

Intended Use

Absoludy VET Canine D-dimer is a single-use only, fluorescent nanoparticle immunoassay designed for in vitro measurement of D-dimer in plasma specimen (sodium citrate) of dog. Absoludy VET Canine D-dimer is designed for use only with the ABSOL VET or ABSOL Carry VET instrument, a fluorescent immunoassay reading instrument manufactured by Absology Co., Ltd.

Test Principle

Absoludy VET Canine D-dimer cartridge is a single-use, rapid sandwich-immunoassay utilizing fluorescent nanoparticles in microfluidic flow to detect and quantify D-dimer in plasma specimens (sodium citrate) of dogs. Fifty microliters (50µL) of sample are added to the Absoludy VET Canine D-dimer pre-treatment tube, where the sample interacts with a proprietary mix of pre-treatment solution. When the sample is dropped onto the inlet hole of the Absoludy VET Canine D-dimer cartridge, the mixture interacts with fluorescent particles and then moves towards the opposite end of the cartridge, passing the test & reference areas by capillary phenomenon. The fluorescence intensities of the sample are measured, and the D-dimer concentration is calculated and printed by the ABSOL VET or ABSOL Carry VET instrument.

Components

One Absoludy VET Canine D-dimer Box contains:

Contents	AVDDI-010	AVDDI-020
Cartridges	10ea	20ea
Pretreatment tube(s)	10ea	20ea
Disposable micropipette tips	12ea	24ea
Code ship	1ea	1ea
Instructions for use	1ea	1ea

Warnings and Precautions

- 1) Absoludy VET cartridges are intended for in vitro diagnostic use only.
- 2) Absoludy VET cartridges are only to be used with ABSOL VET or ABSOL Carry VET instrument.
- 3) Absoludy VET cartridges are disposable, single use devices. Do not reuse them under any circumstance.
- 4) Let reagents and devices at room temperature for 15–30 min. prior to use.
- 5) Cartridges and pretreatment tubes should not be frozen.
- 6) Assure the humidity in the laboratory is within 10–80% when running tests.
- 7) Assure the room temperature remains in 22–30°C when running tests.
- 8) Avoid cross-contamination between samples by using a new micropipette tip for each test.
- 9) Avoid high humidity, direct sunlight or heat where the cartridges are stored.
- 10) Using specimens with contamination, hyperlipidemia or high level of hemolysis or thrombokinas could cause erroneous results.
- 11) Over or under loading of sample may result in inaccurate results.
- 12) Use Universal Precautions when handling specimens and controls.
- 13) Do not use the product beyond the expiration date.
- 14) Do not use the product if the pouch is damaged or broken.
- 15) Perform testing as specified in the Instructions for Use and User Manual.
- 16) Keep the pouch and tube sealed until just ready for use.
- 17) Run the test immediately after opening the pouch.
- 18) Wear disposable gloves during the test and wash hands thoroughly after.
- 19) Handle specimens in accordance with the OSHA standard on Bloodborne

Storage and Shelf Life

All unopened components are stable until the expiration date on the label if stored properly.

Components	Temperature	Expiration Date
Absoludy VET Canine D-dimer (AVDDI-010, AVDDI-020)	2–8°C	Indicated on label

*The expiration date is clearly indicated on the labels of outer box, cartridges, and pretreatment tubes.

the specimen may be stored in the refrigerator (2–8°C) for at most 6 hours or in the freezer (–20°C) for at most 21 days.

- 4) When using the specimen, let it be in the room temperature before the test, and make sure to mix the specimen well.

3. Assay Procedure

- 1) Turn on the ABSOL VET or ABSOL Carry VET instrument.
- 2) Insert Code chip included in the Absoludy VET Canine D-Dimer kit, to the USB port located on the ABSOL VET or ABSOL Carry VET instrument.
- 3) Press 'SETTING' icon on the ABSOL VET or ABSOL Carry VET screen.
- 4) Press 'CODE CHIP' on the screen.
- 5) Press 'OK' to save the Code chip information in the ABSOL VET or ABSOL Carry VET instrument.
- 6) Check if the lot number labeled on the cartridge matches to the lot number appeared on the ABSOL VET or ABSOL Carry VET screen.
- ⚠ If the lot numbers are not matching, the ABSOL VET or ABSOL Carry VET does not proceed and error message will pop-up on the screen. Code chip calibrates the ABSOL VET or ABSOL Carry VET to reduce the deviations of different Absoludy VET lots.
- 7) Return to main screen by pressing 'HOME' icon.
- 8) Open and add 50µL plasma sample to the pretreatment tube.
- 9) Mix well and let the solution concentrate at the bottom of the pretreatment tube.
- 10) Open cartridge pouch and note patient ID immediately on the cartridge.
- 11) Press '▶' icon on the ABSOL VET or ABSOL Carry VET screen.
- 12) Put cartridge on the plate carefully in same direction of arrow indicated on the cartridge.
- 13) Load 50µL of prepared sample solution onto the inlet hole of the cartridge. Inaccurate amount of sample loading may cause erroneous results.
- 14) Input patient's information such as sample ID, and press 'OK' icon. The cartridge inside the instrument and ABSOL VET or ABSOL Carry VET machine will automatically start testing.
- ⚠ For the optimal results, it is recommended to insert the cartridge into the ABSOL VET or ABSOL Carry VET instrument within 30 seconds of the sample loading on the cartridge.
- 15) Upon completion of the test, ABSOL VET or ABSOL Carry VET instrument automatically rejects the cartridge plate and the results are displayed on the screen.
- 16) The results can be printed out by pressing 'PRINT' icon.
※ABSOL Carry VET printer are subjected to be purchased separately
- 17) Please refer to the 'User Manual' of the ABSOL VET or ABSOL Carry VET instrument.
- ⚠ Never disconnect the power cord of the ABSOL VET or ABSOL Carry VET while the cartridge is in the instrument. It may result in the systematic error.

Interpretation of Results

Analytical Measurement Range

Measurement Range	Display
Below 0.1 µg/ml	< 0.1 µg/ml
Above 0.1 µg/ml and below 10.00 µg/dm	Quantitative result (ex: 1.50 µg/ml)
Above 10.00 µg/ml	> 10.00 µg/ml

Calibration

There is no need for calibration to be performed by the end user. The Absoludy VET Canine D-dimer code chip is specific for each lot of Absoludy VET Canine D-dimer, and the calibration of lot deviation is performed automatically. You may use standard Canine D-dimer controls for external calibration, and if so, we recommend you to test at least two different concentration points.

Disposal

All items containing canine sample should be considered as contagious. Used cartridges, pretreatment tubes, micropipette tips, and other used items shall be disposed according to local environmental and hazardous regulations or internal laboratory procedure.

Performance Characteristics

1. Detection Limit & Measurement Range

1) Analytical Measurement Range (AMR)

AMR
0.10 ~ 10.00 ug/ml

2) Limits of Blank, Limit of Detection, and Limit of Quantitation

These studies were conducted in accordance to the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 guideline.

LoB (Limit of Blank)	LoD (Limit of Detection)	LoQ (Limit of Quantitation)
0.040 ug/ml	0.058 ug/ml	0.084 ug/ml

Instructions for Assay Procedure

1. Note Before Taking the Test

- 1) Check the expiration date noted on the labels.
- 2) Use Absoludy VET cartridges only with ABSOL VET or ABSOL Carry VET instrument.
- 3) When running a new test of the new lot number, make sure to save the corresponding information saved in the code chip included in the Absoludy VET kit.

2. Sample Preparation

- 1) The following matrix of canine blood is usable.
- plasma (Sodium citrate)
- 2) Use plasma sample after proper preparation & centrifugation.
- 3) It is best to use the fresh specimen right after the collection, but if necessary,

2. Precision

Repeatability and reproducibility studies were performed in accordance to the EP5-A3 of CLSI guideline; standard control was tested twice per test and twice per day for twenty days for the verification of precision.

Sample		Low	Middle	High
Average (ug/ml)		0.51	1.01	3.95
Within-run	SD	0.041	0.058	0.234
	CV(%)	7.95	5.80	5.92
Between-run	SD	0.014	0.012	0.093
	CV(%)	2.80	1.17	2.35
Between-day	SD	0.010	0.009	0.091
	CV(%)	1.95	0.88	2.30
Within-laboratory	SD	0.044	0.060	0.268
	CV(%)	8.65	5.98	6.77

3. Interference

Interference substance studies were performed in accordance with the EP7-A2 of CLSI guideline, the following interfering substances were evaluated and did not affect the results.

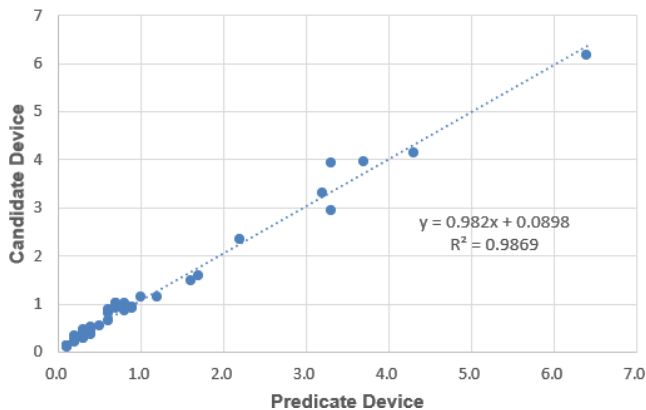
Interfering Substances	
Bilirubin	170 umol/L
Hemoglobin	4,000 mg/L
Triglyceride	5,000 mg/dL
Total protein	70 g/L

4. Correlation

Correlation study was performed in accordance to the EP09-A3 of CLSI guideline; 50 canine specimens were used to evaluate the correlation to the predicate devices.

- Canine			
Predicate Device	Specimen (N)	Equation	Coefficient of Determination (R ²)
S	50	$Y = 0.982X + 0.0898$	0.9869

Correlation



Glossary of Symbols

	Do not reuse
	Use by YYYY-MM-DD
	Lot number
	Catalogue number
	Warning or Caution
	Manufactured by
	Temperature limitation
	Contains sufficient for <n> tests
	Consult instructions for use



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