K 103798

510(k) Summary

BD
Helping all people live healthy lives

BD ProbeTec™ Herpes Simplex Viruses (HSV1 & 2) Q^x Amplified DNA Assays

Applicant	BD Diagnostic Systems 7 Loveton Circle Sparks, MD 21152
Establishment Registration No.	1119779
Contact Person	Thalia Charles tel. 410-316-4145 fax. 410-316-4499 Thalia_E_Charles@bd.com
Summary Date	March 14, 2011
Proprietary Name	BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays
Generic Name	DNA probe, nucleic acid amplification, Herpes Simplex virus
Classification	Class II
Classification Name	Herpes simplex virus serological assays
Regulation Number	21 CFR 866.3305
Product Code	OQO
Predicate Device	ELVIS HSV ID and D³ Typing Test System

MAR 18 2011

Device Description

The BD ProbeTec Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays (HSV Q^x Assays) are based on the simultaneous amplification and detection of target DNA using amplification primers and fluorescently-labeled detector probes. The reagents for SDA are dried in two separate disposable microwells for each HSV Q^x Assay: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. The BD Viper™ System pipettes a portion of the purified DNA solution from each Extraction Tube into a Priming Microwell to rehydrate the contents. After a brief incubation, the reaction mixture is transferred to a corresponding, pre-warmed Amplification Microwell which is then sealed to prevent contamination and incubated in one of the two thermally-controlled fluorescent readers. The presence or absence of Herpes Simplex virus type 1 (HSV1) or Herpes Simplex virus type 2 (HSV2) DNA is determined by calculating the peak fluorescence (Maximum Relative

Fluorescent Units (MaxRFU)) over the course of the amplification process and by comparing this measurement to a predetermined threshold value.

In addition to the fluorescent probe used to detect amplified HSV1 or HSV2 target DNA, a second labeled oligonucleotide is incorporated in each reaction. The Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the HSV1 or HSV2 specific target and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is rehydrated upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the BD Viper System and an automated algorithm is applied to both the EC and target-specific signals to report results as positive, negative, or EC failure.

Intended Use

The BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays, when tested with the BD Viper™ System in Extracted Mode, use Strand Displacement Amplification technology for the direct, qualitative detection and differentiation of Herpes Simplex virus type 1 (HSV1) and Herpes Simplex virus type 2 (HSV2) DNA in clinician-collected external anogenital lesion specimens. The assays are indicated for use with symptomatic individuals to aid in the diagnosis of anogenital HSV1 and HSV2 infections.

Warning: The BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays (HSV Q^x Assays) are not FDA cleared for use with cerebrospinal fluid (CSF). The assays are not intended to be used for prenatal screening or for individuals under the age of 17 years.

Summary and Principles of Operation

When used with the BD Viper System, the BD ProbeTec HSV Q^x Amplified DNA Assays involve automated extraction of DNA from clinical specimens through the chemical lysis of cells, followed by binding of DNA to para-magnetic particles, washing of the bound nucleic acid, and elution in an amplification-compatible buffer. When present, HSV1 or HSV2 DNA is then detected by Strand Displacement Amplification (SDA) of either specific target sequence in the presence of a fluorescently-labeled detector probe.

Analytical Performance Characteristics

Limit of Detection (Analytical Sensitivity)

The Limits of Detection (LODs) for the HSV1 Q^x Assay with HSV1 ATCC strain VR-539 in model matrix specimens when extracted on the BD Viper System were determined to be 23 viral particles/mL (vp/mL) in the Q^x Swab Diluent medium, and 85 vp/mL in the Universal Viral Transport medium (UVT). These values correspond to 7 $TCID_{50}$/mL and 25 $TCID_{50}$/mL,

respectively. The Limits of Detection (LODs) for the HSV2 Q^x Assay with HSV2 ATCC strain VR-734 in model matrix specimens when extracted on the BD Viper System were determined to be 84 vp/mL (35 $TCID_{50}$/mL) in the Q^x Swab Diluent medium and 635 vp/mL (262 $TCID_{50}$/mL) in the UVT medium. Evaluation of the HSV1 Q^x Assay on the BD Viper System in extracted mode with three additional HSV1 strains gave LoD values between 6 and 14 vp/mL in clean Q^x Swab Diluent and between 110 and 185 vp/mL in clean UVT. Evaluation of the HSV2 Q^x Assay on the BD Viper System in extracted mode with one additional HSV2 strain gave an LOD of 34 vp/mL in clean Q^x Swab Diluent and 380 vp/mL in clean UVT.

Analytical Specificity

The DNA from 57 organisms was extracted on the BD Viper System and tested with the BD ProbeTec HSV Q^x Amplified DNA Assays. All potential cross-reactive species were tested at approximately $1x10^8$ Colony Forming Units/mL for bacteria and yeast or $1x10^6$ Plaque Forming Units/mL or greater for viruses, except where noted. Results are summarized in **Table 1**.

Table 1: Potential Cross-Reactants

Actinomyces israelii	Human papillomavirus 16[1]
Adenovirus	Human papillomavirus 18[1]
Alcaligenes faecalis	*Kingella kingae*
Candida albicans	*Klebsiella pneumoniae*
Chlamydia trachomatis serovar H	*Lactobacillus acidophilus*
Chlamydia trachomatis serovar LGV-2	*Listeria monocytogenes*
Clostridium perfringens	*Mobiluncus mulieris*
Corynebacterium genitalium	*Moraxella lacunata*
Cryptococcus neoformans	*Mycobacterium tuberculosis*[1]
HHV-5 Cytomegalovirus (CMV)[1]	*Mycoplasma genitalium*
Enterobacter cloacae	*Neisseria gonorrhoeae*
Enterococcus faecalis	*Neisseria meningitidis*
Enterococcus faecium	*Propionibacterium acnes*
Enterovirus (Echovirus 11)[1]	*Proteus vulgaris*
HHV-4 Epstein Barr virus[2]	*Pseudomonas aeruginosa*
Escherichia coli (strain K1)	*Staphylococcus aureus*
Gardnerella vaginalis	*Staphylococcus epidermidis*
Gemella haemolysans	*Staphylococcus saprophyticus*
Haemophilus ducreyi	*Streptococcus agalactiae*
Haemophilus influenzae	*Streptococcus mitis*
Hepatitis B Virus[1]	*Streptococcus pneumoniae*
HHV-6 (Roseolovirus)[1]	*Streptococcus pyogenes*
HHV-6B (Roseolovirus)[1]	*Treponema pallidum*
HHV-7 (Roseolovirus)[1]	*Trichomonas vaginalis*

HHV-8 (Rhadinovirus)[1]	Varicella Zoster Virus (HHV-3)[1]
Human Immunodeficiency Virus 1 (HIV-1)[2]	*Veillonella parvula*
Human Immunodeficiency Virus 2 (HIV-2)[2]	Herpes Virus Type 1 (HSV1)[2]*
Human papillomavirus 6[1]	Herpes Virus Type 2 (HSV2)[2]**
Human papillomavirus 11[1]	

[1] Genomic DNA tested at $1x10^6$ DNA copies/mL

[2] Viruses tested at $1x10^8$ viral particles/mL

* Tested as a cross-reactant in the HSV2 Q^x Assay only

** Tested as a cross-reactant in the HSV1 Q^x Assay only

Interfering Substances

Potentially interfering substances which may be encountered in external anogenital lesion specimens were tested in the absence and presence of HSV1 and HSV2 targets (for HSV1 target, 69 vp/mL in Qx Swab Diluent and 255 vp/mL in UVT; for HSV2 target, 252 vp/mL in Qx Swab Diluent and 1905 vp/mL in UVT; these levels are 3 times each LOD) and tested with the **BD ProbeTec** HSV Q^x Amplified DNA Assays on the **BD Viper System**. Results are summarized in **Table 2.**

Table 2: Potentially Interfering Substances

Interpretation	Q^x Swab Diluent	UVT
No interference observed at levels listed	Blood (2.5% v/v) Seminal fluid (2.5% v/v) Mucus (2.5% v/v) Feces (2.5%) Urine (2.5% v/v) Cornstarch (2.5%) Over the counter vaginal products and contraceptives (2.5% v/v) Over the counter cold sore products (2.5% v/v) Hemorrhoidal cream (2.5% v/v) Prescription vaginal and anti-viral treatments (2.5% v/v) Leukocytes ($1x10^6$ cells/mL) $1x10^6$ viral particles/mL HSV1 (when tested in the HSV2 Q^x assay) $1x10^6$ viral particles/mL HSV2 (when tested in the HSV1 Q^x assay)	Blood (3.3% v/v) Seminal fluid (3.3% v/v) Mucus (3.3% v/v) Feces (3.3%) Urine (3.3% v/v) Cornstarch (3.3%) Over the counter vaginal products and contraceptives (3.3% v/v) Over the counter cold sore products (3.3% v/v) Hemorrhoidal cream (3.3% v/v) Prescription vaginal and anti-viral treatments (3.3% v/v) Leukocytes ($1x10^6$ cells/mL) $1x10^6$ viral particles/mL HSV1 (when tested in the HSV2 Q^x assay) $1x10^6$ viral particles/mL HSV2 (when tested in the HSV1 Q^x assay)
May cause extraction control (EC) failures	Not applicable	Not applicable
May cause false negative results	Not applicable	Not applicable

Clinical Performance Characteristics

Clinician-collected external anogenital lesion swab specimens were collected from 564 compliant male and female subjects attending family planning, OB/GYN, and sexually transmitted disease clinics at nine geographically diverse clinical sites in North America. Subjects were classified as symptomatic if they presented with an external anogenital lesion that met the study inclusion/exclusion criteria and the physician suspected a herpes infection. Fifty-six subjects were excluded from the data analysis due to age requirement violations, antiviral use in the last 21 days, opting to withdraw from the study after initially consenting, transport errors, informed consent issues, failing to meet the inclusion/exclusion criteria, collection errors, shipping errors, or labeling errors. Therefore, the final data analysis included 508 compliant subjects.

For each of the 508 compliant subjects, two swab specimens were collected from the external anogenital lesion. The first specimen collected was always the Universal Viral Transport specimen followed by the BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens (Q^x Swab Diluent specimen). The UVT was aliquotted into a Q^x Swab Diluent Tube (UVT in Q^x Swab Diluent), and a cryovial (vial suitable for -70 °C storage), and the remaining UVT was sent to one of two laboratories for viral culture and typing. The Q^x Swab Diluent specimen and the UVT in Q^x Swab Diluent specimen were transported to one of the three BD Viper testing laboratories where they were tested using the BD ProbeTec HSV1 and HSV2 Q^x Assays on the BD Viper System. The cryovial containing the UVT aliquot was sent to a laboratory for PCR testing.

All sensitivity and specificity calculations were based on the total number of BD ProbeTec HSV1 and HSV2 Q^x Assays results for Q^x Swab Diluent and UVT in Q^x Swab Diluent specimens, as compared to a commercially available viral culture and typing procedure as the reference method. A PCR method was also used for analysis of discrepant results from the ProbeTec HSV Q^x Amplified DNA Assays and the reference culture and typing method.

Table 3: HSV1 Q^x Assay Performance Compared to Viral Culture (by specimen type)

		Performance Compared to Viral Culture			
Specimen Type	**n[1]**	**Sensitivity**	**95% C.I.**	**Specificity**	**95% C.I.**
UVT in Q^x Swab Diluent	312	96.8% (60/62)[3]	(88.8% - 99.6%)	97.6% (244/250)[4]	(94.8% - 99.1%)
Q^x Swab Diluent	308[2]	96.7% (59/61)[3]	(88.7% - 99.6%)	95.1% (235/247)[5]	(91.7% - 97.5%)

[1] The reference viral culture used in this study was unable to detect co-infected specimens. Only if the specimen is negative for HSV2 is it typed for HSV1. Therefore, the number of samples used for HSV1 analysis equals the number of samples with a reference viral culture typing result (501) minus the number of samples positive for HSV2 by the reference method (189).

[2] A total of four Q^x Swab Diluent specimens were not included in the HSV1 analysis due to insufficient volume, aliquot error, collection error, or extraction error..

[3] Both subjects that were identified as positive for HSV1 with viral culture were negative for HSV1 with the HSV1 Q^x Assay and PCR. Both the HSV Q^x Assays and the PCR assay identified the subjects as positive for HSV2.

[4] There were six UVT in Q^x Swab Diluent specimens that were identified as negative for HSV1 with viral culture but were positive for both the HSV1 Q^x Assay and the PCR assay.

[5] There were twelve Q^x Swab Diluent specimens that were identified as negative for HSV1 with viral culture but were positive with the HSV1 Q^x Assay. Seven of these specimens were also positive with the PCR assay.

Table 4: HSV2 Q^x Assay Performance Compared to Viral Culture (by specimen type)

		Performance Compared to Viral Culture			
Specimen Type	**n**	**Sensitivity**	**95% C.I.**	**Specificity**	**95% C.I.**
UVT in Q^x Swab Diluent	501	98.4% (186/189)[6]	(95.4% - 99.7%)	83.7% (261/312)[7,9]	(79.1% - 87.6%)
Q^x Swab Diluent	498	98.4% (186/189)[6]	(95.4% - 99.7%)	80.6% (249/309)[8,9]	(75.7% - 84.8%)

[6] All three subjects that were identified as positive for HSV2 with viral culture were negative for HSV2 with both the HSV2 Q^x Assay and PCR assay. Both the HSV Q^x Assays and the PCR assays identified all three subjects as positive for HSV1.

[7] 46 of the 51 HSV2 UVT in Q^x Swab Diluent positive and viral culture negative were positive for HSV2 by PCR.

[8] 49 of the 60 HSV2 Q^x Swab Diluent positive specimens and viral culture negatives were positive for HSV2 by PCR.

[9] Detection of nucleic acid by PCR and the HSV2 Q^x Assay in samples that were culture negative could indicate detection of nonviable viral particles.

Frequency distributions of the initial MaxRFU values for the HSV1 Q^x Assay with an assay cutoff of 125 MaxRFU for specimens in each media type are shown in **Figures A** and **B.**

Figure A: Frequency Distribution of MaxRFU for the HSV1 Q^x Assay, UVT in Q^x Swab Diluent

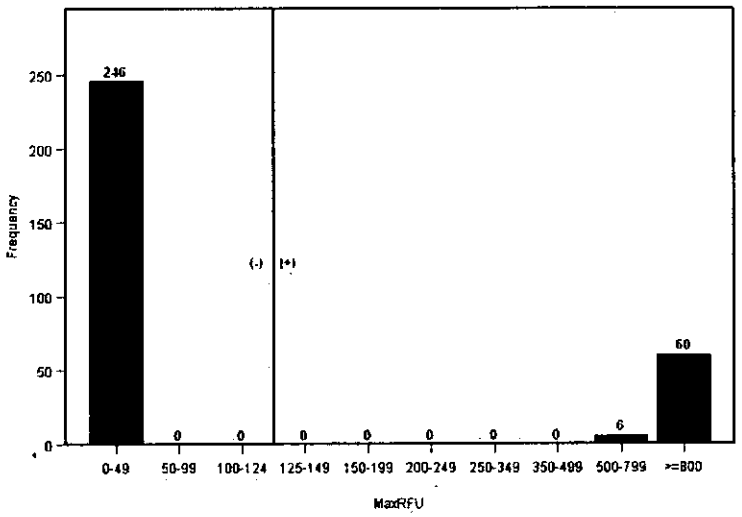
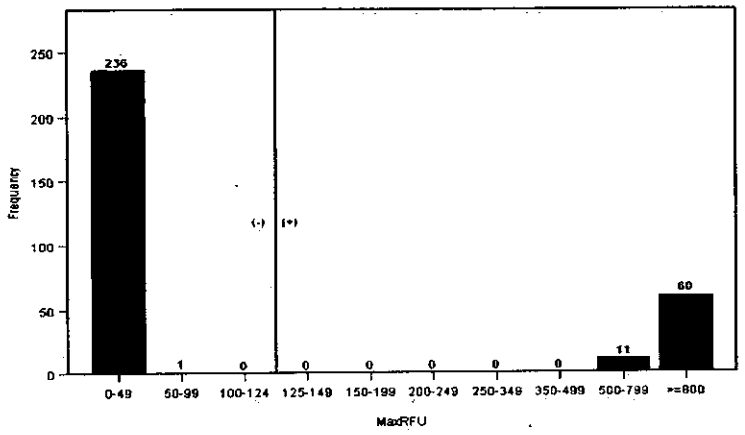


Figure B: Frequency Distribution of MaxRFU for the HSV1 Q^x Assay, Q^x Swab Diluent



Frequency distributions of the initial MaxRFU values for the HSV2 Q^x Assay with an assay cutoff of 125 MaxRFU for specimens in each media type are shown in **Figures C** and **D.**

Figure C: Frequency Distribution of MaxRFU for the HSV2 Q^x Assay, UVT in Q^x Swab Diluent

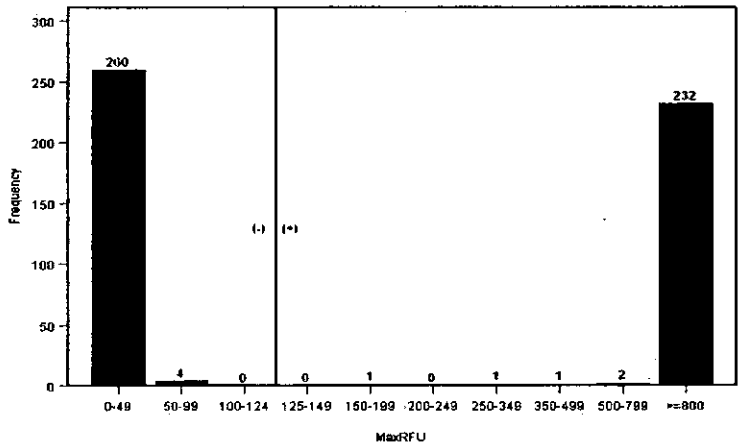
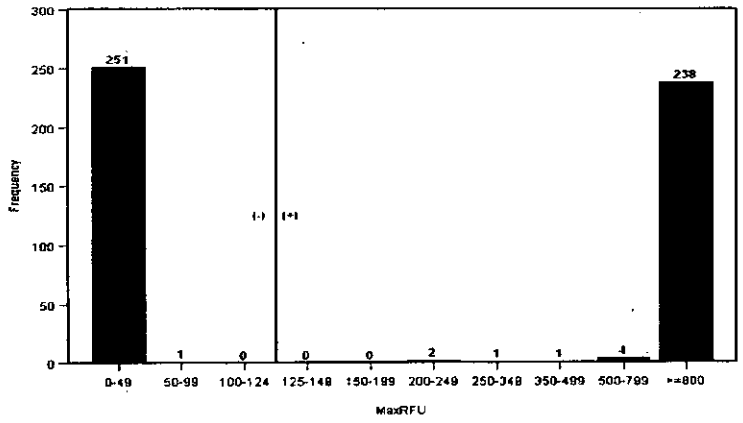


Figure D: Frequency Distribution of MaxRFU for the HSV2 Q^x Assay, Q^x Swab Diluent



Reproducibility

Reproducibility of the BD Viper System using the BD ProbeTec HSV1 and HSV2 Q^x Assays was evaluated at three test sites (two external and one internal) on one BD Viper System per site. Two panels of simulated specimens were tested that were comprised of HSV1 (strain VR-539) and/or HSV2 (strain VR-734) viral particles seeded into either Q^x Swab Diluent containing a swab (simulated Q^x Swab Diluent) or UVT in Q^x Swab Diluent (simulated UVT in Q^x Swab Diluent specimen type). Viral particles were spiked into the simulated samples at 2-fold or 5-fold LOD. Uninoculated Q^x Swab Diluent or UVT in Q^x Swab Diluent was used for the negative samples. Six replicates of each panel member were tested every day for five days on each BD Viper System. A summary of the reproducibility data for the HSV1 and HSV2 Q^x Assays is presented in Tables 7 and 8.

Table 7: Summary of Reproducibility Data on the BD Viper System for the HSV1 Q^x Assay.

		Site #1				Site #2				Site #3					
Simulated Specimen Type	Targets HSV1/HSV2 (xLOD)**	Agreement with Expected Results	Max RFU Mean	Max RFU StdDev	%CV	Agreement with Expected Results	Max RFU Mean	Max RFU StdDev	%CV	Agreement with Expected Results	Max RFU Mean	Max RFU StdDev	%CV	Total Agreement with Expected Results (%)	95% Confidence Interval
UVT in Q^x Swab Diluent	0/0	30/30	2.2	6.7	N/A*	30/30	4.3	12.9	N/A*	30/30	0.7	2.2	N/A*	90/90 (100%)	96% - 100%
	2x/0	29/30	1432.6	447.6	31.2	30/30	1375.4	326.2	23.7	30/30	1474.5	307.9	20.9	89/90 (98.9%)	94% - 100%
	0/2x	30/30	3.8	10.9	N/A*	30/30	7.8	27.6	N/A*	30/30	7.3	10.7	N/A*	90/90 (100%)	96% - 100%
	2x/5x	29/30	1123.1	622.9	55.5	30/30	1144.9	397.7	34.7	30/30	1441.4	205.8	14.3	89/90 (98.9%)	94% - 100%
	5x/2x	30/30	1586.2	346.8	21.9	30/30	1531.5	165.4	10.8	30/30	1619.7	175.7	10.8	90/90 (100%)	96% - 100%
Q^x Swab Diluent	0/0	29/30	24.9	39.0	N/A*	29/30	15.5	84.7	N/A*	30/30	0.9	3.8	N/A*	88/90 (97.8%)	92.2% – 99.7%
	2x/0	30/30	1477.2	392.3	26.6	28/30	999.2	482.9	48.3	30/30	1276.7	396.0	31.0	88/90 (97.8%)	92.2% – 99.7%
	0/2x	30/30	12.3	23.7	N/A*	30/30	0.0	0.0	N/A*	30/30	0.3	0.8	N/A*	90/90 (100%)	96% - 100%
	2x/5x	30/30	1551.0	369.1	23.8	30/30	1395.1	144.3	10.3	30/30	1320.5	349.9	26.5	90/90 (100%)	96% - 100%
	5x/2x	30/30	1751.5	174.0	9.9	30/30	1441.8	214.8	14.9	30/30	1535.1	244.1	15.9	90/90 (100%)	96% - 100%

*The coefficient of variation (CV) is not a useful measure when the mean approaches 0, as the CV is very sensitive to small changes in the mean.

** HSV1 and HSV2 were spiked at either 2-fold (2x) or 5-fold (5x) the LOD.

Table 8: Summary of Reproducibility Data on the BD Viper System for the HSV2 Q^x Assay.

		Site #1				Site #2				Site #3					
Simulated Specimen Type	Targets HSV1/HSV2 (xLOD)**	Agreement with Expected Results	Max RFU Mean	Max RFU StdDev	%CV	Agreement with Expected Results	Max RFU Mean	Max RFU StdDev	%CV	Agreement with Expected Results	Max RFU Mean	Max RFU StdDev	%CV	Total Agreement with Expected Results (%)	95% Confidence Interval
UVT in Q^x Swab Diluent	0/0	29/29***	6.5	9.2	N/A*	30/30	5.2	16.4	N/A*	30/30	7.4	8.1	N/A*	89/89 (100%)	95.9% – 100%
	2x/0	30/30	6.8	9.8	N/A*	30/30	3.9	12.2	N/A*	30/30	14.4	13.5	N/A*	90/90 (100%)	96% - 100%
	0/2x	30/30	1768.6	390.0	22.0	30/30	1806.1	263.6	14.6	30/30	1910.6	236.5	12.4	90/90 (100%)	96% - 100%
	2x/5x	30/30	1946.5	246.8	12.7	30/30	1800.1	267.6	14.9	30/30	1965.1	171.7	8.7	90/90 (100%)	96% - 100%
	5x/2x	30/30	1866.1	319.9	17.1	30/30	1823.8	250.8	13.8	30/30	1861.2	224.8	12.1	90/90 (100%)	96% - 100%
Q^x Swab Diluent	0/0	29/29***	8.2	19.1	N/A*	30/30	0.4	2.2	N/A*	30/30	2.9	11.9	N/A*	89/89 (100%)	95.9% – 100%
	2x/0	30/30	11.2	23.6	N/A*	30/30	0.2	1.3	N/A*	30/30	2.2	4.0	N/A*	90/90 (100%)	96% - 100%
	0/2x	29/29***	2007.1	219.4	10.9	30/30	1679.5	331.1	19.7	30/30	1757.3	289.2	16.5	89/89 (100%)	95.9% – 100%
	2x/5x	29/29***	2028.3	230.6	11.4	30/30	1787.5	327.9	18.3	30/30	1882.7	342.1	18.2	89/89 (100%)	95.9% – 100%
	5x/2x	29/29***	1960.7	254.7	13.0	30/30	1756.2	286.7	16.3	30/30	1762.7	350.3	19.9	89/89 (100%)	95.9% – 100%

*The coefficient of variation (CV) is not a useful measure when the mean approaches 0, as the CV is very sensitive to small changes in the mean.

** HSV1 and HSV2 were spiked at either 2-fold (2x) or 5-fold (5x) the LOD.

*** Non-reportable results due to a BD Viper Instrument error which caused a reduction in the full number of replicates.

Conclusions:

The analytical and clinical study results for the BD ProbeTec Herpes Simplex Viruses (HSV) Q^x Amplified DNA Assays support the determination of substantial equivalence in accordance with the intended use as stated in the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

BD Diagnostic Systems
c/o Thalia Charles
Regulatory Affairs Specialist
7 Loveton Circle
Sparks, MD 21152

MAR 18 2011

Re: K103798

Trade/Device Name:	BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays
Regulation Number:	21 CFR §866.3305
Regulation Name:	Herpes Simplex Virus Nucleic Acid Amplification Assay
Regulatory Class:	Class II
Product Code:	OQO
Dated:	December 22, 2010
Received:	December 27, 2010

Dear Ms. Charles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103798

Device Name: BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays

Indications For Use:

The BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays, when tested with the BD Viper™ System in Extracted Mode, use Strand Displacement Amplification technology for the direct, qualitative detection and differentiation of Herpes Simplex virus type 1 (HSV1) and Herpes Simplex virus type 2 (HSV2) DNA in clinician-collected external anogenital lesion specimens. The assays are indicated for use with symptomatic individuals to aid in the diagnosis of anogenital HSV1 and HSV2 infections.

Warning: The BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays (HSV Q^x Assays) are not FDA cleared for use with cerebrospinal fluid (CSF). The assays are not intended to be used for prenatal screening or for individuals under the age of 17 years.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 103798