



# EVALUATION OF THE CUTOFF FOR INVALID pH DRUG TESTING ADVISORY BOARD DECEMBER 3, 2024

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# CHALLENGES TO THE 9.0 INVALID pH CUTOFF

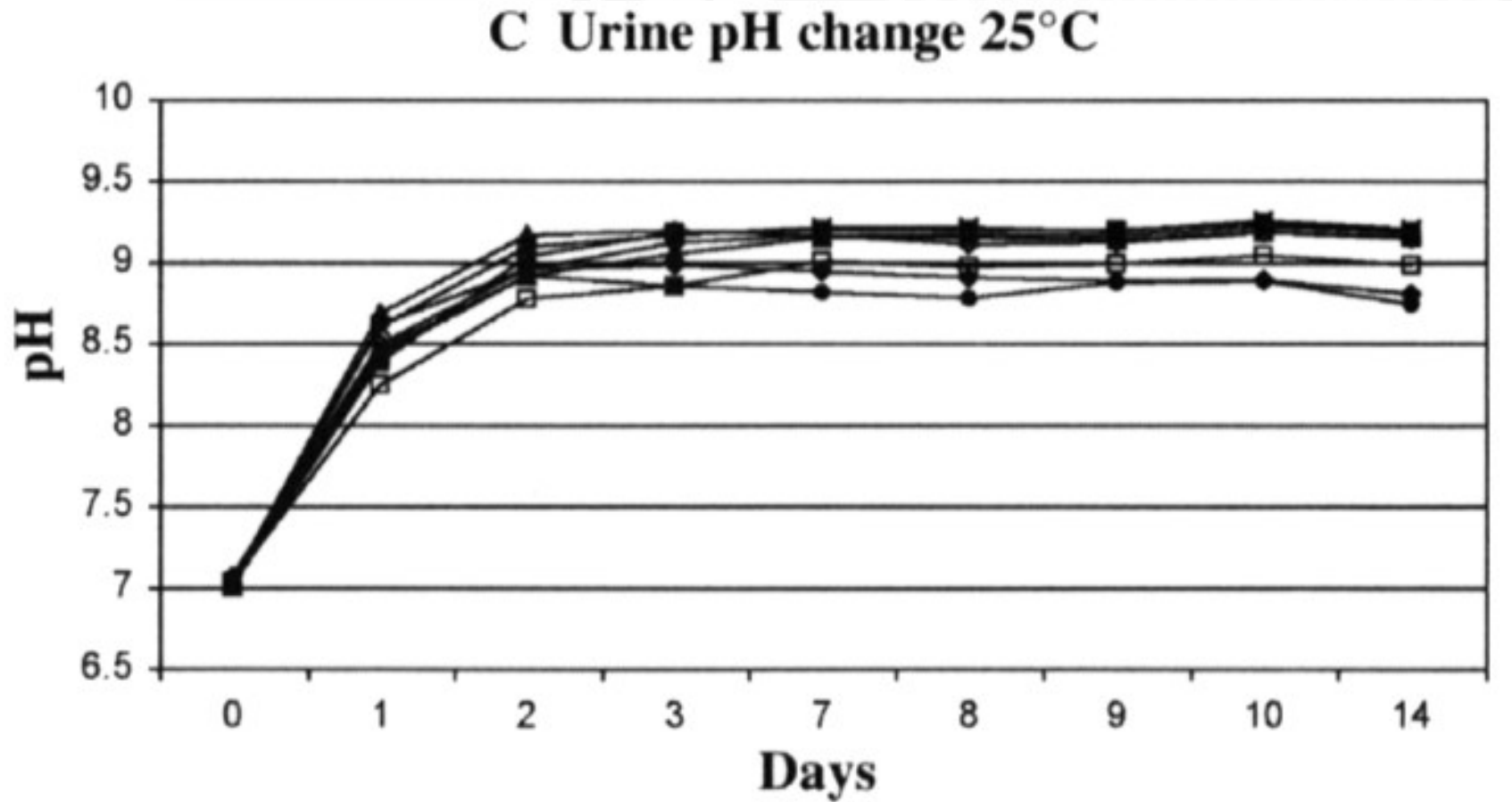
- High pH range to report urine specimens as “Invalid”:  
     $\geq 9.0$  and  $<11.0$
- Invalid – High pH specimens require
  - Two pH meter tests (labor intensive for laboratories)
  - Observed recollections (affecting donors, employers, and MROs)
- Numerous specimens are reported as Invalid based on high pH
- **Concern:** urine pH can rise after collection based on time and temperature (e.g., during transport to the laboratory)
  - Caused by bacterial action converting urea to ammonia, not the addition of an adulterant
  - The pHs reach a plateau of about 9.1 – 9.3
  - Numbers of Invalid – high pH specimens rise during warm months

# URINE pH: THE EFFECTS OF TIME AND TEMPERATURE AFTER COLLECTION

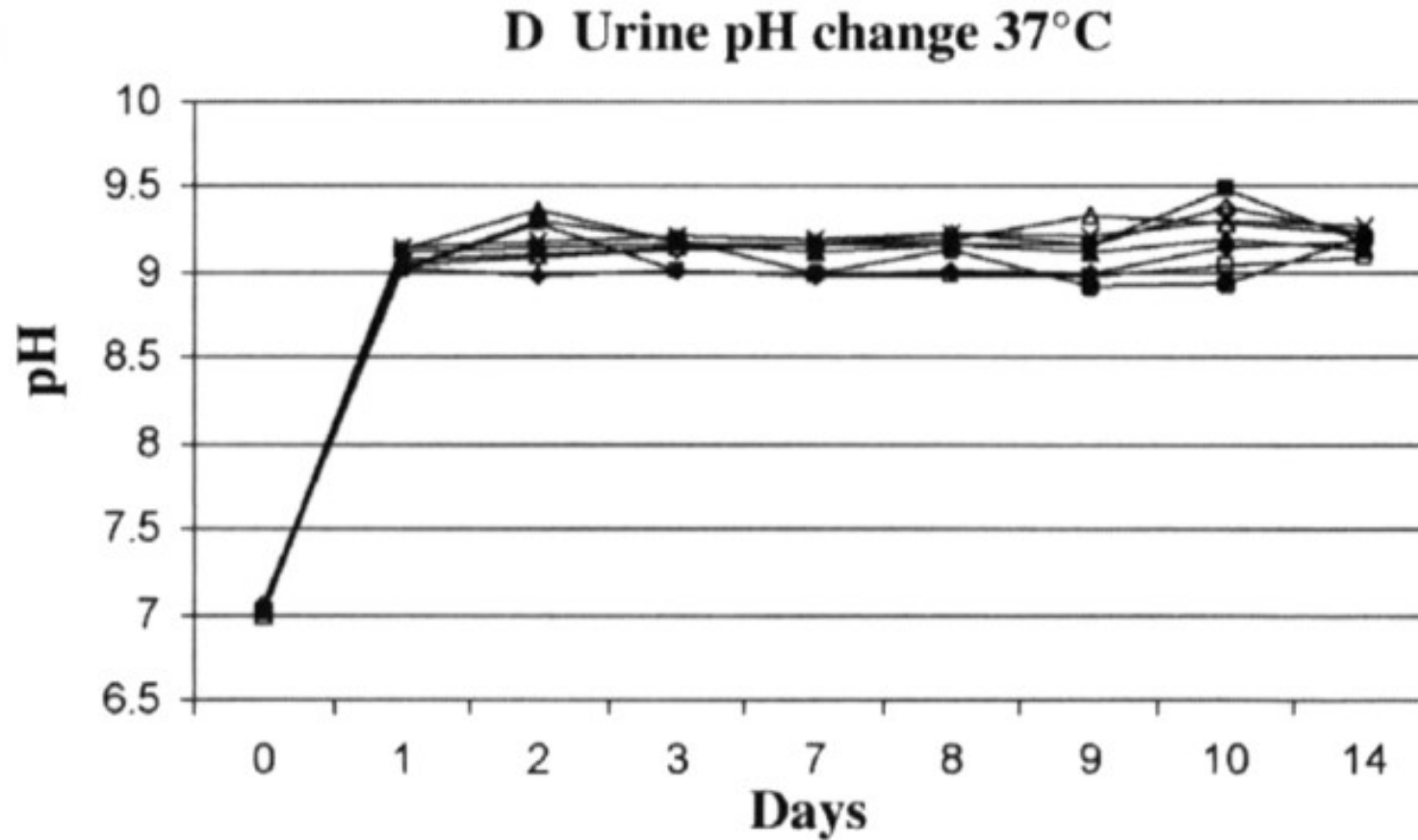
- A 2007 SAMHSA-funded study looked at pH changes in human urine specimens at different temperatures.
- The study confirmed that pH rises to 9.1 – 9.3 when urine samples are stored at elevated temperatures.

Janine D. Cook, Kathy A. Strauss, Yale H. Caplan, Charles P. LoDico, Donna M. Bush, Urine pH: the Effects of Time and Temperature after Collection, *Journal of Analytical Toxicology*, Volume 31, Issue 8, October 2007, Pages 486–496, <https://doi.org/10.1093/jat/31.8.486>

# URINE pH: THE EFFECTS OF TIME AND TEMPERATURE AFTER COLLECTION



# URINE pH: THE EFFECTS OF TIME AND TEMPERATURE AFTER COLLECTION



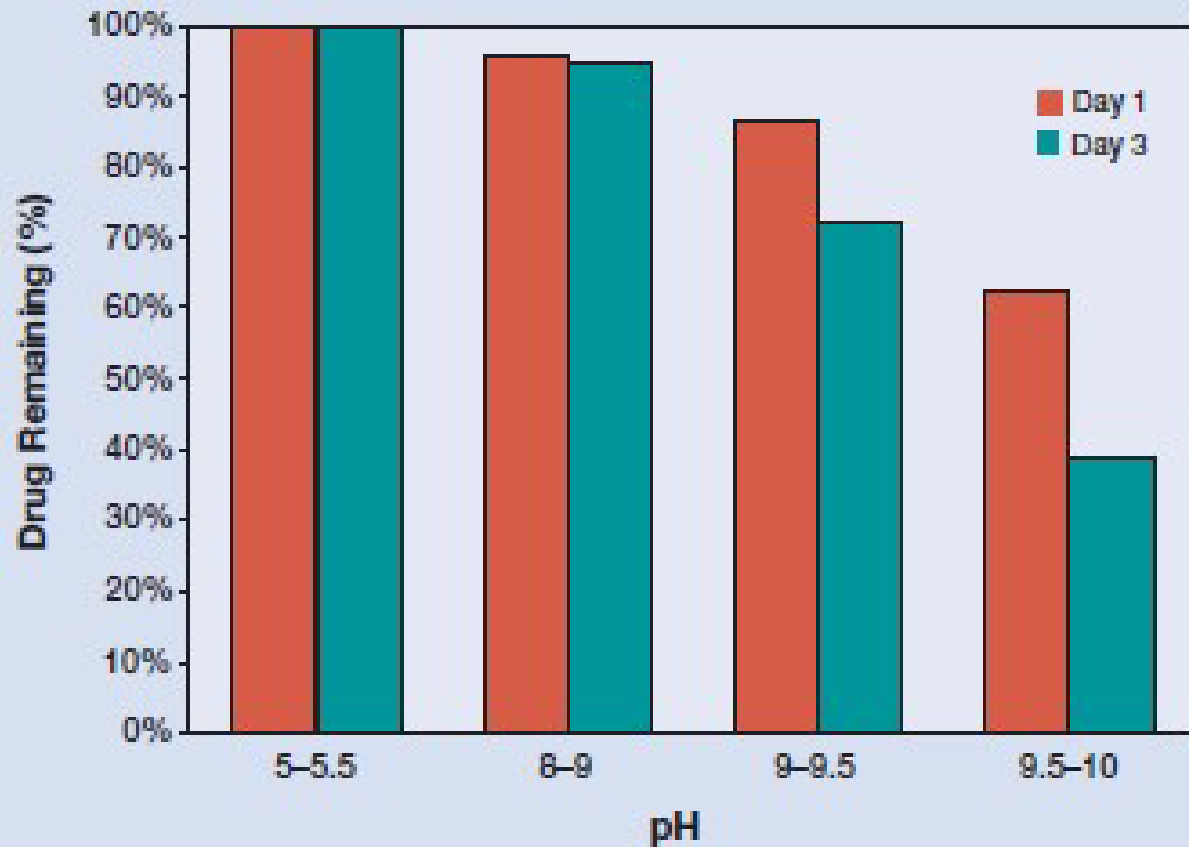
# EFFECT OF ELEVATED pH ON FEDERAL PROGRAM DRUGS

- A 2006 SAMHSA-funded study evaluated the effect of elevated pH on drugs in urine.
  - Added drug analytes at 1.5 – 2 times the federal cutoff for each: THC-COOH, benzoylecgonine (BZE), phencyclidine (PCP), codeine (COD), morphine (MOR), 6-acetylmorphine (6-AM), methamphetamine (MAMP), and amphetamine (AMP)
  - Adjusted pH by titration with sodium hydroxide
  - Tested samples at 1 and 3 days after preparation
- The only drugs affected by pH between 9.0 – 9.5 were BZE, PCP, and 6-AM

Francis M. Esposito, John M. Mitchell, Michael R. Baylor, and Donna M. Bush, Influence of Basic pH on Federal Regulated Drugs in Urine at Room Temperature, Poster presented at Society of Forensic Toxicologists Annual Meeting, 2006

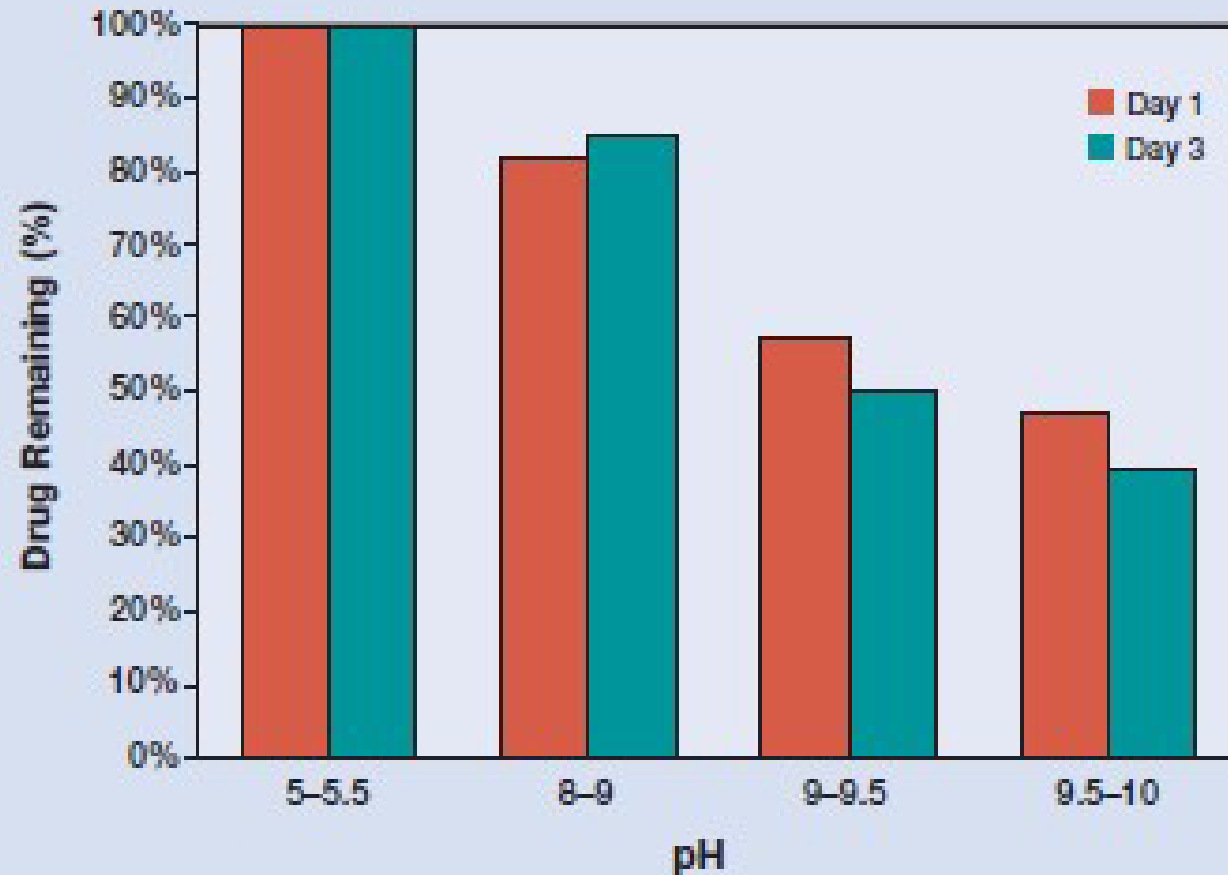
# EFFECT OF ELEVATED pH ON FEDERAL PROGRAM DRUGS

Figure 2. Effect of pH on BZE concentrations



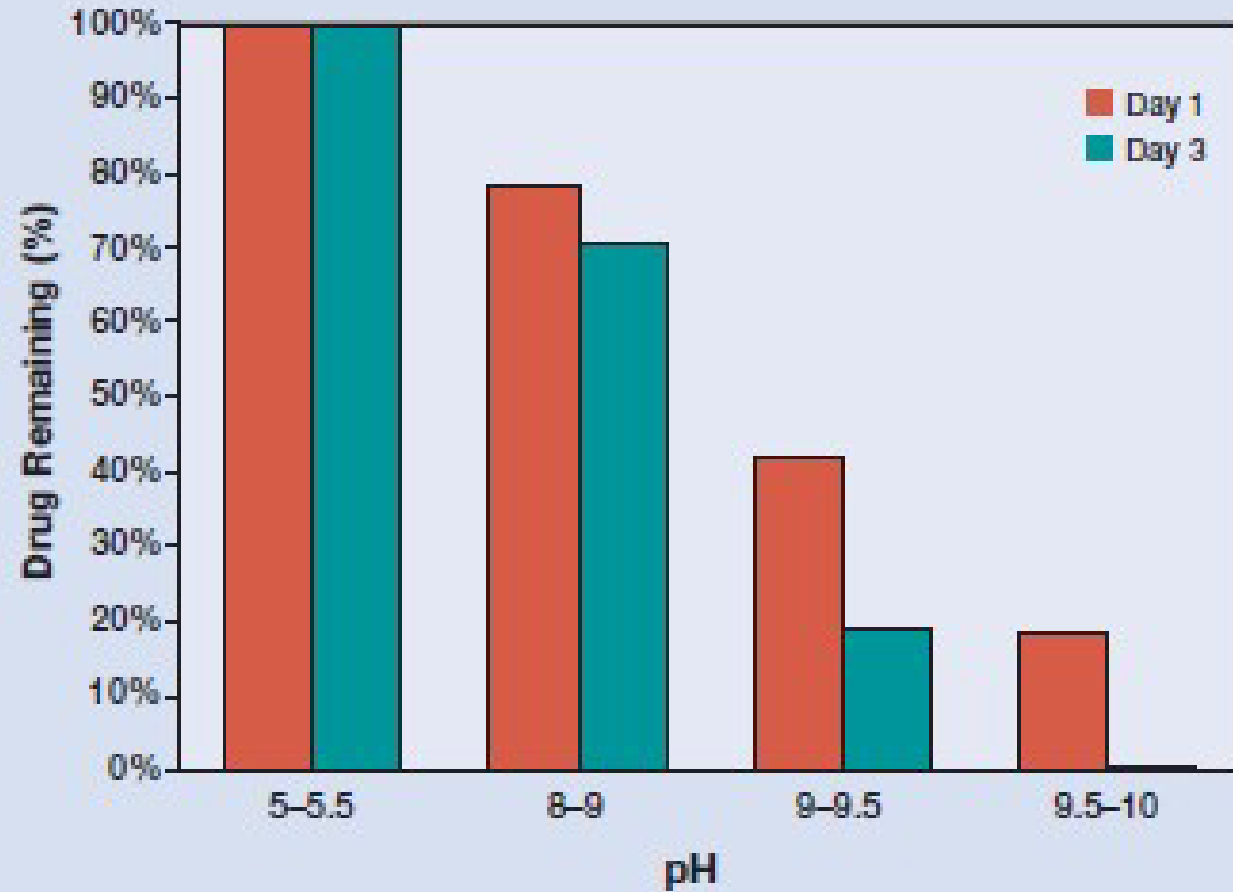
# EFFECT OF ELEVATED pH ON FEDERAL PROGRAM DRUGS

Figure 3. Effect of pH on PCP concentrations



# EFFECT OF ELEVATED pH ON FEDERAL PROGRAM DRUGS

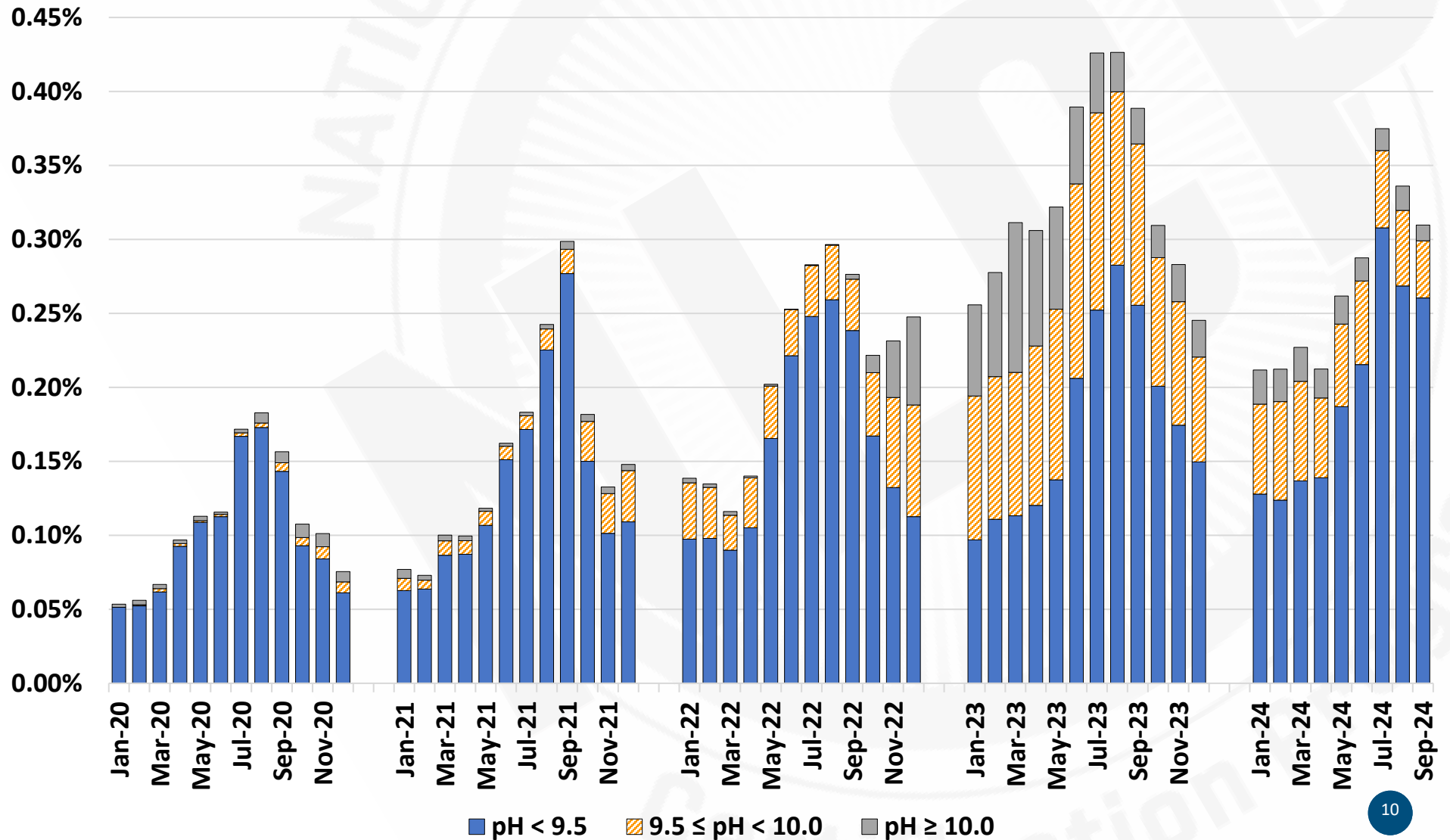
Figure 4. Effect of pH on 6-AM concentrations



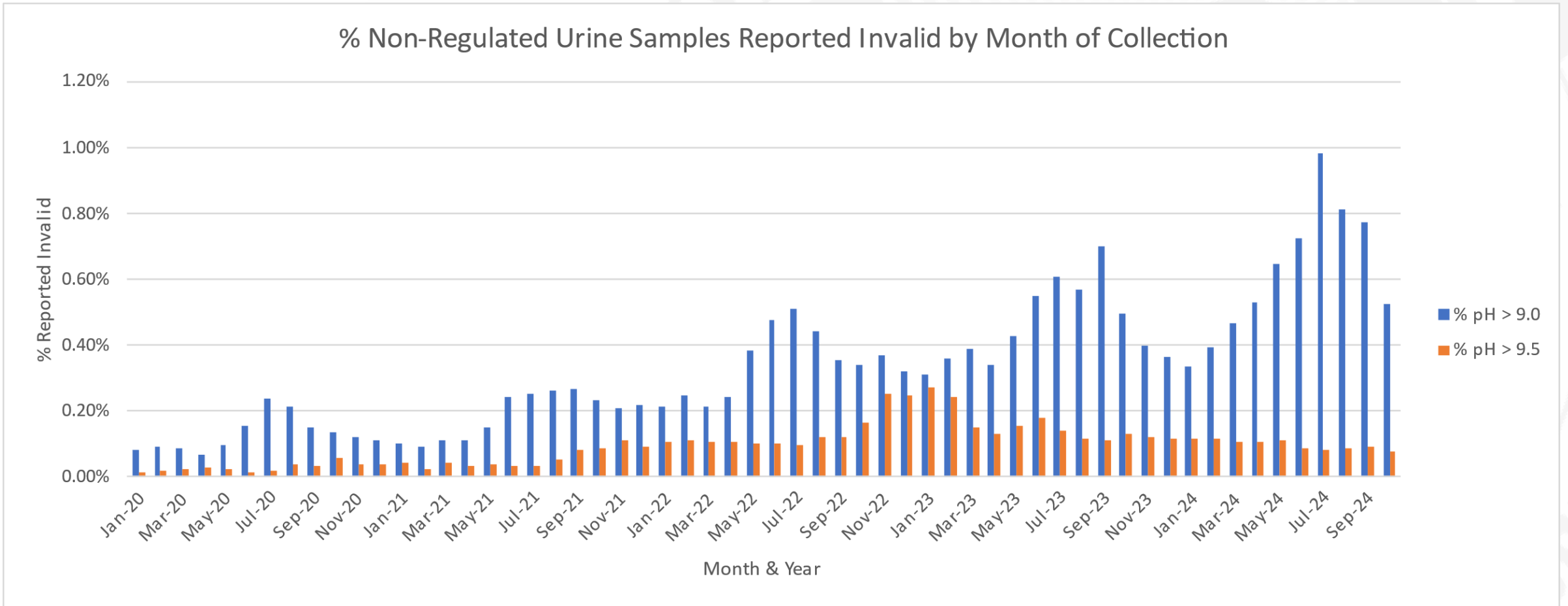
# INVALID pH CATEGORIES FOR FEDERAL LABORATORIES (NON-NEGATIVE SPECIMEN LIST DATA)



Abnormal pH



# pH>9.0 NON-REGULATED SPECIMENS AT CLINICAL REFERENCE LABORATORY (CRL)



## EFFECT OF pH 9-9.5 ON POSITIVE SPECIMENS

- Current federal annual tests: about 7.5 million specimens
- pH 9-9.5 occurs in about 0.2%: 15,000 specimens
- NLCP investigates A and B specimens with inconsistent quantitative results ( $B \geq 30\%$  higher than A,  $B \leq 60\%$  lower than A)
  - 2024 NLCP investigations: **15** BZE specimens were higher on retest due to high pH causing hydrolysis of cocaine. However, none of the pH results were  $>9$ .
  - No 2024 NLCP investigations for PCP
  - 2024 NLCP investigations: **4** 6-AM specimen either failed to reconfirm (3) or were lower (1) on retest due to high pH. However, none of the pH results were  $>9$ .

## CONCLUSIONS

- The incidence of specimens at  $9.0 < \text{pH} < 9.5$  is highest during summer.
- $\text{pH} > 9.5$  does not occur due to elevated temperature and increased shipping time.
- Although BZE, PCP, and 6-AM are affected, the impact is minimal due to the low incidence of pHs in this range vs. the total specimens tested.
- Increasing the Invalid pH cutoff from 9.0 to 9.5 would reduce the burden to donors, MROs, testing agencies and laboratories.

# ACKNOWLEDGEMENTS

- Dr. David Kuntz of Clinical Reference Laboratory for providing data on specimens with elevated pH.

Thank you

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