

Appendix 2: AIS Lesions from Datasets of HPV-013, and 015 (125126/-(b)(4)-, submitted 2/6/08)

AIS cases which occurred in Control subjects, combined datasets for studies HPV-013, and 015 (CBER generated)

AIS Cases in Control Subjects						
AN/Study/Age (Site)	Sero*	Pap baseline	PCR M0, 7	PCR other times	PCR Lesion	Visits with Dx (date, Location)
23000/011/20 (013)	Negative (6=9)	Negative	M0-Negative M7-Negative		+16 in all specimens	M12 4/19/04-cer bx 1 (x2) 4/19/04- cer bx 2 (x2) 6/17/04-def rx A, B, C, D
25426/011/19 (013)	Negative	LSIL	M0-Negative M7-Negative		+16	M19 12/13/04 – cer bx 2 (x2)
25347/011/21 (018)	Negative (6=10)	LSIL	M0-+45, 56, 58	M24 - +16, 18, 31, 56, 58 M30-cer bx 1 = 16, 18, 58	+16, 58	M30 9/21/05-cer bx 2 (x2)
30277/012/23 (011)	Negative	Negative	M0-Negative M7-Negative	M18-+16, 45 M24-+16, 45, 59	+16, 39 +16	M24 9/28/04-cer bx 1 11/1/04-def rx A
31022/012/19 (058)	Negative	ASC-US -	M0-Negative M7-+31	Vaccination 2 - +31	+16 +16	M30 5/31/05-cer bx 1 9/12/05 – def rx A & B
34059/012/19 (058)	Negative	Negative	M0-+56		+16	M12 6/3/04 – def rx C
48973/015/22 (012)	Negative	Negative	M0-+45	M12-+18, 51, 52, 58	+16, 18,,45, 52	M24 3/9/05-cer bx 2
40837/015/20 (019)	Negative (11=10)	Negative	M0-Negative M7-Negative	M24-+31, 59 M48-16, 31	+16	M48 9/13/06-def rx B
46595/015/20 (050)	Negative	Negative	M0-+18		+16, 18, 51, 52	Postvax 3 10/17/03-def rx D

*Serostatus cutoffs: 6=20; 11=16; 16=20; 18=24

AIS cases which occurred in Control subjects, combined datasets for studies HPV-013, and 015 (CBER generated) [CONT]

AIS in Control Subjects-013 and 015						
AN/Study/Age (Site)	Sero*	Pap baseline	PCR M0, 7	PCR other times	PCR Lesion	Visits with Dx (date, Location)
48211/015/22 (016)	<i>Negative</i>	<i>Negative</i>	<i>M0-+56 M7-+6, 16</i>		+16, 52, 6 +16, 52	M12 4/16/04-cer bx 1 4/16/04-cer bx 2
54856/015/18 (044)	<i>Negative (6=11)</i>	<i>ASC-US-</i>	<i>M0-Negative M7-+18</i>		+18	M12 11/19/04 – def rx B&D
43722/015/19 (018)	+18	Negative	M0-+18, 52 M7-+18	M36-+18	+18, 51	M48 10/12/06-def rx D
43950/015/17 (035)	Negative	Negative	M0-+16, 18, 51 M7-+16, 18		+16, 18	M12 6/22/04-cer bx 1
46432/015/21 (047)	+16, +18	AC-US+	M0-+11, 16, 33, 51, 52, 56 M7-+16		+16, 18, 33, 52, 56	M24 2/3/05-def rx A
46779/015/23 (076)	+16, 18	Negative	M0-+18, 45, 56 M7-+18	M12-+18 M24-+18, 33	+18	M24 6/13/05-ECC
48283/015 (012)	+16	HSIL	M0-+16, 45 Vax 1- +16	Vax 2 - +16 (other biopsies)	Negative	Vax 2 4/14/03-def rx B

Key

Bolded numbers: Subjects naïve through Month 7 (sero- and PCR negative at baseline, and PCR negative at Month 7 for relevant vaccine HPV type at baseline).

Italic numbers: Subjects naïve at baseline (sero- and PCR-negative for relevant vaccine HPV type)

Numbers highlighted in yellow: Lesions in subjects infected with relevant HPV type at baseline.

Numbers highlighted in teal: Lesions in subjects naïve (PCR negative) for relevant non-vaccine HPV type associated with lesion.

Numbers highlighted in green: Subjects with lesions negative for any of the 14 HPV types tested (regardless of baseline sero- and/or PCR status).

Source: From datasets labbx.xpt, labxpcr 1-13.xpt, labxpap 1-5.xpt, sero1-2.xpt, studies HPV-013, and 015.

AIS cases which occurred in Gardasil subjects, combined datasets for studies HPV-013, and 015 (CBER generated)

AIS Cases in Gardasil Subjects -013 and 015						
AN/Study/Age (Site)	Sero*	Pap baseline	PCR M0, 7	PCR other times	PCR Lesion	Visits with Dx (date, Location)
30585/012/18 (57)	+18	LSIL	M0+16, 18, 39, 52, 56 Vax 2- +16, 18, 39, 52 Postvax 3- +16, 18, 52		+16 +16, 52	Postvax 3 12/1/03-def rx B 12/1/03-def rx C
40025/015/21 (014)	+16	Negative	M0+16, 58 M7+16, 39, 52, 58 (bx)	M12+39 M24+52	+16	Postvax 3 5/5/03-cer bx 3
44957/015/21 (016)	+18	Negative	M0+18 M7+18	M48+18	+18	M12 1/14/04-cer bx 1
44947/015/20 (020)	+6, 16, 18	HSIL	M0+16, 18, 6, 31, 51 M7+6, 16, 18		+18	Postvax 3 8/26/03-def rx D
48349/015/23 (020)	+16	HSIL	M0+16		+16	Vax 2 6/26/03-def rx C
43250/015/20 (084)	+11 (18=17)	ASC-US+	M0+6, 18, 31, 33, 45 M7+31, 33	M12+18 M36+33	+18	M36 5/3/06-def rx B

Key

Bolded numbers: Subjects naïve through Month 7 (sero- and PCR negative at baseline, and PCR negative at Month 7 for relevant vaccine HPV type at baseline).

Italic numbers: Subjects naïve at baseline (sero- and PCR-negative for relevant vaccine HPV type)

Numbers highlighted in yellow: Lesions in subjects infected with relevant HPV type at baseline.

Numbers highlighted in teal: Lesions in subjects naïve (PCR negative) for relevant non-vaccine HPV type associated with lesion.

Numbers highlighted in green: Subjects with lesions negative for any of the 14 HPV types tested (regardless of baseline sero- and/or PCR status).

Source: From datasets labbx.xpt, labxpcr 1-13.xpt, labxpap 1-5.xpt, sero1-2.xpt, study HPV-007, 013, and 015.;

*Serostatus cutoffs: 6=20; 11=16; 16=20; 18=24