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Veterinary Test Cartridge Refrigerated Storage

[Intended Use]

The veterinary test cartridges are intended to be used with EDAN i15 VET Veterinary Blood Gas and Chemistry Analysis System. The EDAN i15 VET Veterinary Blood Gas and Chemistry Analysis System is designed for the quantitative measurement of blood gases, blood chemistries, and hematocrit in whole blood samples. The system is for in vitro diagnostic use and is intended for use only by trained veterinarians. It is intended for use in a veterinary hospital.

[Important]

Please read this instruction and the EDAN i15 VET Veterinary Blood Gas and Chemistry Analysis System User Manual before using veterinary test cartridges. If you have any questions or need assistance, please contact EDAN or its authorized distributors.

[Principle]

The EDAN i15 VET Veterinary Blood Gas and Chemistry Analysis System utilizes potentiometry and amperometry to determine the concentrations of blood gases and blood chemistries, and utilizes conductivity to determine the concentration of hematocrit.

[Components]

The veterinary test cartridge contains the fillport, the fluidic chamber, electrical contacts, and an array of sensors. The sensors contained depend on the veterinary test cartridge type.

[Veterinary Test Cartridge Types]

Veterinary test cartridges are available in different configurations concerning the parameters reported by them. For details, please refer to the table below:

Cartridge Type	Measured Parameters	Calculated Parameters
BG8	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Hct	cH^+, HCO_3^-act, HCO_3^-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), Ca^{++}(7.4), AnGap, tHb(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2, mOsm
BG3	pH, pCO_2, pO_2	cH^+, HCO_3^-act, HCO_3^-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2
BC4	Na^+, K^+, Cl^-, Ca^{++}, Hct	Ca^{++}(7.4), tHb(est)
BG10	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Hct , Glu, Lac	cH^+, HCO_3^-act, HCO_3^-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), Ca^{++}(7.4), AnGap, tHb(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2 , mOsm
BG9	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Hct , Glu	cH^+, HCO_3^-act, HCO_3^-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), Ca^{++}(7.4), AnGap, tHb(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2 , mOsm
BG4	pH, pCO_2, pO_2, Lac	cH^+, HCO_3^-act, HCO_3^-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2

[Shipping Control]

Veterinary test cartridge shipping cartons include one temperature monitor, which turns gray when the shipping temperature is

outside the specified range.

The temperature monitor should be checked when veterinary test cartridges are received to verify that the temperature limits were not exceeded during shipment. If the temperature monitor turns gray, perform control tests (analyze at least two levels of controls in duplicates) with the received veterinary test cartridges. If veterinary test cartridges pass the tests, they can be used. If veterinary test cartridges fail the tests, do not use them, and contact EDAN immediately for exchange of the veterinary test cartridges.

NOTE:

Never use veterinary test cartridges failing control tests.

[Storage]

Veterinary test cartridges, valid for nine months, should be stored at 2 – 8 °C (avoid freezing) until the expiration date as labeled on the package. They should be kept out of direct sunlight and heat. A veterinary test cartridge should not be removed from its foil pouch until it is at room temperature. One veterinary test cartridge needs five minutes to come to room temperature. Veterinary test cartridges may be stored at room temperature (18 – 30 °C) for two weeks. Write down the two-week room temperature expiration date on the line of a veterinary test cartridge foil pouch or package.

[Warnings and Precautions]

- Veterinary test cartridges are for in vitro diagnostic use only.
- If the pouch has been damaged, the veterinary test cartridge should not be used.
- Only veterinary test cartridges provided by EDAN or its authorized distributors should be used.
- Only veterinary test cartridges properly stored should be used.
- Veterinary test cartridges should be kept out of direct sunlight and heat.
- Veterinary test cartridges should not be dropped or stressed.
- Never reuse veterinary test cartridges.
- Never touch the fillport or electrical contacts of a veterinary test cartridge.
- Once a veterinary test cartridge has been equilibrated to room temperature, it should not be returned to the refrigerator.
- Use veterinary test cartridges before the expiration date as labeled on the package, and use them immediately after removing them from their pouches.
- The analyzer, veterinary test cartridges and the testing environment should be at the same temperature prior to a test.
- Perform the sample test immediately after its collection to get the most accurate results. Measure samples for blood gases and Ca^{++} within 10 minutes, and measure samples for other analytes within 30 minutes.
- The sample is contained in the veterinary test cartridge, so veterinary test cartridges should be disposed of as biohazardous waste, complying with local regulatory guidelines.

[Applicable Instruments]

EDAN i15 VET Veterinary Blood Gas and Chemistry Analysis System

[Sample Collection and Preparation]

Blood samples should be collected according to proper medical guidelines containing collection details, such as site selection, collection procedures, sampling devices, sample handling, etc. Sterile techniques should be followed to prevent the site from being contaminated.

Only those sample devices containing the proper amount of calcium-titrated (balance anticoagulant should be used to collect whole blood samples. If calcium-titrated (balanced) heparin is used as an anticoagulant, the minimum heparin-to-blood ratio should be 2.3 units of heparin per 1.0 mL of blood sample. If a sample is analyzed for ionized calcium, the maximum heparin-to-blood ratio should be 15 units of heparin per 1.0 mL of blood sample; if not, the maximum heparin-to-blood ratio should be 50 units of heparin per 1.0 mL of blood sample.

NOTE:

Don't use the following anticoagulants: EDTA, citrate, ammonium heparin, and oxalate, because they have a great influence on test results for pH and electrolytes.

Samples can be introduced into the system with the following devices: syringes and capillary tubes. It is recommended that VITREX® Blood Gas Capillary Tubes with a minimum volume, filled of 175 µL (Article Number: 182413) or 220 µL (Article Number: 182313) should be used.

NOTE:

- ✓ The system uses 140 µL samples for analysis, and make sure it can aspirate enough sample.
- ✓ The minimum fill volume for a 1 mL syringe is 500 µL.
- ✓ The minimum fill volume for a 2 mL syringe is 800 µL.
- ✓ The minimum fill volume for a 5 mL syringe is 1.5 mL.
- ✓ Dislodge bubbles from the syringe, and cover it as soon as the sample is collected. Cork should never be used to cover the syringe.
- ✓ A capillary tube should be filled to capacity and covered securely. Cork or clay should never be used to cover the capillary tube.

[Quality Control (QC) Tests]

Follow the procedures below to perform a control test:

1. Examine the package label of controls to ensure they have not expired.
2. Remove an ampoule from the box of controls and equilibrate it to room temperature.

   If oxygen is to be measured, the ampoule needs to stand at room temperature for at least 4 hours. If not, the ampoule needs to stand at room temperature for 30 minutes.
3. Press the **On/Off** button on the left hand side of the analyzer to turn it on.
4. Enter the user name and password manually (or enter the user name with the bar code scanner), and then press 

.
5. On the Main screen, press  (**Setup**).
6. Select the desired control type.

   Press  (**BG**) to perform a control test for blood gases and blood chemistries.

   Press  (**Hct**) to perform a control test for Hct.
7. Press **Scan Barcode**, and scan the bar code on a new cartridge foil pouch.

NOTE:

Cartridges stored refrigerated at 2 – 8 °C may be used after standing at room temperature for five minutes.

8. Open the foil pouch and remove the cartridge from it.

NOTE:

For sample introduction with a capillary tube or an ampoule, insert a capillary adaptor/ampoule adaptor into the fillport after removing the cartridge.

9. Press **Scan Barcode**, and scan the bar code on the controls user manual.

NOTE:

Keep the controls user manual for a future control test use.

10. Mix the controls completely by shaking the ampoule gently, and then gently tap the tip of the ampoule carefully with your fingernail to remove any solution.
11. Open the ampoule by snapping off the top and immediately transfer control solution by slowly drawing an appropriate amount of solution with a syringe or capillary tube from the bottom of the ampoule.

NOTE:

When using an ampoule for sample introduction, you need not transfer control solution. Insert the ampoule into the adaptor after opening it, and directly go to step 13.

12. Insert the syringe or capillary tube into the fillport of the cartridge.

NOTE:

- ✓ When using a syringe, discard the first 2 drops of solution first, then remove the needle from it, and finally insert it into the fillport.
- ✓ When using a capillary tube, directly insert the capillary tube into the adaptor till the tube reaches the interface between the adaptor and the cartridge.
- ✓ To avoid inaccurate test results, make sure there are no bubbles in the sample. If bubbles continually exist, use a new ampoule and syringe or capillary tube to collect samples again.

13. Gently insert the cartridge into the cartridge port, and carefully press down to ensure that it clicks into place. If it is properly inserted, the system will start to aspirate calibrant.
14. The system automatically aspirates calibrant, performs calibration, aspirates samples, performs control test and displays test results.
15. View the results.

NOTE:

- ✓ The system will indicate whether the results are within or outside the acceptable ranges with **Under Control/Out of Control**.
- ✓ If a parameter fails calibration, the system will not be able to determine whether it is under control, and will display **Calibration Failure** to prompt you.
- ✓ The system will not report the result for a parameter failing the control test in the blood sample analysis, if QC Lockout function is enabled in Setup. To report the result for the parameter, repeat the control test till the parameter passes it.
- ✓ If the results are outside the acceptable ranges, check the following items first, and then perform another test.
  - Refer to the user manual to confirm that the test procedures are correct.

- Veterinary test cartridges and controls are stored properly and have n
- The system passes the electronic simulator test.

If all the above items are verified, but the results are still outside the acceptable ranges, please stop using the system and contact EDAN or its authorized distributors for assistance.

16. Remove the veterinary test cartridge from the analyzer.
17. Press **Print** to print the results. Press **Home** to return to the Main screen.

[Blood Sample Analysis]

1. Press the **On/Off** button on the left hand side of the analyzer to turn it on.
2. Enter the user name and password manually (or enter the user name with the bar code scanner), and then press  .
3. Press the button for the blood sample type on the Main screen. √ indicates that the button is selected. The default type is **Arterial**.
4. Press **Scan Barcode**, and scan the bar code on a new cartridge foil pouch.

NOTE:

Cartridges stored refrigerated at 2 – 8 °C may be used after standing at room temperature for five minutes.

5. Open the foil pouch and remove the cartridge from it.

NOTE:

For sample introduction with a capillary tube, insert a capillary adaptor into the fillport after removing the cartridge.

6. Roll the syringe or capillary tube between palms and gently invert it end over end for several times to mix the sample completely.
7. Insert the syringe or capillary tube into the fillport of the cartridge.

NOTE:

✓ When using a syringe, discard the first 2 drops of blood sample first, then remove the needle from it, and finally insert it into the fillport.

✓ When using a capillary tube, directly insert the capillary tube into the adaptor till the tube reaches the interface between the adaptor and the cartridge.

✓ To avoid incorrect test results, make sure there are no trapped bubbles or clots in the sample.

8. Gently insert the cartridge into the cartridge port, and carefully press down to ensure that it clicks into place. If the cartridge is inserted properly, the system will automatically start to aspirate calibrant.
9. Enter the parameters for patient information, and press **OK**. The system will go to the screen for aspirating calibrant, calibrating, sampling, measuring or sample results.

NOTE:

If the screen has not been touched for 10 seconds after the test is complete, the test results will be displayed automatically even if you do not press **OK**.

10. View the test results.
11. Remove the veterinary test cartridge from the analyzer.
12. Press **Home** to return to the Main screen.

[Interpretation of Results]

Symbol	Description
> or <	The result is above or below the measurement range.
↑ or ↓	The result is above or below the reference range.
---	This measured parameter fails calibration.
xxx	This measured parameter fails quality control (QC) tests, and QC lockout function is enabled in Setup.
***	This measured parameter fails quality control (QC) tests, and QC lockout function is disabled in Setup.
	The result for this calculated parameter is valid, but the measured parameter used to determine the calculated parameter fails quality control (QC) tests, and QC lockout function is disabled in Setup.
???	The result for this measured parameter is invalid.

NOTE:

- ✓ If test results are inconsistent with the clinical assessment, the sample should be tested again with a new veterinary test cartridge.
- ✓ Never make treatment decisions according to test results containing symbols as described above.

[Reference Ranges]

Parameter	Reference Range		
	Canine	Feline	Equine
Na+(mmol/L)	139 - 150	147 - 162	128 - 142
K+(mmol/L)	3.4 - 4.9	2.9 - 4.2	1.9 – 4.1
Cl-(mmol/L)	106 - 127	112 - 129	100 - 111
Ca++(mmol/L)	1.12 - 1.40	1.20 - 1.32	1.25 – 1.75
Hct (%)	35 - 50	24 - 40	30 - 45
Glu(mg/dl)	60-115	60-130	62-134
Lac(mmol/L)	0.60-2.90	0.50-2.70	0.30-1.50

Parameter	Reference Range (Arterial)		
	Canine	Feline	Equine
pH	7.35 – 7.45	7.25 – 7.40	7.32 – 7.44
pCO2(mmHg)	34.0 – 40.0	28.0 – 34.0	36.0 – 46.0
pO2(mmHg)	85 - 100	90 - 110	90 - 100

Parameter	Reference Range (Venous)		
	Canine	Feline	Equine
pH	7.35 – 7.45	7.25 – 7.40	7.35 – 7.45
pCO2(mmHg)	35.0 – 38.0	33.0 – 51.0	36.0 – 46.0

NOTE:

These reference ranges have been provided by Woodley Equipment Company Ltd.

[Limitations]

- ◆ Veterinary test cartridges are used to analyze whole blood samples only.
- ◆ The results given by the system should be examined based on the overall clinical condition of the patient, and it should not

be a substitute for regular checking.

- Mix the sample thoroughly prior to sample introduction to avoid inaccurate results.
- To avoid inaccurate test results, make sure there are no clots or bubbles in the sample.

[Reference]

CLSI. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. CLSI document EP5-A2 [ISBN 1-56238-542-9], CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

[Performance Characteristics]

Repeatability was estimated using one lot of veterinary test cartridges, and 20 replicates of each level were successively analyzed on one i15 VET Veterinary Blood Gas and Chemistry Analysis System. QC Materials used were RNA Medical® QC823 Blood Gas●Electrolyte●Metabolite●BUN Controls and RNA Medical® QC900 Hematocrit Controls. In the table below, SD refers to the standard deviation.

Parameter	Level	Mean	SD
pH	1	7.152	0.0058
	2	7.425	0.0036
	3	7.608	0.0035
pCO_2	1	69.94	2.387
	2	42.49	1.383
	3	23.66	0.615
pO_2	1	71.6	1.82
	2	99.6	1.64
	3	146.1	1.71
Na^+	1	112.3	0.87
	2	135.3	0.55
	3	159.7	1.53
K^+	1	1.96	0.049
	2	4.40	0.022
	3	6.27	0.047
Cl^-	1	74.5	1.26
	2	92.4	0.67
	3	121.8	0.70
Ca^{++}	1	1.43	0.042
	2	1.18	0.017
	3	0.56	0.014

Glu	1	4.31	
	2	10.81	0.150
	3	15.90	0.126
Lac	1	0.67	0.009
	2	2.67	0.015
	3	7.21	0.054
Hct	Low	18.9	0.49
	High	46.5	0.51

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[Date of Approval for Package Insert]

October, 2015

[Labeling and Information]

	Consult instructions for use		Caution
LOT	Batch code		Do not reuse
IVD	In vitro diagnostic device		Temperature limitation
	Use by		Recycle
	Manufacturer		Sufficient for n tests
EDAN	Trademark	EC REP	Authorized Representative in the European Community

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