

BIOLABO www.biolabo.fr

FABRICANT: BIOLABO SAS. Les Hautes Rives 02160, Maizy, France

STONE ANALYSIS SET

Positive and Negative Controls

For Internal Quality Control during qualitative determination of main individual components of urinary stones.

TECHNICAL SUPPORT AND ORDERS



Tel: (33) 03 23 25 15 50 Fax: (33) 03 23 256 256

PRINCIPLE AND INTENTED USE (2)(3)

This method is used for identification of main mineral components and one organic component (cystine) of urinary calculi by easy chemical tests. Urinary stone controls are as positive reference and negative reference for each test.

These controls should be used with reagents of STONE ANALYSIS SET REF 92315, REF 92330 or reagents referring to the same method in accordance with technical data sheet of the reagent in use.

REAGENTS

Vial R1	CONTROL 1+	Positive Control
	(Calcium, Carbonate, Cystine, Uric Acid, Oxalate)	
Vial R2	CONTROL 2+ (Phosphate, Ammo	Positive Control onia, Magnesium)
Vial R3	CONTROL 3-	Polyvalent negative Control

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- . In case of contact with skin and eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENTS PREPARATION

Ready to use

STABILITY AND STORAGE

Store away from light, well cap in the original vial at 18-25°C.

· When free from contamination, stored and used as described in the insert, reagents are stable until expiry date stated on the label of the kit.

INTERFERENCES (2)

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

IVD IN VITRO DIAGNOSTIC USE

✓ 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 so as 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.

QUALITY CONTROL

When calculi show an unusual morphology or lead to negative or incoherent results during the chemical analysis, one should carry out more appropriate analysis that could highlight a particular composition or aetiology.

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.

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

PERFORMANCE CHARACTERISTICS

See Technical data sheet of reagent used (§ Performances)

MATERIAL REQUIRED BUT NOT PROVIDED

- 1.mg scale (weighing of the calculus powder)
- 2. Tubes, or glass/ceramic cored plate with a white bottom
- 3. Reagents REF 92315 or REF 92330

PROCEDURE (1)

To be used as pulverised stone urinary calculi of a patient (Refer to § Procedure of Technical data sheet of the reagent used)

REFERENCES

- Les calculs urinaires: (1)
- M. DAUDON, le Biotechnologiste, n°4, (02/1994), p.8 à 11.
- Routine Analysis of urinary calculi: Rapid simple method using spot tests, (2)J. H. WINER et MATICE M. R., J. Lab. Clin. Med. (1943), 28, p.898-904
- (3)P-nitrobenzenazoresorcinol solution; use in test reagent for Magnesium: WELCHER F., Chemical solutions (1966)p.244











∏i

See insert





\Σ/