

Quality Control Cartridge Instruction Manual

INTENDED USE

The InSight V-IA QC Cartridges are suitable for quality control of the InSight V-IA Veterinary Immunoassay Analyser.

For *in vitro* diagnostic use only. For veterinary use only.

WARNINGS AND PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only.
2. The Lot No. of all the QC test components (test device, ID chip) must match each other. Do not mix components from different QC kits.
3. Inspect the packaging and labels before use. Do not use if the pouch is broken, torn, unsealed or the cartridge looks damaged.
4. Carefully follow the instructions and procedures described in this insert.
5. Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use. Do not use if the pouch or the device itself is damaged, torn or unsealed.
6. Do not touch the test area of the test device.

STORAGE AND STABILITY

1. Store the test kit at 4-30°C up to the expiration date.
2. Once the pouch has been opened, the QC cartridges are stable for 2 weeks if stored in the foil pouch at room temperature.
3. If removed from a refrigerator, allow 30 minutes for the test to attain room temperature before testing.

TEST PROCEDURE

Refer to the InSight V-IA Veterinary Immunoassay Analyser User Manual for complete instructions for use of the analyser.

The kit contains 9 QC cartridges: 3 x low level (QC-2), 3 x mid level (QC-4) and 3 x high level (QC-7).

1. Set a Test Device on a clean, level horizontal surface.
2. Take out the ID Chip for the QC level to be tested (QC-2/QC-4/QC-7) and insert it into the chip port of the analyser. Be careful not to touch the end of the ID Chip. Click "read ID card" on the main interface. Confirm that the ID Chip is consistent with the batch number of the QC test cartridge.
3. Cartridges should be brought to room temperature (20-25°C) before testing and the test should be conducted at room temperature.
4. Tear open the aluminium foil bag and take out the quality control cartridge (QC-2/QC-4/QC-7).
5. Insert the QC cartridge (QC-2/QC-4/QC-7) into the test port and click the 'test' option. The InSight V-IA Veterinary Immunoassay Analyser will automatically perform the test and read/print the test results.
6. The ID chip should match the QC cartridge.

INTERPRETATION OF QUALITY CONTROL RESULTS

QC No.	QC-2	QC-4	QC-7
	Low	Mid	High
Lower QC Limit	10.95	25.63	53.48
Upper QC Limit	13.39	31.33	65.36

The result of quality control cartridge 2 (QC-2 low level) should be within the target value of 10.95-13.39;

The result of quality control cartridge 4 (QC-4 mid level) should be within the target value of 25.63-31.33;

The result of quality control cartridge 7 (QC-7 high level) should be within the target value of 53.48-65.36.

LIMITATIONS OF PROCEDURE

1. Use only the InSight V-IA Veterinary Immunoassay Analyser.
2. Expired products will affect the test results, please do not use.
3. Do not use a kit with obvious damage or a test cartridge with damaged packaging.
4. Cartridges with different batch numbers should not be mixed and ID Chips and QC cartridges with different batch numbers should not be mixed.
5. Tests should be conducted under the specified test environment. A test cartridge stored at a low temperature should be restored to room temperature before opening to avoid moisture absorption.
6. The aluminium foil bag contains desiccant, which should not be ingested.
7. If you have any questions, please contact Woodley Equipment Company.

MANUFACTURED BY

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