K984631

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510(k) SUMMARY

SUBMITTED BY: BECTON DICKINSON MICROBIOLOGY SYSTEMS
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PREPARED: October 29, 1999

DEVICE NAME: BDProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays

PREDICATE DEVICES:
Chlamydia cell culture
Neisseria gonorrhoeae culture
Abbott LCx® *Chlamydia trachomatis* Assay
Abbott LCx® *Neisseria gonorrhoeae* Assay

INTENDED USE: The BDProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays, when tested with the BDProbeTec™ ET System, use Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis*, *N. gonorrhoeae*, or of co-infection with *C. trachomatis* and *N. gonorrhoeae*. Specimens may be from symptomatic or asymptomatic females for the BDProbeTec ET CT and GC Assays, from symptomatic or asymptomatic males for the BDProbeTec ET CT Assay, and from symptomatic males for the BDProbeTec ET GC Assay. A separate Amplification Control is an option for inhibition testing (BDProbeTec ET CT/GC/AC Reagent Pack).

DEVICE DESCRIPTION:

The BDProbeTec™ ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) amplified DNA assays utilize homogeneous SDA technology as the amplification method and fluorescent energy transfer (ET) as the detection method to test for the presence of CT and GC in clinical specimens.

For each assay, the SDA reagents are dried in two separate microwell strips. First, the processed sample is added to the Priming Microwell which contains the amplification primers, fluorescent labeled detector probe, and other reagents necessary for amplification. However, because no enzymes are present in the priming microwell strips, no amplification occurs at this step. After incubation, the reaction mixture is transferred to the Amplification Microwell, which contains two enzymes (a DNA polymerase and a restriction endonuclease) necessary for SDA. It is in this latter microwell in which amplification and detection occurs. The Amplification Microwells are sealed to prevent contamination and then incubated in a thermally controlled fluorescent reader which monitors each test well for the generation of amplified products. The presence or absence of CT and GC is determined by relating the BDProbeTec ET MOTA (Method Other Than Acceleration) scores for the sample to pre-determined cutoff values. The MOTA score is a metric used to assess the magnitude of signal generated as a result of the reaction.

If the CT/GC Reagent Pack is used, each sample and control are tested in two discrete microwells: *C. trachomatis* and *N. gonorrhoeae*. Results are reported through an algorithm as positive or negative. If the CT/GC/AC Reagent Pack is used, each sample and control are tested in three discrete microwells: *C. trachomatis, N. gonorrhoeae,* and the Amplification Control. The purpose of the Amplification Control is to identify a sample that may inhibit the SDA reaction. Results are reported through an algorithm as positive, negative, or indeterminate.

DEVICE COMPARISON:

Tables 1 and 2 summarize the similarities and differences between the BDProbeTec™ ET CT and GC Amplified DNA Assays and the predicate devices.

Table 1: Device Comparison - *Chlamydia trachomatis* (CT)

Feature	BDProbeTec™ ET	Abbott LCx®	CT Cell Culture
Intended Use	The BDProbeTec™ ET CT Amplified DNA Assay, when used with the BDProbeTec™ ET System, uses SDA technology for the direct, qualitative detection of CT DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis.* Specimens may be from symptomatic or asymptomatic males and females. A separate Amplification Control is an option for inhibition testing (BDProbeTec ET CT/AC Reagent Pack).	The LCx CT Assay uses LCR™ / Ligase Chain Reaction / amplification technology in the LCx Probe System for the direct, qualitative detection of plasmid DNA of CT in female endocervical and male urethral swab specimens or in female and male urine specimens from symptomatic and asymptomatic males and females.	CT cell culture uses tissue cell culture in microtiter plates or dram vials for the direct, qualitative and quantitative detection of CT in a variety of direct specimens such as female endocervical and male urethral swabs.
Type of Assay	Amplified DNA Probe	Amplified DNA Probe	Tissue culture
Technology	SDA	LCR	Culture
Amplification Target	Cryptic plasmid	Cryptic plasmid	Not applicable
Detection format	Simultaneous amplification & detection	Amplification followed by detection	Not applicable
Qualitative or Quantitative	Qualitative	Qualitative	Qualitative and/or quantitative
Assay Formats	CT and CT/GC	CT	CT
Amplification Control	Optional	No	No
Number of Controls / Run	Negative Control (1) Positive Control (1)	Negative Control (2X) Calibrator (2X) Positive Control	At least 1 positive and 1 negative control per batch
Contamination Control Method	Closed System	Chelating metal complex & oxidizing reagent (added by LCx)	None
Dedicated Laboratory Area	1 Room	2 Rooms (separate sample processing and amplification/detection)	Biological safety hood
Dried Reagents	Yes	No	No
Samples to be Tested	Endocervical swabs Urethral swabs Urine (Male/Female)	Endocervical swabs Urethral swabs Urine (Male/Female)	Endocervical swabs Urethral swabs
Swab Specimen Transport	2-27°C up to 4-6 days; media-free transport	2-30°C up to 4 days; liquid transport media	2-8°C up to 48 hrs. or frozen culture transport medium
Urine Specimen Transport 2-8°C	2-8°C up to 4-6 days	2-8°C up to 4 days	Not available
Urine Specimen Transport 15-27°C	15-27°C up to 2 days	Not available	Not available

Table 2: Device Comparison - *Neisseria gonorrhoeae* (GC)

Feature	BDProbeTec™ ET	Abbott LCx®	GC Culture
Intended Use	The BDProbeTec™ ET CT/GC Amplified DNA Assay, when used with the BDProbeTec™ ET System, uses SDA technology for the direct, qualitative detection of CT/GC DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with CT, GC, or of co-infection with both CT and GC. Specimens may be from symptomatic or asymptomatic females for the BDProbeTec ET CT and GC Assays, from symptomatic or asymptomatic males for the BDProbeTec ET CT Assay, and from symptomatic males for the BDProbeTec ET GC Assay. A separate Amplification Control is an option for inhibition testing (BDProbeTec ET CT/GC/AC Reagent Pack).	The LCx GC 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 GC in female endocervical and male urethral swab specimens or in female and male urine specimens from *symptomatic and asymptomatic* males and females.	GC culture may use a variety of selective culture media to grow and isolate gram negative diplococci. Identification of *N. gonorrhoeae* relies on biochemical and/or other identification methods.
Type of Assay	Amplified DNA Probe	Amplified DNA Probe	Growth & detection
Technology	SDA	LCR	Culture
Amplification Target	Pilin gene inverting protein homolog	Opa gene	Not applicable
Detection Format	Simultaneous amplification & detection	Amplification followed by detection	Not applicable
Qualitative or Quantitative	Qualitative	Qualitative	Qualitative and quantitative
Assay Formats	CT/GC (GC not available separately)	GC	GC
Amplification Control	Optional	No	No
Number of Controls / Run	Negative Control (1) Positive Control (1)	Negative Control (2X) Calibrator (2X) Positive Control	1 positive and 1 negative control per batch
Contamination Control Method	Closed System	Chelating metal complex & oxidizing reagent (added by LCx)	None
Dedicated Laboratory Area	1 Room	2 Rooms (separate sample processing and amplification/detection)	None
Dried Reagents	Yes	No	No
Samples to be Tested	Endocervical swabs Urethral swabs Urine (Male/Female)	Endocervical swabs Urethral swabs Urine (Male/Female)	Endocervical swabs Urethral swabs Urine (Male/Female)
Swab Specimen Transport	2-27°C up to 4-6 days; *media-free transport*	2-30°C up to 4 days; *liquid transport media*	Inoculate into selective media. Incubate at 35-39°C in a CO_2 enriched atmosphere immediately after incubation.
Urine Specimen Transport 2-8°C	2-8°C up to 4-6 days	2-8°C up to 4 days	
Urine Specimen Transport 15-27°C	15-27°C up to 2 days	Not available	

SUMMARY OF PERFORMANCE DATA:

ANALYTICAL STUDIES:

Precision of the BDProbeTec™ ET CT and GC Amplified DNA Assay was demonstrated by testing a five member panel consisting of four dilutions co-inoculated with CT and GC in sample diluent and a negative (uninoculated sample diluent). The five member panel is made up of samples containing 0-100 *C. trachomatis* EBs/rxn and 0-100 *N. gonorrhoeae* cells/rxn. This precision panel was run at two clinical sites and internally. Six replicates of each panel were run twice a day for three days. No significant run-to-run or site-to-site variability was observed.

Reproducibility was determined by evaluating one panel consisting of seeded swab specimens, and another panel consisting of seeded buffer to simulate urine specimens. The 30 member swab panels contained 12 replicates of a level seeded with both 500 EBs/rxn (CT) and 500 cells/rxn (GC), 12 replicates of a level seeded with both 50 EBs/rxn (CT) and 30 cells/rxn (GC) and six unseeded samples. The 30 member urine panels contained 12 replicates of a level seeded with both 600 EBs/rxn (CT) and 500 cells/rxn (GC), 12 replicates of a level seed with both 115 EBs/rxn (CT) and 100 cells/rxn (GC) and six unseeded samples. Results were combined across 23 operators and across all sample levels (negative, low level, high level) to estimate reproducibility. Eighteen of 23 (78%) operators were at least 95% reproducible with CT swab specimens; 14/23 (61%) of the operators were at least 95% reproducible for CT buffer specimens. For GC specimens, 22/23 (96%) of the operators were at least 95 % reproducible with GC swab specimens and 20/23 (87%) achieved 95% reproducibility with GC buffer specimens.

The analytical sensitivity (limit of detection) of the BDProbeTec™ ET CT and GC Amplified DNA Assay was determined by diluting 15 *C. trachomatis* serovars and 39 *N. gonorrhoeae* strains in CT/GC Diluent. Quantitated CT cultures were diluted to 0,5,15,35,70 and 200 EBs per reaction for each serovar. Quantitated GC cultures were diluted to 0,5,10,15,and 25 cells per reaction for each strain. Samples were processed and assayed in triplicate. The analytical sensitivity of the CT serovars ranged from 5-200 EBs per reaction with a median of 35 EBs per reaction. The LOD of the 39 *N. gonorrhoeae* strains ranged from 5-25 cells per reaction with a median of 5 cells per reaction. These strains included 14 ATCC strains (including six different *N. gonorrhoeae* auxotypes) and 25 clinical isolates obtained from geographically diverse sites.

A total of 156 bacteria, viruses, and yeast were tested with the BDProbeTec™ ET CT and GC Amplified DNA Assay. Bacterial isolates were tested using at least 10^8 Colony Forming Units (CFU)/ml or equivalent copies of genomic DNA. Viruses were tested using at least 10^8 Plaque Forming Units (PFU)/ml or equivalent copies of genomic DNA. The organisms tested include those commonly found in the urogenital tract as well as others. For *Chlamydia trachomatis*, all results were negative as expected. Three *N. cinerea* strains were tested in the BDProbeTec ET GC assay. Of these, two were repeatedly positive. Sixteen *N. subflava* strains were tested in triplicate. Two strains were positive in one of three replicates. When the new strains were prepared and tested again, all results were negative. Eight *N. lactamica* strains were tested in triplicate. One strain was positive in one of the three replicates. When that strain was prepared and tested again, all results were negative.

Potential interfering substances which may be encountered in swab and/or urine specimens were tested with the BDProbeTec™ ET CT and GC Amplified DNA Assays. Potential interfering substances were evaluated in the absence of target or with 200 CT EBs per reaction and 200 GC cells per reaction. False negative results may be caused by leukocytes and blood > 5% in swabs and by leukocytes, blood, bilirubin, and phenazopyridine in urine. When using the AC, these substances may also cause indeterminate results.

CLINICAL STUDIES:

Performance characteristics for the BDProbeTec™ ET CT and GC Amplified DNA Assays were established in a multicenter study at seven geographically diverse clinical sites. The final data analysis included 4108 CT and 4105 GC specimens collected from 2109 patients attending sexually transmitted disease clinics, OB/GYN clinics, family planning clinics, adolescent clinics, and emergency rooms. Paired specimens (swab and urine) were collected from 2020 of the 2109 patients. Four endocervical swabs and one urine specimen were collected from female patients. The swabs were tested by cell culture for CT, culture for GC, the BDProbeTec ET assay, and a commercially available amplification method (AMP1). The endocervical swab collection order was rotated throughout the study to minimize effects of collection order. For males, two urethral swabs and one urine specimen were collected. The first swab was used for GC culture and then the BDProbeTec ET assay. The second swab was used for CT cell culture. Male and female urine specimens were tested on both the BDProbeTec ET system and AMP1. If cell culture was negative, but either amplification assay was positive, a DFA test was performed from the cell culture transport medium. A different commercially available amplification assay (AMP2) was performed from culture transport medium for those male patients who had a positive urine AMP1 test and the corresponding swabs were culture negative.

Performance characteristics for CT and GC were calculated both with and without the amplification control (AC). Data are presented without the AC. Assay interpretation differences resulting from use of the AC are footnoted at the bottom of each table.

BDProbeTec ET *C. trachomatis* results were compared to culture and patient infected status. Performance estimates for each specimen type and symptomatic status are shown in Table 1. A patient was considered infected if (1) the culture was positive, or (2) positive results were obtained for both AMP1 (in either the swab or urine) and DFA, or (3) AMP1 was positive in both swab and urine paired specimens. Data on pregnant females are footnoted at the bottom of Table 1. Of the 1,419 female swab specimens tested in the clinical evaluations by the BDProbeTec ET CT assay, 101 (7.1%) were classified as grossly bloody and 242 (17.1%) as moderately bloody. Assay performance with moderately to grossly bloody swabs was not statistically different than assay performance with non-bloody or lightly bloody swabs.

BDProbeTec ET *N. gonorrohoeae* results were compared to culture and patient infected status. Performance estimates for each specimen type and symptomatic status are shown in Table 2. A patient was considered infected if (1) the culture was positive or (2) in females, if AMP1 was positive in both swab and urine (paired specimens). Data on pregnant females are footnoted at the bottom of Table 2. Of the 1,411 female swab specimens tested in the clinical evaluations by the BDProbeTec ET GC assay, 102 (7.2%) were classified as grossly bloody and 242 (17.2%) as moderately bloody. Assay performance with moderately to grossly bloody swabs was not statistically different than assay performance with non-bloody or lightly bloody swabs.

Overall performance of the BDProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays on the BDProbeTec™ ET System, is substantially equivalent[1] to CT cell culture and GC culture methods that were in use prior to May 28, 1976 and to the Abbott LCx ® *Chlamydia trachomatis* Assay and the Abbott LCx® *Neisseria gonorrhoeae* Assay.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1: BDProbeTec ET CT Results vs. Culture and Patient Infected Status

Specimen Type	S/A	Performance Compared to Culture		Performance Compared to Patient Infected Status		#Indeterminate Initial/Final (With AC)	DFA or AMP1 Positive in either specimen type/ BDPT Positive- Patient Infected Negative
		Sensitivity 95% C.I.	Specificity 95% C.I.	Sensitivity 95% C.I.	Specificity 95% C.I.		
FS	S	90.9% (50/55) 80.0 – 97.0	97.6% (531/544) 95.9 – 98.7	88.7% (55/62) 78.1 – 95.3	98.5% (529/537) 97.1 – 99.4	3/1	3/8
	A	100% (47/47) 92.5 – 100	96.1% (743/773) 94.5 – 97.4	96.8% (61/63) 89.0 – 99.6	97.9% (741/757) 96.6 – 98.8	6/0	8/16
	Total	95.1% (97/102) 88.9 – 98.4	96.7% (1274/1317) 95.6 – 97.6	92.8% (116/125) 86.8 – 96.7	98.1% (1270/1294) 97.3 – 98.8	9/1	11/24
FU [1]	S	75.9% (41/54) [2] 62.4 – 86.5	97.3% (506/520) 95.5 – 98.5	77.0% (47/61) [3] 64.5 – 86.8	98.2% (505/513) 97.0 – 99.3	71/34	4/8
	A	91.3% (42/46) 79.2 – 97.6	96.9% (694/716) 95.4 – 98.1	83.9% (52/62) [4] 72.3 – 92.0	98.3% (688/700) 97.0 – 99.1	90/47	5/12
	Total[5]	83.0% (83/100) 74.2 – 88.2	97.1% (1200/1236) 96.0 – 98.0	80.5% (99/123) 72.4 – 87.1	98.4% (1193/1213) 97.4 – 99.0	161/81	9/20
MS	S	95.8% (92/96) 89.7 – 98.3	89.9% (356/396) 86.5 – 92.7	95.5% (105/110) 89.7 – 98.5	92.9% (355/382) 89.9 – 95.3	1/0	16/27
	A	88.2% (15/17) 63.6 – 98.5	95.9% (162/169) 91.7 – 98.3	89.5% (17/19) 66.9 – 98.7	97.0% (162/167) 93.2 – 99.0	1/0	2/5
	Total	94.7% (107/113) 88.8 – 98.0	91.7% (518/565) 89.1 – 93.8	94.6% (122/129) 89.1 – 97.8	94.2% (517/549) 91.9 – 96.0	2/0	18/32 [6]
MU [1]	S	95.8% (91/95) 89.6 – 98.8	86.5% (340/393) 82.7 – 89.7	95.4% (104/109) 89.6 – 98.5	89.4% (339/379) 85.9 – 92.4	20/10	28/40
	A	88.2% (15/17) 63.6 – 98.5	94.7% (161/170) 90.2 – 97.6	89.5% (17/19) 66.9 – 98.7	95.8% (161/168) 91.6 – 98.3	16/3	5/7
	Total	94.6% (106/112) 88.7 – 98.0	89.0% (501/563) 86.1 – 91.5	94.5% (121/128) 89.1 – 97.8	91.4% (500/547) 88.7 – 93.6	36/13	33/47 [7]
Total [8]		92.0% (393/427) 89.1 – 94.4	94.9% (3493/3681) 94.1 – 95.6	90.7% (458/505) 87.8 – 93.1	96.6% (3480/3603) 95.9 – 97.1	208/95	71/123

[1] Comparison cultures for female and male urine specimens were performed on endocervical and male urethral swab specimens, respectively.

[2] With AC, two final indeterminates reported (instead of false negative), resulting in increase in sensitivity from 75.9 to 80.8% and decrease in specificity from 97.3 to 96.9%

[3] With AC, two final indeterminates reported (instead of false negative) and one positive recovered (instead of false negative), resulting in increase in sensitivity from 77.0% to 81.4% and decrease in specificity from 98.4% to 98.1%

[4] With AC, one final indeterminate reported (instead of false negative), resulting in increase in sensitivity from 83.9% to 85.2% and decrease in specificity from 98.3% to 98.2%..

[5] With AC, female urine sensitivity and specificity for culture were 85.7% and 96.8%, respectively; and for patient infected status were 83.3% and 98.1%,respectively

[6] 13 of 16 of the AMP1 urine positives were confirmed by AMP2 testing.

[7] 14 of 30 of the AMP1 urine positives were confirmed by AMP2 testing.

[8] With AC, total sensitivity and specificity for culture were 92.7% and 94.7%, respectively; and for patient infected status were 91.4% and 96.5%, respectively

Note: Separate performance characteristics were calculated for specimens collected from pregnant females. Sensitivity and specificity compared to patient infected status for female swabs and urines were 94.4% (17/18), 98.4% (122/124) and 83.3% (15/18), 100% (120/120), respectively.

Table 2: BDProbeTec ET GC Results vs. Culture and Patient ...rected Status

Specimen Type	S/A	Compared to Culture		Compared to Patient Infected Status		# Indeterminate Initial/Final	AMP1 Positive in either specimen type / BDPT Positive- Patient Infected Negative
		Sensitivity 95% C.I.	Specificity 95% C.I.	Sensitivity 95% C.I.	Specificity 95% C.I.		
FS	S	95.8% (46/48)[2] 85.7-99.5	98.7% (545/552) 97.4-99.5	96.1% (49/51)[3] 86.5-99.5	99.3% (545/549) 98.1-99.8	3/1	1/4
	A	97.1% (34/35) 85.1-99.9	99.2% (770/776) 98.3-99.7	97.4% (37/38) 86.2-99.9	99.6% (770/773) 98.9-99.9	5/0	1/3
	Total [4]	96.4% (80/83) 89.8-99.2	99.0% (1315/1328) 98.3-99.5	96.6% (86/89) 90.5-99.3	99.5% (1315/1322) 98.9-99.8	8/1	2/7
FU[1]	S	84.8% (39/46) 71.1-93.7	99.2% (527/531) 98.1-99.8	83.7% (41/49) 70.3-92.7	99.6% (526/528) 98.6-100	79/38	0/2
	A	88.2% (30/34) 72.5-96.7	99.0% (713/720) 98.0-99.6	86.5% (32/37) 71.2-95.5	99.3% (712/717) 98.4-99.8	75/48	1/5
	Total	86.3% (69/80) 76.7-92.9	99.1% (1240/1251) 98.4-99.6	84.9% (73/86) 75.5-91.7	99.4% (1238/1245) 98.8-99.8	154/86	1/7
MS [5]	S	98.4% (187/190) 95.5-99.7	94.8% (290/306) 91.6-97.0	98.4% (187/190) 95.5-99.7	94.8% (290/306) 91.6-97.0	1/0	16/16
MU [1,6]	S	97.9% (185/189) 94.7-99.4	94.4% (286/303) 91.2-96.7	97.9% (185/189) 94.7-99.4	94.4% (286/303) 91.2-96.7	28/15	14/17
Total		96.1% (521/542) 94.1-97.6	98.2% (3131/3188) 97.7-98.6	95.8% (531/554) 93.8-97.4	98.5% (3129/3176) 98.2-99.0	191/102	33/47

[1]Comparison cultures for female and male urine specimens were performed on endocervical and male urethral swab specimens, respectively.

[2]With AC one indeterminate reported (instead of false negative), resulting in increase in sensitivity from 95.8 to 97.9%

[3]With AC, one indeterminate reported (instead of false negative), resulting in increase in sensitivity from 96.1 to 98.0%

[4] With AC, female swabs sensitivity and specificity for culture were 97.6% and 99.0%, respectively; and for patient infected status were 97.8% and 99.5%, respectively

[5] Data from swab specimens collected from 187 asymptomatic males were excluded because there were insufficient number (4) of infected patients to adequately determine performance characteristics.

[6] Data from urine specimens collected from 188 asymptomatic males were excluded because there were insufficient number (4) of infected patients to adequately determine performance characteristics.

*Note: **Separate performance characteristics were calculated for specimens collected from pregnant females. Sensitivity and specificity compared to patient infected status for female swabs and urines were 100% (2/2), 98.6% (137/139) and 100% (2/2), 98.5% (133/135), respectively.***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 4 1999

Ms. Colleen Rohrbeck
Regulatory Affairs Associate
Becton Dickinson Microbiology Systems
7 Loveton Circle
Sparks, Maryland 21152

Re: K984631
Trade Name: BDProbeTec™ ET *Chlamydia trachomatis* and
Neisseria gonorrhoeae Amplified DNA Assay
BDProbeTec™ ET *Chlamydia trachomatis* Amplified DNA Assay
Regulatory Class: II, I
Product Code: LSL, MKZ
Dated: August 10, 1999
Received: August 11, 1999

Dear Ms. Rohrbeck:

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

510(k) Number (if known): K984631

Device Name: **BDProbeTec™** ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assay
BDProbeTec™ ET *Chlamydia trachomatis* Amplified DNA Assay

Indications For Use:

The **BDProbeTec™** ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays, when tested with the **BDProbeTec** ET System, use Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis*, *N. gonorrhoeae*, or of co-infection with both *C. trachomatis and N. gonorrhoeae.* Specimens may be from symptomatic or asymptomatic females for the BDProbeTec ET CT and GC Assays, from symptomatic or asymptomatic males for the BDProbeTec ET CT Assay, and from symptomatic males for the BDProbeTec ET GC Assay. A separate Amplification Control is an option for inhibition testing (BDProbeTec ET CT/GC/AC Reagent Pack).

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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 K984631

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