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510 (k) SUMMARY

Name of Contact Person:	Jimmie R. Kyle Vice President, Manufacturing and Product Reliability
Date of Submission:	June 29, 1995
Name of Device: • Trade Name - • Common Name - • Classification Name	 The White IRIS Leukocyte Differential Analyzer Instrument used in determining WBC Differential None Established
Predicate Method and Legally Marketed Device to which Substantially Equivalent is claimed:	Wright-stain/Light Microscope and The Yellow IRIS® urinalysis workstation and body fluids cell counting system
Intended Use of Device:	The White IRIS is a leukocyte differential analyzer intended for in vitro diagnostic use in determining the proportional leukocyte count (WBC differential) on peripheral blood specimens that have been flagged by an automated hematology analyzer performing differential counts as well as for peripheral blood specimens for which no automated differential has been performed.
Operator competence:	The White IRIS is designed and intended for use by trained, competent operators well skilled in both the use of the instrument and in the recognition of leukocyte classes based on IRISpectracolor stained cell expressions displayed on the ViewStation video monitor. Although leukocyte images are classified presumptively by cell type, a competent technologist is required to confirm or modify the classification of each cell. Laboratories using The White IRIS should maintain adequate operator training and proficiency testing programs for instrument users.

Limitations:

1. Competent human observer band neutrophil identification is generally limited to those cells with a distinct band-form nucleus. Band neutrophils with lobes connected by thin chromatin strands will generally not be distinguished from segmented neutrophils. Consequently, fewer band neutrophils and more polymorphonuclear neutrophils will be reported. However, the combined neutrophil (band plus segmented) proportional count obtained by a competent human observer using The White IRIS will closely match that obtained from a Wright-stain smear.
2. As with Wright-stain smears, distinctions between band and segmented neutrophil, metamyelocyte and myelocyte, myelocyte and promyelocyte will be subject to variation among individual observers.
3. IRISpectracolor stain is not designed for discrimination of nuclear details in leukocytes.
4. Nucleated RBC (NRBC) are generally removed from the leukocyte-rich plasma fraction analyzed by The White IRIS along with RBC. The White IRIS should not be used to determine presence or absence of NRBC.

Summary of Technological Characteristics:

Combining unique cytoprobe, rapid hemacyte fractionation and novel color image analysis, The White IRIS extends automated intelligent microscopy to leukocyte differentiation. It provides flow cytometry precision and microscopical resolution to review specimens flagged by hematology analyzers with differential capabilities or to complement other analyzers without these capabilities. The system includes compartments for closed sampling, rapid leukocyte-rich plasma preparations, cytoprobe-induced metachromasia, and collection and color analysis of leukocyte images, and presents the results as a single-view 500-cell differential on a 20-in touch-screen monitor for examination by a skilled competent observer.

Brief Discussion of Non-Clinical Factors supporting a Determination of Substantial Equivalence:	Involves a competent human observer to examine microscopic images as does the predicate method and other similar predicate devices. See attached Substantial Equivalence comparisons.
Brief Discussion of Clinical Tests Supporting a Determination of Substantial Equivalence:	Conformance to National Committee for Clinical Laboratory Standards Reference leukocyte differential count (proportional) and evaluation of instrumental method: Approved Standard, NCCLS document H20-A and other statistical comparisons to Wright-stain/light microscope reference method.
Conclusions Drawn from Clinical Tests:	Use of The White IRIS provides results equal to or better than the reference method with less time expenditure and less biohazard exposure. See attached Efficacy Demonstration.
Safety of Device:	See attached Hazard Analysis.

Substantial Equivalence.

Table 1- Similarities and differences between The White IRIS and the peripheral blood smear stained with Wright-stain and viewed with a light microscope. (part 1 of 2)

Substantial Equivalence	The White IRIS	Peripheral Blood Smear Stained with Wright Stain/Light Microscope
Intended use is the same.	Production of images of cellular components of peripheral blood preparations to permit a skilled, competent observer to characterize these cells, enabling the generation of a white blood cell differential.	Production of images of cellular components of peripheral blood preparations to permit a skilled, competent observer to characterize these cells, enabling the generation of a white blood cell differential.
Specimen analyzed is the same.	Whole blood collected in blood specimen tube.	Whole blood collected in blood specimen tube.
Stain used differentially colors different cell types in a similar way.	Leukocytes stained supravitally in suspension by 2-Methylpolymethine which produces unique metachromasias among different types of leukocytes.	Leukocytes stained after cells dried and fixed on slide by Wright-stain (consisting of Methylene Blue, Azures, and Eosin Y) produces the Romanowsky effect, differential coloration of cell components.
Separation of WBC from RBC background is similar.	Leukocytes separated gravitationally from erythrocytes to allow mono-disperse presentation for automatic randomized selection.	Leukocytes separated by spreading in the feather edge portion of blood smear to allow manual search and selection from among monodispersed cells.
Mechanisms for presenting individual WBC images to microscope objective are comparable.	Non-overlapping individual cells, in liquid suspension, in a flow cell are automatically presented to and imaged by a microscope objective.	Non-overlapping individual cells, smeared and fixed on a glass slide are manually presented to and imaged by a microscope objective.
Optical means for magnifying images of WBCs for observation and interpretation is the same or similar.	A microscope images individual leukocytes on a camera sensor which produces a magnified video image for view and interpretation.	A microscope directly images and magnifies individual leukocytes for view and interpretation through its oculars.

Table 1 - continued (part 2 of 2).

Substantial Equivalence	**The White IRIS**	**Peripheral Blood Smear Stained with Wright Stain/Light Microscope**
Viewing of images is similar.	Individual cells are observed on a video monitor in machine-ordered and counted groups of like size and color features.	Individual cells are observed through the oculars one-at-a-time while they are classified and counted.
Overview scan analysis is similar and more easily accomplished.	Scanning is accomplished at a glance of 500-cells organized in a montage on a video monitor.	Scanning is accomplished by moving the slide and manually characterizing the kinds of cells observed.
Features used to distinguish among the various WBC types are the same or similar.	Cytoplasm of different leukocyte types stained characteristically. While nucleus is not stained, nuclear shape may often be discerned. Size of nucleus (relative to cell size) and cell size.	Cytoplasm of different leukocyte types stained characteristically. Nuclear stain and shape used to distinguish among different leukocyte types. Size of nucleus (relative to cell size) and cell size.
Image interpretation requirements are the same.	Differentiation of cells requires a skilled competent observer.	Differentiation of cells requires a skilled competent observer.
Result format is the same and quality is better.	The differential proportional count is based on 500-cells.	The differential proportional count is usually based on only 100-cells.

Table 2 - Similarities and Differences between The White IRIS Flow Microscope and the Conventional Light Microscope.

Substantial Equivalence	**The White IRIS/Flow Microscope**	**Conventional Slide Microscope**
Intended use is the same.	To enable a skilled, competent observer to examine, characterize and differentiate WBC compositions.	To enable a skilled, competent observer to examine, characterize and differentiate WBC compositions.
Means for presenting specimen to device is the same principle.	Flow microscopy of leukocytes monodispersed in suspension. (Used in conjunction with video camera, and monitor).	Slide microscopy of leukocytes monodispersed in dried, stained peripheral blood smear. (In some instances, cells may be suspended on the slide in a wet mount).
Microscopic image interpretation requirements are similar.	Differentiation of cells requires a skilled competent observer.	Differentiation of cells requires a skilled competent observer.
Results rely on counting individual cells and are based on the same arithmetic and quality is better.	The differential proportional count is based on observing 500 cells.	The differential proportional count is usually based on observing only 100 cells.

Table 3 - Similarities and Differences between The White IRIS and the Generic Flow Microscope and The Yellow IRIS (part 1 of 2).

Substantial Equivalence	**The White IRIS for WBC Differentiation**	**Flow Microscope/The Yellow IRIS for UA and Body Fluid Blood Cell Examination and Counting**
Intended use is parallel.	Production of images of cellular components of peripheral blood preparations to permit a skilled, competent observer to characterize and count these cells, enabling the generation of a white blood cell differential.	Production of images of formed elements in urine including blood and other cells, and blood cells in other body fluids, to permit a skilled, competent observer to characterize and count these components to compose a white cell differential.
Stain used allows microscopic objects to be identified by differential coloration in a similar way.	Leukocytes stained with 2-Methylpolymethine while in suspension.	Formed elements stained with IRIStain, containing primarily Crystal Violet while in suspension.
Mechanisms for presenting individual cell and other formed element images to microscope objective are comparable.	Individual cells, in liquid suspension, in a flow cell are automatically selected and imaged by a microscope objective.	Individual cells and other formed elements, in liquid suspension, in a flow cell are automatically selected and imaged by a microscope objective.
Presentation of images for viewing are the same.	Individual cells are presented on a video monitor in machine-ordered and counted groups of like size and color features.	Individual cells and other formed elements are presented on a video monitor in machine-ordered and counted groups of like size and color features.
Features used to distinguish among the various leukocyte types are the same or similar.	Cytoplasm of different leukocyte types stained characteristically. While nucleus is not stained, nuclear shape may often be discerned. Size of nucleus (relative to cell size) and cell size.	Cytoplasm of different cells stained characteristically. Nuclear stain and shape used to distinguish among different cell types. Size of nucleus (relative to cell size) and cell size.

Table 3 - continued (part 2 of 2).

Substantial Equivalence	**The White IRIS for WBC Differentiation**	**Flow Microscope/The Yellow IRIS for UA and Body Fluid Blood Cell Examination and Counting**
Presentation of images to skilled, competent observer is the same	Leukocytes in flow cell are viewed through a microscope by a video camera. Images are "captured" and electronically presented to a skilled, competent observer for interpretation on a video monitor	Analytes in flow cell are viewed through a microscope by a video camera. Images are "captured" and electronically presented to a skilled, competent observer for interpretation on a video monitor.
Image montage organization is similar.	Cells are sorted into ranks of comparable size and color.	Cells and other formed elements are sorted into ranks of comparable size.
Results are observed and expressed in the same way.	Scanning is accomplished at a glance of 500-cells organized in a montage on a video monitor. The differential proportional count is based on competent observer acknowledged and assigned classification of 500 cell images.	Scanning is accomplished by observing a sequences of montages on a video monitor. Counts are based on competent observer assigned classification of cell images.

Efficacy Demonstration.

Differential leukocyte composition determined using The White IRIS™ was compared to results obtained by visual interpretation of blood smears stained with Wright-stain as the reference method. Count accuracy, clinical sensitivity and precision were compared according to the NCCLS Approved Standard H20-A "Reference leukocyte differential count (proportional) and evaluation of instrumental methods," National Committee for Clinical Laboratory Standards, Villanova, PA, March 1992, hereinafter referred to as H20-A. Other suitable, well accepted statistical comparisons not prescribed in H20-A were also performed to illustrate the effectiveness of The White IRIS even further. In addition, comparisons to proportional count and flagging results obtained with a Coulter STKS for the same group of specimens demonstrated the need for post primary analyzer review and the efficacy of The White IRIS in fulfilling this need as well as provided perspective with regards to current state-of-the-art hematology analyzers.

The following general conclusions can be made:

1. Inaccuracy, clinical sensitivity and imprecision studies according to H20-A have demonstrated substantial equivalence of leukocyte differential counts (proportional) derived from competent human interpretation of leukocyte images produced by The White IRIS to those from Wright-stained blood smears.
2. Additional statistical comparison (oneway ANOVA and paired t-test) of the results from the two instruments used in the study further demonstrated skilled competent observer inter-instrument agreement as good or better than agreement between the two Wright-stain readers performing the predicate method. Thus both agreement of the proposed new method with the established reference method and consistency within-run, instrument-to-instrument and over a few month period of intense use have been demonstrated in a way even more rigorous than specified by H20-A.
3. Actual comparative performance measure in both review and primary procedural modes demonstrate how well The White IRIS can either complement or replace a 5-part WBC differential capability on the Coulter STKS, the most popular such contemporary product in the market today.
4. Besides its demonstrated Wright-stain equivalency, and demonstrated superiority to the leading contemporary product in every leukocyte measure it makes, use of The White IRIS is also accompanied by significant safety and substantial labor saving benefits for the clinical laboratory.

Performance Characteristics on which Substantial Equivalence is Based

1 Accuracy

Differential leukocyte counts for 1,202 normal and abnormal patient specimens were obtained using both manually prepared and observed Wright stained smears (200 cell differential), read by two skilled technologists, and automated analysis on The White IRIS (2 instruments x 500 cell differential), reviewed by the same two skilled technologists.

Table 4 - Leukocyte Differential count correlation between methods. Neutrophils are the sum of polymorphonuclear neutrophils and bands, lymphocytes are the sum of normal lymphocytes and variant immature lymphocytes.

Cell Type	Correlation	Slope	Intercept	Wright-Stain Mean (%)	TWI Mean (%)
Neutrophils	0.98	0.96	4.16	56.13	57.90
Lymphocytes	0.98	0.93	-0.97	31.06	27.85
Monocytes	0.91	1.03	1.19	7.69	9.12
Eosinophils	0.98	0.97	0.20	3.53	3.64
Basophils	0.87	0.78	0.18	0.70	0.72
Segmented Neutrophils	0.93	0.94	7.18	49.15	53.56
Bands	0.54	0.25	2.58	6.99	4.34
Metamyelocytes	0.84	0.64	0.08	0.40	0.33
Myelocytes	0.74	0.38	0.00	0.12	0.05
Promyelocytes	0.97	1.00	0.00	0.08	0.08
Blasts	0.96	1.13	0.03	0.25	0.32
Normal Lymphocytes	0.98	0.93	-1.05	30.52	27.33
Variant Lymphocytes	0.41	0.31	0.35	0.55	0.52

2 Precision

Short term standard deviations calculated according to H20-A are tabulated for The White IRIS and for the Wright stain reference method in Table 5. Short term imprecision is based on the root square of the differences between replicates. For The White IRIS, each replicate is the average of two determinations (specimen volume permitting) or a single determination for each instrument. For the reference method, each replicate is a 200 cell differential by one or the other reader.

Table 5 - Imprecision of The White IRIS compared to that of the Wright-stain reference method represented by standard deviation (SD) calculated according to the method specified by H20-A.

	The White IRIS (1014 Specimens)		Wright-stain (1277 Specimens)	
Cell type	Mean (%)	SD	Mean (%)	SD
Neutrophils	58.95	2.72	56.28	3.55
Lymphocytes	26.90	3.17	30.91	3.68
Monocytes	9.03	1.62	7.69	2.29
Eosinophils	3.65	0.83	3.54	1.31
Basophils	0.73	0.35	0.71	0.62
Segmented Neutrophils	54.64	4.25	49.47	4.72
Bands	4.33	2.94	6.81	3.68
Metamyelocytes	0.33	0.66	0.39	0.56
Myelocytes	0.05	0.17	0.12	0.27
Promyelocytes	0.04	0.17	0.08	1.33
Blasts	0.32	1.73	0.24	1.82
Normal Lymphocytes	26.38	3.19	30.38	3.67
Variant Lymphocytes	0.52	0.95	0.53	0.99

The following "within" run precision was established using 22 replicates of the same sample.

Table 6 - Precision of the Leukocyte Differential parameters is specified at 95% confidence limits.

Leukocyte	Mean (%)	95% Confidence Limits
Neutrophils	54.96	± 5.0
Lymphocytes	33.46	± 5.0
Monocytes	7.11	± 2.5
Eosinophils	3.93	± 1.5
Basophils	0.51	± 1.0

3 Clinical Sensitivity

The following clinical sensitivity analysis is based on the evaluation of 1202 Leukocyte Differential Summaries performed on The White IRIS.

Table 7 - H20-A defined requirements for abnormal specimens to be included in the clinical sensitivity study.

H20-A requires at least 5 cases of each of these abnormal conditions			This Study
Characteristic Leukocyte Differential Count Finding	**Absolute Cell Count**	**Proportional Cell Count**	**Number of Specimens**
Granulocytosis	≥ 9.0 x 10^9/L	> 80%	152
and/or			
Left Shift (Bands)	≥ 0.9 x 10^9/L	> 6%	197
Monocytosis	≥ 0.8 x 10^9/L	> 10%	64
Eosinophilia	≥ 0.5 x 10^9/L	> 7%	89
Lymphocytosis	≥ 3.5 x 10^9/L	> 50%	64
and/or			
Lymphocytes, Variant Forms	≥ 0.7 x 10^9/L		5
Granulocytopenia	≤ 1.5 x 10^9/L	< 10%	11
Lymphopenia	≤ 1.0 x 10^9/L	< 7%	70
Immature Cells, including Blasts	≥ 0.1 x 10^9/L	> 2%	66

Table 8 reflects reference ranges established from a group of 154 normal (according to H20A criteria) specimens.

Table 8 - Reference Ranges (%) for Wright-Stain Smear and The White IRIS.

	Wright-Stain Smear		The White IRIS	
Leukocyte Type	**Lower Range**	**Upper Range**	**Lower Range**	**Upper Range**
Segmented Neutrophils	31.25	71.68	34.48	72.74
Band Neutrophils	0.00	9.25	0.00	7.68
Lymphocytes	17.50	56.25	14.50	48.97
Variant Lymphocytes	0.00	1.25	0.00	1.17
Monocytes	3.25	11.00	4.60	12.27
Eosinophils	0.00	9.00	0.00	9.71
Basophils	0.00	2.00	0.00	1.54
Metamyelocytes	0.00	0.50	0.00	0.28
Myelocytes	0.00	0.25	0.00	0.05
Promyelocytes	0.00	0.00	0.00	0.00
Blasts	0.00	0.00	0.00	0.00

Using the reference ranges from Table 8, all specimens were classified as normal (all parameters within normal range) or abnormal (any parameter outside of normal range). The comparison after removing those cases for which parameters causing disagreement were within 95% confidence limits is shown in Table 9.

Table 9 - Crosstabulation of combined abnormal classifications after false positive and false negative cases for which differences that are within 95% confidence limits are removed. Values in parentheses ( ) are after false positive and false negative band decisions are removed.

		Results of The White IRIS (Test Method)		
		Positive (Distributional &/or Morphological Abnormals)	**Negative (Normal)**	**Total**
Results of Wright-Stain/Light Microscope (Reference Method)	**Positive (Distributional &/or Morphological Abnormal)**	716	36 (22)	752 (738)
	Negative (Normal)	53 (48)	292	345 (340)
	Total	769 (764)	328 (314)	1097 (1078)

Summary	**Agreement:**	91.89%	(93.51%)
	False Positive:	15.36%	(14.12%)
	False Negative:	4.79%	(2.98%)

A summary of discrepant cases is in Table 10. The 5% significance level of McNemar's statistic is 3.84. Thus for those cases that disagree outside the 95% confidence limits, other than excessive false negative bands and excessive false positive metamyelocytes, discrepancies are balanced.

Table 10 - Analysis of combined abnormality classifications crosstabulation

Statistical Significance	Disagreements by cell types	Total Number of Cases	Number of Combined Abnormal False Negative	Number of Combined Abnormal False Positive	McNemar's Statistic
All Disagreements	***TOTAL***	***194***	***78***	***116***	***7.44***
Within 95% Confidence Limits	PMN	10	2	8	3.60
	Lymphocyte	11	5	6	0.09
	Lymphocyte and PMN	5	2	3	0.20
	Monocyte	27	10	17	1.81
	Monocyte and Lymphocyte	1	0	1	1.00
	Eosinophil	5	3	2	0.20
	Basophil	7	1	6	3.57
	Basophil and Lymphocyte	1	0	1	1.00
	Band neutrophil	1	1	0	1.00
	Band neutrophil and Basophil	1	0	1	1.00
	Variant lymphocyte	10	6	4	0.40
	Metamyelocyte	7	3	4	0.14
	Metamyelocyte and Monocyte	1	1	0	1.00
	Metamyelocyte and Variant lymphocyte	1	0	1	1.00
	Myelocyte	6	2	4	0.67
	Myelocyte and Lymphocyte	1	1	0	1.00
	Myelocyte and Metamyelocyte	1	1	0	1.00
	Promyelocyte	1	1	0	1.00
	Blast	2	0	2	2.00
	Blast and Variant lymphocyte	1	0	1	1.00
	Megakaryocyte	3	1	2	0.33
	Megakaryocyte, Lymphocyte and Variant lymphocyte	1	1	0	1.00
	Plasma cell	1	1	0	1.00
	TOTAL	***105***	***42***	***63***	***4.20***
Outside 95% Confidence Limits	PMN	2	1	1	0.00
	Lymphocyte	5	2	3	0.20
	Lymphocyte and PMN	6	1	5	2.67
	Monocyte	11	3	8	2.27
	Monocyte and PMN	1	0	1	1.00
	Monocyte and Lymphocyte	1	0	1	1.00
	Eosinophil	1	0	1	1.00
	Basophil	3	0	3	3.00
	Band neutrophil	19	14	5	4.26
	Band neutrophil and PMN	2	2	0	2.00
	Band neutrophil and Lymphocyte	2	1	1	0.00
	Variant lymphocyte	20	9	11	0.20
	Variant lymphocyte and PMN	2	1	1	0.00
	Variant lymphocyte and Monocyte	1	0	1	1.00
	Variant lymphocyte and Band neutrophil	2	1	1	0.00
	Metamyelocyte	10	1	9	6.40
	Blast	1	0	1	1.00
	TOTAL	***89***	***36***	***53***	***3.25***

The comparison of normal and abnormal cases prior to removing false positive and false negative cases that are within 95% confidence limits is shown in Table 11.

Table 11 - Crosstabulation of combined abnormality classifications

		Results of The White IRIS (Test Method)		
		Positive (Distributional and/or Morphological Abnormal	**Negative (Normal)**	**Total**
Results of Wright-stain/ Light Microscope (Reference Method)	**Positive (Distributional and/or Morphological Abnormal)**	716	78	794
	Negative (Normal)	116	292	408
	Total	832	370	1202

Summary	**Agreement:**	82.95%
	False Positive:	28.43%
	False Negative:	9.82%

Table 11 is based on a 4 x 4 crosstabulation of the four mutually exclusive outcomes for each sample processed:

1. Normal
2. Distributionally abnormal
3. Morphologically abnormal
4. Both distributionally and morphologically abnormal.

Table 12 - Crosstabulation of specimen classifications by Wright-stain versus those of The White IRIS™

	The White IRIS™ classification				
Wright-stain classification	Normal	Distributionally abnormal	Morphologically abnormal	Both distributionally and morphologically abnormal	Row Sum
Normal	292	62	40	14	408
Distributionally abnormal	30	230	8	73	341
Morphologically abnormal	38	14	32	11	95
Both distributionally and morphologically abnormal	10	122	15	211	358

Table 12 summarizes classifications for both methods. Overall agreement in this table is 63.6%. Based on Cohen's kappa[1] of 0.49 for this table one can reject the hypothesis that the entries in the table are purely random and there is no agreement between methods.

[1] Cohen, J. 1960. A coefficient of agreement for nominal scales. *Educational and Psychological Measurement*, 20: 37-46.

Hazard Analysis.

Laboratory instrument results are generally used by the physician as an adjunct to clinical observations made in the course of establishing a diagnosis and in monitoring the course of disease progress, when appropriate thereafter. Therefore, The White IRIS leukocyte differential analyzer is unlikely to present the patient with a direct hazard. Also, as long as the instrument operator follows the recommended operating procedures in the Operators Manual this risk is minimized.

It is expected that anyone using this instrument is a qualified laboratorian who will follow universal precautions and other "Standard Laboratory Practices" in regards to working with laboratory instruments, reagents, consumables, and patient blood specimens in a safe and precautious manner. Also, the laboratorian is expected to be trained as a skilled competent observer familiar with and experienced in the interpretative qualities of leukocyte images.

The hazard analysis below is intended to identify the potential hardware and software failures that might cause inadvertent erroneous test results and lists the system checks in the design to safeguard against adverse consequences.

Table 13 - List of Hazards, their Causes, and System Responses.

Potential Hazard	Potential Causes	Software/Hardware Responses
Bar code reading failure could cause results to be reported to the wrong patient.	Bar Code Reader failure. Unreadable bar code label. No bar code label.	Software checksum analysis with operator alerts. No detectable bar code or bar code error - no sample processing or missing code flagging.
Sample wheel positioning failure could cause wrong sample to be aspirated and results reported to the wrong patient ID.	Motor failure. Encoder failure.	Optical sensor coupled with software detection and operator alerts.
Insufficient sample aspirated for analysis could cause erroneous results.	Insufficient sample. Sample probe clog. No vacuum or pressure.	Optical and ultrasonic sensors coupled with software detection and operator alerts.
Failure of red blood cells to settle out leaving too many rbc's could cause erroneous results.	No IRISettlant reagent present. IRISettlant reagent no good. Settling tubes non functional.	Optical sensor with software detection and operator alerts.
Insufficient leukocyte-rich plasma preparation could cause erroneous results.	Insufficient sample. No settling of RBCs.	Optical and ultrasonic sensors coupled with software detection and operator alerts.

Potential Hazard	Potential Causes	Software/Hardware Responses
Non staining or improper staining of white blood cells could cause erroneous results.	No IRISpectracolor reagent present. IRISpectracolor no good. Specimen too old.	Optical and software detection with operator alerts.
Total or partial interruption of flow of white cells through the White IRIS flowcell could cause erroneous results.	Flowcell partial or total clog. No vacuum or pressure. Hardware failure.	Optical and software detection with operator alerts.
Failure of the ViewStation sorting algorithms could cause erroneous results.	Power outage with bad reboot. Spike in line voltage. Software lockup.	Reportable results require the optical review, edit and approval of competent operator.
Previous patient sample not properly washed from system (carryover) could cause erroneous results.	No IRIScrub reagent present. No vacuum or pressure. Hardware failure.	Optical and ultrasonic sensors with software detection and operator alerts.
Image data transfer from Flow Microscope Module to View-Station corrupted during transmission could cause erroneous results.	Power outage with bad reboot. Spike in line voltage. Software lockup.	Software detection using checksums to validate data packets. Reportable results require the optical review, edit and approval of competent operator.
Optical System failure could cause erroneous or no results to be reported.	Light source inoperable. Strobe inoperable. Camera inoperable.	Optical and software detection with operator alerts.
Editing errors by competent operator could cause erroneous results to be reported.	Wrong tag used to classify cells. Accidental touch stroke.	Edit confirmation summary to be verified by competent operator prior to reporting results.
Contact of the operator with the cap piercing unit during operation could cause injury to the operator.	Removal of needle cover during operation.	Hardware detection with software operator alerts and instrument shutdown.
Contact with high voltage inside the instrument could cause electrical shock to operator.	Removal of protective covering isolating high voltages. Excessive leakage current.	Warning labels on system and warnings in operating instructions. Grounding per code and all metal parts bonded to ground system.