

K962633

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510(k) SUMMARY

VEGA™ Hematology Analyzer

In accordance with the Safe Medical Devices Act of 1990, a 510(k) summary is provided as outlined in 21 CFR 807.92.

I. Identification of the Sponsor and Objective:

ABX
Parc Euromédecine,
rue du Caducée - BP 7290,
34184 MONTPELLIER Cédex 4 - FRANCE.

510(k) Submission dated 2/7, 1996.

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II. Device Name:

Trade/Proprietary Name - VEGA™ Hematology Analyzer

Common or Usual Name/
Classification Name - Automated cell counter [864.5200] and
Automated Differential Cell Counter [864.5220]

III. Identification of the legally marketed device to which the 510(k) & sponsor claims equivalence:

The VEGA™ Hematology Analyzer is substantially equivalent to the TECHNICON H2® Hematology Analyzer, the ABBOT CELL-DYN® 3500 Hematology Analyzer and the COULTER STKS® Hematology Analyzer.

IV. Description of the Device/Statement of Intended Use:

The VEGA™ Hematology Analyzer is a quantitative, automated *in vitro* diagnostic analyzer capable of performing the following twenty six (26) hematological parameters:

| | |
|--|-------|
| white blood cells (leukocytes) | -WBC |
| red blood cells (erythrocytes) | -RBC |
| hemoglobin | -HGB |
| hematocrit | -HCT |
| mean corpuscular volume | -MCV |
| mean corpuscular hemoglobin | -MCH |
| mean corpuscular hemoglobin concentration | -MCHC |
| red blood cell distribution width | -RDW |
| platelets | -PLT |
| plateletcrit | -PCT |
| platelet distribution width | -PDW |
| mean platelet volume | -MPV |
| lymphocyte (number) | -LYM# |
| lymphocyte (percent of WBC) | -LYM% |
| monocyte (number) | -MON# |
| monocyte (percent of WBC) | -MON% |
| basophil (number) | -BAS# |
| basophil (percent of WBC) | -BAS% |
| neutrophil (number) | -NEU# |
| neutrophil (percent of WBC) | -NEU% |
| eosinophil (number) | -EOS# |
| eosinophil (percent of WBC) | -EOS% |
| Atypical Lymphocyte (number) | -ALY# |
| Atypical Lymphocyte (percent of lymphocyte number) | -ALY% |
| Large Immature cell (number) | -LIC# |
| Large Immature cell (percent of WBC) | -LIC% |

The VEGA Hematology Analyzer can be programmed to printout any of the parameters here above independently.

Only twenty (20) parameter printout will be made available for diagnostic use in the United States (eliminating PCT, PDW, ALY%, ALY#, LIC%, LIC#).

The VEGA Hematology Analyzer utilizes five (5) different reagents.

| | | | |
|---|-------------|---|----------------|
| - | VEGADIL™ | : | Diluant |
| - | VEGALYSETM™ | : | Lysing Agent |
| - | VEGACLEAN™ | : | Cleaner |
| - | EOSINOFIX™ | : | Staining Agent |
| - | BASOLYSETM™ | : | Lysing Agent |

VEGA Measurement Principles:

WBC, RBC, PLT: *The counting principle is based on an impedance variation generated by the passage of cells through the calibrated micro-aperture.*

HGB: *A cyanmethemoglobin compound is measured by spectrophotometry through the optical part of the WBC chamber at a wavelength of 550 nanometers.*

HCT: *The height of the impulse generated by the passage of the cell through the micro-aperture is directly proportional to the volume of analyzed red blood cell. The HCT measurement is performed by a specialized electronic device which adds all the pulse heights.*

MCH, MCHC, MCV *are red blood cell indices calculated from the measured parameters.*

RDW *is a coefficient of variation of the RBC distribution and is expressed as a percent of the average RBC size.*

MPV *is a platelet indice derived from the accumulation of platelet data within the platelet population distribution.*

Leukocyte Differential Counts:

The VEGA Hematology Analyzer uses the similar method counting as the Roche COBAS Argos 5 DIFF Hematology Analyzer. The VEGA Hematology Analyzer combines the use of histochemical stains, measurement of blood cell volume via optical transmission from a tungsten halogen light source to provide leukocyte differentiation. On each individual cell, three methods are applied:

- 1. Cytochemistry with the action of Eosinofix TM reagent.*
- 2. Impedance to measure the volume.*
- 3. Optical transmission measurement to obtain information on the internal structure of the cells.*

V. Summary of the technological characteristics of the new device in comparison to those of the predicate:

The intended use and measurement principles are the same for each analyzer. There are differences in operation, configuration and capabilities of each device. Algorithms and threshold discrimination of each instrument are slightly different.

VI. **Brief discussion of the clinical and non-clinical tests relied on for a determination of substantial equivalence:**

Clinical studies were performed at three hospital university sites.

The clinical study was designed to demonstrate the precision and accuracy of the VEGA Analyzer in a typical setting with operators of various levels of experience and educational backgrounds.

Each site used different reference instrument: Site 1 used a TECHNICON H2 ® Hematology Analyzer; Site 2 used the ABBOT CELL-DYN ® 3500 Hematology Analyzer; and Site 3 used the COULTER STKS ® Hematology Analyzer.

Manual differential count were performed for the samples at all three sites to reflect the widest distribution of normal and abnormal specimens. The cell counts were performed according to NCCLS guidelines H20-A, at all three hospital laboratories. A summary of performance data follows:

Reproducibility (within run):

Reproducibility of an instrument is measured by the coefficient of variation (CV) obtained from the calculation of 20 results of the same sample.

| <i>Parameters</i> | <i>%CV</i> | <i>Reference Values</i> |
|-------------------|------------|--------------------------------------|
| - WBC: | < 2.0% | 10 10 ³ /mm ³ |
| - RBC: | < 2.0% | 5 10 ⁶ /mm ³ |
| - HGB: | < 1.0% | 15.0 g/dL |
| - HCT: | < 2.0% | 45.0% |
| - MCV: | < 1.5% | |
| - MCH: | < 1.5% | |
| - MCHC: | < 1.5% | |
| - RDW: | < 3.5% | |
| - PLT: | < 5.0% | 300 10 ³ /mm ³ |
| - MPV: | < 5.0% | |
| - LYM%: | < 5.0% | 30% |
| - LYM #: | < 5.0% | 2.1 10 ³ /mm ³ |
| - MON%: | < 15.0% | 5% |
| - MON#: | < 15.0% | 0.5 10 ³ /mm ³ |
| - NEU%: | < 3.0% | 60% |
| - NEU#: | < 3.0% | 4.2 10 ³ /mm ³ |
| - EOS%: | < 25.0% | 3% |
| - EOS#: | < 25.0% | 0.3 10 ³ /mm ³ |
| - BASO%: | < 40.0% | 1% |
| - BASO#: | < 40.0% | 0.1 10 ³ /mm ³ |

Linearity:

Linearity can be considered as the high and low limits for the instrument use for each parameter.

| Parameter | Range | Limits |
|---|--|---|
| WBC (10 ³ /mm ³) | 0.1 - 85.0 (10 ³ /mm ³) | 0.2 x10 ³ /mm ³ or 3% of the expected value |
| RBC (10 ⁶ /mm ³) | 0.5 - 8.1 (10 ⁶ /mm ³) | 0.3 x10 ⁶ /mm ³ or 2% of the expected value |
| PLT (10 ³ /mm ³) | 10 - 1000 (10 ³ /mm ³) | 10 x10 ³ /mm ³ or 5% of the expected value |
| HGB (g/dL) | 2.0 - 25.0 (g/dL) | 0.2 g/dL or 2% of the expected value |
| HCT(%) | 10.0 - 70.0 (%) | 3% of the expected value |

Carryover:

| | WBC | RBC | HGB | HCT | PLT |
|---------------------|-------|-------|-------|-------|-------|
| Mean Level | 57.5 | 8.5 | 24.0 | 72.0 | 944 |
| % Carry-over actual | 0.00 | 0.00 | 0.00 | 0.00 | 0.04 |
| CV % Claim | <2.0% | <0.5% | <0.5% | <2.0% | <2.0% |

Normal Ranges:

These values were taken from the " Hematology Clinical and Laboratory Practice " Copyright 1993 by Mosby - Year Book, Inc., Editor in Chief: Rodger L. Bick, MD.

| PARAMETERS | MALE | FEMALE |
|---|-----------|-----------|
| WBC (10 ³ /mm ³) | 4.5 - 11 | 4.5 - 11 |
| Lymphocytes (%) | 25 - 33 | 25 - 33 |
| Monocytes (%) | 3 - 7 | 3 - 7 |
| Neutrophils (%) | 54 - 62 | 54 - 62 |
| Eosinophils (%) | 1 - 3 | 1 - 3 |
| Basophils (%) | 0 - 0.75 | 0 - 0.75 |
| RBC (10 ⁶ /mm ³) | 4.6 - 6.2 | 4.2 - 5.2 |
| HGB (g/dL) | 14 - 18 | 12 - 16 |
| HCT (%) | 40 - 54 | 37 - 47 |
| MCV (fL) | 80 - 96 | 80 - 96 |
| MCH (pg) | 26 - 34 | 26 - 34 |
| MCHC (g/dL) | 32 - 36 | 32 - 36 |
| RDW (%) | 12 - 16 | 12 - 14 |
| PLT(10 ³ /mm ³) | 150 - 350 | 150 - 350 |
| MPV (fL) | 7 - 9 | 8 - 10 |

All parameters here above can be adapted to the lab. requirement.

Accuracy:

| parameter | SITE 1 | | SITE 2 | | SITE 3 | |
|---|--------------|----------------|---------------|----------------|--------------|----------------|
| | N | R ² | N | R ² | N | R ² |
| WBC (10 ³ /mm ³) | 190 | 0.9945 | 238 | 0.9965 | 216 | 0.9975 |
| RBC (10 ⁶ /mm ³) | 190 | 0.9873 | 238 | 0.9857 | 216 | 0.9933 |
| HGB (g/dL) | 190 | 0.9908 | 238 | 0.9947 | 216 | 0.9970 |
| HCT (%) | 190 | 0.9619 | 238 | 0.9820 | 216 | 0.9903 |
| MCV (μm ³) | 190 | 0.8089 | 238 | 0.9346 | 216 | 0.9593 |
| MCH (pg) | 190 | 0.9402 | 238 | 0.9113 | 216 | 0.9646 |
| MCHC (g/dL) | 190 | 0.1484 | 238 | 0.2008 | 216 | 0.5266 |
| RDW (%) | 190 | 0.5457 | 238 | 0.8003 | 216 | 0.7450 |
| PLT (10 ³ /mm ³) | 190 | 0.9822 | 238 | 0.9827 | 216 | 0.9854 |
| MPV (μm ³) | 190 | 0.2286 | 238 | 0.7149 | 216 | 0.8379 |
| %LYMPH | 190 | 0.8081 | 238 | 0.9669 | 216 | 0.9919 |
| %MON | 190 | 0.3030 | 238 | 0.7280 | 216 | 0.6996 |
| %NEUT | 190 | 0.7975 | 238 | 0.9179 | 216 | 0.9829 |
| %EOS | 190 | 0.8853 | 238 | 0.6618 | 216 | 0.9558 |
| %BASO | 190 | 0.3546 | 238 | 0.3789 | 216 | 0.2391 |
| Reference Analyzers | TECHNICON H2 | | CELL DYN 3500 | | COULTER STKS | |

VII. Conclusions:

Based on these data, the VEGA™ Hematology Analyzer is substantially equivalent to the TECHNICON H2® Hematology Analyzer, the ABBOT CELL-DYN® 3500 Hematology Analyzer and the COULTER STKS® Hematology Analyzer. for the intended use of performing a twenty parameters hematological profile of whole blood specimens.