Diluent VET (For Hematology Analyzer)

(For veterinary invitro diagnostic use only)

INTENDED USE

Diluent VET is a buffered, stabilized and micro-filtered solution for automated dilution of human blood samples, quantitative and qualitative determination of WBC, RBC, PLT and estimation of HGB concentration on Hematology Analyzer.

PRINCIPLE

Blood cell are counted and sized by the electrical impedance method. The blood sample enters the WBC detection unit, and the RBC/PLT detection sample enters the RBC detection unit after being diluted twice. The detection unit has a small opening called a detection aperture. There is a pair of positive and negative electrodes on both sides of the small hole to connect the constant current power supply. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive medium "diluent" as it passes through an aperture of known dimensions. A pair of electrodes is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated represents the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

PRESENTATION

REF	1126250020
Pack Size	20 L
Diluent VET	20 L

COMPOSITION

Sodium Chloride, Sodium Dihydrogen Phosphate, Preservatives and Stabilizers.

SPECIMEN COLLECTION AND STORAGE

Diluent VET is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant only.
Coagulated, hemolysis and lipoidemia samples cannot be measured.
Specimens for haematological analysis may be stored for up to 8 hours at 15-30º C or up to 24 hours after collection when refrigerated (2-8º C). The sample should be brought to the room temperature (i.e.15º C-30º C) before use.
Do not use frozen samples.

REAGENT PREPARATION

This reagent is ready for use and can be applied straight from the container, no special reagent preparation is necessary.

SIGNS OF REAGENT DETERIORATION

The reagent should not look turbid or having any precipitation.
Reagent must not have any free suspended particle or agglutinated chemicals. Reagent should not have any colour development.
There should not be any strong odour coming out from the reagent.
When connected to the system it must give a proper background count.
If any of the above mentioned point is observed, then **Diluent Vet** must be replaced, QC check must be carried out and sample should be retested using fresh reagent.

QUALITY CONTROL

The tri-level 3-part hematology QC must be run in QC mode when the new reagent is introduced into the system.
The specified assay values of the system need to be confirmed and used while running the QC programme.
If QC results are outside the acceptance criteria, then recalibration of the system may be necessary.

REAGENT REPLACEMENT

Person installing the reagent must be a trained laboratory professional.
Remove the inlet cap from the reagent container to be replaced.
Connect the reagent inlet to the new reagent container.
Be sure that the colour on each tube, reagent container label and connector in the back of the instrument is same.
Avoid any dust or microbial contamination of the tubing and reagents.
Do not pour and mix the remains of a reagent from a container into other one.
Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

MATERIAL REQUIRED BUT NOT PROVIDED

Hematology Analyzer **Lyse VET** (Hematology Reagent), Laboratory Roller Mixer.

PERFORMANCE CHARACTERISTICS

Precision table for within run

Within Run	n	Parameters	Mean	SD	%CV
Sample 1	10	WBC	1.75	0.01	0.33
		RBC	2.11	0.01	0.27
		HGB	5.1	0.06	1.12
		PLT	74	1.85	2.53
Sample 2	10	WBC	17.70	0.04	0.21
		RBC	5.40	0.02	0.28
		HGB	16.1	0.06	0.36
		PLT	539	1.15	0.31
Sample 3	10	WBC	13.66	0.03	0.19
		RBC	5.13	0.03	0.56
		HGB	10.1	0.00	0.00
		PLT	212	0.58	0.27

Precision table for between run

Between Run	n	Parameters	Mean	SD	%CV
Sample 1	10	WBC	1.77	0.01	0.40
		RBC	2.11	0.01	0.34
		HGB	5.1	0.00	0.00
		PLT	75	1.41	1.89
Sample 2	10	WBC	17.70	0.03	0.16
		RBC	5.43	0.01	0.13
		HGB	16.1	0.00	0.00
		PLT	543	1.41	0.31
Sample 3	10	WBC	7.77	0.01	0.09
		RBC	7.24	0.04	0.59
		HGB	13.7	0.07	0.52
		PLT	316	1.41	0.45

HANDLING PRECAUTIONS

Reagent must be handled by a trained laboratory professional only.
Diluent VET is an environmental friendly azide free reagent; does not contain harmful ingredients.
Avoid contact with eyes, skin and clothing.
In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
Keep the reagent container closed when not in use.
Wear laboratory gloves when handling the reagent.
All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
Refer to the MSDS associated with the reagent.
Use Good Laboratory Practices (GLP) while handling the reagents.

REAGENT STORAGE, STABILITY AND DISPOSAL

Store the **Diluent VET** between 23 ~ 29°C.
The shelf life of the **Diluent VET** is 24 months from the date of manufacture, if stored at the prescribed temperature range.
Do not use reagent beyond the expiration date printed on the label.
Discard opened container after 60 days
Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

LIMITATIONS

Diluent VET should be used with **Lyse VET** (Product code: 1126260500) only.
Erroneous results may be obtained if the reagent is used with third party reagents or instruments.
Refer to the instrument's User Manual for information about machine operation.

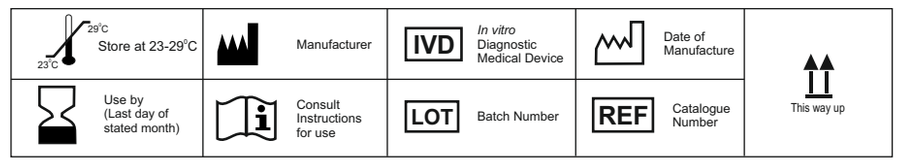
SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent container bottles due to risk of contamination and the potential to compromise reagent performance.
Appropriate bio-safety practices should be used for materials that contain or are suspected of containing infectious materials.
Handle specimens, liquid waste and reagents in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

REFERENCES

1. REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
2. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
3. Technical Guidance Series for WHO Prequalification – Diagnostic Assessment. Designing instructions for use for in vitro diagnostic medical devices. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.
4. Data on file: Coral Clinical Systems.

SYMBOL KEYS



DILV1/0625/VER-01

Manufactured by:

Coral Clinical Systems

A Division of Tulip Diagnostics (P) Ltd.

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