		DE	DE			C
	0434	ML	1	B	Yes	>25	<10	>25	<10									Imp
		ROT	12	B	Yes	>25	<10	<=25	NA									F
		TOC	24	B	Yes	>25	<10	>25	<10		NEISSERIA SP.							F
		TOC	24	B	Yes	>25	<10	>25	<10		NON-HAEMOLYTIC STRKED							F
		TOC	26	B	Yes	>25	<10	>25	<10	N. CAVARUMALIS								F
	0436	ML	1	B	Yes	>25	<10	>25	<10									F
		ROT	14	B	Yes	>25	<10	>25	<10									F
		TOC		B	NA	NA	NA	NA	NA									F
	0438	ML	1	B	Yes	>25	<10	>25	<10									C
		ROT	12	B	Yes	>25	<10	>25	<10									C
		TOC	20	B	Yes	>25	<10	>25	<10	E. COLI	E. COLI							C
	0439	ML	1	Y	Yes	>25	<10	>25	<10	SARMOVILLUS SP.								Imp
		ML	3	Y	Yes	>25	<10	>25	<10		N. INFLUENZAE	N. INFLUENZAE						Imp
		ROT	12	Y	Yes	>25	<10	>25	<10									C
		ROT	12	Y	Yes	>25	<10	>25	<10			N. INFLUENZAE		R	R			Imp
		TOC	22	Y	Yes	>25	<10	>25	<10									C
		TOC	22	Y	Yes	>25	<10	>25	<10			N. INFLUENZAE		R	R			C
	0441	ML	1	B	Yes	>25	<10	>25	<10	KLBERSTELLA	KLBERSTELLA							C
		ROT	12	B	UTE	NA	NA	NA	NA									C
		TOC	22	B	UTE	NA	NA	NA	NA									C
	0442	ML	1	B	Yes	>25	<10	>25	<10									C
		ROT	12	B	UTE	NA	NA	NA	NA									C
		TOC	12	B	UTE	NA	NA	NA	NA									C
	0445	ML	1	B	Yes	>25	<10	NA	>=10	KLBERSTELLA	KLBERSTELLA							C
		ROT	12	B	Yes	<=25	<10	NA	NA									C
		TOC	24	B	UTE	NA	NA	NA	NA									C

TABLE 16' (con't)

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VPT SUBJECT	Visit	Day	MUT MCT	PD EVAL	Sputum Taken??	Drug Status				Pathogen Isolated &		Response**		CLIN ABALY
						Local WBC	Spa Epi	Central WBC	Spa Epi	Local	Control	Pathogen Analyzed	PATN	
AZITH 0646	BL 1	B			Yes	>25	<10	NA	>10	KLEBSIELLA	KLEBSIELLA			
	ROT 11	B	#	#	UTE	NA	NA	NA	NA					C
	TOC 22	B	#	#	UTE	NA	NA	NA	NA					C
0650	BL 1	B			Yes	>25	<10	<=25	>10					
	ROT 11	B	#	#	UTE	<=25	>=10	<=25	>=10					C
	TOC 21	B	#	#	UTE	<=25	<10	NA	>=10					C
0651	BL 1	F			Yes	>25	<10	NA	>10		A. HAEMOLYTIC STREP STRIBERIA SP.			
	BL 1	F			Yes	>25	<10	NA	>10					
	BL 1	F			Yes	>25	<10	NA	>10	S. EPIDIDYMIS				
	BL 1	F			Yes	>25	<10	NA	>10		H. PARAINFLUENZAE	H. PARAINFLUENZAE		
	ROT 11	F	F	F	UTE	<=25	>=10	>25	<10					Imp
	TOC 21	F	F	F	UTE	<=25	<10	>25	<10	S. EPIDIDYMIS S. EPIDIDYMIS		H. PARAINFLUENZAE	DE	DE
0654	BL 1	B			Yes	>25	<10	>25	<10		COAGULASE NEG STREP			
	BL 1	B			Yes	>25	<10	>25	<10		S. PNEUMONIAE			
	ROT 12	B	#	#	UTE	NA	NA	NA	NA					C
0656	BL 1	B			Yes	>25	<10	>25	<10		ENTEROCOCCUS SP.			
	BL 1	B			Yes	>25	<10	>25	<10		ENTEROCOCCUS			
	ROT 12	B	#	#	UTE	NA	NA	NA	NA					C
0657	BL 1	B			Yes	>25	<10	NA	>10		COLIFORM BACILLA			
	BL 1	B			Yes	>25	<10	NA	>10	S. HAEMOLYTIC STREP				
	ROT 10	B	#	#	UTE	NA	NA	NA	NA					C
0659	BL 1	B			Yes	>25	<10	>25	<10	KLEBSIELLA	KLEBSIELLA			
	ROT 15	B	#	#	UTE	NA	NA	NA	NA					C
	TOC 25	B	#	#	UTE	NA	NA	NA	NA					C
0661	BL 0	B			Yes	>25	<10	>25	<10					
	ROT 10	B	#	#	UTE	>25	<10	>25	<10					Imp
	TOC 24	B	#	#	UTE	NA	NA	NA	NA					C
0665	BL 1	B			Yes	>25	<10	NA	>10		COAGULASE NEG STREP			
	BL 1	B			Yes	>25	<10	NA	>10	S. HAEMOLYTIC STREP				
	ROT 11	B	#	#	UTE	NA	NA	NA	NA					C
AZITH 0665	TOC 22	B	#	#	UTE	NA	NA	NA	NA					C
0669	BL 1	F			Yes	>25	<10	>25	<10	S. EPIDIDYMIS				
	BL 1	F			Yes	>25	<10	>25	<10	KLEBSIELLA	KLEBSIELLA			
	BL 1	F			Yes	>25	<10	>25	<10	S. PNEUMONIAE		S. PNEUMONIAE		
	BL 1	F			Yes	>25	<10	>25	<10		H. PARAINFLUENZAE	H. PARAINFLUENZAE		
	ROT 12	F	F	F	UTE	<=25	<10	NA	>10	KLEBSIELLA	KLEBSIELLA			C
	ROT 12	F	F	F	UTE	<=25	<10	NA	>10	KLEBSIELLA	KLEBSIELLA			C
	ROT 12	F	F	F	UTE	<=25	<10	NA	>10	KLEBSIELLA	KLEBSIELLA			C
	TOC 21	F	F	F	UTE	>25	<10	>25	<10	KLEBSIELLA	KLEBSIELLA			C
	TOC 21	F	F	F	UTE	>25	<10	>25	<10	KLEBSIELLA	KLEBSIELLA			C
	TOC 21	F	F	F	UTE	>25	<10	>25	<10	KLEBSIELLA	KLEBSIELLA			C
0675	BL 1	B			Yes	>25	<10	NA	>10					
	ROT 11	B	#	#	UTE	NA	NA	NA	NA					Imp
	TOC 22	B	#	#	UTE	NA	NA	NA	NA					C
0676	BL 1	B			Yes	>25	<10	NA	>10		NEISSERIA SP.			
	BL 1	B			Yes	>25	<10	NA	>10	H. CARYOPHALLIC				
	ROT 12	B	#	#	UTE	>25	>=10	NA	>=10					Imp
0677	BL 1	B			Yes	>25	<10	>25	<10					
	ROT 12	B	#	#	UTE	NA	NA	NA	NA					C
	TOC 22	B	#	#	UTE	NA	NA	NA	NA					C
0679	BL 1	B			Yes	>25	<10	>25	<10		ACINETOBACTER SP.			
	BL 1	B			Yes	>25	<10	>25	<10	KLEBSIELLA				
	ROT 11	B	#	#	UTE	NA	NA	NA	NA					C
0714	BL 1	B			Yes	>25	<10	>25	<10					
	ROT 15	B	#	#	UTE	<=25	>=10	NA	NA	H. CARYOPHALLIC				F
	TOC 21	B	#	#	UTE	NA	NA	NA	NA		NEISSERIA SP.			F
0716	BL 1	B			Yes	>25	<10	>25	<10					
	ROT 11	B	#	#	UTE	<=25	>=10	NA	>=10					Imp
	TOC 21	B	#	#	UTE	<=25	>=10	>25	<10		A. HAEMOLYTIC STREP			F
	TOC 21	B	#	#	UTE	<=25	>=10	>25	<10		NEISSERIA SP.			F
0718	BL 1	B			Yes	>25	<10	>25	<10	P. AERUGINOSA	P. AERUGINOSA			
	ROT 12	B	#	#	UTE	>25	<10	>25	<10		MORAXELLA MORAXANTI			F

TABLE 16 (con't)

PKT SUBJECT	Visit	Day	MITT		Spotus Taken**	Gross Stain				Pathogen Isolated at		Response**			CLIN ABLY
			BACT EVAL	BACT EVAL		WBC	Local Spd	Central WBC	Central Spd	Local	Central	Pathogen Analyzed	PATH	BACT	
ALLEN 0710	BOT	12	#	#	Yes	>25	<10	>25	<10	PROTEUS SP.					P
	TOC		#	#	NA	NA	NA	NA	NA						P
0723	BL	1	#	#	Yes	>25	<10	>25	<10						
	BOT	15	#	#	Yes	<=25	>=10	NA	NA						Imp
	TOC	22	#	#	Yes	>25	<10	>25	<10						C
0724	BL	1	Y	#	Yes	>25	<10	>25	<10	N. CATAEBOALIS	N. CATAEBOALIS	N. CATAEBOALIS			
	BOT	15	Y	#	Yes	>25	<10	>25	<10	SERGIATIA MARCESCENS			E	E	C
	BOT	15	Y	#	Yes	>25	<10	>25	<10	SERGIATIA MARCESCENS					C
	TOC	22	Y	Y	Yes	>25	<10	NA	>=10	SERGIATIA MARCESCENS			E	E	C
0737	BL	1	Y	#	Yes	>25	<10	>25	<10	S. PNEUMONIAE	S. PNEUMONIAE	S. PNEUMONIAE			
	BOT	13	Y	Y	Yes	<=25	>=10	NA	NA						Imp
	BOT	13	Y	Y	Yes	<=25	>=10	NA	NA			S. PNEUMONIAE	PE	PE	Imp
	TOC	21	Y	Y	Yes	>25	<10	>25	<10			S. PNEUMONIAE	E	E	C

* Adopted from NDA 50-784, Letter Date: 01/18/02, Enclosure #4, FDA Query #15.

*UTE: Unable to Expectorate, NA = Not Available.

** Response: Bact. outcome: PATH = by- pathogen, BACT = by- subject. Clinical outcome: ANALY = used for analysis. Bact. Response: E = Eradication, P = Persistence, SI = Superinfection, PE = Presumed Eradication, PP = Presumed Persistence, NA = Not Available.

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Protocol: A0661013 -- PP Summary Analyses

TABLE 17: Combined Clinical Outcome and Bacteriological Outcome Results at TOC

	<i>Haemophilus influenzae</i>	<i>Moraxella catarrhalis</i>	<i>Streptococcus pneumoniae</i>	<i>Haemophilus parainfluenzae</i>
Patients with Isolates	16	13	31	4
Patients Cured	14/16 (87.5%)	11/13 (84.6%)	28/31 (90.3%)	4/4 (100%)
Patient Failures	2/16 (12.5%)	1/13 (7.69%)	3/31 (9.68%)	None
Clinical Outcome Not Given	None	1/13 (7.69%)	None	None
Microorganisms Eradicated	1/16 (6.25%)	3/13 (23.1%)	4/31 (12.9%)	1/4 (25%)
Microorganisms Presumed Eradicated	9/16 (56.3%)	8/13 (61.5%)	23/31 (74.2%)	1/4 (25%)
Microorganisms (Eradicated + Presumed Eradicated)	10/16 (62.5%)	11/13 (84.6%)	27/31 (87.1%)	2/4 (50%)
Bacteriological Outcome Not Given	2/16 (12.5%)	None	1/31 (3.22%)	None
Bacteriological Outcome Not Available (na)	None	2/13 (15.4%)	None	None
Other	4/16 (25%)	None	3/31 (9.68%)	2/4 (50%)

Microbiologist's Comments:

The clinical cure outcome rate and bacteriological (i.e., eradication + presumed eradication) outcome rate for the aforementioned microorganisms in the Per Protocol (PP) population are summarized as follows:

<u>Clinical Outcome Rate (PP)</u> (Cure)	<u>Bacteriological Outcome Rate (PP)</u> (Eradication and Presumed Eradication)
<i>Haemophilus influenzae</i> = 14/16 (87.5%)	<i>Haemophilus influenzae</i> = 10/16 (62.5%)
<i>Moraxella catarrhalis</i> = 11/13 (84.6%)	<i>Moraxella catarrhalis</i> = 11/13 (84.6%)
<i>Streptococcus pneumoniae</i> = 28/31 (90.3%)	<i>Streptococcus pneumoniae</i> = 27/31 (87.1%)
<i>Haemophilus parainfluenzae</i> = 4/4 (100%)	<i>Haemophilus parainfluenzae</i> = 2/4 (50%)

The bacteriological (i.e., eradication + presumed eradication) rates for the Applicant's targeted microorganisms (*Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pneumoniae*) in the Per Protocol (PP) population are acceptable. Although the *Haemophilus influenzae* number of isolates and corresponding bacteriological outcome rate are again seen to be low, 10/16 (62.5%), the bacteriological outcome rate of azithromycin versus *Haemophilus influenzae* is within the expected percentage rate range.

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**Overall Summary of the Clinical Outcome Cure Rate and Bacteriological
 Outcome Eradication Rates on the Modified-to-Treat (MITT) and Per
 Protocol (PP) Populations at TOC**

Clinical Outcome Cure Rate

Bacteriological Outcome Eradication

		<u>(Eradication + Presumed Eradication) Rate</u>				
		<u>MITT</u>	<u>PP</u>			
				<u>MITT</u>	<u>PP</u>	
<i>Haemophilus influenzae</i>		12/15 (80%)	14/16 (87.5%)	<i>Haemophilus influenzae</i>	10/15 (66.7%)	10/16 (62.5%)
<i>Moraxella catarrhalis</i>		10/12 (83.3%)	11/13 (84.6%)	<i>Moraxella catarrhalis</i>	10/12 (83.3%)	11/13 (84.6%)
<i>Streptococcus pneumoniae</i>		30/33 (90.9%)	28/31 (90.3%)	<i>Streptococcus pneumoniae</i>	30/33 (90.9%)	27/31 (81.1%)
<i>Haemophilus parainfluenzae</i>		4/4 (100%)	4/4 (100%)	<i>Haemophilus parainfluenzae</i>	2/4 (50%)	2/4 (50%)

The bacteriological eradication (i.e., eradication + presumed eradication) outcome rates for the Applicant's targeted microorganisms (*Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pneumoniae*) for the Modified-to-Treat (MITT) and the Per Protocol (PP) populations are very close and are acceptable. Although the *Haemophilus influenzae* number of isolates and corresponding bacteriological eradication outcome rates for the MITT, 10/15 (66.7%), and the PP, 10/16 (62.5%), populations are both low, the bacteriological eradication outcome rates are within the expected percentage range.

VI. CONCLUSIONS

From the Clinical Microbiology Reviewer's perspective, the bacteriological data for NDA 50-784 on *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pneumoniae* are "acceptable" and the recommendation for NDA 50-784 is for "approval".

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151

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