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Blood Gas and Electrolyte Controls Use

[Intended Use]

i15/i15VET Blood Gas and Electrolyte Control is intended to be used for the verification of correct operation and measurement of i15/i15VET Blood Gas and Chemistry Analysis System, together with i15/i15VET Calibrator Fluid Pack and i15/i15VET Sensor Cartridge for the analysis of pH, blood gases (pCO_2, pO_2), and electrolytes (Na^+, K^+, Cl^-, Ca^{++}). The System is intended for in-vitro diagnostic use only by trained health care professionals in a laboratory environment, near patient or point-of-care settings.

[Important]

Please read this instruction and i15/i15VET Blood Gas and Chemistry Analysis System User Manual before using blood gas and electrolyte controls. If you have any questions and/or need assistance, please contact EDAN or the authorized local distributors.

[Specification]

i15/i15VET Blood Gas and Electrolyte Control is provided in three (3) levels for monitoring analyzer performance at different points within the clinical range. It is packaged in sealed glass ampoules, each containing 2.5 mL of solution. Ampoules are packaged with five (5) ampoules of a single level in each carton.

Active Ingredients: i15/i15VET Blood Gas and Electrolyte Control is a buffered aqueous solution containing electrolytes (Na^+, K^+, Cl^-, Ca^{++}). It has been equilibrated with specific levels of CO_2, O_2 and N_2 and contains no preservatives and no human or biological materials.

[Storage and Expiration]

Blood gas and electrolyte controls should be stored at 2°C - 8°C (36 – 46 °F) (avoid freezing and temperatures greater than 30 °C) until the expiration date as labeled on the package. They should be kept away from direct sunlight and heat.

[Warnings and Precautions]

- For in vitro diagnostic use only.
- Only blood gas and electrolyte controls provided by EDAN or its authorized distributors should be used.
- Use blood gas and electrolyte controls before the expiration date as labeled on the package.
- Take protective measures when opening the ampoule, such as using gloves, tissue, etc.
- For test cartridges with pH, pCO_2, pO_2, Ca^{++} sensors, a new ampoule and syringe or capillary tube should be used for each test. For test cartridges without pH, pCO_2, pO_2, Ca^{++} sensors, the remaining solution can still be used if the ampoule is opened within 10 minutes.
- Use i15/i15 VET Blood Gas and Chemistry Analysis System at a temperature between 10°C and 30°C (50°F and 86°F) and a relative humidity within 25% - 80% (non-condensing). Outside this range, the system may produce incorrect results.

[Applicable Instruments]

EDAN i15 Blood Gas and Chemistry Analysis System

EDAN i15 VET Blood Gas and Chemistry Analysis System

[Blood Gas and Electrolyte Control Test]

Follow the procedures below to perform a blood gas and electrolyte control test:

1. Examine the package label of blood gas and electrolyte controls to ensure they have not expired.
2. Remove an ampoule from the box of blood gas and electrolyte 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. Press  (**BG**) to perform a control test for blood gases and blood chemistries.

7. Press **Scan Barcode**, and scan the bar code on a new cartridge foil pouch.

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 fill port after removing the cartridge.

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

NOTE:

Keep the blood gas and electrolyte controls user manual for a future control test use.

10. To mix the solution, hold the ampoule at the top and bottom (with forefinger and thumb) and shake for 10 seconds. Tap the ampoule to restore the liquid to the bottom.

11. Using gauze, tissue, or gloves 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 adaptor after opening it and directly go to step 13.

12. Insert the syringe or capillary tube into the fill port 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 fill port.
- ✓ 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 cannot be removed, 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 blood gas and electrolyte 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 blood gas and electrolyte control test in the patient sample analysis, if QC Lockout function is enabled in Setup. To report the result for the parameter, repeat the blood gas and electrolyte 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.
  ·Test cartridges and blood gas and electrolyte controls are stored properly and have not expired.
  ·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 test cartridge from the analyzer.

17. Press **Print** to print the results.

18. Press **Home** to return to the Main screen.

[Target Ranges]

	Blood Gas and Electrolyte Controls					
	Level 1		Level 2		Level 3	
Parameter	Target Value	Acceptable Range	Target Value	Acceptable Ranges	Target Value	Acceptable Ranges
pH	7.146	7.096 - 7.196	7.411	7.361 - 7.461	7.589	7.539 - 7.639
pO_2(mmHg)	74.7	59.7-89.7	108.5	91.5-125.5	148.1	126.1-170.1
pCO_2(mmHg)	66.9	58.9-74.9	44.4	33.4-47.4	21.8	15.8-27.8
Na^+(mmol/L)	112.7	107.7-117.7	132.2	127.2-137.2	157.5	152.5-162.5
K^+(mmol/L)	1.97	1.47-2.47	4.37	3.87-4.87	6.27	5.67-6.87
Ca^{++}(mmol/L)	1.52	1.32 – 1.72	1.16	1.01-1.31	0.57	0.47-0.67
Cl^-(mmol/L)	73.6	68.6-78.6	94.1	88.1-100.1	120.5	112.5-128.5
Glu(mmol/L)	4.42	3.52-5.32	10.77	9.47-12.07	15.54	12.74-18.34
Lac(mmol/L)	0.66	0.16-1.16	2.47	1.97-2.97	6.43	4.93-7.93
	LOT 41526 2017-09		LOT 41625 2017-09		LOT 41726 2017-09	

Note: *Target values for the parameters are traceable to NIST standards. These target ranges are entered automatically into the i15/i15 VET by using the bar codes*

It is known that pO_2 and pCO_2 results are inversely affected by ambient temperature. You can adjust the acceptable ranges to account for ambient temperature effects using the table below. For example, if your institution typically operates at 24 - 26°C and the pCO_2 range for level 1 is 60.2 – 76.2mmHg, the range can be adjusted by subtracting 0.74mmHg from upper and lower limits: Adjusted range = (60.2 – 76.2) mmHg – 0.74 = 59.46 – 75.46mmHg.

Parameter (mmHg)	Level	10 - 12 °C	13 - 15°C	15 - 17°C	18 - 20°C	21 - 23°C	24 - 26°C	27 - 28°C	29 - 31°C
pO_2	Level 1	3.37	2.53	1.69	0.84	0.00	-0.84	-1.69	-2.53
pCO_2	Level 1	2.94	2.21	1.47	0.74	0.00	-0.74	-1.47	-2.21
pO_2	Level 2	6.92	5.19	3.46	1.73	0.00	-1.73	-3.46	-5.19
pCO_2	Level 2	1.47	1.10	0.74	0.37	0.00	-0.37	-0.73	-1.10
pO_2	Level 3	10.48	7.86	5.24	2.62	0.00	-2.62	-5.24	-7.86

Parameter (kPa)	Level	10 - 12 °C	13 - 15°C	15 - 17°C	18 - 20°C	21 - 23°C	24 - 26°C	27 - 28°C	29 - 31°C
pO_2	Level 1	0.45	0.34	0.22	0.11	0.00	-0.11	-0.22	-0.34
pCO_2	Level 1	0.39	0.29	0.20	0.10	0.00	-0.10	-0.20	-0.29
pO_2	Level 2	0.92	0.69	0.46	0.23	0.00	-0.23	-0.46	-0.69
pCO_2	Level 2	0.20	0.15	0.10	0.05	0.00	-0.05	-0.10	-0.15
pO_2	Level 3	1.40	1.05	0.70	0.35	0.00	-0.35	-0.70	-1.05

[Limitations]

- Blood gas and electrolyte controls are sensitive to many instrument related factors which would affect test results. They may not detect certain malfunctions which would affect blood analysis
- Blood gas and electrolyte controls are intended to be used as a quality control material and can help evaluate the performance of i15/i15 VET Blood Gas and Chemistry Analysis System. They are not intended to be used as a calibration standard and their use should not replace other aspects of a complete quality control program.

[References]

Maas A.H.V, "Evaluation of ampouled tonometered buffer solutions as a quality control system for pH, pCO_2 and pO_2 measurements", Clin. Chem., 23(9), 1718-1725, 1977.

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[Labeling and Information]

	Consult instructions for use		Caution!
	Batch code		Do not reuse
	In vitro diagnostic device		Temperature limitation
	Use by		Recycle
	Manufacturer		The device complies with the European Council Directive 98/79/EEC concerning medical devices.
	Date of manufacture		Authorized Representative in the European Community
	Sufficient for n tests		Trademark

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