

The UrineVac® Study: Stability of urinalysis Parameter for Preserved and Unpreserved Specimens

Introduction:

This study was undertaken to evaluate the effectiveness of the UrineVac® system, in preserving urine specimens such as chemical parameters for unrefrigerated, preserved samples should remain stable for periods at 72 hours. Due to the very rapid activity of bacteria in urine and the effects of PH extremes on formed elements, only fresh urine should be acceptable for urinalysis without form of preservative. The results of this study to support the claims of benefits through the use of UrineVac® system.

Procedure:

25 fresh urine specimens were selected based on having abnormal urine chemistries or significant microscopes observations. Urines analyzed were submitted for routine testing from 10 patients, and 4 pooled urine pools were also included for a more complete evaluation of the parameters being analyzed. All the patients were from the same Princeton, M.V., nursing home and all testing performed in the laboratory in Princeton. Urine chemistries were performed using the chemstrip 9L (Bio DynamicsCorp), the Multistix 10SG (Ames), and with specific gravity for Chemstrip analysis by refractometry. Microscopic of urine sediment for each was performed after urine aliquots were centrifuged in conical tubes for 5 minutes at 400 RCF. Resulting sediment was examined as wet mounts on Kova standardized slides. All strip urinalysis were performed according to manufacturer recommendations.

At day 0, the above analysis were performed and then each specimen was split into equal aliquots. One aliquot served as unpreserved control and was stored in capped tubes at 2-9 C. Five of the unpreserved controls were split further so that a third aliquot could be incubated at room temperature and the sediment analyzed at 2 hrs., 4 hrs., 6hrs., and 24hrs. incubation at room temperature. All aliquots were subjected to urinalysis at 24 hrs., 48 hrs., 48 hrs., and 72 hrs. Incubation times. For all but 4 patients specimens, an additional urinalysis was performed on the preserved urines at 96 hrs. of incubation to demonstrate whether stability could be maintained for that length of time.

In addition special formula tablets (95mg) without mercury were analyzed using the basic scheme indicated above. Five additional urines, one patient and four pools were selected for this part of study.

For evaluation purposes, significant differences for chemical parameters were considered to be greater than one grading unit appropriate for the analyte being measured. Trends were considered to be at least days variance from the initial measurement where the change is consistent and at least one grading unit or more. Specific gravity and PH measurement results were analyzed using a paired to test (2 tailed rejection regions).

Results

Specific Gravity

See addendum #1 at end of this report

Leukocytes.

Tables 3 and 4 give the results for leukocyte detection in the urine using the Multistix and Chemstrips, respectively, and table 14 gives the estimates for leukocyte concentration in the sediments. Both strips initially agreed on 18 of 25 urines as having WBC contamination. One specimen initially detected by Multistix was also confirmed by the Clinitest at 24 hrs. incubation (specimen #7). Sediment analysis showed that only 3 of the specimens in the study had no appreciable levels of WBC's (specimen #2, 3 and 19) and were negative by the strips. Differences between the methodologies can be noted from the tables but are not germane to this study. No significant differences were noted using the urinalysis strips, either comparing preserved to unpreserved urines or comparing incubated urines to initial results (see either table 3 or 4). Results were stable even after 96 hrs. at room temperature for preserved urines. Changes were noted in sediments from 5 patients (specimens #1, 9, 15, 18, and 22). In these cases the preserved urines showed much better performance than unpreserved. Specimen #18 gave the most pronounced differences between preserved and unpreserved urine WBC's, going from distinctly positive to borderline normal for the unpreserved. Preserved urines gave good performances through 72 hours of incubation and most were still acceptable at 96 hours incubation.

Evidence for bacterial infection.

As seen in table 5, 6, and 16, essentially no urine in the study failed to provide some evidence of bacteria at least at some point.

With exception to be noted, preserved urine gave the same nitrite reactions through 96 hours incubation as seen initially. Specimen #18, which was nitrite- negative at day 0, became positive in the unpreserved specimen by day 1 and remained positive throughout the test period. There were some specimens, however, where the addition of tablets caused nitrite-positive specimens to become negative (Specimens numbered 5, 16, and 23). This was observed more using Chemstrips than Multistix. It is probable that in these cases, bacterial activity was sufficiently inhibited but nitrite conversion to nitrogen continued. Moderate to many bacteria were present in the sediments of these urines, and at least in specimen #5 there was evidence for continued growth of bacteria in the untreated urine (refrigerated) throughout the incubation period (table 16).

At 72 hours incubation, analysis of table 5 shows that 11 of 15 positives for urines were still positive with preserved urines (specimens with trace reactions at day 72 were considered positive). The specimen (number 14) was not positive for either treated or untreated aliquots after the initial day. Likewise, after 72 hrs. incubation 7 of 8 specimens which were initially nitrate negative, were still negative for the preserved aliquot (with Chemstrip the 8th specimen, number 21, was initially trace positive).

As indicated in table 16, urine preservation did not result in loss of microbe detection in the sediment and numerical estimates appeared to agree most closely with original numbers at least through 72 hours of incubation. As will be discussed with PH later, bacterial growth was more evident in untreated aliquots than in preserved aliquots.

Protein Concentration

No major discrepancies were noted with incubation for either untreated or preserved aliquots when compared with Day 0 results (Table 7 and 8). Thus, this parameter appeared to be stable in preserved aliquots even after 96 hours of incubation at room temperature. Several urines with high levels of protein were included in this study.

PH Concentration - Tables 9 and 10

Urine PH's for untreated aliquots showed the most dramatic changes upon incubation of any parameter evaluated. For those urines which were alkaline upon initiation of the study, no major

changes were noted. However, for four urines with initial PH's within the normal range, the untreated aliquots became alkaline (greater than one PH unit change) and increased in alkalinity as incubation continued. This change was attributed to microbial activity on metabolites within the urine. Since alkaline PH quickens the deterioration of formed elements found within the sediment, such changes are unacceptable for urinalysis. By 72 hrs. incubation the PH readings for untreated urines were significantly elevated ($P < 0.025$) as compared to initial readings. A similar significance was seen when comparing 72 hrs. incubated - untreated aliquots with 72 hrs. incubated- preserved aliquots ($P < 0.005$).

Because of the buffering action of the tablets, urines with elevated PH may become buffered to within normal range. If specimens with initial PH's 7.5 or less were compared with preserved aliquots after 72 hours incubation, no significant differences were noted ($P > 0.1$). However, if all urines in the study were compared (initial values to preserved aliquots after 72 hours incubation) there is a significant trend for preserved specimens to have lowered PH's ($P < 0.05$). Therefore, PH must be tested prior to tablet addition. However, if a PH change +/- 1 unit or less is clinically acceptable, the results of this study show only minor differences for preserved urines (24 of 25 urines by Chemstrip or Multistix show no PH differences greater than 1.0 for preserved vs. initial readings). The buffering activity of the tablet was seen in most case through 96 hrs. incubation, but exceptions were noted where bacterial growth appeared to overcome preservative effects and to raise the PH. Further, some specimens (like specimens numbered 6 and 24) were initially alkaline and showed no change in PH with addition of the tablet. Both of these specimens had high bacterial concentration.

Occult Blood.

Tables 11 and 12 give the results for chemical detection of blood using Multistix and Chemstrip, respectively. Results were duplicated over the entire incubation period and there were no differences between untreated and preserved aliquots. Thus, treated urine was stable for this parameter for up to 96 hrs. of incubation at room temperature, and even trace amounts of RBC's (< 5 /field) were reproducibly detected throughout the incubation. Percent agreement with initial readings was 100% for all levels of occult blood in urine.

In table 5 the semiquantitative estimates for RBC's in urine sediments are given. It should be noted that there was good qualitative correlation between RBC detection in sediment and chemical detection in whole urine using strips. Gradual but not always significant drops in RBC sediment counts were seen with incubation. However, the deterioration was more pronounced in untreated vs. preserved urines. Best examples for comparison are specimen numbered 14, 16, and 24. Specimen 16 shows that while the RBC's in the unpreserved urine was decreasing with time, The bacteria concentration were high and the Ph was becoming more alkaline. The drop off was even more dramatic for the portion of that unpreserved specimen incubated at room temperature. After 24 hrs. incubation, RBC detection in the sediment was at best rare. The greatest change in RBC concentration was observed with specimen number 24. The preserved aliquot maintained RBC Levels fairly comparable to initial numbers for over 72 hrs. incubation, while there was a 2 log drop in concentration for the treated aliquot during the same time period. These results show that like WBC concentration, the RBC levels can deteriorate with time if urine is not preserved.

Casts, mucous threads and abnormal crystals.

The sediments were examined for presence of crystals and to determine if preservation effectively prevented the formation of new crystals (Table 17). The casts were examined to note any loss in casts due to PH or other factors which might have a deteriorating effect on these matrices (Table 17). Mucous threads were also examined for deterioration with time (Table 13).

There were 13 of the 25 urines which showed no crystals upon initial testing (specimens numbered 4, 8, 9, 11, 14, 15, 17-23). All but one of these had initial PH's at neutral or slightly acidic (specimen 8 had initial PH of 8) Five of these (38%) showed no crystal formation (and no PH change) for either preserved or unpreserved aliquots throughout the incubation period. The others showed crystal

formation with a tendency for the preserved aliquots to have less than the unpreserved. Specimens 4, 14, and 18 are good examples where negative specimen remain negative (at least initially) after preservation, while crystal formation progresses in the unpreserved aliquot. Preserved specimen 9 had no crystals until day 4 when its PH changed dramatically from 5.5 to 9.

No examples were seen for either preserved or unpreserved where formed crystals were lost due to incubation. If crystals were present initially, the same type of crystals were seen in the preserved aliquots. For example, specimen 10 had high concentrations of triple phosphates which might be appropriate in the initial PH of 9. After tablet addition, the PH was maintained at 7.0 throughout the 96 hrs. incubation period, but only triple phosphate crystals were seen during this period. Only preserved specimen 7 had an additional crystal type, calcium, calcium oxalate, at day 3 along with the original triple phosphate crystals. The uric acid crystals in preserved specimen 4 is a good example of maintaining crystals during incubation which are normally found in acid urines.

Six specimens had casts at day 0 (specimens 2, 5, 14, 18, 19, and 24). For three of these (specimens 5, 18, and 24) the casts were rapidly lost in the unpreserved aliquots upon incubation. For specimens 5 and 18, the preserved aliquots maintained casts through 72 and 48 hrs. incubation , respectively. Neither preserved nor untreated aliquots had casts after the initial day for specimen 24. For the other three specimens, casts were present in both preserved and untreated aliquots throughout the incubation period.

Table 13 gives the results for mucous threads in the sediment. No differences were noted between preserved and untreated aliquots with incubation. The mucous threads were very stable.

Additional Chemical Screening Results.

Only specimen 25 (pool) contained ketone bodies (initial concentration, 80mg/dl by Multistix or 40-100 mg/dl by Chemstrip). No significant difference was seen for either preserved or untreated aliquots through 48 hrs. incubation. By 72 hrs. incubation at room temperatures the preserved aliquots still had notable levels (15mg/dl) but concentration had dropped significantly from the initial level. Specimen 12 (one of the specimens in this pool was from a patient undergoing a glucose tolerance test) had 2 +/- levels of glucose (1/4 – 1/2 gm/dl). No significant differences were observed for either preserved or untreated aliquots throughout the 72 hour (96 hr. for preserved) incubation period (i.e., good stability in spite of the presence of many bacteria in the sediment). No specimens had detectible levels of bilirubin or urobilirubinogen for which to evaluate in this study.

Control (untreated) urines incubated at Room Temperature.

As indicated previously, some deterioration in WBC's and RBC's occurred in one of five control urines incubated at room temperature. This was rapid when compared to preserved aliquot stabilities. Otherwise no other changes in sediment parameters were noted when compared to initial results.

DISCUSSION

The results do indicate that UrineVac® are effective in stabilizing urine such that equivalent results, compared to initial examination, could be obtained for routine urinalysis and microscopic examination for up to 72 hrs. incubation at room temperature. Most discrepancies between preserved aliquots and initial urine results were minor. Major problematic areas where variability was seen were with PH changes and crystal formation with time. PH could not accurately relied upon to reflect the original specimen value after tablet addition (unless specimen was at PH 7.5 or less originally). PH would, therefore, be evaluated upon arrival at the lab, while other parameters

could be determined later. This, however, is acceptable considering the stabilization benefits of such elements in WBC's, RBC's, crystals and casts. Bacterial growth also appeared to be minimized in the treated urines.

The specific gravities gave a distinct increase after addition of tablets, but this could be corrected effectively through subtraction of a standard factor from specific gravities obtained after tablet addition (negating tablet effect), as indicated in the above text.

This study shows that abnormalities in fresh specimens can be maintained using the UrineVac® tubes. Reproducible results can be obtained for several days with UrineVac® tubes, providing time for repeat testing plus assurance of clinical accuracy in the final results reported.

TABLES 1 & 2

See Addendum # 1

TABLE 3

PARAMETER: Leukocytes in Urine

SOURCE OF ANALYSIS: Multistix 10SG

NO.	INITIAL UNPRE.	24 HR. UNPRE.	24 HR. TABLET	48 HR. UNPRE.	48 HR. TABLET	72 HR. UNPRE.	72 HR. TABLET	96 HR. TABLET
1.	2+	2+	1+	2+	1+	2+	+/-	
2.	0	0	0	0	0	0	0	0
3.	0	0	0	0	0	0	0	
4.	+/-	+/-	+/-	1+	+/-	+/-	+/-	+/-
5.	+/-	+/-	0	+/-	0	+/-	0	0
6.	2-3+	3+	2+	3+	2+	3+	2+	2+
7.	1+	1+	1+	2+	1+	1+	1+	1+
8.	1+	1+	1+	1-2+	1+	2+	2+	1+
9.	2+	2-3+	2-3+	3+	2+	2-3+	2+	1-2+
10.	2+	2+	2+	2+	1-2+	2+	2+	2+
11.P	3+	3+	2+	3+	2+	3+	2+	
12.P	2+	1-2+	1-2+	2+	1+	2+	1+	1+
13.P	3+	3+	2+	2+	2+	3+	2+	2+
14.	2+	2-3+	2+	3+	2+	3+	2+	2+
15.	3+	3+	3+	2+	2+	3+	3+	3+
16.	2+	3+	2+	3+	2+	3+	2+	2+
17.	2+	2+	1+	2+	2+	2+	2+	2+
18.	3+	3+	2+	3+	2+	3+	2+	2+
19.	0	0	0	0	0	0	0	0
20.	3	3+	2+	3+	2+	3+	2+	2+
21.	2+2+	2+	2+	2+	2+	2+	2+	2+
22.	3+	3+	3+	3+	3+	3+	2-3+	3+
23.	3+	2+	2+	2+	2+	3+	2+	2+
24.	2+	3+	2+	3+	3+	3+	3+	QNS
25.P	+/-	+/-	+/-	+/-	+/-	0	0	0

TABLE 149.87

Normal = +/- or less

TABLE 4

PARAMETER: Leukocytes in Urine

SOURCE OF ANALYSIS: Chemstrip 9L

NO.	INITIAL UNPRE.	24 HR. UNPRE.	24 HR. TABLET	48 HR. UNPRE.	48 HR. TABLET	72 HR. UNPRE.	72 HR. TABLET	96 HR. TABLET
1.	2+	2+	1+	2+	1+	2+	2+	
2.	0	0	0	0	0	0	0	0
3.	0	0	0	0	0	0	0	0
4.	+/-	+/-	+/-	+/-	+/-	+/-	+/-	+/-
5.	+/-	+/-	+/-	+/-	+/-	+/-	+/-	0
6.	2+	2+	2+	2+	1-2+	2+	2+	2+
7.	+/-	1+	1+	1+	1+	1+	1+	1+
8.	1+	1+	1+	1+	1+	1+	1+	1+
9.	1+	1+	2+	2+	2+	2+	2+	1-2+
10.	2+	2+	2+	2+	1-2+	2+	1+	1+
11.P	2+	2+	2+	2+	2+	2+	2+	
12.P	2+	2+	2+	2+	2+	2+	2+	2+
13.P	2+2+	2+	2+	2+	2+	3+	2+	2+
14.	2+	2+	2+	2+	2+	2+	2+	2+
15.	2+	2+	2+	2+	2+	3+	3+	2+
16.	2+	2+	2+	2+	2+	2+	1-2+	2+
17.	2+	2+	2+	2+	2+	2+	2+	2+
18.	2+	2+	2+	2+	2+	2+	2+	2+
19.	0	0	0	0	0	0	0	0
20.	2+	2+	2+	2+	2+	2+	2+	1+
21.	2+	2+	2+	2+	2+	2+	2+	2+
22.	2+	2+	2+	2+	2+	2+	2+	2+
23.	2+	2+	2+	2+	2+	2+	2+	2+
24.	2+	2+	3+	2+	2+	3+	3+	QNS

25. +/- +/- 0 +/- 0 0 0 0

TABLE 149.87 Normal = +/- or less

TABLE 5

PARAMETER: Nitrites

SOURCE OF ANALYSIS: Multistix 10SG

NO. INITIAL 24 HR. 24 HR. 48 HR. 48 HR. 72 HR. 72 HR. 96 HR. BACTERIA
UNPRE. UNPRE. TABLET UNPRE. TABLET UNPRE. TABLET TABLET IN SEDMNT

1.	+	+	+	+	+	+	+	+	many
2.	0	0	0	0	0	0	0	0	moderate
3.	0	0	0	0	0	0	0	0	few
4.	+	+	+	+	+	+	+	+	many
5.	+	+	0	+	0	+	0	0	moderate
6.	+	+	+	+	+	+	+	0	many
7.	+/-	+/-	+/-	0	+/-	+/-	+/-	+/-	many
8.	+	+	+	+	+	+	+	+	many
9.	0	0	0	0	0	0	0	0	moderate
10.	0	0	0	0	0	0	0	0	many
11.P	+	+	+	+	+	+	+	+	many
12.P	+	+	+	+	+	+	+	+	many
13.P	+	+	+	+	+	0	+	+	many
14.	+	0	0	0	0	0	0	0	many
15.	+	+	+	+	+	+/-	+/-	+/-	many
16.	+	+	0	+	0	+/-	0	0	many
17.	+	+	+	+	+	+	+/-	+	many
18.	0	+	0	+	0	+	0	0	moderate
19.	0	0	0	0	0	0	0	0	few
20.	+	+	+	+	+	+	+	+	many
21.	0	+/-	+/-	+/-	0	+/-	+/-	+/-	few

20.	+	+	+	+	+	+	+	+	many
21.	+/-	+	0	+/-	+/-	+/-	+/-	+	few
22.	+	+	+	+	+	+	+	+	many
23.	+	+	+	+/-	+/-	+/-	+/-	+/-	many
24.	+/-	+/-	0	0	+/-	0	0	QNS	many
25.P	0	0	0	0	0	0	0	+	0

TABLE 149.87 Negative = 0; all other values suggest bacteruria

TABLE 7

PARAMETER: Protein

SOURCE OF ANALYSIS: Multistix 10SG

NO.	INITIAL UNPRE.	24 HR. UNPRE.	24 HR. TABLET	48 HR. UNPRE.	48 HR. TABLET	72 HR. UNPRE.	72 HR. TABLET	96 HR. TABLET
1.	2+	2+	2+	+	2+	2+	2+	
2.	1+	2+	1+	2+	2+	2+	2+	2+
3.	trace	trace	1+	trace	1+	1+	1+	
4.	0	trace	trace	trace	trace	trace	trace	trace
5.	trace	trace	trace	trace	tr-1+	trace	trace	1+
6.	trace	0-tr	trace	0-tr	trace	trace	1+	trace
7.	trace	1+	1+	trace	1+	trace	1+	1+
8.	1+	1+	1+	1+	1+	1+	1+	1+
9.	trace	trace	trace	trace	1+	trace	1+	1+
10.	trace	1+	1+	1+	1+	1+	1+	1+
11.P	trace	trace	trace	trace	trace	trace	trace	
12.P	trace	1+	1+	1+	1+	1+	1+	1+
13.P	1+	1+	2+	1+	2+	1+	1+	2+
14.	trace	1+	1+	1+	1+	1+	1+	1+
15.	0	0	trace	0	trace	0	0	0
16.	1+	1+	1+	1+	2+	1+	2+	2+
17.	1+	1+	trace	trace	1+	trace	1+	1+
18.	trace	trace	trace	trace	tr-1+	1+	trace	trace
19.	3+	3+	3+	4+	4+	4+	4+	4+

20.	1+	trace	trace	trace	trace	1+	1+	trace
21.	1+	1+	1+	1+	1+	1+	1+	1+
22.	1+	trace	0-tr	trace	trace	trace	trace	0-tr
23.	2+	2+	2+	2+	2+	2+	2+	2+
24.	3+	3+	3+	3+	3+	3+	3+	QNS
25. P	2+	2+	2+	2+	1-2+	2+	2+	2+

Values used above: Trace = 6-20mg/dl
1+ = 30 mg/dl
2+ = 100mg/dl
3+ = >500 mg/dl
0 = Normal

TABLE 9

PARAMETER: PH

SOURCE OF ANALYSIS: Multistix 10SG

NO.	INITIAL UNPRE.	24 HR. UNPRE.	24 HR. TABLET	48 HR. UNPRE.	48 HR. TABLET	72 HR. UNPRE.	72 HR. TABLET	96 HR. TABLET
1.	5.5	5.5	5.0	5.5	5.0	6.0	6.0	
2.	5.5	5.0	5.0	5.5	6.0	5.0	5.5	5.5
3.	5.5	6.0	5.0	5.5	6.0	6.0	6.0	
4.	6.5	7.5	6.5	8.0	6.5	8.0	6.5	6.5
5.	6.0	6.5	5.5	6.0	6.0	6.5	5.5	6.0
6.	8.5	8.5	7.5	8.5	8.0	8.5	8.0	8.5
7.	7.0	8.0	7.0	8.0	7.0	8.0	7.0	7.0
8.	8.0	8.5	7.0	8.0	7.0	8.0	7.0	7.0
9.	6.0	7.0	5.0	7.0	6.0	7.0	6.0	8.5
10.	8.5	8.5	7.0	8.5	7.0	8.5	7.5	7.5
11.P	7.0	7.0	6.0	7.0	6.0	7.0	6.0	
12.P	6.0	6.5	6.0	6.5	6.0	6.5	6.0	6.0
13.P	7.5	7.0	6.5	6.5	6.5	7.5	6.0	6.5
14.	6.0	6.0	5.0	6.5	6.0	6.5	6.0	6.0
15.	6.0	7.5	6.0	8.0	6.0	8.0	5.0	6.0
16.	6.5	7.0	6.5	7.5	6.5	8.0	6.5	6.5
17.	6.5	6.0	6.0	6.5	6.0	6.5	6.0	6.0
18.	6.5	6.5	6.0	8.5	6.0	8.5	6.0	6.0

19.	7.0	7.0	6.0	6.5	6.0	6.5	6.0	6.0
20.	7.0	7.5	6.0	7.5	6.0	7.5	6.0	6.0
21.	7.0	7.0	6.0	7.5	6.0	7.0	6.0	6.0
22.	6.5	7.0	6.0	7.5	6.0	7.0	6.0	6.0
23.	6.5	6.5	6.0	6.5	6.0	6.5	6.0	6.0
24.	8.0	8.5	8.5	8.5	8.5	8.5	8.5	QNS
25. P	7.0	7.0	6.5	6.5	6.5	7.0	6.5	6.5

Normal range = 4.6 -8.0; average 6.0

TABLE 249.87

TABLE 10

PARAMETER: PH

SOURCE OF ANALYSIS: Chemstrip 9L

NO.	INITIAL UNPRE.	24 HR. UNPRE.	24 HR. TABLET	48 HR. UNPRE.	48 HR. TABLET	72 HR. UNPRE.	72 HR. TABLET	96 HR. TABLET
1.	5.0	5.0	5.0	5.0	5.0	5.5	5.5	
2.	5.0	5.0	5.0	5.5	5.5	5.0	5.0	5.0
3.	6.0	5.0	5.0	5.0	5.0	5.5	5.5	
4.	6.5	7.5	6.0	7.0	6.0	7.5	6.0	6.0
5.	5.5	6.0	5.5	5.5	5.5	6.0	5.5	5.5
6.	8.5	9.0	7.5	9.0	8.0	9.0	8.5	9.0
7.	7.0	7.5	6.5	8.0	7.0	8.0	6.0	6.5
8.	8.0	8.0	6.0	8.0	6.5	8.0	7.0	6.5
9.	6.5	7.5	5.0	6.5	6.0	7.0	5.5	9.0
10.	9.0	9.0	7.0	9.0	7.0	9.0	7.0	7.0
11.P	7.0	6.5	5.0	6.5	5.0	7.0	6.0	
12.P	6.0	6.0	5.0	6.0	6.0	6.0	6.0	5.5
13.P	7.0	7.0	6.0	7.0	6.0	7.0	6.0	6.0
14.	6.0	5.5	5.0	6.0	6.0	6.0	5.5	5.0
15.	7.0	8.0	6.0	8.0	5.5	7.5	5.0	6.0
16.	7.0	7.0	6.0	7.5	6.5	7.0	6.0	6.0
17.	6.0	6.0	5.5	6.0	5.5	6.0	6.0	6.0
18.	5.5	6.0	6.0	8.5	5.5	9.0	5.5	6.0

16.	-	-	-	-	-	-	-	-
17.	m	m	m	m	m	m	m	m
18.	f	f	f	f	f	f	f	f
19.	f	f	f	f	f	f	f	f
20.	m	m	m	m	m	m	m	m
21.	l	l	m	l	m	m	m	l
22.	m	m	m	m	m	m	m	m
23.	-	-	-	-	-	-	-	-
24.	-	-	-	-	-	-	-	qns
25.	m	m	m	m	m	m	m	m

- = negative oc = occasional f = few
m = moderate amount l = large amount
TABLE249.87

TABLE 14

PARAMETER: Leukocytes
SOURCE OF ANALYSIS: Urine Sediment Microscopy

NO.	INITIAL UNPRE.	24 HR. UNPRE.	24 HR. TABLET	48 HR. UNPRE.	48 HR. TABLET	72 HR. UNPRE.	72 HR. TABLET	96 HR. TABLET
1.	180-220	170-210	150-200	140-180	150-200	45-105	120-140	
2.	0-2	0-2	0-2	1-3	0-2	0-2	1-2	1-3
3.	0-1	0-1	0-1	0-1	0-1	0-1	0-1	
4.	8-10	8-10	8-10	4-7	3-6	5-7	2-5	4-6
5.	12-15	6-10	4-13	9-13	8-12	7-12	8-12	8-12
6.	0-2	1-2	1-2	0-1	0-1	1-2	0-2	0-2
7.	8-12	8-12	8-12	8-10	8-12	6-9	8-10	8-10
8.	8-10	8-10	8-10	10-14	6-8	8-12	8-12	10-14
9.	20-25	20-25	20-25	10-14	15-20	14-16	10-12	3-6
10.	6-10	4-7	3-6	5-8	8-10	5-8	5-9	5-8
11.	65-75	50-55	60-70	50-55	25-30	40-50	50-55	qns
12.	40-50	35-45	40-50	25-30	28-34	20-30	28-34	24-28
13.	50-65	45-55	48-58	40-45	40-45	35-48	46-50	48-55
14.	30-35	30-35	30-35	30-35	24-28	25-30	30-35	25-30
15.	50-55	45-50	50-55	25-30	45-50	12-18	50-55	40-50

16.	18-24	6-10	6-10	6-8	8-10	4-6	7-10	9-11
17.	50-60	55-65	45-55	40-50	50-60	45-50	40-45	50-60
18.	35-45	14-20	30-36	8-12	22-28	5-8	24-28	24-28
19.	1-3	1-2	2-3	1-3	1-3	1-2	1-2	0-1
20.	14-16	15-20	15-20	20-25	16-20	20-25	15-20	18-23
21.	100-115	95-110	90-110	90-110	90-110	90-105	90-110	75-85
22.	70-75	85-95	85-90	55-70	85-95	45-55	85-95	75-85
23.	55-65	60-70	65-75	60-70	48-58	50-60	50-60	50-60
24.	0-1	1-2	6-8	1-3	3-4	0-1	2-5	QNS
25.	6-8	5-8	4-6	6-8	5-7	6-9	5-9	6-8

Values = Avg. #WBC/field
Normal = < 5/field
TABLE249.87

TABLE 15

PARAMETER: Erythrocytes
SOURCE OF ANALYSIS: Urine Sediment Microscopy

NO.	INITIAL	24 HR.	24 HR.	48 HR.	48 HR.	72 HR.	72 HR.	96 HR.	OCCLT.
	UNPRE.	UNPRE.	TABLET	UNPRE.	TABLET	UNPRE.	TABLET	TABLET	BLOOD*
1.	2-4	1-2	1-2	1-2	1-2	1-2	1-3		2+
2.	45-55	40-45	45-55	30-40	50-60	35-45	50-60	55-60	3+
3.	<4	<4	<4	<4	<4	<4	<4		0
4.	<4	<4	<4	<4	<4	<4	<4	<4	0
5.	1-3	1-3	1-3	1-3	1-3	1-3	1-4	1-4	1+
6.	<4	<4	0	0	0	0	0	0	0-tr
7.	2-4	1-3	1-3	1-3	2-3	2-4	2-4	1-3	tr
8.	5-9	3-5	4-7	3-5	2-4	4-7	4-6	3-6	tr
9.	1-3	0-2	1-2	0-2	0-2	1-2	0-1	0-1	1+
10.	1-3	1-2	1-3	1-2	1-3	1-2	1-3	1-3	1+
11.P	<4	0	<4	<4	<4	0-1	<4	QNS	2+
12.P	0-2	0-2	1-3	0-2	1-3	0-2	2-3	1-3	tr
13.P	2-5	3-4	4-6	2-4	4-6	2-3	3-5	3-6	2+
14.	20-28	14-18	20-25	12-16	18-22	8-12	15-20	15-20	3+

16.	n	n	n	n	n	n	n	n
17.	n*	m	m	n	n	n	n	n
18.	m*	n	n	n	m	n	m-n	m
19.	f	f	f	f	0	f	f	f
20.	n*	n	n	n	n	n	n	n
21.	f*	f	m	f	f	m	f	f
22.	n*	n	n	n	n	n	n	n
23.	n*	m	m	m	n	f	m	m
24.	n*	n	n	n	n	n	n	n
25.	-	f	f	f	f	m	f	n

Values above:

- = Negative (normal)

m = Moderate numbers

f = Few numbers

n = Many of numerous

*= Yeasts also present in sediment. Seen at all incubation times.

TABLE 17

PARAMETER: Crystals/Casts

SOURCE OF ANALYSIS: Urine Sediment Microscopy

NO.	INITIAL UNPRE.	24 HR. UNPRE.	24 HR. TABLET	48 HR. UNPRE.	48 HR. TABLET	72 HR. UNPRE.	72 HR. TABLET	96 HR. TABLET
1.	+Ca	+Ca	+Ca	+Ca	+Ca	+Ca	+Ca	
2.	3Ca/g,h	3Ca/g,h	3Ca/g,h	3Ca/g,h	3Ca/g,h	3Ca/g,h	3Ca/g,h	3Ca/g,h
3.	3 U	3 U	3 U	3 U	3 U	3 U	3 U	
4.	Neg	2 Ca	+ Ca					
5.	12-15	6-10	4-13	9-13	8-12	7-12	8-12	8-12
6.	0-2	1-2	1-2	0-1	0-1	1-2	0-2	0-2
7.	8-12	8-12	8-12	8-10	8-12	6-9	8-10	8-10
8.	8-10	8-10	8-10	10-14	6-8	8-12	8-12	10-14
9.	20-25	20-25	20-25	10-14	15-20	14-16	10-12	3-6
10.	6-10	4-7	3-6	5-8	8-10	5-8	5-9	5-8
11.	65-75	50-55	60-70	50-55	25-30	40-50	50-55	qns
12.	40-50	35-45	40-50	25-30	28-34	20-30	28-34	24-28
13.	50-65	45-55	48-58	40-45	40-45	35-48	46-50	48-55
14.	30-35	30-35	30-35	30-35	24-28	25-30	30-35	25-30

15.	50-55	45-50	50-55	25-30	45-50	12-18	50-55	40-50
16.	18-24	6-10	6-10	6-8	8-10	4-6	7-10	9-11
17.	50-60	55-65	45-55	40-50	50-60	45-50	40-45	50-60
18.	35-45	14-20	30-36	8-12	22-28	5-8	24-28	24-28
19.	1-3	1-2	2-3	1-3	1-3	1-2	1-2	0-1
20.	14-16	15-20	15-20	20-25	16-20	20-25	15-20	18-23
21.	100-115	95-110	90-110	90-110	90-110	90-105	90-110	75-85
22.	70-75	85-95	85-90	55-70	85-95	45-55	85-95	75-85
23.	55-65	60-70	65-75	60-70	48-58	50-60	50-60	50-60
24.	0-1	1-2	6-8	1-3	3-4	0-1	2-5	QNS
25.	6-8	5-8	4-6	6-8	5-7	6-9	5-9	6-8

Values = Avg. #WBC/field

Normal = < 5/field

TABLE249.87

ADDENDUM # 1

The effects of UrineVac® on the specific gravity of Urine.

This addendum to the UrineVac® study concerns the effect of UrineVac® on the specific gravity of urine. The testing was done between January 27 and February 21 1992 except as noted.

This study was conducted as in the 1987 study except 31 urine specimens were tested instead of 25 and tests were done after 0, 24, 48, and 72 hours but not done after 96 hours. Each specimen was divided into two 10ml portions, one containing a 50mg stabilizer tablet and the other without any preservative. Each portion of the specimen was tested for specific gravity by the refractometer method and by Multistix 10SG after 0, 24, 48, and 72 hours.

Tables 1 and 2 give the specific gravities obtained during the incubation periods. As would be expected, no significant effect on specific gravity was observed as the result of incubation time for either preserved or unpreserved urines. The mean specific gravity by refractometer at day 0 for urines listed in table 2 was 1.015 +/- 0.009 and the mean for Multistix was 1.014 +/- 0.008. Good agreement was usually found between refractometer and Multistix strip results.

An increase in specific gravity was noted as a result of tablet addition to the urine. Specific gravity increased on the average of 0.005 by the Multistix method and 0.002 by the refractometer method. The specific gravity was read by the manufacturer of assayed urine by densitometer and it was found to be in agreement with the assay and an increase of 0.002 from the addition of Stabilizer tablet.

These results show that both the refractometer and Multistix method measured an increase in specific gravity caused by the addition of stabilizer tablet, with the refractometer values being closer to expected values if read directly by densitometer.

TABLE 1

ADDENDUM #1

The effects of UrineVac® on the Specific Gravity of Urine

SOURCE OF ANALYSIS: Multistix 10SG

NO.	INITIAL UNPRE.	INITIAL TABLET	24HR UNPRE.	24HR TABLET	48HR UNPRE.	48HR TABLET	72HR UNPRE.	72HR TABLET
1.	1.027	1.030	1.030	1.030	1.027	1.030	1.029	1.030
2.	1.017	-	1.015	1.025	1.017	1.020	1.018	1.022
3.	1.010	1.015	1.013	1.025	1.010	1.017	1.010	1.018
4.	1.013	1.015	1.015	1.025	1.014	1.015	1.015	1.020
5.	1.010	1.015	1.015	1.025	1.012	1.015	1.013	1.019
6.	1.013	1.023	1.015	1.025	1.013	1.020	1.015	1.020
7.	1.025	1.028	1.030	1.028	1.025	1.030	1.025	1.028
8.	1.025	1.025	1.020	1.025	1.020	1.025	1.022	1.025
9.	1.008	1.010	1.010	1.012	1.008	1.013	1.008	1.012
10.	1.017	1.023	1.018	1.025	1.010	1.025	1.020	1.025
11.	1.013	1.017	1.012	1.022	1.013	1.017	1.012	1.021
12.	1.020	1.023	1.020	1.023	1.017	1.023	1.015	1.020
13.	1.005	1.007	1.005	1.010	1.005	1.010	1.006	1.010
14.	1.030	1.030	1.030	1.030	1.030	1.030	1.030	1.030
15.	1.010	1.012	1.010	1.011	1.010	1.012	1.011	1.011
16.	1.003	1.008	1.003	1.010	1.003	1.011	1.005	1.011
17.	1.014	1.018	1.016	1.019	1.017	1.020	1.017	1.018
18.	1.010	1.013	1.011	1.016	1.011	1.019	1.011	1.013
19.	1.028	1.028	1.028	1.030	1.027	1.028	1.027	1.028
20.	1.022	1.027	1.022	1.027	1.023	1.027	1.024	1.026
21.	1.006	1.012	1.007	1.012	1.008	1.012	1.008	1.011
22.	1.022	1.023	1.021	1.024	1.020	1.024	1.020	1.023
23.	1.018	1.022	1.019	1.022	1.019	1.022	1.018	1.023
24.	1.013	1.018	1.013	1.019	1.012	1.019	1.012	1.019
25.	1.007	1.020	1.010	1.018	1.010	1.020	1.010	1.020
26.	1.005	1.011	1.007	1.012	1.007	1.011	1.007	1.012

27	1.007	1.011	1.008	1.013	1.010	1.013	1.010	1.013
28	1.006	1.012	1.007	1.012	1.008	1.012	1.010	1.012
29	1.010	1.015	1.011	1.020	1.011	1.019	1.012	1.020
30	1.010	1.015	1.011	1.020	1.012	1.018	1.013	1.019
31	1.010	1.015	1.010	1.018	1.010	1.018	1.011	1.020

TABLE 2

ADDENDUM #1

The effects of UrineVac® on the Specific Gravity of Urine

SOURCE OF ANALYSIS: Refractometer

NO.	INITIAL UNPRE.	INITIAL TABLET	24HR UNPRE.	24HR TABLET	48HR UNPRE.	48HR TABLET	72HR UNPRE.	72HR TABLET		
1	1.029	1.030	1.028	1.030	1.028	1.030	1.028	1.030		
2	1.016	1.015	1.016	1.015	1.017	1.015	1.016	1.016		
	1.011	1.011	1.011	1.010	1.011	1.009	1.010	1.010	3	
	1.014	1.011	1.011	1.014	1.012	1.015	1.012	1.014	1.012	4
	1.012	1.010	1.012	1.010	1.012	1.010	1.011	1.010	5	
	1.014	1.011	1.014	1.011	1.014	1.012	1.014	1.011	6	
	1.025	1.022	1.025	1.022	1.025	1.022	1.025	1.025	7	
	1.026	1.026	1.025	1.025	1.028	1.026	1.025	1.025	8	
	1.008	1.006	1.008	1.006	1.009	1.005	1.006	1.005	9	
	1.018	1.016	1.018	1.015	1.018	1.016	1.015	1.015	10	
	1.015	1.012	1.015	1.012	1.015	1.012	1.015	1.012	11	
	1.025	1.022	1.025	1.022	1.025	1.022	1.024	1.022	12	
	1.005	1.003	1.005	1.003	1.005	1.002	1.004	1.002	13	
	1.035	1.033	1.035	1.032	1.036	1.032	1.035	1.032	14	
	1.023	1.021	1.023	1.020	1.023	1.020	1.023	1.020	15	
	1.005	1.002	1.005	1.002	1.005	1.002	1.005	1.002	16	
	1.015	1.014	1.016	1.013	1.015	1.013	1.016	1.014	17	
	1.015	1.013	1.015	1.011	1.015	1.012	1.015	1.012	18	
	1.030	1.027	1.030	1.027	1.030	1.027	1.029	1.028	19	
	1.024	1.021	1.024	1.022	1.024	1.021	1.024	1.022	20	
	1.008	1.006	1.008	1.006	1.008	1.005	1.008	1.006	21	
	1.031	1.030	1.032	1.030	1.031	1.030	1.031	1.030	22	
	1.020	1.018	1.020	1.018	1.020	1.018	1.020	1.019	23	
	1.036	1.035	1.036	1.035	1.036	1.035	1.036	1.035	24	
	1.008	1.006	1.009	1.006	1.007	1.006	1.009	1.006	25	

1.008	1.005	1.007	1.006	1.007	1.006	1.008	1.005	26
1.008	1.005	1.008	1.006	1.008	1.006	1.008	1.006	27
1.009	1.005	1.010	1.006	1.009	1.006	1.009	1.005	28
1.016	1.012	1.016	1.014	1.015	1.013	1.015	1.014	29
1.016	1.014	1.016	1.014	1.016	1.014	1.016	1.015	30
1.015	1.011	1.015	1.011	1.015	1.012	1.015	1.013	31