

PRODUCTION DATA - PRODUCTION MODE 21:58 Jun 19, 1995 PAGE: 1  
 Appendix HGAJ.7.207.01  
 Treatment-Emergent Abnormal, High, or Low Laboratory Values at Any Time  
 FID-MC-HGAJ Acute Phase

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 --- p-Value \*1 ---

O1z(1) (Total=1336)		Ha1(2) (Total=660)		Overall
N	n (%)	N	n (%)	

Lab Test: HEMATOCRIT

LOW	1208	37 (2.9)	621	14 (2.3)	.433
HIGH	1276	23 (1.8)	617	9 (1.5)	.586

Lab Test: HEMOGLOBIN

LOW	1286	22 (1.7)	629	7 (1.1)	.314
HIGH	1281	12 (0.9)	617	6 (1.0)	.940

Lab Test: ERYTHROCYTE COUNT

LOW	1292	33 (2.6)	628	8 (1.3)	.069
HIGH	1295	6 (0.5)	625	3 (0.5)	.960

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLLIB(SSAFE6J)  
 RMP.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having  
 both baseline and endpoint visits.

N = Total number of at risk patients with the lab test.  
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 (e.g. HIGH).

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--- p-Value \*1 ---

Incidence Group	01z(1) (Total=1336)		Hal(2) (Total=660)		Overall
	N	(%)	N	(%)	
LOW	1271	55 (4.3)	610	15 (2.5)	.045
HIGH	1273	47 (3.7)	619	19 (3.1)	.489

Lab Test: MEAN CELL HEMOGLOBIN CONCENTRATION (MCHC)

LOW	1288	2 (0.2)	626	1 (0.2)	.982
HIGH	1277	24 (1.9)	628	10 (1.6)	.656

Lab Test: MEAN CELL HEMOGLOBIN (MCH)

LOW	1293	27 (2.1)	630	9 (1.4)	.317
HIGH	1235	66 (5.3)	594	30 (5.1)	.792

Lab Test: LEUCOCYTE COUNT

LOW	1293	27 (2.1)	630	9 (1.4)	.317
HIGH	1235	66 (5.3)	594	30 (5.1)	.792

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.F1DP.JCLLIB(SSAFE6J)  
 RMP.F1DP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.  
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O1z(1)		Hel(2)		--- p-Value #1 ---	
(Total=1336)		(Total=660)			
Incidence Group	N n (%)	N n (%)	n (%)	Overall	

Lab Test: BANDS

HIGH	1301	0	632	1	(0.2)	.151
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Lab Test: NEUTROPHILS, SEGMENTED

LOW	1207	29	(2.3)	629	11	(1.7)	.468
HIGH	1206	101	(8.4)	583	47	(8.1)	.822

Lab Test: LYMPHOCYTES

LOW	1273	31	(2.4)	615	18	(2.9)	.529
HIGH	1285	25	(1.9)	620	7	(1.1)	.194

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLLIB(SSAFEE6J)  
 RMP.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.  
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 FID-MC-HGAJ Acute Phase

--- p-Value \*1 ---

Incidence Group	Olz(1) (Total=1336)		Hal(2) (Total=660)		Overall
	N	n (%)	N	n (%)	
Lab Test: <u>MONOCYTES</u>					
HIGH	1203	103 (8.6)	587	46 (7.8)	.602
Lab Test: <u>EOSINOPHILS</u>					
HIGH	1272	62 (4.9)	616	7 (1.1)	.000
Lab Test: <u>BASOPHILS</u>					
HIGH	1286	35 (2.7)	624	17 (2.7)	.997

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLLIB(SSAFE6J)  
 RMP.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.  
 N = Total number of at risk patients with the lab test.  
 n = Total number of at risk patients with the specific lab result (e.g. HIGH).

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--- p-Value \*1 ---

Incidence Group	01z(1) (Total=1336)		Ha1(2) (Total=660)		Overall
	N	n (%)	N	n (%)	

Lab Test: MEAN CELL VOLUME (MCV)

LOW	1279	3 (0.2)	621	0	.227
HIGH	1274	31 (2.4)	616	14 (2.3)	.830

Lab Test: PLATELET COUNT

LOW	1292	12 (0.9)	623	4 (0.6)	.518
HIGH	1271	23 (1.8)	618	12 (1.9)	.842

Lab Test: LYMPHOCYTES, ATYPICAL

HIGH	1300	1 (0.1)	632	0	.486
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Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.  
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 n = Total number of at risk patients with the specific lab result (e.g. HIGH).

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Incidence Group	01z(1) (Total=1336)		01z(2) (Total=660)		Overall
	N	n (%)	N	n (%)	

Lab Test: UA-SPECIFIC GRAVITY

LOW	1189	128 (10.8)	586	62 (10.6)	.906
HIGH	1292	4 (0.3)	628	1 (0.2)	.564

Lab Test: UA-PH

HIGH	1290	3 (0.2)	630	0	.226
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Lab Test: AST/SGOT

LOW	1283	25 (1.9)	627	17 (2.7)	.286
HIGH	1290	57 (4.4)	632	9 (1.4)	.001

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FLDP.JCLLIB(SSAFE6J)  
 RMP.FLDP.SASMACRO(SSAFE6)

\* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.

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 FID-MC-HGAJ Acute Phase

0 --- p-Value \*1 ---

Incidence Group	Olz(1) (Total=1336)		Hal(2) (Total=660)		Overall
	N	n (%)	N	n (%)	
LOW	1281	13 (1.0)	630	9 (1.4)	.425
HIGH	1289	102 (7.9)	629	7 (1.1)	.009

Lab Test: ALI/SGPI

Lab Test: CREATINE PHOSPHOKINASE

LOW	1295	2 (0.2)	634	2 (0.3)	.465
HIGH	1244	87 (7.0)	603	33 (5.5)	.214

Lab Test: ALKALINE PHOSPHATASE

LOW	1291	4 (0.3)	634	5 (0.8)	.148
HIGH	1287	15 (1.2)	630	2 (0.3)	.063

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLLIB(SSAFE6J)  
 RMP.FIDP.SASMACRO(SSAFE66)  
 \* Frequencies are analyzed using a Chi-Square test.  
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--- p-Value \*1 ---

Incidence Group	01z(1) (Total=1336)		Hal(2) (Total=660)		Overall
	N	n (%)	N	n (%)	

Lab Test: GETIGSPT/SSGT/YGGT

LOW	1294	3 (0.2)	633	3 (0.5)	.370
HIGH	1292	15 (1.2)	633	4 (0.6)	.270

Lab Test: UREA NITROGEN

LOW	1201	115 (9.6)	582	58 (10.0)	.794
HIGH	1291	16 (1.2)	632	4 (0.6)	.218

Lab Test: CREATININE

LOW	1296	7 (0.5)	635	2 (0.3)	.495
HIGH	1285	14 (1.1)	627	5 (0.8)	.546

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLLIB(SSAFE6J)  
 RMP.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.  
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Incidence Group	01z(1)		Hal(2)		Overall
	N	n (%)	N	n (%)	
	(Total=1336)		(Total=660)		
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Lab Test: CALCIUM

LOW	1283	43 (3.4)	629	13 (2.1)	.117
HIGH	1290	6 (0.5)	634	4 (0.6)	.635

Lab Test: PHOSPHORUS

LOW	1267	46 (3.6)	619	10 (1.6)	.015
HIGH	1269	64 (5.0)	624	19 (3.0)	.046

Lab Test: SODIUM

LOW	1237	73 (5.9)	588	41 (7.0)	.377
HIGH	1294	7 (0.5)	629	2 (0.3)	.501

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLLIB(SSAFE6J)  
 RMP.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
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 FID-MC-HGAJ Acute Phase

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Oiz(1)		Hal(2)		p-Value *1	
(Total=1336)		(Total=660)			
Group	N n (%)	N n (%)	N n (%)	Overall	

Lab Test: POTASSIUM

LOW	1289	20	(1.6)	631	12	(1.9)	.573
HIGH	1287	14	(1.1)	633	9	(1.4)	.527

Lab Test: CHLORIDE

LOW	1268	30	(2.4)	617	21	(3.4)	.193
HIGH	1288	29	(2.3)	632	7	(1.1)	.082

Lab Test: TOTAL PROTEIN

LOW	1283	42	(3.3)	620	19	(3.1)	.808
HIGH	1269	17	(1.3)	619	10	(1.6)	.636

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLIB(SSAFE6J)  
 RMP.FIDP.SASMACRO(SSAFE6)

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 FID-MC-HGAJ Acute Phase

----- p-Value \*1 -----

Incidence Group	01z(1) N	(Total=1336) n (%)	Hal(2) N	(Total=660) n (%)	Overall
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Lab Test: ALBUMIN

✓ LOW	✓ 1275	80 (6.3)	✓ 624	15 (2.4)	.000 ✓
✓ HIGH	✓ 1291	2 (0.2)	✓ 625	7 (1.1)	.005 ✓

Lab Test: GLUCOSE, NON-FASTING

LOW	1251	96 (7.7)	611	38 (6.2)	.254
HIGH	1294	34 (2.6)	625	7 (1.1)	.031 ✓

Lab Test: URIC ACID

✓ LOW	✓ 1282	4 (0.3)	✓ 626	9 (1.4)	.005 ✓
HIGH	1285	24 (1.9)	627	9 (1.4)	.496

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 RMP.FIDP.JCLLIB(SSAFEE6J)  
 RMP.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
 Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.  
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 FID-MC-HGAJ Acute Phase

--- p-Value \*1 ---

Incidence Group	01z(1) (Total=1336)		Hal(2) (Total=660)		Overall
	N	n (%)	N	n (%)	

Lab Test: CHOLESTEROL

LOW	1291	20 (1.5)	622	10 (1.6)	.923
HIGH	1272	29 (2.3)	622	5 (0.8)	.023

Lab Test: BICARBONATE, HCO3

LOW	1117	216 (19.3)	542	68 (12.5)	.001
HIGH	1299	0	634	1 (0.2)	.152

Lab Test: BILIRUBIN, TOTAL

LOW	1295	16 (1.2)	632	6 (0.9)	.579
HIGH	1288	8 (0.6)	628	3 (0.5)	.697

Using Lilly Reference Ranges  
 Reporting SI Units  
 Patients with Baseline Abnormality are Excluded  
 R1P.FIDP.JCLLIB(SSAFE6J)  
 R1P.FIDP.SASMACRO(SSAFEE6)  
 \* Frequencies are analyzed using a Chi-Square test.  
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\*\*\*\*\* END OF REPORT \*\*\*\*\*