

Chemistry Control Data Sheet

For Use on the Element DCX,™ Element DC5X,™ Element DC,™ and DRI-CHEM® Veterinary Chemistry Analyzers

CATALOG NUMBER: 5725 (3 vials) or 5729 (1 vial)

LOT NUMBER: 72962

SIZE: 5 mL

EXPIRATION DATE: 2028Nov30

Intended Use

For *in vitro* veterinary diagnostic use only, to monitor instrument performance and reagent handling.

Principles

Controls are solutions that contain known amounts of the analytes measured by a laboratory instrument. As part of good laboratory practice, a control solution should be tested at least once a month and the results compared to target values to ensure that the analyzer is generating accurate results.

Description and Precautions

Chemistry Control is prepared from human serum with human and nonhuman enzymes and nonprotein constituents added. Bacteriostatic agents have been added to prolong reconstituted stability.

CAUTION: Human serum was used in the manufacture of this product. Each unit of donor blood used was tested with licensed reagents and found negative for Hepatitis B antigen and nonreactive for HIV antibody. Because no test method can offer complete assurance that this material will not transmit infectious agents, it is recommended that gloves be worn when opening, reconstituting, and handling Chemistry Control.

Preparation

USING A NEW CONTROL VIAL:

1. Tap the vial lightly to dislodge any lyophilized material adhering to the cap.
2. Unscrew the cap and take out the rubber stopper.
3. Using a 5 or 6-mL syringe, add exactly 5 mL of sterile water to the control vial. A bottle of water is enclosed with your control materials.
4. Replace the stopper on the control vial and swirl gently to mix.
5. Let sit undisturbed at room temperature for at least 60 minutes for complete reconstitution.
6. Immediately before use, swirl again to mix, then gently invert the vial five (5) times.
7. Pipette into a plain sample tube (no anticoagulant) and place in the analyzer for testing.
8. Recap the vial and write the date on the label. Immediately return the vial to the refrigerator.

USING RECONSTITUTED CONTROL:

1. Remove the vial from refrigerator.
2. Swirl to mix, then gently invert the vial five (5) times.
3. Pipette aliquot of control into a plain sample tube (no anticoagulant) and warm to room temperature for at least five (5) minutes.
4. Recap the vial and immediately return it to the refrigerator.
5. Place the sample tube in the analyzer for testing.

Storage and Stability

The lyophilized (i.e., un-reconstituted) Chemistry Control should be stored in the refrigerator 35.6–46.4°F (2–8°C). If stored properly, this product may be expected to remain stable until the date indicated on the label. After reconstitution, the levels of constituents remain relatively stable for up to 10 days when stored at 35.6–46.4°F (2–8°C). Reconstituted controls that show any evidence of contamination (change in color, development of particulate matter, etc.) should be discarded.

Limitations

1. The listed control ranges apply to the listed lot number of Chemistry Control only when used exclusively with DRI-CHEM and Element DC Veterinary Chemistry Analyzers using the appropriate methods.
2. The control ranges for each analyzer encompass variations in performance from instrument to instrument. Ninety-five percent of user-derived values are expected to fall within these specific ranges.

Use

It is recommended to perform a quality check at a regular interval on your routinely used slides using Chemistry Control.

Element DCX and DC5X Veterinary Chemistry Analyzers

1. From the main screen, make sure [Ready to test] or [Lamp warming up] is displayed.
2. Open the sample cover.
3. Set a 0.5 mL sample rack in the analyzer.
4. Load slides in a slide cartridge and place a slide weight on the slides.
Note: If using an electrolyte slide, place it on top of the stack.
5. Place the slide cartridges into the analyzer.
6. Pipette control solution into a 0.5 mL plain tube (Red Top) and place the tube in the sample rack.
Note: To avoid an error, make sure there are no bubbles in the sample.
Note: Step 7 for DC5X only. For DCX, skip to step 8.
7. Touch the desired sample position (A, B, C, D or E).
8. Touch SAMPLE ID.
9. Input a sample ID. Inputting the control lot number as the ID is recommended..
10. Touch OK.
11. Touch ANIMAL, then touch CONTROL.
12. Make sure Sample Type is Plasma/Serum.
13. Touch OK. Touch START.
14. At the end of the run, compare the results to the control insert sheet or to the displayed ranges if they have been input into the instrument.

Element DC Veterinary Chemistry Analyzer

1. From the Measurement screen, make sure [Ready to Test] is displayed.
2. Open the sampler cover.
3. Set a 0.5 mL sample rack in the analyzer.
4. Load slides in a slide cartridge and place a slide weight on the slides.
Note: If using an electrolyte slide, place it first or last in the stack.
5. Place the slide cartridge into the analyzer.
6. Put an AUTO TIP into hole "A" on the sample rack.
7. Pipette the control solution into a 0.5 mL plain tube and place the tube in the sample rack.
Note: To avoid an error, make sure there are no bubbles in the sample.
8. Touch ANIMAL and then touch CONTROL.
Note: Make sure Sample type is P/S (plasma/serum).
9. Input a sample ID. Inputting the control lot number as the ID is recommended.
10. Close the sampler cover.
11. Press START.
12. At the end of the run, compare the results to the control insert sheet or to the displayed ranges if they have been input into the instrument.

DRI-CHEM 7000 Veterinary Chemistry Analyzer

1. Make sure [Ready] is displayed.
2. Open the sampler cover.
3. Set a 0.5 mL sample rack in the analyzer.
4. Load slides in a slide cartridge and place a slide weight on the slides.
Note: If using an electrolyte slide, place it last in the stack.
5. Place the slide cartridge into the analyzer.
6. Make sure there are tips and RE solution, if applicable.
7. Pipette the control solution into a 0.5 mL plain tube and place the tube in the sample rack.
Note: To avoid an error, make sure there are no bubbles in the sample.
8. Select sample position (A,B,C,D,E), then press ID.
9. Input sample ID and press ENTER.
Note: Inputting the control lot number as the ID is recommended.
10. Using the ▼▲ keys, select [Control], and press ENTER.
11. Press SAVE.
12. Close the sampler cover.
13. Press START.
14. At the end of the run, compare the results to the control insert sheet or to the printed ranges if they have been input into the instrument.

DRI-CHEM 4000 Veterinary Chemistry Analyzer

1. Make sure [Ready] is displayed.
2. Open the sampler cover.
3. Set a 0.5 mL sample rack in the analyzer.
4. Load slides in a slide cartridge and place a slide weight on the slides.
Note: If using an electrolyte slide, place it first or last in the stack.
5. Place the slide cartridge into the analyzer.
6. Put an AUTO TIP into hole "A" on the sample rack.
7. Pipette the control solution into a 0.5 mL plain tube and place the tube in the sample rack.
Note: To avoid an error, make sure there are no bubbles in the sample.
8. Press REF until [Control] is displayed then press ENTER.
9. Input a sample number and sample ID.
Note: Inputting the control lot number as the ID is recommended.
10. Close the sampler cover.
11. Press START.
12. At the end of the run, compare the results to the control insert sheet or to the printed ranges if they have been input into the instrument.

Element DCX , Element DC5X, Element DC, and DRI-CHEM, Veterinary Chemistry Analyzers

New control range update for:
 Material: Chemistry Control
 Part Number: CAT 5725 (3 vials) or 5729 (1 vial)
 Lot Number: 72962
 Expiration: 2028Nov30

ANALYTE	LOW	HIGH	US UNITS	LOW	HIGH	SI UNITS
Albumin	3.4	5.0	g/dL	34	50	g/L
ALP (Alkaline Phosphatase)	251	417	U/L	251	417	U/L
ALT (GPT)	62	97	U/L	62	97	U/L
Amylase	628	934	U/L	628	934	U/L
AST (GOT)	156	237	U/L	156	237	U/L
Bilirubin, Total	0.2	1.3	mg/dL	3.4	22.2	umol/L
BUN (Blood Urea Nitrogen)	40	55	mg/dL	14.2	19.8	mmol/L
Calcium	10.5	15.7	mg/dL	2.63	3.93	mmol/L
Cholesterol	88	110	mg/dL	2.28	2.84	mmol/L
CK	423	558	U/L	423	558	U/L
Creatinine	4.2	6.0	mg/dL	371	530	umol/L
GGT	160	216	U/L	160	216	U/L
Glucose	236	289	mg/dL	13.1	16.0	mmol/L
LDH	242	367	U/L	242	367	U/L
Lipase	57	97	U/L	57	97	U/L
Magnesium	4.6	6.4	mg/dL	1.89	2.63	mmol/L
Phosphorus	6.5	9.0	mg/dL	2.10	2.91	mmol/L
Total Protein	2.2	4.0	g/dL	22	40	g/L
Triglyceride	56	91	mg/dL	0.63	1.03	mmol/L
Uric Acid	8.8	11.5	mg/dL	523	684	umol/L
Sodium (Na)	116	147	mEq/L	116	147	mmol/L
Potassium (K)	5.5	7.2	mEq/L	5.5	7.2	mmol/L
Chloride (Cl)	70	92	mEq/L	70	92	mmol/L
TCO ₂ *	6.4	16.4	mmol/L	6.4	16.4	mmol/L

*TCO₂ is not available on the DRI-CHEM 4000 Veterinary Chemistry Analyzer.