

**MRO ADVISORY:  
Specimen Validity Testing—Invalid Results (9.x pH)**

**Mandatory Observed Collections Following 9.x pH Invalid Urine Results May Constitute an Illegal Search**

Medical Review Officers need to be aware of the following:

- Recently published research indicates that **all** urine specimens have been found to equilibrate at a pH between 9.0 and 9.5 after one day stored in warm conditions and two days at room temperature.
- Mandatory Guidelines and DOT regulations require observed collections.
  - SAMHSA now attempts to shift risk and place responsibility on MROs for requiring observed collections.
  - *SAMHSA tells laboratories it is up to the MRO to determine when an observed collection is necessary.*
- On October 23, 2007, **AAMRO** requested DOT to issue an emergency Interim Final Rule to change pH level for an Invalid Result to equal to or greater than pH 9.5.

**Recommendations**

- MROs should inform private employers *not to require observed collections* on urine that has a pH of 9.0 to 9.5 recorded more than two hours after collection.
- Employers and MROs should request an exemption from DOT modal agencies for the observed collection requirement for all 9.x urine results.

**Background**

Over two years ago, MRO *ALERT* published an MRO Advisory noting that an increase in invalid results due to elevated pH was seen during the summer months and hot spells.<sup>1</sup> MROs also reported that a number of specimens that were subsequently collected under direct observation were also reported to be “Invalid” for having an elevated pH in the 9.0–9.4 range. (Coined by MRO *ALERT* as the 9.x urine.)

Numerous reports were received by MRO *ALERT* that this group of 9.x urines, collected under observation, had no indication of any adulterant, were negative to limits of detection and had normal creatinine levels. As the result of an informal study, MRO *ALERT* also found that there was no evidence of any surfactant or bleach in these specimens, although some specimens appeared to be slightly cloudy or contain bacteria. It was also determined that a significant

---

<sup>1</sup> MRO ADVISORY: Validity Testing Invalid Results—the 9.x pH Urine. MRO *ALERT*, Vol. XVI No. 4, July 2005.

number of the 9.x specimens were from female donors. There was no evidence of an increase in specimens over pH 10 related to temperature changes.

It was postulated by MRO *ALERT* in 2005 that since these were not clean urine collections, and that the pH was measured a day or two after collection, that the elevated pH was merely an artifact of bacterial incubation and the natural production of ammonia by the bacteria in warm weather.

**However, a recently published study indicates that ALL urine stored at or above room temperature will have an elevated pH between 9.0 and 9.5.**

In a paper presented at the annual meeting of the Society of Forensic Toxicologists (SOFT) in Chapel Hill, North Carolina, in October 2007 (literally the very last paper of the week), SAMHSA revealed a startling finding. The paper, appropriately titled “*Urine pH: the Effects of Time and Temperature after Collection,*” was also published in the October 2007 issue of the *Journal of Analytical Toxicology*.<sup>2</sup> The study revealed that the increased pH in urine samples during the summer is not due to bacteria at all. It is simply due to the heat and time lapse between collection and measurement!

The data is summarized nicely in the following graphs. Each line represents a different type of urine:

- Neat urine ■
- Urine + bacteria △
- Urine + glucose ◆
- Urine + bacteria + glucose □
- Urine + protein ▲
- Urine + bacteria + protein ◇
- Urine + yeast ×
- Urine + yeast + glucose ●

---

<sup>2</sup>J.D. Cook et al. Urine pH: the effects of time and temperature after collection. *Journal of Analytical Toxicology*, Vol. 31, October 2007, pp. 486-496.

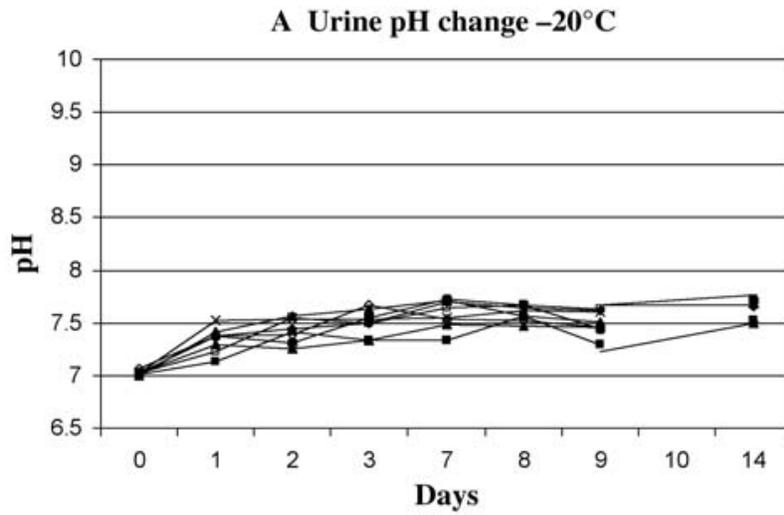


Figure 1: pH of frozen urine over time.

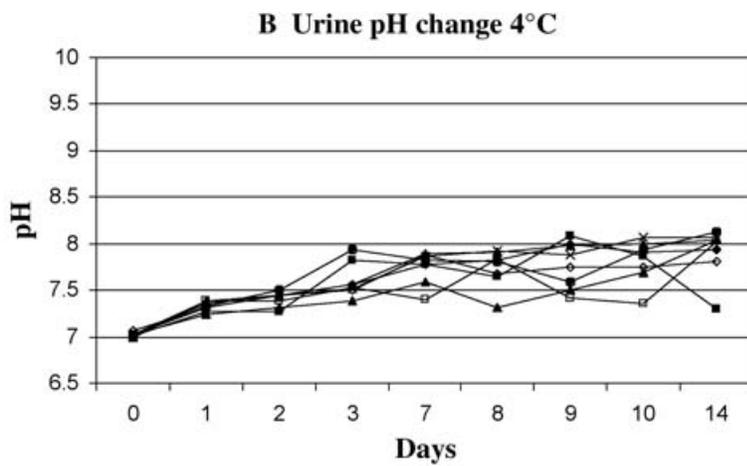


Figure 2: pH of urine kept at 4° C over time (39° F, refrigerated urine).

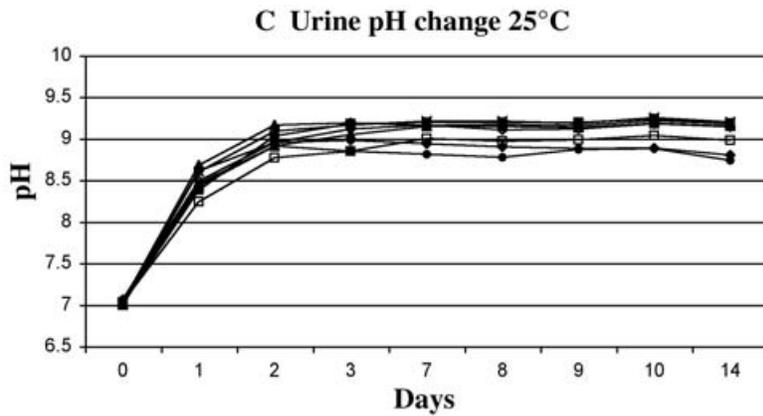


Figure 3: pH of urine at 25° C over time (77° F, room temperature).

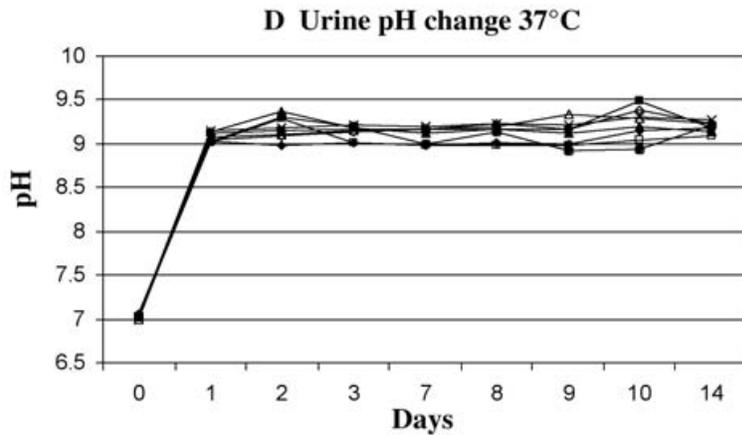


Figure 4: pH of urine stored in hot environment (98° F, an example of summertime transit).

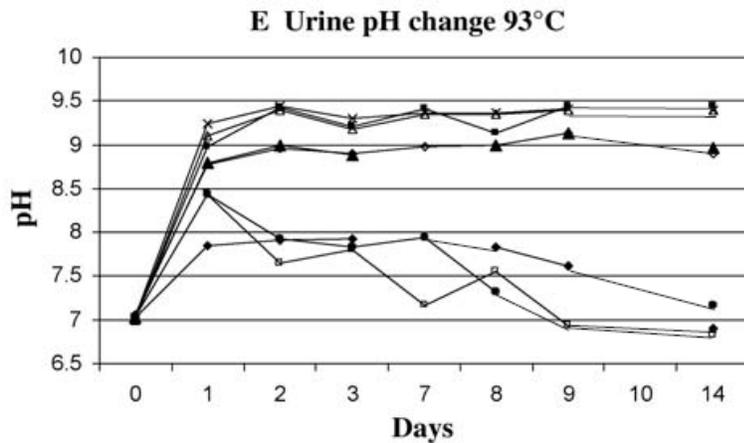


Figure 5: pH of urine stored in excessive heat (199° F, an example of urine stored in closed van or trunk of car in summer).

### The Results

The phenomena of increased invalid 9.x urine specimens during the summer and hot spells is due to the differences between the rate of increase in pH over time between Figure 2 and Figure 3 (refrigerated urine and urine kept at moderate temperature) and the more rapid rate of increase seen in urine stored in hot ambient conditions (Figure 4 and Figure 5). In cool weather the pH of all urine tends to reach a level of 8.5. In hot weather the pH gets over 9.0 in one day or less.

### Legal Issues

In a nutshell, the legal basis for an observed collection in governmentally mandated programs is that there is individualized suspicion that the donor has attempted to adulterate or substitute his or her urine.

The data in this new study makes it clear that the mere fact that urine which is tested over two hours after collection has an elevated pH in the range of 9.0–9.5 is not a reasonable basis to suspect that a donor has attempted to adulterate his or her urine. **Every** urine specimen will have a pH between 9.0 and 9.5 within twenty-four hours after exposure to heat. Thus, there is no legal basis for requiring the donor of such a specimen to be subjected to a second observed collection. These observed collections, although mandated by federal regulations, may be found to constitute an illegal search in violation of the Fourth Amendment.

The current rules of HHS and DOT do not allow the MRO to exercise discretion based on an analysis of time and temperature factors, nor would such a rule be practical or reasonable.

The reasons for the rise in urine pH as a function of time and temperature are interesting but irrelevant in respect to requiring a second observed collection. It is not the fault of the donor that the urine specimen is shipped in warm weather in unrefrigerated conditions.

It has been long understood that high heat conditions result in the degradation of drugs and metabolites in urine specimens. About twenty years ago it was observed that urine specimens stored in the trunk of a car during the summer resulted in the thermal degradation of all the drugs and metabolites of the specimens, including blind quality control specimens.<sup>3</sup> The real problem is the heat, not the pH.

### **Insult to Injury**

Although it is widely acknowledged in the drug testing community that the MRO *ALERT* advisory in 2005 was the basis for this study, the advisory is not mentioned or cited as even a footnote in the JAT paper.

From 2005, following the publication of the MRO Advisory, MROs and other drug testing service agents that made inquiries to SAMHSA about the 9.x pH were told the following:

- The 9.x pH results were due to an unidentified adulterant.
- Observed collections were needed because bacteria were digesting THC.
- Observed collections are needed because drugs and metabolites are unstable at alkaline pH.
- This new SAMHSA-financed research “*validates*” the need for observed collections because some drugs are not stable at this pH level.

**SAMHSA** fails to comprehend or simply ignores the legal issues involved in mandating observed collections. As with the substituted specimen problem in 2003, it is doing its homework after issuing the rules, and then attempting to cover up after discovering it is wrong.

**SAMHSA** and the individuals responsible for misleading federal agencies, MROs, laboratories and the public should be held accountable for its actions in any litigation resulting from unnecessary observed collections.

---

<sup>3</sup> Personal observation of specimens transported from Fort Bragg, North Carolina to CompuChem Laboratories in August circa 1986.