K990641

SEP 17 1999

CALTAG
LABORATORIES

510(K) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Caltag Fetal Hemoglobin Test for the Detection of Fetal Red Blood Cells in the Maternal Circulation (Fetal-Maternal Hemorrhage)

NAME AND LOCATION OF THE MANUFACTURER:

Caltag Laboratories, Inc.
1849 Old Bayshore Highway
Suite 200
Burlingame, CA 94010
(800) 874-4007

NAME OF CONTACT PERSON:

Robert C. Johnson
Executive Vice President
Caltag Laboratories, Inc.

DATE OF PREPARATION OF THE SUMMARY:

July 09, 1999

TRADE NAME OF THE DEVICE:

Caltag Fetal Hemoglobin Test for the Detection of Fetal Red Blood Cells in the Maternal Circulation (Fetal-Maternal Hemorrhage)

COMMON NAME:

Caltag Fetal Hemoglobin Test

CLASSIFICATION NAME:

Fetal Hemoglobin Assay; 21CFR 864.7455
Product Code: GHQ

LEGALLY MARKETED (PREDICATE) DEVICE TO WHICH THE MANUFACTURER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Caltag Fetal Hemoglobin Test is substantially equivalent to Sure-Tech Fetal Hemoglobin Test for in vitro diagnostic use (K892241), manufactured by Sure-Tech Diagnostic Associates, Inc., 11012 Un Valle, Suite D, St. Louis, Mo. 63123.

DESCRIPTION OF THE DEVICE:

An anticoagulated peripheral blood sample is drawn from an appropriate donor. The erythrocyte count is determined and adjusted, followed by brief fixation of the cells in gluteraldehyde.

Fixed and washed cells are permeabilized with a detergent in a manner that is frequently used to enable macromolecules such as monoclonal antibodies to penetrate cellular membranes. Caltag HbF FITC, HbF R-PE and HbF TRI-COLOR monoclonal antibodies bind to fetal hemoglobin in fetal red cells. To identify cells containing fetal hemoglobin, fixed and permeabilized cells are incubated with the monoclonal antibody, and washed to remove unbound antibody. Antibody stained cells are subsequently analyzed by flow cytometric methods.

Positive and negative control samples must be used with sample analysis, to establish that all reagents are performing in a consistent manner and that the positive fluorescence attributed to antibody-stained fetal red cells is differentiated from unstained normal red blood cells, leukocytes and any cellular debris. If cord blood is not available for the performance of positive controls, the assay cannot be performed reliably. The recommended positive control samples consist of both 1% and 5% fetal erythrocyte-containing placental cord blood in normal adult blood. The recommended negative control sample consists of 1% anticoagulated sample from a normal male or non-pregnant adult female.

INTENDED USE OF THE DEVICE:

The Caltag Fetal Hemoglobin Test, containing monoclonal antibodies to fetal hemoglobin (hemoglobin F) conjugated with either FITC, R-PE or TRI-COLOR®, is intended for the identification followed by enumeration of fetal red blood cells. Fetal cells are identified by the presence of fetal hemoglobin by a flow cytometric method. The presence of fetal cells in the maternal circulation, resulting from fetal-maternal hemorrhage, may be attributed to a variety of causes, including fetal trauma, various obstetrical emergencies and placental trauma. Hemorrhage of Rh+ fetal blood into Rh- maternal blood may result in the formation of sensitizing Rh antibodies in the mother. This Rh immunization may be prevented by the administration to the mother of Rh immune globulin (RhIg) soon after delivery. The Caltag Fetal Hemoglobin Test may be used as an aid in identifying fetal-maternal hemorrhage and determining the need for immunoprophylaxis with immune globulin.

SUMMARY OF TECHNICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE:

Comparisons of Caltag and Predicate Fetal Hemoglobin Tests

No.	Item	Caltag Test	Predicate Test	Comparison
1.	Intended Use	Enumeration of Fetal cells	Enumeration of Fetal cells	Substantially equivalent
2.	Specificity	Fetal hemoglobin	Fetal hemoglobin	Substantially equivalent
3.	Target cell	Fetal erythrocyte	Fetal erythrocyte	Substantially equivalent

Continued..

4.	Method of Detection	Flow Cytometry	Light Microscopy	Different methods used
5.	Chemical form	Monoclonal antibody	Pink staining with erythrocin	Substantially equivalent
6.	Device Configuration	Diagnostic Kit with Reagents	Diagnostic Kit with Reagents	Substantially equivalent
7.	Sample prep. methods	Fixed, Permeabilized Whole Blood	Whole Blood	Substantially equivalent
8.	Correlation of Methods (FACscan & EPICS-XL Site)			
	Prepared Samples (n=50)			Substantially
	Mean % Positive	FITC 4.54	KB 4.51	equivalent
	r squared value	97.95		
	Mean % Positive	R-PE 4.50	KB 4.41	
	r squared value	98.16		
	Mean % Positive	TC 4.49	KB 4.41	
	r squared value	97.98		
	Patient Samples (n=30)			Substantially
	Mean % Positive	FITC 0.51	KB 0.51	equivalent
	r squared value	96.80		
	Mean % Positive	R-PE 0.50	KB 0.51	
	r squared value	96.84		
	Mean % Positive	TC 0.47	KB 0.51	
	r squared value	97.50		

NON-CLINICAL TESTS SUPPORTING A DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

Expected Value Data:

Blood samples were collected from a total of 161 adult female normal donors in an age range of 19-50, with a mean and median age of 33. These consisted of approximately 50 female normal donors in each of three independent laboratories. In each laboratory, normal donors were distributed approximately equally among the three age ranges of 19-29, 30-39 and 40-50. A single sample from each donor was analyzed for the determination of expected values of the Caltag FITC, R-PE and TRI-COLOR® monoclonal antibodies to HbF.

The normal donor population consisted of members of differing ethnic origins, including adult Caucasians, Blacks, Orientals and Hispanics.
The three independent laboratories were located in geographically diverse areas within the United States, including the Northern, South-central and Western regions.

Normal ranges are expressed as the 95% reference intervals (17), consisting of the mid-95% of values for all donors when rank ordered from lowest to highest percent of fetal cells detected, as indicated on the following table:

EXPECTED VALUES IN ALL ADULT FEMALE NORMAL DONORS

procedure	mean % positive	S.D.	95% Reference Interval (Normal Range)	n
FITC	0.03	0.04	0.00--0.15	153
R-PE	0.04	0.05	0.00--0.14	153
TRI-COLOR	0.03	0.04	0.00--0.14	153

Specificity Data:
This study was conducted to evaluate any staining of blood elements other than fetal erythrocytes by the Caltag HbF monoclonal antibodies. Blood samples were obtained from healthy normal donors of Caucasian, Black, Hispanic and Oriental ethnic origins.
Samples of each donor were stained with Caltag HbF FITC, HbF R-PE and HbF TRI-COLOR monoclonal antibodies. Cells contained in the lymphocyte, monocyte and granulocyte regions were selected for analysis. Separate sample were prepared for analysis of red blood cells and platelets and were stained with each of the Caltag monoclonal antibodies.

The specificity study indicated no staining of any of the indicated blood elements by the Caltag HbF monoclonal antibodies in samples from normal donors.

Reproducibility Data: intra-lab
Intra-lab reproducibility for the Caltag HbF FITC, HbF R-PE and HbF TRI-COLOR (TC) conjugated monoclonal antibodies was determined by performing 6 replicated determinations for each antibody in each of three ranges; high, medium and low. Thus, a total of 18 determinations were performed for each HbF antibody. In this manner, reproducibility was demonstrated throughout the entire measurement range for the Caltag Fetal Hemoglobin Test.

The 6 determinations for each range were performed by the staining, processing and analysis of 6 separate samples consisting of varying mixtures of placental cord blood in normal adult blood. Fetal cells were selected for the analysis of percent cells stained in each of the three ranges.
The study was performed in each of three independent laboratories, in the manner that each laboratory obtained, stained and analyzed separate blood samples.

The following data are representative:

procedure	Level	mean % positive	S.D.	% CV	n
HbF FITC	high	9.51	0.22	2.42	6
	mid	5.10	0.22	4.30	6
	low	2.19	0.05	2.26	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF R-PE	high	9.61	0.40	4.25	6
	mid	5.10	0.14	2.66	6
	low	2.14	0.10	4.75	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF TC	high	9.64	0.37	3.84	6
	mid	5.13	0.21	4.16	6
	low	2.23	0.10	4.58	6

Reproducibility Data, inter-lab

Inter-lab reproducibility for the Caltag HbF FITC, HbF R-PE and HbF TRI-COLOR (TC) conjugated monoclonal antibodies was determined by performing 6 replicated determinations for each antibody in each of three ranges; high, medium and low. In this manner, reproducibility was demonstrated throughout the entire measurement range for the Caltag Fetal Hemoglobin Test.

The 6 determinations for each range were performed by the staining, processing and analysis of 6 separate samples consisting of varying mixtures of placental cord blood in normal adult blood. Fetal cells were selected for the analysis of percent cells stained in each of the three ranges.
The study was performed in each of three laboratories. All laboratories stained and analyzed the same samples.

Unstained and unfixed samples containing mixtures of cord blood in normal adult blood representing the appropriate ranges were prepared by one of the participating laboratories for staining and analysis by each of the participating laboratories. The following data were obtained:

SITE 1

procedure	Level	mean % positive	S.D.	% CV	n
HbF FITC	high	6.34	0.09	1.48	6
	mid	4.05	0.08	2.09	6
	low	1.48	0.04	2.91	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF R-PE	high	7.90	0.29	3.64	6
	mid	5.35	0.30	5.60	6
	low	2.84	0.21	7.34	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF TC	high	7.43	0.10	1.37	6
	mid	4.37	0.11	2.57	6
	low	1.60	0.07	4.55	6

SITE 2

procedure	Level	mean % positive	S.D.	% CV	n
HbF FITC	high	8.84	0.21	2.32	6
	mid	5.69	0.13	2.36	6
	low	2.44	0.08	3.28	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF R-PE	high	8.81	0.22	2.51	6
	mid	5.70	0.14	2.45	6
	low	2.36	0.04	1.89	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF TC	high	8.82	0.12	1.39	6
	mid	5.68	0.15	2.69	6
	low	2.41	0.05	1.90	6

SITE 3

procedure	Level	mean % positive	S.D.	% CV	n
HbF FITC	high	8.95	0.36	4.04	6
	mid	5.85	0.23	3.86	6
	low	2.57	0.14	5.32	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF R-PE	high	8.43	0.12	1.44	6
	mid	5.60	0.41	7.40	6
	low	2.38	0.07	3.16	6

procedure	Level	mean % positive	S.D.	% CV	n
HbF TC	high	8.70	0.46	5.24	6
	mid	5.65	0.18	3.12	6
	low	2.41	0.17	7.13	6

Linearity Data:

Linearity of measurement was determined for samples consisting of mixtures of cord blood cells in normal adult blood in the range of 0.0-5.0% cord blood cells. This range was selected to represent the entire range of values for the percent of fetal cells that are likely to be experienced in fetal-maternal hemorrhage. The linear regression method was used to plot the known expected values versus the observed values for the percent of fetal cells determined by the flow cytometric method for the Caltag FITC, R-PE and TRI-COLOR® monoclonal antibodies to HbF:

LINEARITY OF MEASUREMENT

procedure	r^2 value	slope	Y intercept	n
HbF FITC	99.97	1.01	-0.04	10
HbF R-PE	99.96	1.02	-0.03	10
HbF Tri-Color	99.98	1.02	-0.02	10

An additional study was conducted to identify saturating conditions for each of the Caltag monoclonal antibodies, consisting of preparations of cord blood alone (100% cord blood). Five different cord blood samples were stained and analyzed in a single laboratory, to determine the ability of the Caltag Fetal Hemoglobin Test to detect all fetal cells present, and to assure that the concentration and potency of the HbF monoclonal antibodies is sufficient to detect all fetal cells in a test sample. Therefore, samples employed in this study contained a greater than tenfold higher content of fetal cells than would be expected to occur in clinical specimens.

Summary of values obtained for the percent of fetal cells detected by the Caltag HbF FITC, HbF R-PE and HbF TRI-COLOR antibodies in 100% cord blood samples:

procedure	mean % positive	S.D.	% CV	n
HbF FITC	95.66	3.88	4.05	5
HbF R-PE	96.70	2.70	2.80	5
HbF TRI-COLOR	95.60	2.58	2.70	5

CLINICAL TESTS SUPPORTING A DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Correlation Data:
The Correlation study was conducted in 3 independent laboratories. Samples were analyzed with the Caltag Fetal Hemoglobin Test and a commercially available test based on the Kleihauer-Betke (KB) microscopic staining method for the detection of fetal hemoglobin in fetal cells (4) in each site. In all studies, confidence intervals are expressed at the 95% limit.

In study site #1, the percent of fetal cells detected by each of the HbF monoclonal antibodies to fetal hemoglobin was correlated with the percent of fetal cells detected by the KB test on patient samples (n=30) and prepared samples (n=50). Patient samples were obtained from women having clinical indications that were consistent with fetal-maternal hemorrhage and prepared samples consisted of mixtures of fetal cord blood in normal adult blood prepared in differing cell ratios in the range of 0-10% fetal cells. This range included up to the equivalent of 500 ml of fetal blood in maternal blood and greatly exceeded the 150--300 ml of fetal blood encountered in the most severe cases of fetal-maternal hemorrhage (3).

In study sites #2, the percent of fetal cells detected by the HbF FITC monoclonal antibody to fetal hemoglobin was correlated with the percent of fetal cells detected by the KB test in patient samples (n = 38) and prepared samples (n = 15) in the range of 0-3.0%. The Caltag test was analyzed on the EPICS-XL flow cytometer.

In study site #3, the percent of fetal cells detected by the HbF R-PE monoclonal to fetal hemoglobin was correlated with the percent of fetal cells detected by the KB test in patient samples (n = 13) and prepared samples (n = 15) in the range of 0-3.0% and analyzed on the EPICS-XL flow cytometer.

In study site #1, the same prepared samples (n = 50) were analyzed on both the Becton Dickinson Facscan and Coulter EPICS-XL flow cytometers, as follows

Summary of Correlations on FACscan Flow Cytometer
Prepared Samples

Comparisons	Mean % Positive	Confidence Interval (95%)	r^2 value	n
HbF FITC	4.54	3.63	97.95	50
KB	4.41	3.52		
HbF R-PE	4.50	3.59	98.16	50
KB	4.41	3.52		
HbF TC	4.49	3.58	97.98	50
KB	4.41	3.52		
HbF FITC	4.54	3.63	99.59	50
HbF R-PE	4.50	3.59		
HbF FITC	4.54	3.63	99.63	50
HbF TC	4.49	3.58		
HbF R-PE	4.50	3.59	99.70	50
HbF TC	4.49	3.58		

Summary of Correlations on EPICS-XL Flow Cytometer
Prepared Samples

Comparisons	Mean % Positive	Confidence Interval (95%)	r^2 Value	n
HbF FITC	4.22	3.38	98.48	50
KB	4.40	3.52		
HbF R-PE	4.24	3.40	98.41	50
KB	4.40	3.52		
HbF TC	4.20	3.36	97.96	50
KB	4.40	3.52		
HbF FITC	4.22	3.38	99.61	50
HbF R-PE	4.24	3.40		
HbF FITC	4.22	3.38	99.54	50
HbF TC	4.20	3.36		
HbF R-PE	4.24	3.40	99.67	50
HbF TC	4.20	3.36		

In the following linear regression analyses, the correlations of the Caltag Fetal Hemoglobin test and KB test are presented separately for each study site with prepared and patient samples identified within each site. However, prepared samples analyzed in study site #1 are as indicated in the above tables.

Site 1
HbF FITC Patient Samples
FACscan Flow Cytometer

procedure	mean % positive	Confidence Interval (95%)	r^2 value	n
HbF FITC	0.51	0.04	96.80	30
KB Method	0.51	0.03		

HbF R-PE Patient Samples

procedure	mean % positive	Confidence Interval (95%)	r^2 value	n
HbF R-PE	0.50	0.05	96.84	30
KB Method	0.51	0.03		

HbF TC Patient Samples

procedure	mean % positive	Confidence Interval (95%)	r^2 value	n
HbF TC	0.47	0.05	97.50	30
KB Method	0.51	0.03		

Site 2
HbF FITC Patient Samples
EPICS-XL Flow Cytometer

procedure	mean % positive	Confidence Interval (95%)	r^2 value	n
HbF FITC	0.22	0.07	98.34	38
KB Method	0.20	0.05		

HbF FITC Prepared Samples
EPICS-XL Flow Cytometer

procedure	mean % positive	Confidence Interval (95%)	r^2 value	n
HbF FITC	1.52	1.04	85.50	15
KB Method	1.61	1.11		

Site 3
HbF R-PE Patient Samples
EPICS-XL Flow Cytometer

procedure	mean % positive	Confidence Interval (95%)	r^2 value	n
HbF R-PE	0.08	9.43	64.00	13
KB Method	0.11	0.01		

HbF R-PE Prepared Samples
EPICS-XL Flow Cytometer

procedure	mean % positive	Confidence Interval (95%)	r^2 value	n
HbF R-PE	1.38	0.93	84.01	15
KB Method	1.40	0.81		

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 1999

Caltag Laboratories
c/o David C. Bishop, Ph.D.
605 Dilworth Road
Downingtown, Pennsylvania 19335

Re: K990641
Trade Name: Caltag Fetal Hemoglobin Test
Regulatory Class: II
Product Code: GHQ
Dated: July 13, 1999
Received: July 14, 1999

Dear Dr. Bishop:

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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/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): K 990641

Device Name: CALTAG FETAL HEMOGLOBIN TEST

Indications For Use:

The Caltag Fetal Hemoglobin Test, containing either FITC, R-PE or TRI-COLOR® conjugated monoclonal antibodies to fetal hemoglobin (hemoglobin F), is intended for the identification followed by enumeration of fetal red blood cells. Fetal red cells are identified by the presence of fetal hemoglobin by a flow cytometric method. Fetal cells, when found in the maternal circulation, may be an indication of fetal or maternal trauma or various obstetrical complications. The hemorrhage of Rh+ fetal blood into Rh- maternal blood may result in the formation of sensitizing Rh antibodies in the mother. Sensitization may be prevented by the administration to the mother of Rh immune globulin (RhIg) soon after delivery. The Caltag Fetal Hemoglobin Test may be used as an aid in detecting Rh incompatible fetal-maternal hemorrhage and determining the need for immunoprophylaxis with Rh immune globulin.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maddux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990641

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)