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STONE ANALYSIS SET

Chemical qualitative method

Reagent for qualitative determination of main individual components of urinary stones (urinary calculi).

REF 92315 (100 tests): **R1** 2x30 mL **R2** 2x30 mL **R3** 1x5 mL **R4** 1x5 mL **R5** 1x10 mL **R6** 1x5 mL **R7** 1x10 mL **R8** 1x5 mL **R9** 1x5 mL **R10** 10g

REF 92330 (40 tests) **R1** 1x30 mL **R2** 1x30 mL **R3** 1x2 mL **R4** 1x2 mL **R5** 1x4 mL **R6** 1x2 mL **R7** 1x4 mL **R8** 1x2 mL **R9** 1x2 mL **R10** 4 g

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

Reagent for qualitative determination of main individual components of urinary stones (urinary calculi) to assess main components of calculi excreted by urines.
Laboratory professional use (manual method).

GENERALITIES (1) (2)

The presence of calculus in urines is due to the conglomeration and the crystallization of matter in supersaturation. There can be various reasons for this imbalance: nutritional, metabolic, genetical, anatomical, iatrogenic, neurological or infectious reasons. Several ones can occur, at the same time or successively, to the formation and the growth of the calculus.
The more frequently met chemical components are (in descending frequency order): calcium oxalates, calcium phosphate and magnesium ammonium phosphates, uric acids and urates, various proteins, cystine.

PRINCIPLE (4) (5)

Identification of main mineral components and one organic component (cystine) of urinary calculi by easy chemical tests.

REAGENTS COMPOSITION

vial R1:	Hydrochloric Acid (HCl 1,65 M) Eye irrit 2: H319, Skin irrit.2 H315, STOT SE3: H335 P280 P271, P403+233, P501
vial R2	Sodium Hydroxide (NaOH 6,25 M) Met. Corr. 1: H290, Skin Corr. 1A: H314, P260, P280
vial R3	1er Reagent for Cystine determination (NaOH, Sodium Cyanide) Acute Tox. 2, 3, 4: H310, H331, H302, Aquatic Chronic 2: H411, Met Corr. 1: H290, Skin Corr. 1A: H314 P280, P271, P403+233, P501
vial R4	2nd reagent for cystine determination (Sodium nitroprussiate)
vial R5	Reagent for Phosphates determination (Sulfuric Acid, Ammonium Molybdate, Ferric Sulphate) Eye irrit 2 : H319, Skin Irrit 2 : H315, P280
vial R6	Reagent for Magnesium determination (NaOH, paranitrophenylazoréesorcinol)
vial R7	Reagent for Calcium determination (KOH, calcein) Eye irrit 2 : H319, Skin Irrit 2 : H315, P280
vial R8	Reagent for Ammonia determination (Potassium Iodide, Mercuric Iodide) Acute Tox. 1, 2, 3: H310, H330, H301, P280, P271, P403+233, P5019
vial R9	Reagent for Uric Acid determination (Acetic Acid, neocuproïne, Copper Sulphate)
vial R10	Reagent for Oxalate determination (Manganese dioxide) Acute Tox.4 : H302-H332, P271, P501
SPATULA	For use with R10 reagent only. Store and wipe away dust after use

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Reagents are ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 18-25°C, when stored and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- Transfer requested quantity and well cap.
- At least 3 months, away from light and without contamination.

SPECIMEN COLLECTION AND HANDLING

Morphological studies should be made with a whole calculus cleared out of possible impurities. Qualitative analysis and flame test should be realised on pulverised calculus using clean pestle and mortar to obtain finely ground powder.

LIMITES (4)

✓Cobalt and nickel do not interfere with the determination of the magnesium because of their weak concentration in the organism.

✓Carbonate testing: if there has been effervescence during the addition of R1 revealing the presence of carbonate, add R1 drop by drop until the end of the gas evolution. Then, shake vigorously ("Vortex") for at least one minute to get rid of all the carbon dioxide (or failing that, bring to the boil a few seconds in a Pyrex tube and bring back at room temperature). This process is necessary to avoid a false-positive result during the determination of oxalate.

✓When calculi show an unusual morphology or lead to negative or incoherent results during the chemical analysis, a more appropriate analysis that could highlight a composition or etiology should be carried out.

✓It is recommended that each laboratory establishes its own investigation procedure by techniques adapted to the diversity not only of the structure, but also of the molecular composition of the calculus studied.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Low power stereo microscope
2. Clean porcelain pestle and mortar
3. mg scale (weighing of the calculus powder)
4. Pipette to dispense 1 drop (50µL) of reagents and mixture M1, M2.
5. Tubes, or glass/ceramic cored plate with a white bottom
6. REF 95315: stone analysis set positive and negative controls

QUALITY CONTROL

REF 95315: STONE ANALYSIS SET Positive and Negative Controls

1) Negative control: Use CONTROL 3 -

2) Positive control: Use CONTROL 1+ and CONTROL 2 +

Treat controls as pulverized patient calculus.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.

PERFORMANCE CHARACTERISTICS

Detection limits:

Carbonate: 1 mg of Calcium carbonate

Cystine: 1 mg of L-Cystine

Phosphate: 1 mg of Calcium phosphate

Ammonium: 1 mg of Ammonium magnesium Phosphate

Magnesium: 3 mg of Ammonium magnesium Phosphate

Calcium: 0.1 mg of calcium (phosphate, carbonate, oxalate)

Uric acid: 0.1 mg of uric acid

Oxalate: 2.5 mg of Calcium Oxalate

Specificity: Each reaction is specific to the tested component. For oxalate, see also § LIMITES.

Sensitivity: Reagents are very sensitive and so allow the detection of the different components even as trace

PROCEDURE (1)

Morphological analysis of calculus should be made before pulverizing the calculus for chemical test.

Flame test: Immerse a metallic seeding loop into distilled water, then into the calculus powder. Bring to the flame. The carbonization or the disappearance of the powder is the sign that the components are mostly of organic origin. The absence of carbonization shows that the calculus is of mineral origin.

Qualitative chemical tests: (see table below)

- Step 1: Weigh about 50 mg of the calculus powder, transfer into a test tube and add 10 drops of reagent R1. An effervescence shows the presence of carbonate (see § LIMITES). In this case, shake vigorously for 1 minute. The remaining mixture is called M1 in the table below.
- Preparation of the mixture M2: Mix 50 µl of M1 and 5 ml of distilled water. Mix well and use only for the determination of calcium (Step 5).
- According to the step below, dispense 1 drop (approx. 50 µL) of the mixture M1 or M2 in each cavity of a ceramic cored plate or in tubes and carry out the next tests (Step 2 to 8):

	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8
	CARBONATE	**CYSTINE**	**PHOSPHATE**	**MAGNÉSIUM**	**CALCIUM**	**AMMONIUM**	**URIC ACID**	**OXALATE**
	CALCULUS POWDER 50 mg + R1 10 drops (500 µL) **= M1**	1 DROP **M1** **+** **R3** 1 DROP MIX, LET STAND FOR 5 MIN. **+ R4** 1 DROP	1 DROP **M1** **+** **R5** 2 DROPS (100 µL) MIX, LET STAND FOR 5 MIN.	1 DROP **M1** **+** **R6** 1 DROP **+** **R2** 5 DROPS (250 µL) MIX	1 DROP M2 **+** **R2** 1 DROP **+** **R7** 2 DROPS (100 µL) MIX	1 DROP **M1** **+** **R2** 1 DROP **+** **R8** 1 DROP MIX	1 DROP **M1** **+** **R2** 1 DROP **+** **R9** 1 DROP MIX	REMAINING MIXTURE **M1** **+** **R10** THE TIP OF A SPATULA Approximately. 60 mg WAIT FOR FEW SECONDS
POSITIVE RESULT	EFFERVESCENCE visible and audible	RED COLOUR	BLUE COLOUR	BLUE PRECIPITATE	YELLOW COLOUR	ORANGE-BROWN PRECIPITATE	YELLOW/ORANGE COLOUR	EFFERVESCENCE visible and audible
NEGATIVE RESULT	NO EFFERVESCENCE	YELLOW COLOUR	NO CHANGE OF COLOUR	NO PRECIPITATE PURPLE COLOUR	ORANGE COLOUR	CLEAR TO SLIGHLY YELLOW	NO CHANGE OF COLOUR	NO EFFERVESCENCE

REFERENCES

(1) Les calculs urinaires: M. DAUDON, le Biotechnologiste, n°4, (02/1994), p.8 à 11.

(2) Comment analyser un calcul et comment interpréter un résultat: M. DAUDON, l'Euro biologiste (1993), 27, n°203, p.35-46

(3) Revue critique des méthodes d'analyse des calculs urinaires M. DAUDON et R. J. REVEILLAUD., Actualités néphrologiques de l'hôpital Necker, Flammarion médecine sciences, éd. Paris,(1985) p. 203-224

(4) Routine Analysis of urinary calculi: Rapid simple method using spot tests, J. H. WINER et MATICE M. R., J. Lab. Clin. Med. (1943), 28, p.898-904

(5) P-nitro benzene azo resorcinol solution; use in test reagent for Magnesium: WELCHER F., Chemical solutions (1966)p.244

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with