The Summer of 2024 Effects on Invalid pH Sample Results. Is it Time to Change the Federal Levels?

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Introduction

The SVT cutoffs for drug testing have been in effect for at least 3 decades. The original values were based on clinical data with freshly voided urine, as the experience with workplace drug testing was in its infancy. Adjustments have taken place in the past to creatinine and pH values as additional evidence determined that the original cutoffs did not account for unusual diets, high summer temperatures, and/or delays in transportation to the laboratory.

All urine contains a variety of biologicals such as endogenous steroids, glucose, and proteins which are metabolized by bacteria and yeast. This metabolism results in the generation of ammonia byproducts. The ammonia will then raise the pH from freshly voided urine from 5-7 to 9, and greater by the time of testing by the lab.

Background

Due to seasonal variations in the pH acceptability of samples, CRL completed a retrospective analysis of millions of non-regulated samples a couple of years ago to initiate a pH change to 9.5 with the client's approval. The latest data now includes data through October 2024. The drug testing industry is aware of elevated pH and the business impact but continues to follow HHS/DOT guidelines for invalid and adulterated samples.

CRL samples were evaluated monthly by their pH levels. It was clear that the summer heat and transportation times to CRL caused the sample pH to rapidly rise without any evidence of tampering. As summer gave way to fall, and fall to winter, the pH values dropped with fewer invalid results reported. However, in the last several years the problem of invalid pH samples has increased as compared to previous years because of elevated temperatures of 100 degrees or more.

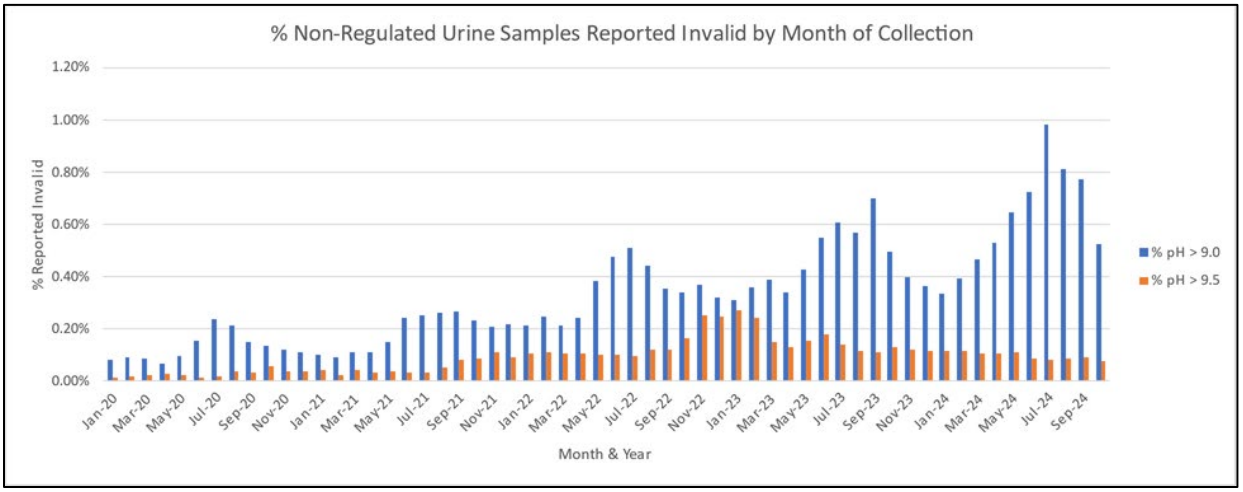
Based on HHS guidance for pH acceptability, donors with a sample pH of 9 or greater would be reported as "Invalid" and a recollection would be initiated with the hope that the next sample would be within the acceptable range. In these scenarios the delays involved with an extra collection could have prevented the donor from receiving a job offer or added days without pay waiting for a hiring start date.

Evaluating pH Results by CRL

To assist our TPAs and employers to hire faster, CRL established a new standard by increasing the new upper limit of pH acceptability to 9.5 rather than 9. Millions of pH results were evaluated from January 2020 to October 2024 and are represented in the graph below. The graph provides the seasonal changes by month and percentage of samples affected by pH each month. It is apparent for invalid pH values greater than 9 (percentages in blue), the number of samples increased each year to almost 1% in July 2024. However, the values of 9.5 or greater are stable month-over-month without a seasonal impact. This indicates that summer heat is affecting donor samples and is not due to changes in donor behavior, such as use of adulterants or improperly created synthetic urine.

More than 20,000 donors avoided recollections based on a pH of 9.5 rather than 9. This means that more than 20,000 jobs were filled during a period of low unemployment and critical vacancies were filled as quickly as possible.

A rise was observed in samples with a pH greater than 9.5 (orange bars) beginning in October 2022 for nearly a year. This was attributed to an improperly prepared synthetic urine that was nationally distributed with an unacceptable pH, creatinine, and specific gravity results. Once this product was no longer available, the normal percentage samples of greater than 9.5 was reduced to less than 0.1%.



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Summary

The increase in summer temperatures has a significant impact on drug testing when evaluating pH based on the HHS guidelines and results in an unacceptable increase in invalid pH samples each year. The high number of sample recollections due to invalid pH is affecting employer hiring without any attempt by the donor to circumvent the drug test.

It is time to re-evaluate the federal pH range to account for summer temperatures. An analysis of these "out of normal range" samples should be conducted to account for the increase in elevated pH samples on a seasonal basis and why each year the number of unacceptable samples are increasing. A correlation between elevated pH, creatinine, glucose, protein, bacteria/yeast, and other urine excreted products should be considered to understand the relationships and possible root cause. It may be as simple as the rise in Type I and Type II diabetics with urine glucose present.

Each summer has been hotter than the last and this trend is predicted to continue. Donors should not be negatively impacted by hotter summer temperatures and prevented from a job. It is time to re-evaluate the pH acceptance criteria.