

ATTACHMENT 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE -- FOOD AND DRUG ADMINISTRATION GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE		FORM APPROVED: OMB NO. 0910-0138 EXPIRATION DATE: January 31, 2003 (See OMB Statement on Page 2)
PANEL MEMBER / PETITIONER HiFi DNA Tech, LLC (Petitioner)		DATE 3/7/07
GENERIC TYPE OF DEVICE Human Papillomavirus DNA Polymerase Chain Reaction Detection		CLASSIFICATION RECOMMENDATION Class II
1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	If "Yes," go to Item 6. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH <u>SPECIAL CONTROLS</u> IN ADDITION TO <u>GENERAL CONTROLS</u> TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	If "Yes," Classify in Class II and go to Item 7. If "No," Classify in Class III.
7. IF THERE IS SUFFICIENT INFORMATION TO ESTABLISH <u>SPECIAL CONTROLS</u> TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II.		
<input checked="" type="checkbox"/> Guidance Document <input checked="" type="checkbox"/> Performance Standard(s) <input checked="" type="checkbox"/> Device Tracking <input checked="" type="checkbox"/> Testing Guidelines <input checked="" type="checkbox"/> Other (Specify) See Special Controls under 21CFR§860.123(a)(6) in Reclassification Petition for Human Papillomavirus DNA Nested Polymerase Chain Reaction Detection (formerly K063649)		
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY ANDEFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD.		
<input type="checkbox"/> Low Priority _____ <input type="checkbox"/> Medium Priority _____ <input type="checkbox"/> High Priority _____ <input checked="" type="checkbox"/> Not Applicable _____		
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD HE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN LACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NOT Applicable	
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS.		
<input type="checkbox"/> Low Priority _____ <input type="checkbox"/> Medium Priority _____ <input type="checkbox"/> High Priority _____ <input checked="" type="checkbox"/> Not Applicable _____		

11. IDENTIFY THE NEEDED RESTRICTION(S)

- Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device
- Use only by persons with specific training or experience in its use
- Use only in certain facilities
- Other (*Specify*) For professional use within the confines of a licensed high-complexity laboratory, as defined by the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration, (HFZ-215)
2094 Gaither Road
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

INSTRUCTIONS FOR GENERAL DEVICE QUESTIONNAIRE

1. Answer each question by checking yes or no in the middle column and follow the instructions in the column on the right. The preparer should refer to Title 21 Part 860 of the Code of Federal Regulations for classification/reclassification definitions and procedures.
2. The General Device questionnaire is designed to aid in the determination of the proper class for all medical devices.
3. A medical device should be placed in the lowest class which will provide adequate controls to reasonably assure the safety and effectiveness of the device.
4. Questions 1, 2, and 3 pertain to the degree of risk of the device and can be answered broadly.
5. Questions 8 & 9 are not applicable unless a regulatory standard, subject to section 514 of the Food, Drug, and Cosmetic Act, as amended, 1976, has been designated as a "special control."
6. Question 10 is applicable only to devices recommended for class III.
7. Question 11 refers to restriction such as prescription use or similar limitations as to the use of the device.
8. Use this completed questionnaire to prepare the Supplemental Data Sheet. Send both forms to the address indicated in question 12.

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Attachment 3:

Volume A:

**513 Clinical Specimens Tested for HPV
by Nested PCR/DNA Sequencing and by
Digene HC2 Assay**

PCR - positive = 107 cases

HC2 - positive = 75 cases

Case #	Patient name Number	PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
					Hi	Low			
1	1132		NEG				neg		Pos
2	1133		NEG				neg		Pos
3	1134		NEG				neg		Pos
4	1135		NEG				neg		Pos
5	1136		NEG				neg		Pos
6	1137		NEG				neg		Pos
7	1138		NEG				neg		Pos
8	1139		NEG				neg		Pos
9	1140		NEG				neg		Pos
10	1141		NEG					unsatisfactory	Pos
11	1142		NEG				neg		Pos
12	1143	HPV 31					neg		Pos
13	1144	HPV 45			High risk				Pos
14	1145		NEG				neg		Pos
15	1146		NEG				neg		Pos
16	1147	HPV 56			High risk				Pos
17	1148		NEG				neg		Pos
18	1149		NEG				neg		Pos
19	1150		NEG				neg		Pos
20	1151		NEG				neg		Pos
21	1152		NEG				neg		Pos
22	1153		NEG				neg		Pos
23	1154		NEG				neg		Pos
24	1157		NEG				neg		Pos
25	1158		NEG				neg		Pos
26	1159		NEG				neg		Pos
27	1160		NEG				neg		Pos
28	1161		NEG					unsatisfactory	Pos
29	1162		NEG				neg		Pos
30	1163		NEG				neg		Pos
31	1164		NEG				neg		Pos
32	1165		NEG				neg		Pos
33	1166		NEG				neg		Pos
34	1167	HPV 16			High risk				Pos
35	1168		NEG				neg		Pos
36	1169		NEG					unsatisfactory	Pos

Case #	Patient name Number	PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
					Hi	Low			
37	1170		NEG						Pos
38	1173		NEG				neg		Pos
39	1180		NEG				neg		Pos
40	1183		NEG				neg		Pos
41	1184		NEG					unsatisfactory	Pos
42	1194		NEG				neg		Pos
43	1195		NEG				neg		Pos
44	1196		NEG				neg		Pos
45	1197		NEG				neg		Pos
46	1198		NEG				neg		Pos
47	1199		NEG				neg		Pos
48	1200	HPV 16					neg		Pos
49	1201		NEG				neg		Pos
50	1202		NEG				neg		Pos
51	1204	HPV 45					neg		Pos
52	1205		NEG				neg		Pos
53	1243		NEG				neg		Pos
54	1247		NEG				neg		Pos
55	1248		NEG				neg		Pos
56	1249		NEG				neg		Pos
57	1250		NEG				neg		Pos
58	1251		NEG				neg		Pos
59	1252		NEG				neg		Pos
60	1253		NEG				neg		Pos
61	1254		NEG						Pos
62	1246		NEG					unsatisfactory	Pos
63	1245		NEG				neg		Pos
64	1244		NEG				neg		Pos
65	1242		NEG				neg		Pos
66	1241		NEG				neg		Pos
67	1232		NEG					unsatisfactory	Pos
68	1231		NEG					unsatisfactory	Pos
69	1284		NEG				neg		Pos
70	1283		NEG				neg		Pos
71	1281		NEG				neg		Pos
72	1282		NEG				neg		Pos

Case #	Patient name Number	PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
					Hi	Low			
73	1280		NEG					unsatisfactory	Pos
74	1279		NEG				neg		Pos
75	1278		NEG				neg		Pos
76	1277		NEG				neg		Pos
77	1276		NEG				neg		Pos
78	1275	HPV 16					neg		Pos
79	1274	HPV 59			High risk				Pos
80	1273		NEG					unsatisfactory	Pos
81	1272		NEG				neg		Pos
82	1271		NEG				neg		Pos
83	1268		NEG				neg		Pos
84	1267	HPV 56			High risk				Pos
85	1266	HPV 66			High risk				Pos
86	1265		NEG				neg		Pos
87	1264		NEG				neg		Pos
88	1263		NEG				neg		Pos
89	1289		NEG		High risk				Pos
90	1290		NEG					unsatisfactory	Pos
91	1291		NEG				neg		Pos
92	1292		NEG				neg		Pos
93	1293	HPV 16					neg		Pos
94	1294		NEG				neg		Pos
95	1295		NEG				neg		Pos
96	1296	HPV 6B					neg		Pos
97	1297		NEG				neg		Pos
98	1298		NEG				neg		Pos
99	1299		NEG				neg		Pos
100	1300		NEG				neg		Pos
101	1301		NEG				neg		Pos
102	1302		NEG					unsatisfactory	Pos
103	1303		NEG					unsatisfactory	Pos
104	1304		NEG				neg		Pos
105	1305		NEG				neg		Pos
106	1306		NEG				neg		Pos
107	1307		NEG				neg		Pos
108	1308	HPV 18			High risk				Pos

Case #	Patient name		PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number					Hi	Low			
109	1309			NEG				neg		Pos
110	1310			NEG				neg		Pos
111	1311		HPV 59			High risk				Pos
112	1312			NEG				neg		Pos
113	1314			NEG					unsatisfactory	Pos
114	1315			NEG				neg		Pos
115	1316			NEG				neg		Pos
116	1328			NEG				neg		Pos
117	1329			NEG				neg		Pos
118	1330			NEG			Low risk		unsatisfactory	Pos
119	1331			NEG				neg		Pos
120	1332			NEG				neg		Pos
121	1333			NEG				neg		Pos
122	1334			NEG					unsatisfactory	Pos
123	1335			NEG				neg		Pos
124	1336			NEG					unsatisfactory	Pos
125	1337			NEG				neg		Pos
126	1338			NEG				neg		Pos
127	1339			NEG				neg		Pos
128	1340			NEG				neg		Pos
129	1341		HPV 73					neg		Pos
130	1342			NEG				neg		Pos
131	1343			NEG				neg		Pos
132	1344			NEG				neg		Pos
133	1345			NEG				neg		Pos
134	1346			NEG				neg		Pos
135	1347			NEG				neg		Pos
136	1348			NEG				neg		Pos
137	1349			NEG					unsatisfactory	Pos
138	1350			NEG					unsatisfactory	Pos
139	1351			NEG					unsatisfactory	Pos
140	1352			NEG				neg		Pos
141	1353			NEG				neg		Pos
142	1354			NEG				neg		Pos
143	1355			NEG				neg		Pos
144	1356		HPV 16			High risk				Pos

Case #	Patient name		PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number					Hi	Low			
145	1357		HPV 16					neg		Pos
146	1358			NEG				neg		Pos
147	1359			NEG				neg		Pos
148	1360			NEG					unsatisfactory	Pos
149	1411			NEG				neg		Pos
150	1412		HPV 56			High risk				Pos
151	1413			NEG					unsatisfactory	Pos
152	1414			NEG				neg		Pos
153	1415			NEG				neg		Pos
154	1416			NEG					unsatisfactory	Pos
155	1417		HPV 18			High risk				Pos
156	1418			NEG				neg		Pos
157	1419			NEG				neg		Pos
158	1420			NEG				neg		Pos
159	1426			NEG					unsatisfactory	Pos
160	1427			NEG				neg		Pos
161	1428			NEG				neg		Pos
162	1429			NEG				neg		Pos
163	1430			NEG				neg		Pos
164	1431			NEG				neg		Pos
165	1432			NEG				neg		Pos
166	1433			NEG				neg		Pos
167	1434			NEG				neg		Pos
168	1435			NEG				neg		Pos
169	1436			NEG				neg		Pos
170	1437			NEG				neg		Pos
171	1440			NEG				neg		Pos
172	1450		HPV 16						unsatisfactory	Pos
173	1451			NEG				neg		Pos
174	1452			NEG					unsatisfactory	Pos
175	1453			NEG					unsatisfactory	Pos
176	1454			NEG				neg		Pos
177	1455		HPV 16			High risk				Pos
178	1456			NEG				neg		Pos
179	1457			NEG				neg		Pos
180	1459			NEG				neg		Pos

Case #	Patient name		PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number					Hi	Low			
181	1460		NEG					neg		Pos
182	1461		NEG					neg		Pos
183	1462		NEG					neg		Pos
184	1465		NEG					neg		Pos
185	1466		NEG					neg		Pos
186	1467		NEG					neg		Pos
187	1468		HPV 16					neg		Pos
188	1469		HPV 35			High risk				Pos
189	1525		NEG						unsatisfactory	Pos
190	1526		NEG					neg		Pos
191	1528		NEG					neg		Pos
192	1529		NEG					neg		Pos
193	1530		NEG					neg		Pos
194	1531		NEG					neg		Pos
195	1532		NEG					neg		Pos
196	1533		NEG					neg		Pos
197	1534		NEG					neg		Pos
198	1535		NEG					neg		Pos
199	1536		NEG						unsatisfactory	Pos
200	1537		NEG					neg		Pos
201	1538		NEG					neg		Pos
202	1539		NEG					neg		Pos
203	1540		HPV 83					neg		Pos
204	1541		NEG					neg		Pos
205	1542		NEG						unsatisfactory	Pos
206	1543		NEG					neg		Pos
207	1544		NEG					neg		Pos
208	1545		NEG						unsatisfactory	Pos
209	1546		NEG						unsatisfactory	Pos
210	1547		HPV 18			Hgh risk				Pos
211	1548		NEG					neg		Pos
212	1549		NEG					neg		Pos
213	1550		NEG					neg		Pos
214	1558		NEG					neg		Pos
215	1561		NEG					neg		Pos
216	1562		NEG					neg		Pos

Case #	Patient name		PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number					Hi	Low			
217	1563		NEG						unsatisfactory	Pos
218	1564		NEG					neg		Pos
219	1571		NEG				Low risk			Pos
220	1573		NEG					neg		Pos
221	1574		NEG					neg		Pos
222	1577		NEG					neg		Pos
223	1579		NEG					neg		Pos
224	1580		NEG					neg		Pos
225	1581		NEG					neg		Pos
226	1585		HPV 52					neg		Pos
227	1587		NEG					neg		Pos
228	1588		NEG					neg		Pos
229	1606		NEG					neg		Pos
230	1609		NEG					neg		Pos
231	1610		NEG					neg		Pos
232	1673		HPV 66			High risk				Pos
233	1678		NEG						unsatisfactory	Pos
234	1679		NEG						unsatisfactory	Pos
235	1680		NEG					neg		Pos
236	1681		NEG					neg		Pos
237	1683		NEG					neg		Pos
238	1684		NEG					neg		Pos
239	1685		NEG					neg		Pos
240	1687		NEG					neg		Pos
241	1688		HPV 6B					neg		Pos
242	1689		NEG					neg		Pos
243	1690		HPV 39			High risk				Pos
244	1691		NEG					neg		Pos
245	1692		NEG					neg		Pos
246	1693		NEG					neg		Pos
247	1697		NEG					neg		Pos
248	1698		NEG					neg		Pos
249	1699		HPV 54					neg		Pos
250	1700		NEG					neg		Pos
251	1702		NEG					neg		Pos
252	CH06-3839	(PLS)	NEG					neg		Pos

Case #	Patient name	PCR +	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number	Type or Mixed	Hi		Low				
253	CH06-3855	HPV 56			High risk				Pos
254	CH06-3860	HPV 31			High risk				Pos
255	CH06-3873	HPV 56			High risk				Pos
256	CH06-3900	HPV 33			High risk				Pos
257	CH06-3901		NEG				neg		Pos
258	CH06-3902		NEG				neg		Pos
259	CH06-3906	HPV 66			high risk				Pos
260	CH06-3929		NEG				neg		Pos
261	CH06-3921		NEG				neg		Pos
262	CH06-3932		NEG				neg		Pos
263	CH06-3965		NEG				neg		Pos
264	CH06-3972		NEG				neg		Pos
265	CH06-4009		NEG				neg		Pos
266	CH06-4035		NEG				neg		Pos
267	CH06-4036		NEG				neg		Pos
268	CH06-4037		NEG				neg		Pos
269	CH06-4039		NEG				neg		Pos
270	CH06-4068		NEG				neg		Pos
271	CH06-4069	HPV 16					neg		Pos
272	CH06-4070		NEG				neg		Pos
273	CH06-4071	HPV 58			high risk				Pos
274	CH06-4072		NEG				neg		Pos
275	CH06-4105	HPV 66			high risk				Pos
276	CH06-4116		NEG				neg		Pos
277	CH06-4155		NEG				neg		Pos
278	CH06-4157	HPV 6					neg		Pos
279	CH06-3801	HPV 40					neg		Pos
280	CH06-3981		NEG				neg		Pos
281	CM06- 40357	HPV 32					neg		Pos
282	CM06-40596		NEG				neg		Pos
283	CM06-41111		NEG				neg		Pos
284	CM06-41122		NEG				neg		Pos
285	CM06-41244	HPV 83			high risk				Pos
286	CM06-41246		NEG				neg		Pos
287	CM06-41298		NEG				neg		Pos
288	CM06-42295		NEG				neg		Pos

Case #	Patient name Number	PCR + Type or Mixed	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
					Hi	Low			
289	CM06-42428		NEG				neg		Pos
290	CM06-42499	HPV 66			high risk				Pos
291	CM06-43471		NEG				neg		Pos
292	CM06-44146		NEG				neg		Pos
293	CM06-44148		NEG				neg		Pos
294	CM06-44150		NEG				neg		Pos
295	G06- 6050		NEG				neg		Pos
296	G06- 6099		NEG				neg		Pos
297	MS06-12976	HPV 16			high risk				Pos
299	MS06-13073	HPV 18			high risk				Pos
300	MS06-13180	HPV 16					neg		Pos
301	MS06-13181	HPV 16 & 18			high risk				Pos
302	MS06-13361		NEG		high risk				Pos
303	MS06-13367	HPV 58			high risk				Pos
304	NH06- 1749		NEG				neg		Pos
305	NH06-1776	HPV 16 (mixed)			high risk				Pos
306	NH06-1811		NEG				neg		Pos
307	NH06-1823	HPV 6					neg		Pos
308	NH06-1826	HPV 16			high risk				Pos
309	SM06- 4615		NEG				neg		Pos
310	SM06-4620	HPV 40					neg		Pos
311	SM06-4706		NEG		high risk				Pos
312	SM06-4707	HPV 16					neg		Pos
313	SM06-4710		NEG				neg		Pos
314	SM06-4787		NEG				neg		Pos
315	SM06-4789		NEG				neg		Pos
316	SM06-4790		NEG				neg		Pos
317	SM06-4791		NEG				neg		Pos
317	SM06-4822		NEG				neg		Pos
319	SM06-4827		NEG				neg		Pos
320	SM06-4848		NEG				neg		Pos
321	SM06-4853		NEG				neg		Pos
322	SM06-4893		NEG				neg		Pos
323	SM06-4896	HPV 16			high risk				Pos
324	SM06-4899		NEG				neg		Pos
325	SM06-4910		NEG				neg		Pos

Case #	Patient name	PCR +	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number	Type or Mixed	Hi		Low				
326	SM06-4920	HPV 16			high risk				Pos
327	SM06-4930	HPV 16					neg		Pos
328	SM06-4950		NEG				neg		Pos
329	SM06-4951		NEG				neg		Pos
330	SM06-4958		NEG		high risk				Pos
331	SM06-4968		NEG				neg		Pos
332	SM06-4971		NEG				neg		Pos
333	SM06-4972		NEG				neg		Pos
334	SM06-4976		NEG				neg		Pos
335	SM06-4978	HPV 53			high risk				Pos
336	SM06-5002		NEG				neg		Pos
337	SM06-5010	HPV mixed (not 6,11,16,18)			high risk				Pos
338	SM06-5013		NEG				neg		Pos
339	SM06-8670		NEG				neg		Pos
340	SM06-8730		NEG				neg		Pos
341	SM06-8761		NEG				neg		Pos
342	VIN06- 8785		NEG				neg		Pos
343	VIN06-8802		NEG				neg		Pos
344	VIN06-8844		NEG				neg		Pos
345	VIN06-8906		NEG				neg		Pos
346	VIN06-8917	HPV 54					neg		Pos
347	VIN06-9040		NEG				neg		Pos
348	VIN06-9046		NEG				neg		Pos
349	VIN06-9048		NEG				neg		Pos
350	VIN06-9143		NEG				neg		Pos
351	VIN06-9167		NEG				neg		Pos
352	VIN06-9302	HPV 59			high risk				Pos
353	CM06-4016 (PLS)	HPV 31							Pos
354-1	VIN06-9248	HPV 68			high risk				Pos
355-2	VIN06-9251		NEG				neg		Pos
356-3	VIN06-9329		NEG				neg		Pos
357-4	VIN06-9330	HPV 16					neg		Pos
358-5	VIN06-9332	HPV 56			high risk				Pos
359-6	VIN06-9337		NEG		high risk				Pos
360-7	VIN06-9342	mixed(not 6,11,16,18)					neg		Pos
361-8	VIN06-9350		NEG				neg		Pos

Case #	Patient name	PCR +	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number	Type or Mixed			Hi	Low			
362-9	VIN06-9355		NEG				neg		Pos
363-10	VIN06-9393		NEG				neg		Pos
364-11	VIN06-9454		NEG				neg		Pos
365-12	VIN06-9456	HPV 16			high risk				Pos
366-13	VIN06-9477		NEG				neg		Pos
367-14	VIN06-9513	HPV 16			high risk				Pos
368-15	VIN06-9534		NEG				neg		Pos
369-16	VIN06-9543	HPV 54			high risk				Pos
370-17	VIN06-9652		NEG				neg		Pos
371-18	VIN06-9653	HPV 62					neg		Pos
372-19	SM06-5369		NEG				neg		Pos
373-20	SM06-5370	HPV 6			high risk				Pos
374-21	SM06-5371	HPV 59			high risk				Pos
375-22	SM06-5372	HPV 58					neg		Pos
376-23	WU06-249		NEG				neg		Pos
377-24	CY06-7920	HPV 39							Pos
378-25	CH06-4178	HPV 16					neg		Pos
379-26	CH06-4122	HPV 16					neg		Pos
380-27	CH06-4185		NEG				neg		Pos
381-28	CH06-4187		NEG				neg		Pos
382-29	CH06-4189	HPV 56			high risk				Pos
383-30	CH06-4196		NEG				neg		Pos
384-31	CH06-4200	HPV 83			high risk				Pos
385-32	CH06-4205		NEG				neg		Pos
386-33	CH06-4206	HPV 16					neg		Pos
387-34	CH06-4209		NEG				neg		Pos
388-35	CH06-4211		NEG				neg		Pos
389-36	CH06-4223	HPV 16					neg		Pos
390-37	CH06-4226		NEG				neg		Pos
391-38	CH06-4247	HPV 16					neg		Pos
392-39	CH06-4248		NEG		high risk				Pos
393-40	CH06-4249		NEG				neg		Pos
394-41	CH06-4263		NEG				neg		Pos
395-42	VIN06-9395		NEG				neg		Pos
396-43	CH06-4265		NEG				neg		Pos
397-44	CH06-4300		NEG				neg		Pos

Case #	Patient name	PCR +	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number	Type or Mixed			Hi	Low			
398-45	CH06-4301		NEG				neg		Pos
399-46	CH06-4318		NEG				neg		Pos
400-47	CH06-4319		NEG				neg		Pos
401-48	CH06-4333		NEG				neg		Pos
402-49	CH06-4335	HPV 16			high risk				Pos
403-50	CH06-4336		NEG				neg		Pos
404-51	CH06-4343		NEG				neg		Pos
405-52	CH06-4394		NEG				neg		Pos
406-53	CM06-44151	HPV 52			high risk				Pos
407-54	CM06-44875		NEG				neg		Pos
408-55	CH06-9300		NEG				neg		Pos
409-56	CM06-45502		NEG				neg		Pos
410-57	CM06-45503	HPV 54					neg		Pos
411-58	CM06-45966		NEG				neg		Pos
412-59	G06-6696		NEG				neg		Pos
413-60	MS06-13529		NEG				neg		Pos
414-61	MS06-13534	HPV 35					neg		Pos
415-62	MS06-13867	HPV 6			high risk				Pos
416-63	MS06-14045		NEG				neg		Pos
417-64	NH06-1865	HPV 58			high risk				Pos
418-65	NH06-1903	HPV 56			high risk				Pos
419-66	NH06-1915		NEG				neg		Pos
420-67	NH06-1940	HPV 32					neg		Pos
421-68	NH06-1941	HPV 58			high risk				Pos
422-69	NH06-1949		NEG				neg		Pos
423-70	SA06-882		NEG				neg		Pos
424-71	SA06-883		NEG				neg		Pos
425-72	VIN06-9075	HPV 54			high risk				Pos
426-73	VIN06-9222		NEG				neg		Pos
427-74	SM06-5095	HPV 31			high risk				Pos
428-75	SM06-5112		NEG				neg		Pos
429-76	SM06-5150		NEG				neg		Pos
430-77	SM06-5151		NEG				neg		Pos
431-78	SM06-5154		NEG				neg		Pos
432-79	SM06-5176		NEG				neg		Pos
433-80	SM06-5187		NEG				neg		Pos

Case #	Patient name	PCR +	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number	Type or Mixed			Hi	Low			
434-81	SM06-5211		NEG				neg		Pos
435-82	SM06-5217		NEG				neg		Pos
436-83	SM06-5242		NEG				neg		Pos
437-84	SM06-5247		NEG				neg		Pos
438-85	SM06-5248		NEG				neg		Pos
439-86	SM06-5249	HPV 66			high risk				Pos
440-87	SM06-5268	HPV45			high risk				Pos
441-88	SM06-5277	HPV 31			high risk				Pos
442-89	SM06-5280		NEG				neg		Pos
443-90	SM06-5281		NEG				neg		Pos
444-91	SM06-5282		NEG				neg		Pos
445-92	SM06-5284		NEG				neg		Pos
446-93	SM06-5285		NEG				neg		Pos
447-94	SM06-5286	HPV 18			high risk				Pos
448-95	SM06-5287		NEG				neg		Pos
449-96	SM06-5289	HPV 18			high risk				Pos
450-97	SM06-5336	mixed(not 6,11,16,18)					neg		Pos
451-98	SM06-5344		NEG				neg		Pos
452-99	SM06-5346	HPV 31			high risk				Pos
453-100	SM06-5349		NEG				neg		Pos
454-101	SM06-5350		NEG				neg		Pos
455-102	SM06-5352	HPV 16			high risk				Pos
456-103	SM06-5373		NEG				neg		Pos
457-104	SM06-5390	HPV 58			high risk				Pos
458-105	VIN06-9187		NEG				neg		Pos
459-106	1892		NEG				neg		Pos
460-107	1893		NEG				neg		Pos
461-108	1899		NEG		High risk				Pos
462-109	1900		NEG				neg		Pos
463-110	1901		NEG				neg		Pos
464-111	1902		NEG				neg		Pos
465-112	1903		NEG					unsatisfactory	Pos
466-113	1904		NEG				neg		Pos
467-114	1905		NEG				neg		Pos
468-115	1906		NEG		High risk				Pos
469-116	1911		NEG				neg		Pos

Case #	Patient name		PCR +	PCR -	Unsatisfactory	Digene+		Digene -	Unsatisfactory	Beta
	Number		Type or Mixed			Hi	Low			
470-117	1912			NEG				neg		Pos
471-118	1914		HPV 56			High risk				Pos
472-119	1915			NEG				neg		Pos
473-120	1916		HPV 70				Low risk			Pos
474-121	1917			NEG				neg		Pos
475-122	1918		HPV 31			High risk				Pos
476-123	1925			NEG				neg		Pos
477-124	1926			NEG				neg		Pos
478-125	1928		HPV 72					neg		Pos
479-126	1932		HPV 54			High risk				Pos
480-127	1946			NEG				neg		Pos
481-128	1938			NEG				neg		Pos
482-129	1940			NEG				neg		Pos
483-130	1942			NEG				neg		Pos
484-131	1943			NEG				neg		Pos
485-132	1956			NEG				neg		Pos
486-133	1957			NEG				neg		Pos
487-134	1958			NEG				neg		Pos
488-135	1959			NEG				neg		Pos
489-136	1960			NEG				neg		Pos
490-137	1961		HPV 16			High risk				Pos
491-138	1962		HPV 16					neg		Pos
492-139	1963			NEG				neg		Pos
493-140	1964			NEG				neg		Pos
494-145	1976			NEG				neg		Pos
495-146	1977			NEG				neg		Pos
496-147	1978			NEG				neg		Pos
497-148	1979			NEG				neg		Pos
498-149	1980			NEG				neg		Pos
499-150	1981			NEG				neg		Pos
500-151	1982				Unsatisfactory			neg		Unsat.
501-152	1983				Unsatisfactory			neg		Unsat.
502-153	1984			NEG				neg		Pos
503-154	1985			NEG				neg		Pos
504-155	1986			NEG				neg		Pos
505-156	1987			NEG		High risk				Pos

