510(k) Summary of Safety and Effectiveness

HerpeSelect 1 and 2 Plexus IgG Catalog No. RT0920G
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Applicant	Focus Diagnostics, Inc. 10703 Progress Way Cypress, California 90630 USA
Establishment Registration No.	2023365
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Summary Date	May 31, 2007
Proprietary Name	HerpeSelect Express IgG
Generic Name	Herpes Simplex Virus Types 1 and 2 Serological Assays
Classification	Class II
Predicate Devices	HerpeSelect 1 and 2 Immunoblot IgG HerpeSelect-2 ELISA IgG
Reference Method	HerpeSelect 1 and 2 Immunoblot IgG

SEP 2 4 2007

Device Description
Rapid Lateral Flow assay for the qualitative detection of human IgG class antibodies to HSV-2

Intended Use
HerpeSelect® Express is a rapid test intended for qualitatively detecting the presence or absence of human IgG class antibodies to herpes simplex virus type 2 (HSV-2) in human whole blood (venous or capillary) or serum. The test is indicated for testing sexually active adults or pregnant women to aid in the presumptive diagnosis of HSV-2 infection.

The HerpeSelect® Express IgG device has not been established for use in the pediatrics population, for neonatal screening, or for testing immunocompromised patients. This kit is not intended for self-testing, and this test is neither FDA cleared nor approved for testing blood or plasma donors.

Test Principle
HerpeSelect® Express is an immunochromatographic test that uses purified antigen bound to a nitrocellulose membrane to detect HSV-2 antibodies. Sample is added to the sample well and filtered through the blood separation membrane in the lid of the housing. The lid of the housing is opened after 30 seconds after sample addition, where a buffer well is accessible. The buffer is added to the buffer well to cause the sample and antibody-gold conjugate specific for human IgG deposited between the buffer pad and the sample deposition zone to migrate across the nitrocellulose membrane until captured by human IgG. As the sample continues to migrate, the HSV-2 test line captures any HSV-2 antibodies present in the sample. If there is no HSV-2 antibody present in the sample no test line is seen. The sample contacts the control line, which captures human IgG present in the sample. Formation of a pink line in the control zone of the device indicates the device is working correctly.

EXPECTED VALUES
An outside investigator assessed the device with masked, prospected samples from 1) sexually active adults (n = 575), and 2) from pregnant women (n = 401). The reference method was the Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG. The observed prevalences and the hypothetical predictive values for the two populations are shown below. The positive predictive value will decrease proportionally to the prevalence of HSV infection as reflected in the following table.

Observed Prevalence	Observed Rate of Positives in Indicated Populations			
	HerpeSelect Express In Sera	HerpeSelect Express In Venous Whole Blood	HerpeSelect Express In Capillary Whole Blood	HerpeSelect Immunoblot
HSV-2 positives(+) with Pregnant Women	(118/400) 29.5%	(118/400) 29.5%	(124/400) 31.0%	(117/399) 29.3%
HSV-2 positives(+) with Sexually Active Adults	(241/573) 42.1%	(240/573) 41.9%	(243/573) 42.4%	(226/570) 39.6%

Prevalence vs. Hypothetical Predictive Values (In Pregnant Women)

Prevalence	Serum		Venous Whole Blood		Capillary Whole Blood	
	PPV	NPV	PPV	NPV	PPV	NPV
50%	96.7%	94.8%	97.0%	93.4%	95.7%	94.9%
40%	95.2%	96.5%	95.6%	95.5%	93.7%	96.6%
30%	92.7%	97.7%	93.4%	97.1%	90.5%	97.8%
25%	90.8%	98.2%	91.6%	97.7%	88.1%	98.2%
20%	88.1%	98.7%	89.1%	98.3%	84.7%	98.7%
15%	83.9%	99.0%	85.3%	98.8%	79.7%	99.1%
10%	76.6%	99.4%	78.5%	99.2%	71.2%	99.4%
5%	60.8%	99.7%	63.3%	99.6%	53.9%	99.7%

Prevalence vs. Hypothetical Predictive Values (In Sexually Active Adults)

Prevalence	Serum		Venous Whole Blood		Capillary Whole Blood	
	PPV	NPV	PPV	NPV	PPV	NPV
50%	92.0%	93.6%	92.5%	93.3%	92.0%	93.7%
40%	88.4%	95.7%	89.1%	95.4%	88.5%	95.7%
30%	83.1%	97.2%	84.1%	97.0%	83.1%	97.2%
25%	79.3%	97.8%	80.4%	97.7%	79.3%	97.8%
20%	74.2%	98.3%	75.5%	98.2%	74.2%	98.3%
15%	67.0%	98.8%	68.5%	98.7%	67.0%	98.8%
10%	56.1%	99.2%	57.8%	99.2%	56.1%	99.3%
5%	37.7%	99.6%	39.3%	99.6%	37.7%	99.6%

Note: Sexually active adult and pregnant women populations in different geographic areas may produce different frequency distributions from the table above. Each laboratory should establish frequency distributions for their specific patient populations.

PERFORMANCE CHARACTERISTICS

Summary of Studies

Study	Criteria	Specificity and Sensitivity with HerpeSelect Immunoblot
Pregnant Women (Indicated population) in Serum	Specificity Sensitivity	92.3% (108/117) 96.1% (271/282)
Pregnant Women (Indicated population) in Venous Whole Blood	Specificity Sensitivity	93.2% (109/117) 97.2% (274/282)
Pregnant Women (Indicated population) in Capillary Whole Blood	Specificity Sensitivity	94.9% (111/117) 95.4% (269/282)
Sexually Active Adults (Indicated population) in Serum	Specificity Sensitivity	92.9% (210/226) 91.8% (315/343)

Study	Criteria	Specificity and Sensitivity with HerpeSelect Immunoblot
Sexually Active Adults (Indicated population) in Venous Whole Blood	Specificity Sensitivity	93.4% (211/226) 92.4% (317/343)
Sexually Active Adults (Indicated population) in Capillary Whole Blood	Specificity Sensitivity	93.4% (211/226) 92.4% (317/343)
Non-Sexually Active Adults (Low Prevalence Population) in Serum	Specificity Sensitivity	0% (0/2) 100% (101/101)
Non-Sexually Active Adults (Low Prevalence Population) in Venous Whole Blood	Specificity Sensitivity	0% (0/2) 100% (101/101)
Non-Sexually Active Adults (Low Prevalence Population) in Capillary Whole Blood	Specificity Sensitivity	0% (0/2) 100% (101/101)
CDC HSV/CMV Panel	Specificity Sensitivity	100% (35/35) 98.5% (64/65)
Cross-reactivity:	Overall Cross-reactivity	4.2% (9/213)
Inter-Lot Reproducibility	%CV	<10%
Inter-Operator & Inter-Site Reproducibility	% CV range	≤ 65.0%
Intra-Operator Reproducibility	% CV	≤ 35.1%
Intra-Site Reproducibility	% CV of positives	≤ 23.0%
Interference	No effect on sample results	

Sensitivity and Specificity with Pregnant Women (n = 401)
External Investigator I (n = 161), External Investigator II (n = 120), and External Investigator III (n = 120) assessed the device's agreement in subjects from pre-natal clinics. The capillary and venous whole blood and sera from sequential prospective subjects were collected, tested, and masked at the external investigator sites. The masked sera sample was submitted to the Focus laboratory and tested in the reference methods. External investigator I was a medical school clinic in Southeastern United States; External investigator II was a pre-natal clinic located in the Mid-Atlantic Region of the United States; and External investigator III was an Ob-GYN practice in the Mid-Atlantic Region of the United States. The Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG was the typing reference method for calculation of sensitivity and specificity.

Pregnant Women in Sera
The HerpeSelect Express showed 96.1% (271/282) agreement with Immunoblot negatives, and 92.3% (108/117) agreement with Immunoblot positives. Two samples were not tested in Immunoblot.
Of the 401 sera, the HerpeSelect Immunoblot IgG was negative with 282 and positive with 117. Two samples were not tested in Immunoblot; one due to insufficient quantities and the other due to improper storage.
Of the 282 negative HerpeSelect Immunoblot sera, Express was negative with 96.1% (271/282), positive with 9, and invalid with 2.
Of the 117 positive HerpeSelect Immunoblot sera, Express was negative with 6, positive with 92.3% (108/117), and invalid with 3.

HerpeSelect Express compared to Immunoblot with Pregnant Women in Sera (n = 401)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	117	108	6	3	92.3% (108/117) 95%CI 85.9-96.4%	N/A
Negative	282	9	271	2	N/A	96.1% (271/282) 95%CI 93.1-98.0%
Equivocal	0	0	0	0	N/A	N/A

[1] Two samples were not tested.

Pregnant Women in Venous Whole Blood

The HerpeSelect Express showed 97.2% (274/282) agreement with Immunoblot negatives, and 93.2% (109/117) agreement with Immunoblot positives.

Of the 401 samples, the HerpeSelect Immunoblot IgG was negative with 282 and positive with 117. Two samples were not tested; one due to insufficient quantity and one due to improper storage.

Of the 282 negative HerpeSelect Immunoblot samples, Express was negative with 97.2% (274/282), positive with 8, and invalid with 0.

Of the 117 positive HerpeSelect Immunoblot samples, Express was negative with 8, positive with 93.2% (109/117), and invalid with 0.

HerpeSelect Express compared to Immunoblot with Pregnant Women in Venous Whole Blood (n = 401)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	117	109	8	0	93.2% (109/117) 95%CI 87.0-97.0%	N/A
Negative	282	8	274	0	N/A	97.2% (274/282) 95%CI 94.5-98.8%
Equivocal	0	0	0	0	N/A	N/A

[1] Two samples were not tested.

Pregnant Women in Capillary Whole Blood

The HerpeSelect Express showed 95.4% (269/282) agreement with Immunoblot negatives, and 94.9% (111/117) agreement with Immunoblot positives.

Of the 401 samples, the HerpeSelect Immunoblot IgG was negative with 282 and positive with 117. Two samples were not tested in Immunoblot due to insufficient quantities.

Of the 282 negative HerpeSelect Immunoblot samples, Express was negative with 95.4% (269/282), positive with 12, and invalid with 1.

Of the 117 positive HerpeSelect Immunoblot samples, Express was negative with 6, positive with 94.9% (111/117), and invalid with 0.

HerpeSelect Express compared to Immunoblot with Pregnant Women in Capillary Whole Blood (n = 401)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	117	111	6	0	94.9% (111/117) 95%CI 89.2-98.1%	N/A
Negative	282	12	269	1	N/A	95.4% (269/282) 95%CI 92.2-97.5%
Equivocal	0	0	0	0	N/A	N/A

[1] Two samples were not tested.

HerpeSelect Express Percent Negative and Positive Agreement with HerpeSelect 2 (ELISA) in Pregnant Women (n = 401)

The gold-standard reference method was the Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG for calculation of sensitivity and specificity. The device was also evaluated with the HerpeSelect2 ELISA IgG a cleared predicate device which is not required for regulatory clearance for typing assay.

HerpeSelect Express Agreement with ELISA in Sera with Pregnant Women

The HerpeSelect Express showed 96.7% (267/276) agreement with ELISA negatives in sera, and 91.7% (111/121), agreement with ELISA positives. Two ELISA equivocals were excluded. One sample was not tested due to improper storage.

Of the 401 sera, the HerpeSelect 2 ELISA IgG was negative with 276, positive with 121, and equivocal with 2. One sample was not tested due to improper storage.

Of the 276 negative HerpeSelect 2 ELISA sera, Express was negative with 96.7% (267/276), positive with 7, and invalid with 2.

Of the 121 positive HerpeSelect 2 ELISA sera, the Express was negative with 7, positive with 91.7% (111/121), and invalid with 3.

Express Agreement with ELISA in Sera with Pregnant Women (n = 401)

ELISA	n[1]	HerpeSelect Express			% Agreement
		Positive	Negative	Invalid	
Positive	121	111	7	3	91.7% (111/121) 95%CI 85.3-96.0%
Negative	276	7	267	2	96.7% (267/276) 95%CI 93.9-98.5%
Equivocal	2	0	2	0	N/A

[1] One sample was not tested in ELISA.

HerpeSelect Express Agreement with ELISA in Venous Whole Blood with Pregnant Women

The HerpeSelect Express showed 97.8% (271/277) agreement with ELISA negatives in samples, and 92.6% (112/121) agreement with ELISA positives. Two ELISA equivocals were excluded and one sample was not tested due to improper storage.

Of the 401 samples, the HerpeSelect 2 ELISA IgG was negative with 277, positive with 121, and equivocal with 3. One sample was not tested due to improper storage.

Of the 277 negative HerpeSelect 2 ELISA samples, Express was negative with 97.8% (271/277), positive with 6, and invalid with 0.

Of the 121 positive HerpeSelect 2 ELISA samples, the Express was negative with 9, positive with 92.6% (112/121), and invalid with 0.

Express Agreement with ELISA in Venous Whole Blood with Pregnant Women (n = 401)

ELISA	n[1]	HerpeSelect Express			% Agreement
		Positive	Negative	Invalid	
Positive	121	112	9	0	92.6% (112/121) 95%CI 86.4-96.5%
Negative	277	6	271	0	97.8% (271/277) 95%CI 95.3-99.2%
Equivocal	3	0	3	0	N/A

[1] One sample was not tested in ELISA

HerpeSelect Express Agreement with ELISA in Capillary Whole Blood with Pregnant Women

The HerpeSelect Express showed 96.4% (266/276) agreement with ELISA negatives in samples, and 94.2% (114/121), agreement with ELISA positives. Two ELISA equivocals were excluded.

Of the 401 samples, the HerpeSelect 2 ELISA IgG was negative with 276, positive with 121, and equivocal with 3. One sample was not tested due to improper storage.

Of the 276 negative HerpeSelect 2 ELISA samples, Express was negative with 96.4% (266/276), positive with 9, and invalid with 1.

Of the 121 positive HerpeSelect 2 ELISA samples, the Express was negative with 7, positive with 94.2% (114/121), and invalid with 0.

Express Agreement with ELISA in Capillary Whole Blood with Pregnant Women (n = 401)

ELISA		HerpeSelect Express			
	n[1]	Positive	Negative	Invalid	% Agreement
Positive	121	114	7	0	94.2% (114/121) 95%CI 88.4-97.6%
Negative	276	9	266	1	96.4% (266/276) 95%CI 93.4-98.3%
Equivocal	3	1	2	0	N/A

[1] One sample was not tested in ELISA

Sensitivity and Specificity with Sexually Active Adults (n = 575)

External investigator I (n = 195), External investigator II (n = 190), and External investigator III (n = 190) assessed the device's agreement with sexually active adult subjects at medical school, student and public health clinics. The capillary and venous whole blood and sera from sequential prospective subjects were collected, tested, and masked at the external investigator sites. The masked sera sample was submitted to the Focus laboratory and tested in the reference methods. External investigator I was a medical school clinic in Southeastern United States; External investigator II was a public health clinic located in the Rocky Mountain Region of the United States; and External investigator III was a student health clinic in the Southeastern United States. The Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG was the typing reference method for calculation of sensitivity and specificity.

Sexually Active Adults in Sera

The HerpeSelect Express showed 91.8% (315/343) agreement with Immunoblot negatives, and 92.9% (210/226) agreement with Immunoblot positives.

Of the 575 sera, the HerpeSelect Immunoblot IgG was negative with 343, positive with 226, and equivocal with 1. Five samples were not tested in Immunoblot. Two samples were lost between the Investigator and the Focus Laboratory, and three were not tested due to insufficient quantities.

Of the 343 negative HerpeSelect Immunoblot sera, Express was negative with 91.8% (315/343), positive with 28, and invalid with 0.

Of the 226 positive HerpeSelect Immunoblot sera, Express was negative with 14, positive with 92.9% (210/226), and invalid with 2.

HerpeSelect Express compared to Immunoblot with Sexually Active Adult in Sera (n = 575)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	226	210	14	2	92.9% (210/226) 95% CI 88.8-95.9%	N/A
Negative	343	28	315	0	N/A	91.8% (315/343) 95% CI 88.4-94.5%
Equivocal	1	0	1	0	N/A	N/A

[1]Five samples were not tested.

Sexually Active Adults in Venous Whole Blood

The HerpeSelect Express showed 92.4% (317/343) agreement with Immunoblot negatives, and 93.4% (211/226) agreement with Immunoblot positives.

Of the 575 samples, the HerpeSelect Immunoblot IgG was negative with 343 and positive with 226. Five samples were not tested in Immunoblot. Two samples were lost between the Investigator and the Focus Laboratory, and three were not tested due to insufficient quantities.

Of the 343 negative HerpeSelect Immunoblot samples, Express was negative with 92.4% (317/343), positive with 26, and invalid with 0.

Of the 226 positive HerpeSelect Immunoblot samples, Express was negative with 15, positive with 93.4% (211/226), and invalid with 0.

HerpeSelect Express compared to Immunoblot with Sexually Active Adult in Venous Whole Blood (n = 575)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	226	211	15	0	93.4% (211/226) 95% CI 89.3-96.2%	N/A
Negative	343	26	317	0	N/A	92.4% (317/343) 95% CI 89.1-95.0%
Equivocal	1	0	1	0	N/A	N/A

[1]Five samples were not tested.

Sexually Active Adults in Capillary Whole Blood

The HerpeSelect Express showed 91.8% (315/343) agreement with ELISA negatives, and 93.8% (212/226) agreement with Immunoblot positives.

Of the 575 samples, the HerpeSelect Immunoblot IgG was negative with 343 and positive with 226. Five samples were not tested in Immunoblot. Two samples were lost between the Investigator and the Focus Laboratory, and three were not tested due to insufficient quantities

Of the 343 negative HerpeSelect Immunoblot samples, Express was negative with 91.8% (315/343), positive with 28, and invalid with 0.

Of the 226 positive HerpeSelect Immunoblot samples, Express was negative with 14, positive with 93.8% (212/226), and invalid with 0.

HerpeSelect Express compared to Immunoblot with Sexually Active Adult in Capillary Whole Blood

(n = 575)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	226	212	14	0	93.8% (212/226) 95% CI 89.8-96.6%	N/A
Negative	343	28	315	0	N/A	91.8% (315/343) 95% CI 88.4-94.5%
Equivocal	1	0	1	0	N/A	N/A

[1]Five samples were not tested.

HerpeSelect Express Percent Agreement with HerpeSelect 2 (ELISA) in Sexually Active Adults (n = 575)

The gold-standard reference method was the Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG for calculation of sensitivity and specificity. The device was also evaluated with the HerpeSelect2 ELISA IgG a cleared predicate device which is not required for regulatory clearance for typing assay.

HerpeSelect Express Agreement with ELISA in Sera with Sexually Active Adults

The HerpeSelect Express showed 98.8% (323/327) agreement with ELISA negatives in sera, and 97.1% (236/243) agreement with ELISA positives. Three ELISA equivocals were excluded.

Of the 575 sera, the HerpeSelect 2 ELISA IgG was negative with 327, positive with 243, and equivocal with 3. Two samples were not tested in ELISA. The samples were lost between the Investigator and the Focus Laboratory.

Of the 327 negative HerpeSelect 2 ELISA sera, Express was negative with 98.8% (323/327), positive with 4, and invalid with 0.

Of the 243 positive HerpeSelect 2 ELISA sera, the Express was negative with 5, positive with 97.1% (236/243), and invalid with 2.

Express Agreement with ELISA in Sera with Sexually Active Patients (n = 575)

ELISA		HerpeSelect Express			
	n[1]	Positive	Negative	Invalid	% Agreement
Positive	243	236	5	2	97.1% (236/243) 95% CI 94.1-98.8%
Negative	327	4	323	0	98.8% (323/327) 95% CI 96.9-99.7%
Equivocal	3	1	2	0	N/A

[1] Two samples were not tested in ELISA

HerpeSelect Express Agreement with ELISA in Venous Whole Blood with Sexually Active Adults

The HerpeSelect Express showed 98.8% (322/327) agreement with ELISA negatives in samples, and 97.1% (236/243), agreement with ELISA positives. Three ELISA equivocals were excluded.

Of the 575 samples, the HerpeSelect 2 ELISA IgG was negative with 327, positive with 243, and equivocal with 3. Two samples were not tested in ELISA. The samples were lost between the Investigator and the Focus Laboratory.

Of the 327 negative HerpeSelect 2 ELISA samples, Express was negative with 98.8% (323/327), positive with 4, and invalid with 0.

Of the 243 positive HerpeSelect 2 ELISA samples, the Express was negative with 7, positive with 97.1% (236/243), and invalid with 0.

Express Agreement with ELISA in Venous Whole Blood with Sexually Active Patients (n = 575)

ELISA		HerpeSelect Express			
	n[1]	Positive	Negative	Invalid	% Agreement
Positive	243	236	7	0	97.1% (236/243) 95%CI 94.1-98.8%
Negative	327	4	323	0	98.8% (323/327) 95% CI 96.9-99.7%
Equivocal	3	0	3	0	N/A

[1] Two samples were not tested in ELISA

Express in Capillary Whole Blood Agreement with ELISA

The HerpeSelect Express showed 98.5% (322/327) agreement with ELISA negatives in samples, and 97.5% (237/243) agreement with ELISA positives. Three ELISA equivocals were excluded.

Of the 575 samples, the HerpeSelect 2 ELISA IgG was negative with 327, positive with 243, and equivocal with 3. Two samples were not tested in ELISA. The samples were lost between the Investigator and the Focus Laboratory.

Of the 327 negative HerpeSelect 2 ELISA samples, Express was negative with 98.5% (322/327), positive with 5, and invalid with 0.

Of the 243 positive HerpeSelect 2 ELISA samples, the Express was negative with 6, positive with 97.5% (237/243), and invalid with 0.

Express Agreement with ELISA in Capillary Whole Blood with Sexually Active Patients (n = 575)

ELISA		HerpeSelect Express			
	n[1]	Positive	Negative	Invalid	% Agreement
Positive	243	237	6	0	97.5% (237/243) 95%CI 94.7-99.1%
Negative	327	5	322	0	98.5% (322/327) 95% CI 96.5-99.5%
Equivocal	3	1	2	0	N/A

[1] Two samples were not tested in ELISA

Sensitivity and Specificity with Non-Sexually Active Adults {Low Prevalence} (n =104)

External investigator I (n = 46) and External investigator II (n = 58) assessed the device's agreement with non-sexually active adult subjects (low prevalence) from a metropolitan population and student population. The capillary and venous whole blood and sera from sequential prospective subjects were collected, tested, and masked at the external investigator sites. The masked sera sample was submitted to the Focus laboratory and tested in the reference methods. External investigator I was a medical school clinic in Southeastern United States; External investigator II was an STD clinic located in the Pacific Northwest. The Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG was the typing reference method for calculation of sensitivity and specificity.

Non-Sexually Active Adults (Low Prevalence) in Sera

The HerpeSelect Express showed 100.0% (101/101) agreement with Immunoblot negatives, and 0.0% (0/2) agreement with Immunoblot positives.

Of the 104 sera, the HerpeSelect Immunoblot IgG was negative with 101 and positive with 2. One sample was not tested in Immunoblot due to insufficient quantities.

Of the 101 negative HerpeSelect Immunoblot sera, Express was negative with 100.0% (101/101), positive with 0, and invalid with 0.

Of the 2 positive HerpeSelect Immunoblot sera, Express was positive with 0.0% (0/2), negative with 2, and invalid with 0.

HerpeSelect Express compared to Immunoblot with Non-Sexually Active Adults (Low Prevalence) in Sera

(n =104)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	2	0	2	0	0% (0/2)	N/A
Negative	101	0	101	0	N/A	100% (101/101) 95% CI 96.4-100
Equivocal	0	0	0	0	N/A	N/A

[1]One sample was not tested.

Non-Sexually Active Adults (Low Prevalence) in Venous Whole Blood

The HerpeSelect Express showed 100.0% (101/101) agreement with Immunoblot negatives, and 0.0% (0/2) agreement with Immunoblot positives.

Of the 104 sera, the HerpeSelect Immunoblot IgG was negative with 101 and positive with 2. One sample was not tested in Immunoblot due to insufficient quantities.

Of the 101 negative HerpeSelect Immunoblot sera, Express was negative with 100.0% (101/101), positive with 0, and invalid with 0.

Of the 2 positive HerpeSelect Immunoblot sera, Express was positive with 0.0% (0/2), negative with 2, and invalid with 0.

HerpeSelect Express compared to Immunoblot with Non-Sexually Active Adults (Low Prevalence) in Venous Whole Blood

(n =104)

Immunoblot	n[1]	Express			Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	2	0	2	0	0% (0/2)	N/A
Negative	101	0	101	0	N/A	100% (101/101) 95% CI 96.4-100
Equivocal	0	0	0	0	N/A	N/A

[1]One sample was not tested.

Non-Sexually Active Adults (Low Prevalence) in Capillary Whole Blood

The HerpeSelect Express showed 100.0% (101/101) agreement with Immunoblot negatives, and 0.0% (0/2) agreement with Immunoblot positives.

Of the 104 sera, the HerpeSelect Immunoblot IgG was negative with 101 and positive with 2. One sample was not tested in Immunoblot due to insufficient quantities.

Of the 101 negative HerpeSelect Immunoblot sera, Express was negative with 100.0% (101/101), positive with 0, and invalid with 0.

Of the 2 positive HerpeSelect Immunoblot sera, Express was positive with 0.0% (0/2), negative with 2, and invalid with 0.

HerpeSelect Express compared to Immunoblot with Non-Sexually Active Adults (Low Prevalence) in Capillary Whole Blood

(n = 104)

Immunoblot	n[1]				Specificity	Sensitivity
		Positive	Negative	Invalid		
Positive	2	0	2	0	0% (0/2)	N/A
Negative	101	0	101	0	N/A	100% (101/101) 95% CI 96.4-100
Equivocal	0	0	0	0	N/A	N/A

[1]One sample was not tested.

HerpeSelect Express Percent Agreement with Focus Diagnostics HerpeSelect 2 (ELISA) with Non-Sexually Active Adults {Low Prevalence} (n =104)

The gold-standard reference method was the Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG for calculation of sensitivity and specificity. The device was also evaluated with the HerpeSelect2 ELISA IgG a cleared predicate device which is not required for regulatory clearance for typing assay.

HerpeSelect Express in Sera Agreement with ELISA

The HerpeSelect Express showed 100.0% (102/102) agreement with ELISA negatives in sera, and, 0.0% (0/1) agreement with ELISA positives. One ELISA equivocal was excluded.

Of the 104 sera, the HerpeSelect 2 ELISA IgG was negative with 102, positive with 1, and equivocal with 1.

Of the 102 negative HerpeSelect 2 ELISA sera, the Express was negative with 100.0% (102/102), positive with 0, and invalid with 0.

Of the 1 positive HerpeSelect 2 ELISA sera, Express was negative with 1, positive with 0.0% (0/1), and invalid with 0.

Express Agreement with ELISA in Sera with Non-Sexually Active Adults{Low Prevalence} (n = 104)

ELISA		HerpeSelect Express			
	n	Positive	Negative	Invalid	% Agreement
Positive	1	0	1	0	0% (0/1)
Negative	102	0	102	0	100% (102/102) 95% CI 96.4-100%
Equivocal	1	0	1	0	N/A

HerpeSelect Express in Venous Whole Blood Agreement with ELISA

The HerpeSelect Express showed 100.0% (102/102) agreement with ELISA negatives in sera, and, 0.0% (0/1) agreement with ELISA positives. One ELISA equivocal was excluded.

Of the 104 sera, the HerpeSelect 2 ELISA IgG was negative with 102, positive with 1, and equivocal with 1.

Of the 102 negative HerpeSelect 2 ELISA sera, the Express was negative with 100.0% (102/102), positive with 0, and invalid with 0.

Of the 1 positive HerpeSelect 2 ELISA sera, Express was negative with 1, positive with 0.0% (0/1), and invalid with 0.

Express Agreement with ELISA in Venous Whole Blood with Non-Sexually Active Adults {Low Prevalence} (n = 104)

ELISA	n	HerpeSelect Express			% Agreement
		Positive	Negative	Invalid	
Positive	1	0	1	0	0% (0/1)
Negative	102	0	102	0	100% (102/102) 95% CI 96.4-100
Equivocal	1	0	1	0	N/A

Express in Capillary Whole Blood Agreement with ELISA

The HerpeSelect Express showed 100.0% (102/102) agreement with ELISA negatives in sera, and, 0.0% (0/1) agreement with ELISA positives. One ELISA equivocal was excluded.

Of the 104 sera, the HerpeSelect 2 ELISA IgG was negative with 102, positive with 1, and equivocal with 1.

Of the 102 negative HerpeSelect 2 ELISA sera, the Express was negative with 100.0% (102/102), positive with 0, and invalid with 0.

Of the 1 positive HerpeSelect 2 ELISA sera, Express was negative with 1, positive with 0.0% (0/1), and invalid with 0.

Express Agreement with ELISA in Capillary Whole Blood with Non-Sexually Active Adults {Low Prevalence} **(n = 104)**

ELISA	n	HerpeSelect Express			% Agreement
		Positive	Negative	Invalid	
Positive	1	0	1	0	0% (0/1)
Negative	102	0	102	0	100% (102/102) 95% CI 96.4-100%
Equivocal	1	0	1	0	N/A

Agreement with CDC Panel (n = 100)

The following information is from a serum panel obtained from the CDC and tested by Focus Diagnostics. Results from the panel were previously received during studies for the Plexus HerpeSelect Multi-Analyte Diagnostic. These results were masked from the person performing the testing with the Express device and the person performing the data analysis. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel and do not imply an endorsement of the assay by the CDC.

The test panel consists of 100 samples. There are 65 HSV-2 negative and 35 HSV-2 positive specimens.

Determination of positive and negative samples

Of the 65 HSV-2 negative samples, the HerpeSelect® Express IgG correctly identified 98.5% (64/65).
Of the 35 HSV-2 positive samples, the HerpeSelect® Express IgG correctly identified 100% (35/35).

Agreement with CDC Panel (n = 100)

CDC HSV2	n	HerpeSelect® Express			% Agreement
		Positive	Negative	Invalid	
Positive	35	35	0	0	100% (35/35) 95% CI 90.0-100.0%
Negative	65	1	64	0	98.5% (64/65) 95% CI 91.7 - 100.0%

Cross-Reactivity (n = 213)

Focus assessed cross-reactivity with samples that were sero-negative and sero-positive by at least one of

- (n= 25) Herpes Simplex 1 Virus (HSV-1)
- (n= 25) Rubella virus
- (n= 42) Varicella-Zoster virus, (VZV)
- (n= 25) Epstein-Barr virus (EBV)
- (n= 32) Cytomegalovirus (CMV)
- (n= 33) Rheumatoid Factor (RF)
- (n= 31) Anti-nuclear Antibodies (ANA)

Express Reactivity with Cross-Reactants

The HerpeSelect Express showed 4.2% (9/213) overall cross-reactivity.
With the HSV-1 IgG positives the Express was positive with 0.0% (0/25), negative with 25, and invalid with 0.
With the Rubella virus positives the Express was positive with 4.0% (1/25), negative with 24, and invalid with 0.
With the VZV IgG positives the Express was positive with 9.5% (4/42), negative with 38, and invalid with 0.
With the EBV IgG positives the Express was positive with 4.0% (1/25), negative with 24, and invalid with 0.
With the CMV IgG positives the Express was positive with 3.1% (1/32), negative with 31, and invalid with 0.
With the RF positives the Express was positive with 3.0% (1/33), negative with 32, and invalid with 0.
With the ANA positives the Express was positive with 3.2% (1/31), negative with 30, and invalid with 0.

Express Agreement Cross-Reactant

Cross-reactant	n	HerpeSelect Express			% Cross-Reactivity
		Positive	Negative	Invalid	
HSV-1 IgG +	25	0	25	0	0.0% (0/25) 95%CI 0.0 - 13.7%
Rubella +	25	1	24	0	4.0% (1/25) 95%CI 0.0 – 20.4%
VZV IgG +	42	4	38	0	9.5% (4/42) 95%CI 2.7 – 22.6%
EBV IgG +	25	1	24	0	4.0% (1/25) 95%CI 0.0 – 20.4%
CMV IgG +	32	1	31	0	3.1% (1/32) 95%CI 0.0-16.2%
RF +	33	1	32	0	3.0% (1/33) 95%CI 0.0 – 15.8%
ANA +	31	1	30	0	3.2% (1/31) 95%CI 0.0-15.8%
Combined Cross-reactants	213	9	204	0	4.2% (9/213) 95%CI 1.9.0-7.8%

Interference
The device performance was evaluated with the presence of interferents. Two subjects were drawn: one positive for herpes simplex virus-2 and negative for herpes simplex virus-1 and one negative for both herpes simplex virus 1 and herpes simplex virus 2 by HerpeSelect ELISA IgG. Baseline levels for triglycerides, albumin, bilirubin, and hemoglobin were established for each subject. The remaining serum was spiked with purchased interferents at levels which exceeded the expected human range. The spiked samples were tested again in the assay to determine if the elevated levels of interferents affected the assay. No interference was observed for any of the interferents in either the positive or negative sample.

Matrix Comparison
Focus compared the device's relative reactivity with serum with venous whole blood by spiking a HerpeSelect 2 ELISA positive serum into negative serum and negative venous whole blood, serially diluting the spiked serum and whole blood, and testing the diluted serum and blood with the device in triplicates. Two of three of the serum replicates end-pointed at 1:8 and one at 1:4. Three of three whole blood replicates end-pointed at 1:4.

Reproducibility
Focus, a clinical laboratory located in Southern California, a public health clinic located in the Rocky Mountain Region of the United States; a student health clinic in the Southeastern United States, and an STD clinic located in the Pacific Northwest assessed the device's Inter-lot, Inter/Intra-operator reproducibility and Inter/Intra-site reproducibility. Each of the sites tested at ten samples in singlicate on three different days.

		Inter-Lot Reproducibility			Inter-Operator			Inter-Site	
ELISA Range	**Sample ID**	**Mean**	**%CV**	**Accuracy**	**Precision**	**%CV**	**Accuracy**	**Precision**	**%CV**
High Negative	HSV-1	100.0%	0.0%	100.0%	100.0%	0.0%	100.0%	100.0%	0.0%
Borderline	HSV-2	100.0%	0.0%	98.8%	96.3%	3.7%	98.8%	97.8%	2.2%
Negative	HSV-11	100.0%	0.0%	97.5%	92.4%	7.6%	97.5%	95.6%	4.4%
High Positive	HSV-12	100.0%	0.0%	100.0%	100.0%	0.0%	100.0%	100.0%	0.0%
Positive	HSV-13	100.0%	0.0%	97.5%	92.4%	7.6%	97.5%	95.6%	4.4%
Low Positive	HSV-14	100.0%	0.0%	59.3%	35.0%	65.0%	59.3%	65.2%	34.8%
Negative	HSV-15	77.8%	24.7%	82.7%	71.4%	28.6%	82.7%	83.0%	17.0%
Positive	HSV-26	100.0%	0.0%	97.5%	95.0%	5.0%	97.5%	97.8%	2.2%
Negative	HSV-27	100.0%	0.0%	100.0%	100.0%	0.0%	100.0%	100.0%	0.0%
Positive	HSV-28	100.0%	0.0%	98.8%	96.3%	3.7%	98.8%	97.8%	2.2%

Intra-Operator			
Operator	**Accuracy**	**Precision**	**%CV**
1	96.7%	89.1%	10.9%
2	97.8%	95.2%	4.8%
3	90.0%	64.9%	35.1%
4	98.9%	96.4%	3.6%
5	87.8%	70.5%	29.5%
6	96.7%	89.1%	10.9%
7	87.8%	86.1%	13.9%
8	92.2%	77.2%	22.8%
9	91.1%	69.1%	30.9%
Intra-Site			
Site	**Accuracy**	**Precision**	**%CV**
1	94.8%	87.6%	12.4%
2	94.4%	87.3%	12.7%
3	90.4%	79.0%	21.0%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Constance Bridges
Director, Regulatory and Compliance
Focus Diagnostics, Inc.
10703 Progress Way
Cypress, CA 90630

SEP 2 4 2007

Re: k071510
Trade/Device Name: *HerpeSelect® Express IgG*
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes simplex virus serological reagents
Regulatory Class: Class II
Product Code: MYF
Dated: May 31, 2007
Received: June 4, 2007

Dear Ms. Bridges:

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 either class II (Special Controls) or class III (PMA), 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); 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 Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

510(k) Number (if known): **K071510**

Device Name: HerpeSelect Express IgG

Indications for Use: HerpeSelect® Express is a rapid test intended for qualitatively detecting the presence or absence of human IgG class antibodies to herpes simplex virus type 2 (HSV-2) in human whole blood (venous or capillary) or serum. The test is indicated for testing sexually active adults or pregnant women to aid in the presumptive diagnosis of HSV-2 infection.

The HerpeSelect® Express IgG device has not been established for use in the pediatrics population, for neonatal screening, or for testing immunocompromised patients. This kit is not intended for self-testing, and this test is neither FDA cleared nor approved for testing blood or plasma donors.

Prescription Use __X__ 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) K071510