K981485

NOV 29 1999

510(k) Summary

Digene GC-ID Test Hybrid Capture® II

INTENDED USE:

The Digene HCII GC-ID Test is a nucleic acid hybridization assay with signal amplification using microplate chemiluminescence for the qualitative detection of N. gonorrhoeae DNA in cervical specimens collected using the Digene Cervical Sampler™ (Digene cervical brush and Digene Specimen Transport Medium) and in cervical specimens collected using the Digene Swab Specimen Collection Kit ([Swab SCK] Dacron® swab and Digene Specimen Transport Medium). The Digene HCII GC-ID Test is indicated for use as an aid in diagnosing infection with N. gonorrhoeae in symptomatic or asymptomatic females.

The HCII GC-ID Test may be used alone or as a supplemental test to the Digene HCII CT/GC Test to detect *N. gonorrhoeae* in specimens that are positive by the HCII CT/GC Test.

DECRIPTION OF THE DEVICE:

The *Digene GC-ID Test* using *Hybrid Capture* II technology is a nucleic acid hybridization assay with signal amplification that utilizes microplate chemiluminescent detection. Specimens containing the target DNA hybridize with a specific GC RNA probe cocktail. The resultant RNA:DNA hybrids are captured onto the surface of a microplate well coated with antibodies specific for RNA:DNA hybrids. Immobilized hybrids are then reacted with alkaline phosphatase conjugated antibodies specific for RNA:DNA hybrids, and detected with a chemiluminescent substrate. Several alkaline phosphatase molecules are conjugated to each antibody. Multiple conjugated antibodies bind to each captured hybrid resulting in substantial signal amplification. As the substrate is cleaved by the bound alkaline phosphatase, light is emitted which is measured as relative light units (RLUs) on a luminometer. The intensity of the light emitted denotes the presence or absence of target DNA in the specimen.

An RLU measurement equal to or greater than the Cutoff Value indicates the presence of GC DNA in the specimen. An RLU measurement less than the Cutoff Value indicates the absence of GC DNA or GC DNA levels below the detection limit of the assay.

The GC Probe Cocktail contains a probe mixture specifically chosen to eliminate or minimize cross-reactivity with DNA sequences from human cells, other bacterial species, or Neisseria species other than *gonorrhoeae*. The GC Probe Cocktail supplied with the *Digene GC-ID Test* is complementary to approximately 9,700 bp or 0.5% of the *Neisseria gonorrhoeae* genomic DNA (1.9×10^6 bp)[8]. One probe is complementary to 100% of the cryptic plasmid of 4,200 bp.

SIMILARITIES AND DIFFERENCES TO PREDICATE DEVICE:

The Gen-Probe® Pace® 2 System for *Neisseria Gonorrhoeae* is the predicate device to which Digene claims the HCII GC-ID Test is substantially equivalent. The Gen-Probe Pace 2 test is a legally marketed device made available for commercial distribution in the United States as of April 26, 1994 after FDA cleared 510(k) premarket notification K920301. Both the Pace 2 test and the Digene Hybrid Capture® II GC-ID Test share the same intended use. Analytical and clinical data have been submitted to demonstrate that the Digene device is as safe and effective as the Gen-Probe® device.

NON-CLINICAL PERFORMANCE:

Precision

A precision study was performed at three sites to determine the within run and total precision of Digene's HCII GC-ID Test using a panel of positive and negative masked, simulated clinical specimens. In addition, the intra- and inter-instrument precision observed with the two luminometers recommended for use with the HCII GC-ID Test (Models DML2000 and MLX) was assessed using the same specimen panel. One of the three sites experienced difficulties with other Hybrid Capture II assays being performed as part of this study that were attributable to assay technique most likely caused by improper or inadequate training. Although, the HCII GC-ID Test precision testing results were unaffected, the technologist performing the testing was retrained in the proper assay technique.

Table 1 shows the performance of the Digene GC-ID Test for all sites combined (including the site that experienced technical problems prior to retraining the technologist in the proper assay technique). The assay demonstrated equivalent precision after technologist retraining, however, for panel member 3 (which contained low concentrations of GC organism), the RLU/CO values observed were within or near the assay's equivocal zone of 1.0-2.5. For the purposes of these data analyses, all of those RLU/CO values that fell within the equivocal zone or exceeded 2.5 were interpreted as positive. Although not evident from this table, the qualitative results were 100% (54/54) (93.4%-100% 95%CI) in agreement with expected results at the three sites.

Table 1 Within Instrument, Between Instrument, Within Run, Total Precision Estimates For RLU/CO By Test and Target

			Within Instrument		*Between Instrument*		*Within Run*		*Total*	
Panel Member	*N*	*Mean*	*(SD)*	*(%CV)*	*(SD)*	*(%CV)*	*(SD)*	*(%CV)*	*(SD)*	*(%CV)*
1	54	0.0974	0.0104	10.6818	0.0017	1.7328	0.0275	28.2556	0.0275	28.1978
2	54	0.0967	0.0111	11.5031	0.0015	1.5618	0.0338	34.9362	0.0342	35.4230
3	54	3.2335	0.1502	4.6462	0.0356	1.0997	0.3520	10.8869	0.3866	11.9551
4	54	3.8407	0.2078	5.4092	0.0525	1.3671	0.3401	8.8541	0.3487	9.0802
5	54	16.1676	1.0507	6.4986	0.1122	0.6940	2.1788	13.4766	2.1437	13.2589
6	54	18.0704	1.0539	5.8321	0.3456	1.9124	2.3701	13.1158	2.3316	12.9027

For panel member 3, which has a low concentrations of GC organism, the RLU/CO values observed were within or near the assay's equivocal zone of 1.0-2.5. For the purposes of these data analyses, all of those RLU/CO values that fell within the equivocal zone or exceeded 2.5 were interpreted as positive.

Analytical Sensitivity

The analytical sensitivity (limits of detection) of the Digene GC-ID Test was determined by directly comparing a dilution series of a specimen panel consisting of 114 separate isolates of *Neisseria gonorrhoeae*. The 114 isolates represented 13 auxotypes, 5 serovars, 10 antibiotic resistant strains, 6 plasmidless strain isolates, and 2 uncharacterized isolates found discordant in the multicenter trial. Four-point dilution series of each of the isolates were tested once using the Digene GC-ID Test to establish the limits of detection for the test. The limit of detection for each Neiserria auxotype is summarized in Table 2. The detectable limit range stated was the dilution

of each auxotype that was detected within or very near to the assay's equivocal zone of 1.0-2.5 RLU/CO.

The analytical sensitivity of the GC-ID Test varied from 25 to 50,000 CFU/assay for the 114 Neisseria gonorrhoeae isolates tested, including auxotypes, serovars, plasmidless, and antibiotic-resistant strains. Only one of the six plasmidless strains and one of five of the Neisseria gonorrhoeae IA-5 serovars tested were detected at 50,000 CFU/assay; none of the other 112 isolates were detected at concentrations in excess of 5000 CFU/assay. The average detectable limit for all 114 isolates ranged from 974 to 2887 CFU/assay when taking into consideration isolate dilutions that fell both within the assay's equivocal zone and above 2.5 RLU/CO. The overall average limit of detection was 1931 CFU/assay (3.8×10^4 CFU/ml). Clinical specimens that contain organism at or near the limit of detection may need to be retested by an alternate test procedure or on a new specimen from the patient as defined in the Interpretation of Results section of this package insert."

Table 2: Summary of Detectable Limits of Sensitivity for GC Auxotypes, Serovars, Plasmidless, and Antibiotic-resistant Strains

Auxotype	***Detectable Concentration***	
	CFU/ml	**CFUs/assay**
N. gonorrhoeae Auxotype 1	1000	50
N. gonorrhoeae Auxotype 12	500 - 5000	25 - 250
N. gonorrhoeae Auxotype 16	10^3 - 10^4	50 - 500
N. gonorrhoeae Auxotype 22	10^4 - 10^5	500 - 5000
N. gonorrhoeae Auxotype 5	500 - 5000	25 - 250
N. gonorrhoeae Auxotype 9	5×10^4	2500
N. gonorrhoeae Auxotype AHU (5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae Auxotype Arg (5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae Auxotype AU (5 isolates)	10^3 - 10^4	50 - 500
N. gonorrhoeae Auxotype PAU (5 isolates)	10^3 - 10^5	50 - 5000
N. gonorrhoeae Auxotype Pro(5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae Auxotype Proto(5 isolates)	10^3 – 10^4	50 - 500
N. gonorrhoeae Ciprofloxacin Intermediate (CipI) (5 isolates)	10^3 - 10^5	50 - 5000
N. gonorrhoeae Ciprofloxacin Resistant (Cip R) (4 isolates)	10^3 - 10^4	50 - 500
N. gonorrhoeae CMRNG(5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae Other- 5423	10^4 - 10^5	500 - 5000
N. gonorrhoeae Other- 5658	10^3 - 10^4	50 - 500
N. gonorrhoeae PenR (5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae Plasmidless strains (6 isolates)	10^3 - 10^6	50 - 50,000
N. gonorrhoeae PPNG 3.05 (5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae PPNG 3.2	10^4 - 10^5	500 - 5000
N. gonorrhoeae PPNG 4.4 (4 isolates)	10^3 - 10^5	50 - 5000
N. gonorrhoeae Serovar IA-1 or IA-2 (5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae Serovar IA-5 (4 isolates)	10^4 - 10^6	500 - 50,000
N. gonorrhoeae Serovar IB-1 (5 isolates)	10^3 - 10^4	50 - 500
N. gonorrhoeae Serovar IB-4 or IB-15 (5 isolates)	10^3 - 10^5	50 - 5000
N. gonorrhoeae Serovar IB-5 (5 isolates)	10^3 - 10^5	50 - 5000
N. gonorrhoeae Spectinomycin Resistant (SpeR)	10^5	5000
N. gonorrhoeae TetR (5 isolates)	10^3 - 10^5	50 - 5000
N. gonorrhoeae TRNG American (5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae TRNG Dutch (5 isolates)	10^4 - 10^5	500 - 5000
N. gonorrhoeae Type Strain	500 - 5000	25 - 250

CLINICAL PERFORMANCE:

Digene GC-ID Test performance characteristics were determined by comparing the assay results to results of Gonorrhea culture. 1825 specimens were tested from patients at 5 different sites including STD, Family Planning and OB/GYN clinics. PCR testing was performed for specimens that were *Digene GC-ID Test*-positive/culture-negative. *Digene GC-ID Test* results were NOT resolved by PCR test results and therefore PCR had no impact on the calculations of the *Digene GC-ID Test* performance characteristics. Results from the clinical trial for specimens collected with the *Digene Cervical Sampler* (cervical brush) are shown in Table 3 and specimens collected with the *Digene* Swab SCK in Table 4.

The performance characteristics of the GC-ID Test were calculated applying both a 1.0 and a 2.5 cut-off without consideration of the presumptive positive specimens falling in the equivocal zone described in the Interpretation of Results section of this package insert. Therefore, the performance of the test may vary in your laboratory depending on the distribution of values that fall within the equivocal zone and the repeat results obtained when retesting presumptive positive (equivocal zone) specimens is performed. As a point of reference, less than 0.9% of the specimens (17/1825) tested during the Multicenter clinical study used to establish this test's performance fell into this range.

Sufficient data have not been generated to accurately determine whether the sensitivity and positive predictive value of the Hybrid Capture® II GC-ID test using the Digene Swab SCK (Dacron® swab) is equivalent to the sensitivity and positive predictive value observed with specimens collected using the Digene Cervical Sampler™. Since the use of the Digene Cervical Sampler™ is contraindicated in the collection of cervical specimens from pregnant women, the ability of the test to detect the presence of GC DNA may be reduced in this population of patients or whenever a Dacron® swab is used for specimen collection".

Performance estimates for the assay are based on specimens stored at 2-8°C or frozen and tested within 1-2 weeks of collection.

Table 3 Digene GC-ID Test versus GC Culture Results for Brush Specimens

Performance Characteristics were calculated utilizing RLU/CO cutoff values of 1.0 and 2.5 are presented below. Values stated parenthetically represent differences in the point estimates when performance was calculated considering the 2.5 RLU/CO Cutoff.

		GC-ID:	*POS*	*POS*	*NEG*	*NEG*					
		Culture:	*POS*	*NEG*	*POS*	*NEG*					
	Site	*n=*					*Sensitivity*	*PPV*	*Specificity*	*NPV*	*GC-ID+/Cult-Tested + PCR[1]*
Symptomatic	1	351	39 (38)	7 (3)	1 (2)	304 (308)	97.50 (95.00)	84.78 (92.68)	97.75 (99.04)	99.67 (99.35)	5/7 (2/3)
95% CI							83.1-99.9	80.1-98.5	97.2-99.8	98.2-100	
	2	188	13	2	4	169	76.47	86.67	98.83	97.69	1/2
95% CI							50.1-93.2	59.5-98.3	95.8-99.9	94.2-99.4	
	3	233	14	6 (3)	1	212 (215)	93.33	70.00 (82.35)	97.25 (98.62)	99.54	0#/6
95% CI							68.1-99.8	56.6-96.2	96.0-99.7	97.4-100	
	4	163	4	0	0	159	100.00	100.00	100.00	100.00	N/A
95% CI							39.8-100	39.8-100	97.7-100	97.7-100	
	All	935	70 (69)	15 (8)	6 (7)	844 (851)	92.11 (90.79)	82.35 (89.61)	98.25 (99.07)	99.29 (99.18)	6#/15
95% CI							83.6-97.1	80.1-95.4	98.2-99.6	98.5-99.7	
Asymptomatic	1	101	10 (9)	2	0 (1)	89	100.00 (90.00)	83.33 (81.82)	97.80	100.00 (98.89)	2/2
95% CI							69.2-100	51.6-97.9	92.3-99.7	95.9-100	
	2	12	2	0	0	10	100.00	100.00	100.00	100.00	N/A
95% CI							15.8-100	15.8-100	69.2-100	69.2-100	
95% CI	3	84	1 (0)	0	0 (1)	83	100.00 (0.00) (2.5-100)	100.00 (2.5-100)	100.00 (95.7-100)	100.00 (98.81) (95.7-100)	N/A
	4	226	4	2 (0)	1	219 (221)	80.00	66.67 (100.00)	99.10 (100.00)	99.55	1/2 (N/A)
95% CI							28.4-99.5	39.8-100	98.3-100	97.5-100	
	5	1	0	0	0	1	NA	NA	100.00	100.00	NA
95% CI									2.5-100	2.5-100	
	All	424	17 (15)	4 (2)	1 (3)	402 (404)	94.44 (83.33)	80.95 (88.24)	99.01 (99.51)	99.75 (99.26)	3/4 (2/2)
95% CI							72.7-99.9	63.6-98.5	98.2-99.9	98.6-100	
ALL	1	452	49 (47)	9 (5)	1 (3)	393 (397)	98.00 (94.00)	84.48 (90.38)	97.76 (98.76)	99.75 (99.25)	7/9 (4/5)
95% CI							89.4-100	79.0-96.8	97.1-99.6	98.6-100	
	2	200	15	2	4	179	78.95	88.24	98.90	97.81	1/2
95% CI							54.4-94.0	63.6-98.5	96.1-99.9	94.5-99.4	
	3	317	15 (14)	6 (3)	1 (2)	295 (298)	93.75 (87.50)	71.43 (82.35)	98.01 (99.00)	99.66 (99.33)	0#/6
95% CI							69.8-99.8	56.6-96.2	97.1-99.8	98.1-100	
	4	389	8	2 (0)	1	378 (380)	88.89	80.00 (100.00)	99.47 (100.00)	99.74	1/2 (N/A)
95% CI							51.8-99.7	63.1-100	99.0-100	98.5-100	
	5	1	0	0	0	1	NA	NA	100.00	100.00	NA
95% CI									2.5-100	2.5-100	
	All	1359	87 (84)	19 (10)	7 (10)	1246 (1255)	92.55 (89.36)	82.08 (89.36)	98.50 (99.21)	99.44 (99.21)	9#/19
95% CI							85.3-97.0	81.3-94.8	98.6-99.6	98.9-99.8	

1 This information is provided for information only; specimen results were not resolved using PCR.

2 Site number 4 did not have any swab specimens from symptomatic patients.

in two cases PCR was not done.

NA = Not Applicable

Table 4 Digene GC-ID Test versus GC Culture Results for Swab Specimens

Performance Characteristics were calculated utilizing RLU/CO cutoff values of 1.0 and 2.5 are presented below. Values stated parenthetically represent differences in the point estimates when performance was calculated considering the 2.5 RLU/CO Cutoff.

		GC-ID:	*POS*	*POS*	*NEG*	*NEG*					
		Culture:	*POS*	*NEG*	*POS*	*NEG*					
	Site	*n=*					*Sensitivity*	*PPV*	*Specificity*	*NPV*	*GC-ID+/Cult-Tested+PCR*[1]
Symptomatic	1	7	2	0	0	5	100.00	100.00	100.00	100.00	N/A
95% CI							15.8-100	15.8-100	47.8-100	47.8-100	
	2	92	13	2 (0)	1	76 (78)	92.86	86.67 (100.00)	97.44 (100.00)	98.70 (98.73)	0/2
95% CI							66.1-99.8	75.3-100	95.4-100	93.2-100	
	3	5	2	0	0	3	100.00	100.00	100.00	100.00	N/A
95% CI							15.8-100	15.8-100	29.2-100	29.2-100	
	5	162	0	3 (1)	0	159 (161)	NA	0.00	98.15 (99.38)	100.00	1#/3
95% CI								2.5-100	96.6-100	97.7-100	
	All	266	17	5 (1)	1	243 (247)	94.44	77.27 (94.44)	97.99 (99.60)	99.59 (99.60)	1#/5
95% CI							72.7-99.9	54.6-99.9	95.4-100	97.8-100	
Asymptomatic	1	1	0	0	0	1	N/A	NA	100.00	100.00	N/A
95% CI									2.5-100	2.5-100	
	2	10	2	0	0	8	100.00	100.00	100.00	100.00	N/A
95% CI							15.8-100	15.8-100	63.1-100	63.1-100	
	3	2	0	0	0	2	NA	NA	100.00	100.00	N/A
95% CI									15.8-100	15.8-100	
	4	1	0	0	0	1	N/A	NA	100.00	100.00	N/A
95% CI									2.5-100	2.5-100	
	5	186	1	0	0	185	100.00	100.00	100.00	100.00	N/A
95% CI							2.5-100	2.5-100	98.0-100	98.0-100	
	All	200	3	0	0	197	100.00	100.00	100.00	100.00	N/A
95% CI							29.2-100	29.2-100	98.1-100	98.1-100	
All	1	8	2	0	0	6	100.00	100.00	100.00	100.00	N/A
95% CI							15.8-100	15.8-100	54.1-100	54.1-100	
	2	102	15	2 (0)	1	84 (86)	93.75	88.24 (100.00)	97.67 (100.00)	98.82 (98.85)	0/2
95% CI							69.8-99.8	63.6-100	91.9-100	93.6-100	
	3	7	2	0	0	5	100.00	100.00	100.00	100.00	N/A
95% CI							15.8-100	15.8-100	47.8-100	47.8-100	
	4	1	0	0	0	1	N/A	NA	100.00	100.00	N/A
95% CI									2.5-100	2.5-100	
	5	348	1	3 (1)	0	344 (346)	100.00	25.00 (50.00)	99.14 (99.71)	100.00	1#/3
95% CI							2.5-100	1.3-98.7	98.4-100	98.9-100	
	All	466	20	5 (1)	1	440 (444)	95.24	80.00 (96.24)	98.88 (99.78)	99.77	1#/5
95% CI							76.2-99.9	59.3-99.9	97.4-100	98.0-100	

[1] This information is provided for information only; specimen results were not resolved using PCR.

[2] Site number 4 did not have any swab specimens from symptomatic patients.

in two cases PCR was not done.

NA = Not Applicable

The clinical sensitivity and specificity of GC-ID for detecting those patients with clinically active infection that can be transmitted to partners or cause GC-related sequelae has not been determined in comparison to all commercially-available NAA methods for detection of GC DNA. In clinical studies, testing by a modified commercial NAA assay showed positivity in some GC-ID positive specimens obtained from culture negative patients. Estimated sensitivity is based on the number of GC-ID positive results found in patients who were culture positive for *N. gonorrhoeae.* Therefore, the GC-ID sensitivity can only be deduced relative to culture positivity which may have a sensitivity of 60-85%.

Retesting of HCII CT/GC Test Positive Specimens using the GC-ID Test

A summary of the performance of the GC-ID Test when used for the retesting of specimens initially positive with the Digene Hybrid Capture® II CT/GC Test is presented below. The results have been stratified by the collection device used to collect the specimen, the *Digene Cervical Sampler* (designated in Table 6 as "Brush") and the Digene Specimen Collection Kit (designated in Table 6 as "Swab"). A total of nine specimens (all using the Brush) that were positive by culture and PCR combined tested negative with the CT/GC test (0.6%, 9/1560). Twelve of the 144 CT/GC positive specimens that tested negative with the GC-ID Test also tested negative with the Digene CT-ID Test. Only two of those 144 specimens were GC culture/PCR positive and 118 were determined to be CT culture positive. No additional NAA testing was performed on these specimens.

As indicated in Table 6, five of the nine CT/GC positive specimens which fell into the equivocal zone upon retesting with the GC-ID Test confirmed positive by GC culture and PCR combined. As suggested by these five specimens, the usefulness of the GC-ID to confirm the presence of GC DNA in specimens that test positive by the CT/GC is not compromised by interpreting GC-ID Test equivocal specimens as presumptive positive, as instructed in the "Interpretation of Results" section of this package insert.

Table 5 Summary of HCII GC-ID Test Results Obtained for Specimens Tested with the HCII CT/GC Test
n=1825

HCII Test Results			*Combined GC Culture and PCR*			
CT/GC	*GC-ID*	*n*	*Brush*		*Swab*	
			POS	*NEG*	*POS*	*NEG*
POS	**POS**	112	88	3	21	0
	EQUIV	9	5	2	0	2
	NEG	144	1	116	1	26
	TOTAL	***265***	***94***	***121***	***22***	***28***
NEG	**POS**	3	1	2	0	0
	EQUIV	7	2	3	0	2
	NEG	1550	6	1130	0	414
	TOTAL	***1560***	***9***	***1135***	***0***	***416***

Of particular interest are the 32 specimens positive by HCII CT/GC and determined by GC culture and CT culture/DFA to be coinfected with these organisms; all but two (6.3%) of these coinfected specimens confirmed positive by the GC-ID Test. Based on these data, the GC-ID test is effective for confirming the presence of GC DNA in specimens that yield an initial positive result with the HCII CT/GC Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 29 1999

Mr. Mark A. Del Vecchio
Associate Director, Regulatory and Clinical Affairs
Digene
9000 Virginia Manor Road
Beltsville, Maryland 20705

Re: K981485
Trade Name: Digene Hybrid Capture® II GC-ID Test
Regulatory Class: II
Product Code: LSL
Dated: September 10, 1999
Received: September 13, 1999

Dear Mr. Del Vecchio:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K981485

Device Name: Digene Hybrid Capture® II GC-ID Test

Indications for Use:

The Digene HCII GC-ID Test is a nucleic acid hybridization assay with signal amplification using microplate chemiluminescence for the qualitative detection of N. gonorrhoeae DNA in cervical specimens collected using the Digene Cervical Sampler™ (Digene cervical brush and Digene Specimen Transport Medium) and in cervical specimens collected using the Digene Swab Specimen Collection Kit ([Swab SCK] Dacron® swab and Digene Specimen Transport Medium). The Digene HCII GC-ID Test is indicated for use as an aid in diagnosing infection with N. gonorrhoeae in symptomatic or asymptomatic females.

The HCII GC-ID Test may be used alone or as a supplemental test to the Digene HCII CT/GC Test to detect *N. gonorrhoeae* in specimens that are positive by the HCII CT/GC Test.

For *In Vitro* Diagnostic Use.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981485

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)