

DRAFT PACKAGE INSERT: URINEVAC® FOR CULTURE

URINE SPECIMEN PRESERVATION FOR CULTURE - 682703GLV, 982002GLV, 682-UR12S, 982-UR12S

INDICATION FOR USE: Current research (2) indicates that common practices of office personnel and courier do not insure continuous refrigerator or guarantee stable optimum conditions of temporarily stored specimens collected for subsequent testing. 1) Standing time after specimen collection varies greatly depending on the specific local working and environmental conditions. 2) Insulated pails or “ice chest” generally use cool packs instead of dry ice to avoid freezing of specimens and therefore often provide holding temperatures of up to 10-15 Centigrade (50 and 60 degrees Fahrenheit. 3) Specimens are subjected to the temperatures of the interior of the couriers’ transport vehicles which can vary drastically depending on the environmental conditions as well as scheduled and unscheduled standing time.

Immediate collecting the specimen via vacuum system to our UrineVac® test tube which contains a special stabilizer, protects against loss of formed elements in the specimen due to the three main causes of loss: temperature, osmolality, and pH rise due to bacterial growth.

UrineVac® tubes with the stabilizer tablets protect the viability of bacteria in the urine specimen and the prevention of overgrowth. The following UrineVac® tubes are available: 16x100 tube for 10ml draw and 13x100 tube for 7ml draw.

INTENDED USE: UrineVac® tubes are intended for use in protection of urine specimens for transport and subsequent culture analysis in clinical laboratories.

The product provides specimen protection for up to 3 days without refrigeration, when used as directed and when specimens are stored/transported at 4-30 Centigrade.

982002GLV, 982-UR12S, 682703GLV, 682-UR12S are not meant to preserve urine specimens for chemical analysis. For chemical analysis use 981002GLV, 981-UR12S, 683703GLV, 683-UR12S.

SUMMARY AND PRINCIPLE: Reagent strip chemistries performed in the hospital or physician’s office are key diagnostic indicators for urinary tract disease and infection. It has been advocated (1) that a positive result on four of the dipstick chemistries is cause to continue with a urine sediment microscopic examination, and a culture.

Presence of sufficient WBCs to test positive on the leukocyte esterase, or sufficient nitrite from gram negative bacteria, and especially the presence of both, are indications for sediment exam and culture. Presence of protein (which may signal urinary tract disease, and may also mask leukocyte esterase positives), and blood are indication for sediment exam followed by culture if greater than 20 WBCs per high power field and many bacteria are observed.

Bacterial quantitation, culture and identification of: clean voided, midstream collected, urine is widely used diagnostically for the identification and specific treatment of urinary tract infections (U.T.I.) (2,5). Colony Forming Units of 100,000

Microorganisms of greater per milliliter of urine are typically considered positive for U.T.I.(5).

Urine frequently supports the growth of bacteria, which may increase at the same rate as in nutrient broth (6). The incubation conditions (extended time and elevated temperature) of storage or transport can, therefore, give erroneous results (7,8).

To limit the proliferation of bacteria from sources exogenous to the bladder, refrigeration or culturing of the urine specimen within two hours is recommended (5,7,8). Since delays and transport conditions are not always within the control of the laboratory, inaccurate results can occur unless the urine culture specimen is protected by the UrineVac® and its stabilizer. The stabilizer tablet, when dissolved in the correct volume of urine holds the bacterial population in the urine specimen for a period of 3 days at room temperature at levels comparable to those urine specimens, without additive, held under refrigeration for the same period of time.

WARNING AND PRECAUTIONS: Read direction carefully before use. For in vitro diagnostic use only. Use the correct urine volume – i.e. as specified on tubes and wait the complete of urine drawing.

LIMITATION: 1: The stabilizer tablet will not inactivate antibiotics. Therefore, patients receiving antibiotic treatment or chemotherapy may have negative culture. 2: The microbial load in urine from a given patient may be affected by the time of collection and fluid intake. Symptomatic patients may have counts below 100,000 microorganisms/ml if specimens are collected late in the day, or if diuresis is occurring (4). 3: Failure to add urine in the proper volume could result in early loss of viability of bacteria during the normally protected period, or bacterial overgrowth.

STORAGE: UrineVac® with its stabilizer is stable for up to 2 years when stored in 25-45% relative humidity at 4-45 Centigrade.

SPECIMEN COLLECTION: Clean-voided, mid stream urine specimens should be collected in clean container, preferably in our container with our integrated closure enable to draw the urine to our vacuum tubes via the closure without opening the container.

PROCEDURE: 1: Patient ! –Collect the mid stream urine into a clean container (UR-12S with integrated closure is the preferred one) and re close the container.
2: Nurse ! – Open the yellow label covering the top of closure.
3: Nurse ! – Insert the test tube toward the integrated holder with needle and wait the urine to be flow from the container into the tube.
4: Nurse ! – pull out the tube and wait until tablet is dissolved in the urine (aprox. 1 hour to wait) – if take more time agitate until dissolved.
5: Nurse ! – close again the container with the label.
6: Store or transport to laboratory at 4-30 Centigrade.

QUALITY CONTROL: To verify the retention of viability of bacteria in UrineVac® protected room temperature urine as being comparable to that of split samples held at refrigerator temperature the following microorganisms can be used for

quality control. Inoculate them at the level of 10-10 microorganisms/ml into either a sterile urine pool, or sterile filtered artificial urine (*).

1 stain of Citobacter freundii	1 stain of Proteus mirabilis
2 stains of Escherichia coli	1 stain of Streptococcus faecalis

The urine containing the inoculum is triplicate plated and split sampled by filling 3 UrineVac® with stabilizer tablets and 3 UrineVac® without stabilizer tablets. Mark the tubes “Treated” (containing tablets) or “Untreated” and “day 1”, “day 2”, or “day 3” as appropriate. The tubes with tablets are held at the highest normal operational temperature (up to 30 Centigrade). The tubes without are held in the refrigerator at 4 Centigrade. Triplicate plates of each tube are made on its respective test day, i.e., day 1, 2,3 ; (i.e. 24, 48, 72 hours post inoculation).

The time zero data comes from the plates made with the initial “pre-split” inoculated urine. Comparative results for each day should agree in number of organisms by one being no less than 10% of the other. The refrigerated samples should be used as a base line for comparison and reproducibility of technique.

[(*) Artificial urine: 2g yeast extract, 10g urea, 0.072g glucose, 9g sodium chloride in 1 liter water.]

The results reported below show comparisons of sterile urine specimens inoculated with specific U.T.I. bacteria at the level of 100,000 colony forming units (C.F.U.), and held (untreated) at 4 Centigrade and stabilizer protected (treated) at room temperature for 3 days. Theses results were obtained with triplicate plating at 0, 24, 48, and 72 hours from inoculating. In every case the organisms which plated out were biochemically re-identified to verify that the tablets ingredients do not interfere with the identification chemistry. Data was developed by an independent microbiological testing laboratory (9).

Number of Organisms Observed-(x 100,000) C.F.U.

	<u>Day 1</u>		<u>Day 2</u>		<u>Day3</u>	
	<u>Untreated</u>	<u>Treated</u>	<u>Untreated</u>	<u>Treated</u>	<u>Untreated</u>	<u>Treated</u>
Streptococcus faecalis ATCC29212	53	34	40	31	20	18
Streptococcus agalactia ATCC12386	25	11	20	33	28	5
Streptococcus pyogenes Group a ATCC19615	6	15	11	3	16	6
Enterobacter cloacae ATCC23355	28	23	25	16	32	45
Proteus mirabilis 760	15	18	18	21	16	23
Morganella morgani 86-133	21	17	21	21	14	12
Escherichia coli 86-101	14	7	3	8	9	13
Escherichia coli 86-130	12	9	6	2	11	4
Escherichia coli 86-140	12	7	11	11	15	5
Escherichia coli 86-182	28	23	27	14	22	18
Klebsiella pneumoniae ATCC13883	17	26	13	13	14	17
Klebsiella pneumoniae 86-52	5	7	5	13	12	8
Proteus vulgaris ATCC13315	69	44	25	35	73	70
Pseudomonas aeruginosa ATCC27853	10	22	34	24	22	33
Escherichia coli ATCC25922	11	8	9	11	24	6
Staphylococcus aureus ATCC25923	54	92	27	169	25	183
Citobacter freundii ATCC33128	18	20	24	13	31	12
Acienobacter biovar calcoaceticus annitratus 86-247	16	11	8	32	4	12

Viability of candida albicans is not maintained by the use of tablet.

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