

K935833

510 (k) SUMMARY

MAY -6 1996

LCx® *Neisseria gonorrhoeae* Assay

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
SUPPORTING A SUBSTANTIAL EQUIVALENCE DETERMINATION

The following information as presented in the Premarket Notification (510(k) for LCx *Neisseria gonorrhoeae* Assay) constitutes data supporting a substantially equivalent determination.

The LCx *Neisseria gonorrhoeae* Assay uses LCR™ (Ligase Chain Reaction) amplification technology in the LCx Probe System for the direct, qualitative detection of a specific target nucleic acid sequence in the Opa gene of *Neisseria gonorrhoeae* in female endocervical and male urethral swab specimens or in male and female urine specimens from symptomatic and asymptomatic males and females.

The LCx *Neisseria gonorrhoeae* Assay is substantially equivalent to the culture method.

The two methods are similar in that:

- Both assays detect the presence of *N. gonorrhoeae*.
- Both assays are in vitro tests.

The two methods differ in that:

- The LCx *Neisseria gonorrhoeae* Assay detects the DNA of *N. gonorrhoeae* organisms, while the culture method detects the whole organism.
- The LCx *Neisseria gonorrhoeae* Assay detects the DNA of *N. gonorrhoeae* in male and female urine.

In four U.S. sites, the performance characteristics of the LCx *Neisseria gonorrhoeae* Assay were determined by comparing assay results to results of culture for *Neisseria gonorrhoeae*. The overall results presented by specimen type and storage condition are shown in the table below.

Performance Summary Compared to Culture: Frozen Specimens

Sample Type	Symptomatology	Total	LCx Culture	Pos Pos	Pos Neg	Neg Pos	Neg Neg	Sensitivity (95% C.I.)	Specificity (95% C.I.)
Female Endocervical	Asymptomatic	623		24	11	3	585	88.9% (24/27) (70.8-97.6)	98.2% (505/506) (96.7-99.1)
	Symptomatic	332		47	8	0	277	100.0% (47/47) (92.5-100.0)	97.2% (277/285) (94.5-99.8)
Female Urine	Asymptomatic	140		23	1	2	114	92.0% (23/25) (74.0-99.0)	99.1% (114/115) (95.3-100.0)
	Symptomatic	237		43	0	2	192	95.6% (43/45) (84.5-99.5)	100.0% (192/192) (98.1-100.0)
Male Urethra	Asymptomatic	172		6	2	1	163	85.7% (6/7) (42.1-99.6)	98.8% (161/165) (95.7-99.9)
	Symptomatic	412		155	6	2	249	98.7% (155/157) (95.5-99.8)	97.6% (249/255) (94.5-99.1)
Male Urine	Asymptomatic	234		6	1	1	226	85.7% (6/7) (42.1-99.6)	99.0% (226/227) (97.5-100.0)
	Symptomatic	466		170	10	1	285	99.4% (170/171) (96.6-100.0)	96.6% (285/295) (93.5-98.4)
Total	Asymptomatic	1169		59	15	7	1088	89.4% (59/66) (81.5-95.3)	96.6% (1088/1103) (94.5-98.4)
	Symptomatic	1447		415	24	5	1003	98.8% (415/420) (97.5-99.8)	97.7% (1003/1027) (96.5-98.8)

Performance Summary Compared to Culture: Fresh Specimens

Sample Type	Symptomatology	Total	LCx Culture	Pos Pos	Pos Neg	Neg Pos	Neg Neg	Sensitivity (95% C.I.)	Specificity (95% C.I.)
Female Endocervical	Asymptomatic	78		10	3	0	55	100.0% (10/10) (69.2-100.0)	95.6% (65/68) (87.6-99.1)
	Symptomatic	132		20	1	0	111	100.0% (20/20) (83.2-100.0)	99.1% (111/112) (95.1-100.0)
Female Urine	Asymptomatic	74		9	1	0	64	100.0% (9/9) (66.4-100.0)	98.5% (64/65) (91.7-100.0)
	Symptomatic	129		17	1	3	108	85.0% (17/20) (62.1-96.8)	99.1% (108/109) (95.0-100.0)
Male Urethra	Asymptomatic	74		1	0	0	73	100.0% (1/1) (2.5-100.0)	100.0% (73/73) (95.1-100.0)
	Symptomatic	92		47	1	0	44	100.0% (47/47) (92.5-100.0)	97.8% (44/45) (88.2-99.9)
Male Urine	Asymptomatic	74		1	0	0	73	100.0% (1/1) (2.5-100.0)	100.0% (73/73) (95.1-100.0)
	Symptomatic	93		47	1	1	44	97.9% (47/48) (88.9-99.9)	97.8% (44/45) (86.2-99.9)
Total	Asymptomatic	300		21	4	0	275	100.0% (21/21)	98.6% (275/279)
	Symptomatic	446		131	4	4	307	97.0% (131/135)	98.7% (307/311)

The analytical sensitivity of this assay (limit of detection) is 10 Colony Forming Units (CFU) of any of the 6 auxotrophs of *Neisseria gonorrhoeae*. The analytical sensitivity of this assay was determined by a serial dilution study on all 6 auxotrophs (auxotype 1, 5, 9, 12, 16, and 23) of *Neisseria gonorrhoeae*. Each auxotroph was diluted to less than 10 CFU per reaction and tested in the LCx *Neisseria gonorrhoeae* Assay. In all cases, each replicate of a dilution giving 10 CFU per test (100 ul specimen volume) was positive by the LCx *Neisseria gonorrhoeae* Assay.

91 bacteria, parasites, viruses, yeast and fungi, including organisms that are commonly found in the urogenital tract and 12 non-gonococcal *Neisseria* species were tested by the LCx *Neisseria gonorrhoeae* Assay. All gave negative results indicating the specificity of the test.

In conclusion the LCx *Neisseria gonorrhoeae* Assay is substantially equivalent to culture for detection of *Neisseria gonorrhoeae* in endocervical, male urethral, female and male urine specimens.

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