

APPENDIX 3 – TABLES OF CIN 2 AND CIN 3 CASES ASSOCIATED WITH NON-VACCINE HPV TYPES 31, 33, 35, 39, 45, 51, 52, 56, 58, AND 59 IN SUBJECTS NAÏVE (PCR NEGATIVE) FOR THE SPECIFIC NON-VACCINE HPV TYPE AT BASELINE.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 31 and P- at baseline for relevant HPV types (Close-out of Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV <i>31</i>	15	32 (8 also naïve for Vax HPV)	HPV <i>31</i> Total	8	21 (5 also naïve for Vax HPV)
<i>31</i> alone	7	14	<i>31</i> alone	7	7
<i>31, 6</i>	0	1	<i>31, 6, 16, 39</i>	0	1
<i>31, 6, 33, 35</i>	0	1	<i>31, 16</i>	0	1
<i>31, 16</i>	1	2 (2 naïve 16)	<i>31, 16, 18, 56, 58</i>	0	1
<i>31, 16, 18</i>	0	1	<i>31, 16, 33, 45, 58</i>	0	1
<i>31, 16, 33, 58</i>	0	1	<i>31, 18, 51</i>	0	1
<i>31, 16, 39, 51</i>	0	1	<i>31, 35</i>	0	1
<i>31, 16, 51, 52</i>	0	2 (1 naïve 16)	<i>31, 45, 51</i>	0	1
<i>31, 16, 56, 58, 59</i>	0	1	<i>31, 51, 58</i>	1	0
<i>31, 18, 45</i>	0	1	<i>31, 51, 59</i>	0	1
<i>31, 18, 51, 58</i>	0	1	<i>31, 52</i>	0	3
<i>31, 33</i>	2	0	<i>31;52</i>	0	1
<i>31, 35</i>	0	1	<i>31, 56</i>	0	1
<i>31, 39</i>	0	1	<i>31, 59</i>	0	1
<i>31, 51</i>	0	1			
<i>31, 51, 52</i>	0	1			
<i>31, 51, 58</i>	1	0			
<i>31, 52</i>	1	1			
<i>31, 52, 56</i>	1	0			
<i>31, 52, 58</i>	0	1			
<i>31, 52, 59</i>	1	0			
<i>31, 56, 58</i>	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

**CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 33 and P- at baseline
for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)**

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 33 Total	18	19 (8 also naïve for Vax HPV)	HPV 33 Total	15	14 (2 also naïve for Vax HPV)
<i>33 alone</i>	8	5	<i>33 alone</i>	6	6
<i>33, 6</i>	0	1	<i>33, 16</i>	0	1
<i>33, 6, 16</i>	0	1	<i>33, 16, 31, 45, 58</i>	0	1
<i>33, 6, 31, 35</i>	0	1	<i>33, 16, 39, 51, 52</i>	0	1
<i>33, 16</i>	0	2	<i>33, 18, 56</i>	0	1
<i>33, 16, 18</i>	0	2	<i>33, 35</i>	0	1
<i>33, 16, 39</i>	1	0	<i>33, 39</i>	1	1
<i>33, 16, 31, 58</i>	0	1	<i>33, 39, 45, 52</i>	0	1
<i>33, 16, 51, 56</i>	0	1	<i>33, 51, 52</i>	1	0
<i>33, 16, 52</i>	0	1	<i>33, [52], 56</i>	1	0
<i>33, 18</i>	0	1	<i>33, 56</i>	5	1
<i>33, 31</i>	2	0	<i>33, 58</i>	1	0
<i>33, 31, 51, 56</i>	1	0			
<i>33, 35</i>	1	0			
<i>33, 39</i>	0	1			
<i>33, 39, 59</i>	0	1			
<i>33, 51, 56</i>	1	0			
<i>33, 52</i>	1	0			
<i>33, 56</i>	2	0			
<i>33, 56, 58</i>	0	1			
<i>33, 59</i>	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types

Case may appear in more than one table for both CIN 2 and CIN 3 cases.

**CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 35 and P- at baseline
for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)**

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 35 Total	10	5 (1 also naïve for Vax HPV)	HPV 35 Total	4	11 (3 also naïve for Vax HPV)
<i>35 alone</i>	4	2	<i>35 alone</i>	2	6
<i>35, 6, 18, 45, 51, 52, 56</i>	0	1	<i>35, 16</i>	0	1
<i>35, 6, 31, 33</i>	0	1	<i>35, 16, 39</i>	0	1
<i>35, 16</i>	1	0	<i>35, 16, 51</i>	0	1
<i>35, 31</i>	0	1	<i>35, 31</i>	0	1
<i>35, 33</i>	1	0	<i>35, 31, 39, 52</i>	1	0
<i>35, 45</i>	1	0	<i>35, 33</i>	0	1
<i>35, 51</i>	2 (1 naïve 51)	0	<i>35, 39, 56</i>	1	0
<i>35, 52</i>	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

**CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 39 and P- at baseline
for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)**

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 39 Total	5	12 (1 also naïve for Vax HPV)	HPV 39 Total	9	14 (5 also naïve for Vax HPV)
<i>39 alone</i>	1	0	<i>39 alone</i>	4	3
<i>39, 6, 16, 58</i>	0	1	<i>39, 6</i>	0	1
<i>39, 16</i>	0	3	<i>39, 6, 16, 31</i>	0	1
<i>39, 16, 31, 51</i>	0	1	<i>39, 16</i>	0	1
<i>39, 16, 33</i>	1	0	<i>39, 16, 33, 51, 52</i>	0	1
<i>39, 16, 52, 58</i>	1	0	<i>39, 16, 35</i>	0	1
<i>39, 31</i>	0	1	<i>39, 18, 52</i>	0	1
<i>39, 31, 52</i>	0	1	<i>39, 33</i>	1	1
<i>39, 33</i>	0	1	<i>39, 33, 45, 52</i>	0	1
<i>39, 33, 45, 52</i>	0	1	<i>39, 35, 56</i>	1	0
<i>39, 33, 59</i>	0	1	<i>39, 51, 52</i>	1	0
<i>39, 45</i>	1	0	<i>39, 52</i>	0	1
<i>39, 45, 52</i>	0	1	<i>39, 52, 56</i>	0	1
<i>39, 52</i>	0	1	<i>39, 56</i>	1	0
<i>39, 56</i>	1	0	<i>39, 58</i>	1	1

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

**CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 45 and P- at baseline
for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)**

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 45 Total	10	8 (4 also naïve for Vax HPV)	HPV 45 Total	2	5 (2 also naïve for Vax HPV)
<i>45 alone</i>	3	1	<i>45 alone</i>	1	0
<i>45, 16</i>	2	1 (naïve for 16)	<i>45, 16</i>	0	1
<i>45, 16, 18, 31</i>	0	1	<i>45, 16, 18, 51, 52</i>	0	1
<i>45, 16, 52</i>	1	1 (naïve for 16 and 52)	<i>45, 16, 31, 33, 58</i>	0	1
<i>45, 16, 58</i>	1	0	<i>45, 31, 51</i>	0	1
<i>45, 18, 31</i>	0	1	<i>45, 33, 39, 52</i>	0	1
<i>45, 33, 39, 52</i>	0	1	<i>45, 52, 56, 58</i>	1	0
<i>45, 35</i>	1	0			
<i>45, 39</i>	1	0			
<i>45, 51, 52</i>	0	1			
<i>45, 51, 56</i>	0	1			
<i>45, 56</i>	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

**CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 51 and P- at baseline
for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)**

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 51 Total	11	13 (3 also naïve for Vax HPV)	HPV 51 Total	18	25 (11 also naïve for Vax HPV)
<i>51</i> alone	4	2	<i>51</i> alone	6	5
<i>51, 6, 16</i>	0	1	<i>51, 6</i>	0	1
<i>51, 6, 18, 35, 45, 52, 56</i>	0	1	<i>51, 6, 56</i>	1	0
<i>51, 16</i>	1 (naïve for 16)	1	<i>51, 11</i>	0	1
<i>51, 16, 31</i>	0	1	<i>51, 16</i>	0	3
<i>51, 16, 31, 52</i>	0	2 (1 naïve for 16, 1 naïve for 52)	<i>51, 16</i>	0	1
<i>51, 16, 33, 56</i>	0	1	<i>51, 16, 18, 45, 52</i>	0	1
<i>51, 16, 56</i>	0	1	<i>51, 16, 33, 39, 52</i>	0	1
<i>51, 18, 31, 58</i>	0	1	<i>51, 16, 35</i>	0	1
<i>51, 31, 52</i>	0	1	<i>51, 16, 52, 58</i>	0	1
<i>51, 31, 58</i>	1	0	<i>51, 18, 31</i>	0	1
<i>51, 33</i>	1	0	<i>51, 18, 52</i>	0	1
<i>51, 33, 56</i>	1	0	<i>51, 18, 52, 58</i>	0	1
<i>51, 35</i>	1	0	<i>51, 31</i>	0	1
<i>51, 39, 56</i>	1	0	<i>51, 31, 45</i>	0	1
<i>51, 45, 56</i>	0	1	<i>51, 31, 52, 58</i>	1	0
<i>51, 58</i>	1	0	<i>51, 31, 59</i>	0	1
			<i>51, 33, 52</i>	1	0
			<i>51, 39, 52</i>	1	0
			<i>51, 52</i>	2	0
			<i>51, 52, 56, 58</i>	1	0
			<i>51, 52, 58</i>	0	2
			<i>51, [52], 59</i>	1	0
			<i>51, 56</i>	3	1
			<i>51, 56, 58</i>	0	1
			<i>51, 59</i>	1	0

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

**CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 52 and P- at baseline
for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)**

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 52 Total	18	26 (8 also naïve for Vax HPV)	HPV 52 Total	24	25 (6 also naïve for Vax HPV)
52 alone	7	6	52 alone	13	6
52, 16	1	5 (4 naïve for 16)	52, 6	0	1
52, <i>16, 18</i>	0	1	52, 6, 31	0	1
52, 16, <i>31, 51</i>	0	2	52, <i>16</i>	0	1
52, 16, 33	0	1	52, <i>16, 18, 45, 51</i>	0	1
52, 16, 39, 58	1	0	52, 16, 33, 39, 51	0	1
52, <i>16, 45</i>	0	1	52, <i>16, 51, 58</i>	0	1
52, 16, 56	0	3 (2 naïve for 16 and 2 naïve for 56)	52, 18, 51	0	1
52, 16, 58	0	1	52, 18, 51, 58	0	1
52, 31	1	1	52, 18, 56, 59	0	1
52, 31, 51	0	1	52, 31	0	3
52, 31, 56	1	0	52; 31	0	1
52, 31, 58	0	1	52, 31, 35, 39	1	0
52, 31, 59	1	0	52, 31, 51, 58	1	0
52, 33	1 (naïve for 33)	1	52, 33, 39, 45	0	1
52, 39	1	0	52, 33, 51	1	0
52, 45	0	1	<i>[52], 33, 56</i>	1	0
52, 51	1	1	52, 39	0	1
52, 51, 56	1	0	52, 39, 51	1	0
52, 58	1	0	52, 39, 56	0	1
52, 59	1	0	52, 45, 56, 58	1	0
			52, 51	2	0
			52, 51, 58	0	2
			<i>[52], 51, 59</i>	1	0
			52, 56	0	1
			52, 58	1	0
			52, 58, 59	1	0

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 56 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 56 Total	9	16 (7 also naïve for Vax HPV)	HPV 56 Total	21	16 (6 also naïve for Vax HPV)
<i>56</i> alone	1	1	<i>56</i> alone	8	1
<i>56, 6, 18, 35, 45, 51</i>	0	1	<i>56, 16</i>	0	2
<i>56, 11, 16</i>	0	1	<i>56, 16, 31, 58</i>	0	1
<i>56, 11, 16, 18, 51, 58</i>	0	1	<i>56, 18</i>	0	2
<i>56, 16</i>	2	1 (naïve for 16)	<i>56, 18, 33</i>	0	1
<i>56, 16, 18</i>	0	1	<i>56, 18, 52, 59</i>	0	1
<i>56, 16, 31, 58, 59</i>	0	1	<i>56, 31</i>	0	1
<i>56, 16, 33, 51</i>	0	1	<i>56, 33</i>	5	1
<i>56, 16, 35</i>	0	1	<i>56, 33, [52]</i>	1	0
<i>56, 16, 51</i>	0	1	<i>56, 35, 39</i>	1	0
<i>56, 16, 52</i>	0	2	<i>56, 39</i>	1	0
<i>56, 31, 33, 51</i>	1	0	<i>56, 39, 52</i>	0	1
<i>56, 31, 58</i>	1	0	<i>56, 51</i>	3	1
<i>56, 33</i>	1	0	<i>56, 51, 52, 58</i>	1	0
<i>56, 33, 58</i>	0	1	<i>56, 51, 58</i>	0	1
<i>56, 45</i>	1	0	<i>56, 52</i>	0	1
<i>56, 45, 51</i>	0	1	<i>56, 58</i>	1	1
<i>56, 51, 33</i>	1	0	<i>56, 59</i>	0	1
<i>56, 51, 39</i>	1	0			
<i>56, 58</i>	0	2			

18 above indicates serology below cutoff but not undetectable

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types

Case may appear in more than one table for both CIN 2 and CIN 3 cases.

**CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 58 and P- at baseline
for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)**

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 58 Total	8	16 (5 also naïve for Vax HPV)	HPV 58 Total	12	17 (6 also naïve for Vax HPV)
58 alone	4	4	58 alone	6	6
58, 6	0	1	58, 6	0	1
58, <i>11</i> , 16, <u>18</u> , 51, 56	0	1	58, 16, 31, 33, 45	0	1
58, 16	0	1	58, 16, 18, 31, 56	0	1
58, 16, 31, 33	0	1	58, 16, 51, 52	0	1
58, 16, 31, 56, 59	0	1	58, 18, 51, 52	0	1
58, 16, 56	0	1	58, 31	0	1
58, 18, 31, 51	0	1	58, 33	1	0
58, 31, 51	1	0	58, 39	1	1
58, 31, 52	0	1	58, 51, 52	0	2
58, 31, 56	1	0	58, 51, 52, 56	1	0
58, 33, 56	0	1	58, 51, 56	0	1
58, 51	1	0	58, 52	1	0
58, 52	1	0	58, 52, 59	1	0
58, 56	0	2	58, 56	1	1
58, 59	0	1			

18 above indicates serology below cutoff but not undetectable

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types

Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 Cases and CIN 2 Cases associated with Non-Vaccine HPV type 59 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV 59 Total	6	6 (3 also naïve for Vax HPV)	HPV 59 Total	3	7 (3 also naïve for Vax HPV)
<i>59 alone</i>	2	0	<i>59 alone</i>	0	1
<i>59, 16</i>	0	3 (2 naïve for 16)	<i>59, 16</i>	0	1
<i>59, 16, 31, 56, 58</i>	0	1	<i>59, 18</i>	0	1
<i>59, 31</i>	1	0	<i>59, 18, 52, 56</i>	0	1
<i>59, 31, 52</i>	1	0	<i>59, 31</i>	1	1
<i>59, 33</i>	1	0	<i>59, 31, 51</i>	0	1
<i>59, 33, 39</i>	0	1	<i>59, 51</i>	1	0
<i>59, 52</i>	1	0	<i>59, 51, [52]</i>	1	0
<i>59, 58</i>	0	1	<i>59, 56</i>	0	1
			<i>59, 52, 58</i>	1	0

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.