JAN 22 1997

K964754

REVISED 510(k) SUMMARY

SUBMITTER:	Ortho Diagnostic Systems 1001 U.S. Hwy 202 Raritan, NJ 08869-0606	**CONTACT:**	Joanne Harris Tel: (908) 218-8404 Fax: (908) 218-8168
DEVICE NAME:	Ortho-mune™ OKB™19A (CD19) Monoclonal Antibody (Murine) Phycoerythrin Conjugate	**PREDICATE:**	Monoclonal Antibody Test for B Cells [Anti-Leu-12 (CD19) PE Phycoerythrin]
DATE:	May 14, 1996		

DEVICE DESCRIPTION

Ortho-mune OKB19A Monoclonal Antibody (Murine) Phycoerythrin (PE) Conjugate contains the purified monoclonal antibody OKB19A conjugated to the fluorochrome phycoerythrin.

INTENDED USE

Ortho-mune OKB19A PE Conjugate is intended for use in identification and enumeration of CD19+ human B lymphocytes in whole blood by flow cytometry. The intended use is the same as the intended use of the predicate device, Monoclonal Antibody Test for B Cells [Anti-Leu-12 (CD19) PE (Phycoerythrin)] commercially distributed by Becton Dickinson Immunocytometry Systems.

TECHNOLOGICAL CHARACTERISTICS

Both Ortho-mune OKB19A Monoclonal Antibody (Murine) PE Conjugate and Monoclonal Antibody Test for B Cells utilize monoclonal antibodies specific for human B cells (OKB19A/Leu-12) respectively, conjugated to the same fluorochrome, phycoerythrin.

PERFORMANCE CHARACTERISTICS

Performance of Ortho-mune OKB19A Monoclonal Antibody (Murine) PE Conjugate was compared with that of Monoclonal Antibody Test For B Cells at three external, geographically distinct sites. Whole blood specimens from 205 normal donors, and 87 AIDS/ARC patients were stained and analyzed using the ORTHO CYTORONABSOLUTE™ flow cytometer, Ortho Diagnostic Systems Inc.

For each specimen, the percentage of gated cells which showed positive by each marker was calculated. The mean and range of the percent CD19+ cells for the normal donor and AIDS/ARC population are shown in Table 1 and Table 2 respectively.

TABLE 1

PERCENT POSITIVE STAINED CELLS IN NORMAL DONORS DETECTED BY OKB19A AND LEU-12 ASSAYED ON THE CYTORONABSOLUTE
N=205

Ortho-mune Reagent	Mean %	Range %	BD Reagent	Mean %	Range %
OKB19A (CD19)+	13.3	1.3 - 31.1	LEU-12 (CD19)+	14.1	0.1 - 31.3

TABLE 2

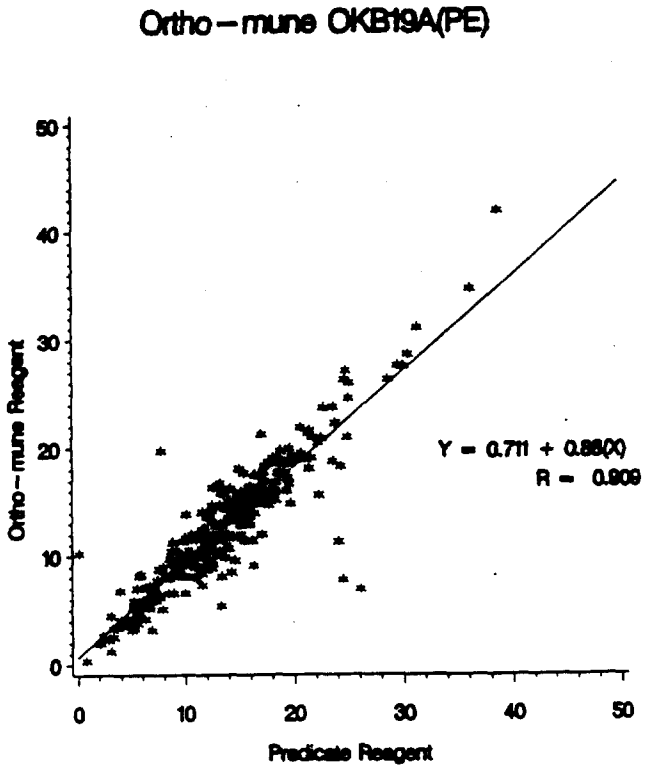
PERCENT POSITIVE STAINED CELLS IN AIDS/ARC PATIENTS DETECTED BY OKB19A AND LEU-12 ASSAYED ON THE CYTORONABSOLUTE
N=87

Ortho-mune Reagent	Mean %	Range %	BD Reagent	Mean %	Range %
OKB19A (CD19)+	10.2	0.4 - 41.9	LEU-12 (CD19)+	11.1	0.8 - 38.7

Linear regression analysis of total percent CD19+ cells from the combined normal and AIDS/ARC populations is found in Chart 1.

CHART 1

Ortho-mune OKB19A (CD19) PE vs Monoclonal Antibody Test for B Cells (Leu-12)



This study demonstrates that the performance of Ortho-mune OKB19A (CD19) Monoclonal Antibody (Murine) PE Conjugate is equivalent to Monoclonal Antibody Test for B Cells [Anti-Leu-12 (CD19) PE (Phycoerythrin)] reagent in identification and enumeration CD19+ human lymphocytes in whole blood by flow cytometry.

Reproducibility studies were performed at three independent laboratories using samples with low, normal, and high relative percent CD19+ cells.

Specimens from each of ten normal donors (whole blood, EDTA) were processed using monoclonal antibodies bound to microbeads to produce samples of low, normal, and high relative percent CD19+ cells. The samples were separated into aliquots for each laboratory. Samples were stained in replicates of 10 with Ortho-mune OKB19A (CD19) PE Conjugate reagent and analyzed using the ORTHO CYTORONABSOLUTE flow cytometer.

For within laboratory reproducibility, the variance for the replicate results was calculated within site, concentration and donor. The variance was averaged across site, concentration and donor. The square root replicate variance (SD) was divided by the appropriate mean percent positive result (by site and concentration) and multiplied by 100 to obtain the CV. Within laboratory reproducibility results for determination of total percent CD19+ cells are presented in Table 3.

TABLE 3

WITHIN LABORATORY REPRODUCIBILITY Ortho-mune OKB19A(PE) N = 10 donors							
	All SITES Mean	Site A		Site B		Site C	
Ortho-mune OKB19A(PE)	Percent Positive	CV	# Reps	CV	# Reps	CV	# Reps
TOTAL $CD19^+$ Low	1.134	24.182	100	20.793	100	22.106	100
TOTAL $CD19^+$ Normal	15.330	5.082	100	4.635	98	4.545	100
TOTAL $CD19^+$ High	26.760	3.438	99	3.401	100	3.447	100

The between laboratory CV was computed as follows. The mean percent positive for each site within concentration was calculated. The SD was computed on the three site means within concentration and the CV was obtained by dividing the SD by the overall mean within concentration and multiplying by 100. Between laboratory reproducibility results for determination of total percent CD19+ cells are presented in Table 4.

TABLE 4

BETWEEN LABORATORY REPRODUCIBILITY Ortho-mune OKB19A(PE) N = 10 donors					
	SITE A	SITE B	SITE C	ACROSS SITE	
Ortho-mune OKB19A(PE)	Mean Percent Positive (All Donors)	Mean Percent Positive (All Donors)	Mean Percent Positive (All Donors)	Coefficient of Variation	# Reps
TOTAL $CD19^+$ Low	1.132	1.152	1.119	1.466	300
TOTAL $CD19^+$ Normal	15.395	15.410	15.144	0.976	298
TOTAL $CD19^+$ High	26.518	26.787	26.930	0.782	299

Ortho-mune OKB19A (CD19) Monoclonal Antibody (Murine) PE Conjugate immunophenotyping reagent shows acceptable within and between laboratory reproducibility for determination of CD19+ lymphocyte percentages

A linearity study was performed using an automated hematology analyzer to determine total lymphocyte count, and the CYTORONABSOLUTE flow cytometer to determine the percent positive CDx cells.

Specimens from four normal donors (whole blood, EDTA) were processed to produce samples with low, normal and high numbers of lymphocyte subsets. Each whole blood specimen was concentrated by harvesting the buffy coat to obtain a white blood cell count between 20,000 and 40,000 cells/uL and then diluting to produce samples of high, normal and low numbers of lymphocyte subsets. A portion of each sample was stained in triplicate using Ortho-mune OKB19A (CD19) PE Conjugate immunophenotyping reagent and analyzed using the CYTORONABSOLUTE flow cytometer. The total lymphocyte count of the concentrated sample for each donor was obtained using an automated hematology analyzer.

Linear regression analyses were performed as follows. The expected (X axis) values were calculated by multiplying the corresponding serial dilutions by the hematology analyzer derived buffy coat lymphocyte count and by the CYTORONABSOLUTE derived lymphocyte subset percent positive. The observed (Y axis) values were determined as the total lymphocyte count calculated from the hematology derived value of the concentrated sample times the CYTORONABSOLUTE derived lymphocyte subset percent positive at each dilution.

The Ortho-mune OKB19A (CD19) PE Conjugate reagent demonstrated linear performance for total CD19+ lymphocyte subsets across a lymphocyte count range of 20 cells/uL to 9000 cells/uL as demonstrated with slopes indistinguishable from 1 and R values of 1.000.

Linear regression analyses of observed versus expected values for total percent CD19+ cells for each donor specimen are shown in. Regression analysis statistics are provided in Table 5.

CHART 2

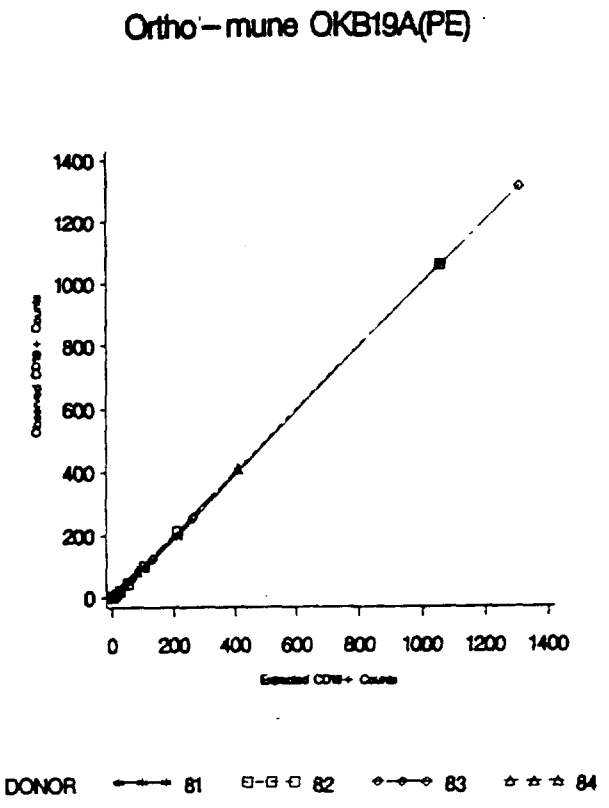

Ortho-mune OKB19A(PE)
1400
1200
1000
800
600
400
200
0
0
200
400
600
800
1000
1200
1400
DONOR
81
82
83
84

TABLE 5

LINEARITY Ortho-mune OKB19A(PE) N = 4						
Ortho-mune OKB19A(PE)	**Donor**	**SLOPE**	**CI**	**INTERCEPT**	**CI**	**R**
TOTAL $CD19^+$	**1**	1.003	0.01	-6.012	5.33	1.000
TOTAL $CD19^+$	**2**	1.004	0.00	-4.017	2.59	1.000
TOTAL $CD19^+$	**3**	1.003	0.00	-4.126	2.20	1.000
TOTAL $CD19^+$	**4**	1.001	0.00	0.311	1.36	1.000
TOTAL $CD19^+$	**All**	1.002	0.00	-3.308	1.50	1.000

CONCLUSION

Performance of Ortho-mune OKB19A (CD19) Monoclonal Antibody (Murine) Phycoerythrin Conjugate is substantially equivalent to Monoclonal Antibody Test for B Cells [Anti-Leu-12 (CD19) PE (Phycoerythrin)] in the identification and enumeration of CD19+ human T lymphocytes in whole blood by flow cytometry.

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