InSight™ Mini Chem

Renal Test Strip

Intended Use

InSight Mini Chem Renal Test Strips work with the InSight Mini Chem Meter to measure the Uric Acid (UA), Creatinine (CR/CREA) and Urea (UR/UREA) concentration in whole blood, plasma and serum. For veterinary use only.

Renal Function measurements are used in the diagnosis of various kidney diseases such as nephritis and renal insufficiency.

Measurement Range

Test Type	Measurement Range
Uric Acid (UA)	90 – 1200 µmol/L (1.51 ~ 20.17 mg/dL)
Creatinine (CR)	44 - 1320 µmol/L (0.50 ~ 14.93 mg/dL)
Urea (UR)	0.90 ~ 40.00 mmol/L (5.41 ~ 240.24 mg/dL)

Results below the range will show “Lo” and results above the range will show “Hi”.

Principle and Reference Values

InSight Mini Chem Test Strips use a timed endpoint method to measure the Uric Acid (UA), Creatinine (CR) and Urea (UR) concentrations in whole blood, serum or plasma. The system monitors the change in absorbance at 620 nm at a fixed-time interval. The change in absorbance is directly proportional to the concentration of metabolite in the sample.

UA – In the reaction, the uric acid is oxidised to allantoin and hydrogen peroxide by uricase. Peroxidase catalyses the reaction of hydrogen peroxide with 4-aminoantipyrine and phenol to produce a coloured quinoneimine product. The change in absorbance is directly proportional to the concentration of uric acid in the sample.

CR – Creatinine is hydrolysed to creatine by the action of creatininase. A sequence of three coupled enzymatic steps using creatinase, sarcosine oxidase and peroxidase causes the oxidative coupling of 4-aminoantipyrine to form a blue dye.

UR – Urea is hydrolysed to NH_3 and CO_2 by the action of urease and an indicator layer containing an indicator which produces a detectable change by ammonia gas.

Reference values are listed in the chart below:

Tests	Desirable
Uric Acid (UA)	Canine: 0 – 100 µmol/L Feline: 0 – 60 µmol/L
Creatinine (CR)	Canine: 35 – 141 µmol/L Feline: 62 – 177 µmol/L
Urea (UR)	Canine: 2.1 – 9.3 mmol/L Feline: 4.6 – 13.2 mmol/L

Reference ranges may vary between laboratories. Every laboratory should establish its own reference range as needed.

Reagents and Performance Characteristics

Based on the dry weight at the time of manufacture, the concentrations given may vary within manufacturing tolerances.

Tests	Components
Uric Acid (UA)	Uricase>1.5U, Peroxidase>1U, Ascorbate Oxidase>1.5U, 4-aminoantipyrine>0.006 mg
Creatinine (CR)	Creatininase>1.5U, Creatinase>2U, Sarcosine Oxidase>0.9U, Ascorbate Oxidase>1.5U, 4-aminoantipyrine>0.006 mg
Urea (UR)	Urease>1.5U, Indicator>0.04 mg

The performance characteristics of these strips have been determined in both laboratory and clinical tests. This test has been developed to be specific for the parameters to be measured with the exception of the interferences listed. Refer to the 'Limitations' section for detailed information.

Precautions

- For in vitro diagnostic use only
- The test strips should remain in the packaging until use
- Do not use the test strips after the expiration date
- Discard any discoloured or damaged test strips
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent
- The used test strips should be discarded according to local regulations after testing
- Check the code chip before performing a test. Make sure to use the code chip that is included with the test strips. Insert the code chip into the code chip slot. The code chip slot is located on the left side of the meter
- Check that the sample type being tested is the same as the sample type selected on the meter

Storage and Stability

- Store as packaged in the sealed pouch or canister at room temperature or refrigerated (2-30°C)
- Keep out of direct sunlight. Test strips are stable up to the expiration date printed on the test strip packaging
- Remove only enough test strips for immediate use. Replace the cap on the canister immediately
- Do not freeze. Do not use beyond expiration date

Specimen Collection and Preparation

- For veterinary use. Fresh capillary blood, heparinised or EDTA venous whole blood, plasma or serum
- Heparinised or EDTA venous whole blood, plasma and serum must be kept in a closed container and must be used within 8 hours of collection. Mix stored specimen adequately before testing
- Use fresh capillary blood immediately after collection
- The capillary transfer tube (supplied with each test strip), must be used to collect the capillary specimen for accurate results

Materials

Materials Provided:

- InSight Mini Chem Test Strips
- Code Chip
- Capillary Transfer Tube
- Instructions for Use

Materials Required but Not Provided:

- InSight Mini Chem Meter
- Safety Lancets
- Gauze for Puncture Site
- Gloves
- Alcohol Swab

Directions for Use

Allow the test strip, sample and/or controls to reach operating temperature (10-35°C) prior to testing.

Refer to the InSight Mini Chem User Manual for detailed instructions.

1. Insert the code chip into the meter. Refer to the 'Coding the Meter' section in the User Manual for details. Compare the code number on the code chip with the code number printed on the test strip foil pouch and ensure they are identical to avoid inaccurate results.
2. Check that the sample type displayed on the meter screen is the same as the sample type tested. If not, set the correct sample type. Refer to the User Manual for details.
3. Remove the test strip from the foil pouch.
4. Wait for the meter to flash the test strip symbol. Insert the test strip completely into the test strip slot in the same direction as the arrows printed on the test strip.
5. Prepare the sample to be tested. For capillary blood, wipe away the first drop of blood. Collect 35µl of the second drop of capillary blood using a capillary transfer tube or pipette. Refer to the InSight Mini Chem User Manual for details. Hold the tube slightly downward and touch the tip of the capillary transfer tube or pipette to the blood drop.
6. While the meter is flashing the blood drop symbol, apply 35µl of sample to the sample application area of the test strip using a pipette or a capillary transfer tube. Align the tip of the pipette or capillary transfer tube with the sample application area to apply the blood. 4 dashed lines will appear on the meter to show the test is in progress.
7. Read the results on the screen after 5 minutes. Refer to the InSight Mini Chem User Manual for detailed test procedures.

Note: Avoid direct sunlight during the test.

Interpretation of Results

The meter automatically measures concentrations of UA, CR and UR. In the event of unexpected or questionable results, the following steps are recommended:

- Confirm that the test strips have been used within the expiration date printed on the foil pouch
- Run a Quality Control to check meter and test strip accuracy
- If the problem persists, discontinue using the test strips immediately and contact Woodley Equipment Company

Performance Characteristics

Linearity

Ten replicate assays were drawn and tested on the InSight Mini Chem Meter (y), using ten concentration levels of heparin preserved venous whole blood samples on 3 different lots of test strips. Several InSight Mini Chem Systems were used to perform tests at each concentration (n=5). The same samples were also tested using a reference method (x). Linearity results are presented below.

Uric Acid

Test Strip Lot	Linearity Equation	R
Lot 1	y = 0.9817x + 0.221	0.994
Lot 2	y = 1.0602x – 0.0176	0.996
Lot 3	y = 1.021x + 0.0002	0.997

Creatinine

Test Strip Lot	Linearity Equation	R
Lot 1	y = 0.9715x + 0.0188	0.996
Lot 2	y = 0.9885x + 0.0087	0.997
Lot 3	y = 1.021x + 0.0002	0.997

Urea

Test Strip Lot	Linearity Equation	R
Lot 1	y = 0.9758x + 0.2219	0.997
Lot 2	y = 1.0049x – 0.3004	0.995
Lot 3	y = 1.0112x + 0.0123	0.995

Reproducibility and Precision

Twenty replicate assays were tested. Fresh heparin preserved venous whole blood samples at three concentration levels were used with three test strip lots, producing the following within-run precision and total precision results.

Within-run precision using whole blood samples. Statistical analysis gives the mean, standard deviations (SD) and coefficients of variation (CV%) listed below.

Uric Acid

Precision	Level 1 (n=20)			Level 11 (n=20)			Level 111 (n=20)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mmol/L)	0.131	0.13	0.129	0.256	0.255	0.254	0.462	0.467	0.471
SD or %CV	0.006	0.006	0.005	0.013	0.012	0.012	3.35%	4.46%	4.25%

Total precision is listed below:

Total Precision	Level 1 (n=60)	Level 11 (n=60)	Level 111 (n=60)
Mean (mmol/L)	0.130	0.255	0.467
SD or %CV	0.006	0.012	4.05%

Creatinine

Precision	Level 1 (n=20)			Level 11 (n=20)			Level 111 (n=20)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mmol/L)	0.080	0.079	0.078	0.139	0.139	0.141	0.28	0.272	0.278
SD or %CV	0.004	0.003	0.004	0.005	0.006	0.006	3.96%	3.51%	3.56%

Total precision is listed below:

Total Precision	Level 1 (n=60)	Level 11 (n=60)	Level 111 (n=60)
Mean (mmol/L)	0.079	0.140	0.277
SD or %CV	0.003	0.006	3.83%

Urea

Precision	Level 1 (n=20)			Level 11 (n=20)			Level 111 (n=20)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mmol/L)	2.99	3.01	3.03	9.23	9.08	9.08	19.09	18.85	19.04
SD or %CV	0.11	0.13	0.14	0.30	0.39	0.37	4.30%	3.87%	4.14%

Total precision is listed below:

Total Precision	Level 1 (n=60)	Level 11 (n=60)	Level 111 (n=60)
Mean (mmol/L)	3.01	9.13	18.99
SD or %CV	0.13	0.35	4.07%

Accuracy

InSight Mini Chem Test Strips were used by a trained technician to test heparin preserved venous whole blood samples from 100 participants. The same samples were analysed using a reference method (x). The results are compared below:

Uric Acid

Specimen	Slope	Intercept	R	N
Venous whole blood	0.9806	0.0023	0.996	100

Creatinine

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0019	-0.0005	0.998	100

Urea

Specimen	Slope	Intercept	R	N
Venous whole blood	1.0021	-0.0301	0.997	100

Quality Control

For best results, performance of test strips should be confirmed by testing known samples/controls whenever a new lot is first opened. Each laboratory should establish its own goals for adequate standards of performance. Contact Woodley Equipment Company for information of specific controls for this product.

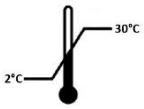
Limitations

The following substances do not interfere with test results:

Substance	Amount	Substance	Amount
Acetaminophen	1324 µmol/L (20 mg/dL)	Cholesterol	12.9 mmol/L (500 mg/dL)
Ascorbic Acid	568 µmol/L (10 mg/L)	Triglyceride	7.3 mmol/L (650 mg/dL)
Conjugated Bilirubin	240 µmol/L (20 mg/dL)	Uric Acid	0.6 mmol/L (10 mg/dL)
Creatinine	442 µmol/L (5 mg/dL)	Haemoglobin	2 g/L (200 mg/dL)
Ibuprofen	2425 µmol/L (50 mg/dL)	Dopamine	5.87 µmol/L (0.09 mg/dL)
Methyldopa	71 µmol/L (1.5 mg/dL)		

High concentrations of ascorbic acid can lead to low measurements. Anticoagulants, such as heparin and EDTA, are recommended for use with venous whole blood. Do not use EDTA plasma as it can lead to higher results. Do not use other anticoagulants, such as iodoacetate, sodium citrate or those containing fluoride. Arterial blood isn't recommended for use. Haemolysed blood or thrombolytic therapy blood may give lower results.

Symbols

	Consult instructions for use		Use by		Manufacturer
	Do not reuse		Store between 2-30°C		Lot No.

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