AmiShield® Urine II Panel (Non-sterile)

For Veterinary Use only
For Professional Use Only

Product Part Number : 001-25JD

----------Please follow the instructions before use----------

Intended use

The disposable AmiShield Urine II Panel (Non-sterile) in conjunction with the AmiShield Clinical Chemistry Analyzer utilizes dry and liquid reagents to provide quantitative determinations of microalbumin (mALB), urine protein (UP) and urine creatinine (UCRE), then calculate to get ACR and UPCR in urine.

Clinical Significance

The disposable AmiShield Urine II Panel (Non-sterile) and the AmiShield Clinical Chemistry Analyzer assist the doctor in diagnosing the following disorders:

Microalbumin (mALB): liver and kidney disease, early predictor of chronic kidney disease (CKD).

Urine protein (UP): heart and kidney disease

Urine creatinine (UCRE): kidney disease

Microalbumin / Urine creatinine (ACR): kidney disease

Urine protein / Urine creatinine (UPCR): kidney disease

As with any diagnostic test procedure, the clinical samples or other test procedures should be considered prior to final diagnosis.

Principles of Procedures

(1) Microalbumin (mALB)

mALB in the sample specifically combines with the mALB antibodies to form a precipitate that causes increased turbidity. The degree of turbidity can be measured optically and is proportional to the concentration of mALB in the sample.

Albumin +Anti-albumin antibody → albumin-antibody complex

(2) Urine protein (UP)

UP uses the Pyrogallol Red methodology to measure urine protein concentration in urine. Pyrogallol Red- molybdate complexes will bind to basic amino acid roots of protein molecules. This binding reaction increases the signal at a wavelength of 600 nm. The signal strength is directly proportional to the urine protein concentration, and the UP concentration can be calculated.

Progallol Red (PR) + Molybdate (Mo) + Protein → PR-Mo-Protein complex

(3) Urine creatinine (UCRE)

The creatinine concentration in urine (UCRE) was measured by the modified Jaffe reaction method. Creatine and picric acid react at an alkaline solution, and the changing color is directly proportional to the concentration of creatinine. The signal strength of UCRE can be measured and calculated.

Creatinine + Alkaline Picrate → Creatinine picrate complex

Storage

1. The expiration date is printed on the foil pouch. Do not use the discs after the expiration date.
2. Store the discs that sealed in their foil pouches at 2 – 8 °C (36 – 46 °F). When stored as described above, all reagents in the disc are stable until the date of use by which printed on the disc foil pouch.
3. Open the pouch and remove the disc just prior to use. Do not expose opened or unopened discs to direct sunlight or temperatures above 30 °C (86 °F).
4. Do not use the discs after the date of use by. The date of use by is printed on the disc foil pouch.
5. Do not use the discs from a damaged foil pouch. Because, a torn or otherwise damaged foil pouch may lead moisture to reach the unused disc and adversely affect reagent performance.
6. Notice: After removing the pouch at 2 – 8 °C, please use it immediately, do not return to room temperature. Disc which is return to the room temperature may result in a pseudo-high value.

Materials Required but not Provided

1. AmiShield Clinical Chemistry Analyzer
2. Sample collector
3. Pipette and tip
4. Controls

Instructions for Reagent Handling

1. The disc should be used for assay immediately following take out from refrigerator. Disc which is return to the room temperature may result in a pseudo-high value.
2. Open the sealed foil pouch and remove carefully the disc. Don’t touch the barcode located on the top of the disc. The contaminated or scratched barcode will not be scanned by analyzer.
3. The disc should be used **within 10 minutes** after opening the pouch. The disc in

opened pouches can't be placed back into the refrigerator for reuse.

4. Reverse the disc buckle press firmly into the disc till hearing "click". After clicking the buckles, please avoid reversing the disc to effuse the reagent.
5. Open the cap of diluent tube in the foil, and transfer 0.06ul (60ul) the urine sample to the diluent tube. Close the cap of tube and invert the tube 10 times or vortex the tube 5 seconds to make sure sample mixed completely with diluent.
6. Embed the disc on the holder (Note: three discs should be assembled into the holder before analysis) and ensure the balance (Note: the dummy disc could be used for balance). The holder assembling three discs would be firmly pressed onto the spindle of AmiShield Clinical Chemistry Analyzer.
7. Transfer 0.06 mL (60μL) the fully mixed **diluted-urine sample** to disc inlet through the sample port by pipette.
8. Use only urine sample for AmiShield Urine II Panel (Non-sterile).
9. The analyzer maintains the disc at a temperature of 37 °C over the measurement interval. The analysis time is about 15-17 minutes. In addition, the AmiShield System operates at ambient temperatures between 15°C and 30°C.

Sample Collection and Preparation

1. **Suggest that method of collecting the urine is direct, such as cystocentesis, catheterized, natural voiding (free catch) and so on.**
2. The minimum required sample size is 0.06 mL (60μL) of urine or control.
3. Centrifuge urine sample at ~3000 rpm for 5 minutes and take 60 μL of supernatant for following test.
4. The test must be started once sample is transferred into the disc. A long delay time may affect the analytical performance.
5. Run the urine sample within 60 minutes of centrifugation. If this is impossible, refrigerate the sample in a stoppered test tube at 2 – 8 °C (36 – 46 °F) for no longer than 48 hours, or freeze it for no more than 7 days.

⚠ ***Precautions***

- ***Wear a laboratory coat and gloves to avoid the biohazard and puncture injury.***
- ***The medical waste should be disposed following the local regulations.***
- ***See the AmiShield Clinical Chemistry Analyzer. Operator's Manual for complete information on using the analyzer.***

Warnings ⚠

1. ***The diluent container in the disc should be manually opened by reversing the buckle in the disc and firmly pressing it before embeds into the spindle. A disc with an opened diluent container can't be reused. Ensure that the sample or***

control has been placed into the disc before running the test.

2. ***The AmiShield products used only with the AmiShield Clinical Chemistry Analyzer, vice versa. Before START the test, please confirm the disc is properly and evenly embedded into the spindle, in addition, the assembled holder should be well placed on the spindle in the Analyzer.***
3. ***Please avoid colliding or falling damages. In this case, the disc can't be used.***
4. ***Reagents in the disc may contain acids or caustic substances. The operator does not come into contact with the reagents when following the recommended procedures. In the event that the reagents are handled (e.g., cleaning up after dropping and cracking a reagent disc), avoid ingestion, skin contact, or inhalation of the reagents.***
5. ***Some reagents contain sodium azide, which may react with lead and copper plumbing to form highly explosive metal azides. Reagents will not come into contact with lead and copper plumbing when following recommended procedures. However, if the reagents do come into contact with such plumbing, flush with a large volume of water to prevent azide buildup.***

Quality Control and Calibration

1. The AmiShield Clinical Chemistry Analyzer is calibrated by the manufacturer before shipment.
2. The barcode printed on the upper cover provides the analyzer with disc-specific calibration data.
3. Controls may be run periodically on the AmiShield Clinical Chemistry Analyzer to verify the accuracy of the analyzer by user.
4. A urine-based control is only available from producer. Run controls on the disc in the same manner as for patient samples. See the AmiShield Clinical Chemistry Analyzer Operator's Manual to run controls.
5. The QA/QC should be conducted following the local regulations or the laboratory guideline.

Known Interference Substances

Urine samples containing blood such as hematuria and menstruation may cause elevated albumin measurements. False positives may occur when the urine is too concentrated or too alkaline.

Summary of Endogenous Interferences

Test Item	Substance concentration with interferences of less than ± 10%	
	Hemoglobin (mg/dL)	Total bilirubin (mg/dL)
mALB	26.41	0.787

UP	16.54	3.89
UCRE	28.66	2.16

Base on NCCLS: EP07

Reference Intervals

These normal intervals are provided only as a guideline. The most definitive reference intervals are established for your animal population. Test results should be interpreted in conjunction with the animal's clinical signs. Diabetes, high blood pressure, kidney inflammation, inflammation or infection of the bladder and urinary tract, after intense exercise or fever, long standing, menstrual contamination, vaginal secretions, prostatic fluid, sperm, dehydration, pregnancy may cause an increase microalbumin. If there are doubts or clinical signs and symptoms are inconsistent with the test results, please retest or further to the hospital to determine the total amount of microalbumin for 24 hours.

Analyte - Canine	**Common units**	**SI units**
Microalbumin (mALB)	< 2.50 mg/dL	< 25.00 mg/L
Urine protein (UP)	6-25 mg/dL	60-250 mg/L
Urine creatinine (UCRE)	4.0-400 mg/dL	0.35-35.36 mmol/L
Albumin / Creatinine ratio (ACR)	< 30.0 mg/g	< 30.0 mg/g
Protein / Creatinine ratio (UPCR)	0.2-0.5 g/g	0.2-0.5 g/g

Analyte - Feline	**Common units**	**SI units**
Microalbumin (mALB)	< 2.50 mg/dL	< 25.00 mg/L
Urine protein (UP)	6-20 mg/dL	60-200 mg/L
Urine creatinine (UCRE)	4.0-400 mg/dL	0.35-35.36 mmol/L
Albumin / Creatinine ratio (ACR)	< 30.0 mg/g	< 30.0 mg/g
Protein / Creatinine ratio (UPCR)	0.2-0.4 g/g	0.2-0.4 g/g

Performance characteristics

Dynamic range

The chemistry for each analyte is linear over the dynamic range listed below. The intervals below do not represent normal ranges.

Analyte	Common units	SI units
mALB	0.50 – 50.00 mg/dL	5.00 – 500.00 mg/L
UP	6.00-200.00 mg/dL	600.00-2000.00 mg/L
UCRE	4-400 mg/dL	0.35-35.36 mmol/L

Method Comparison

The same clinical samples were tested on the AmiShield Clinical Chemistry Analyzer and the comparison machine (BECKMAN COULTER Synchron UniCel DxC 800 Clinical Systems), and the results of the tests were correlated using statistical methods base on NCCLS:EP09.

Analyte	Correlation Coefficient	Slope	Intercept	Sample No.	Sample Range
mALB	0.998	0.993	0.025	60	0.72-48.83 mg/dL
UP	0.988	1.067	-2.166	60	12.50-161.70mg/dL
UCRE	0.986	1.022	-3.117	60	22.6-316.2 mg/dL

Bibliography

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Symbols

	Consult Instructions for use		Caution
	Temperature Limitation		Reference Number
	Batch code		Manufacturer
	Use by		Do Not Reuse


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