Modification of Specimen Validity Testing Ranges in Non-Regulated Urine Testing

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INTRODUCTION

Testing for urine specimen acceptability has been termed by the National Laboratory Certification Program (NLCP) as Specimen Validity Testing (SVT). The national program requires laboratories to test for creatinine, pH, and at least one oxidizing adulterant (general oxidant) in addition to the drugs included in the federal panel. To determine whether a specimen is normal, dilute, or substituted, creatinine levels less than 20 mg/dL must be further tested for specific gravity by refractometer. Sample pH must be within the acceptable range of 4.5 to 9.0; specimens with values outside of this range must be realiquoted and analyzed by pH meter, and report as normal, invalid, or adulterated based on the confirmatory result. The general oxidant test was added to curb specimen adulteration by foreign substances or chemicals during collection.

Original SVT parameters, which were established using the limited data available at the time, are conservative and generate superfluous laboratory handling and testing. Repeated analysis for low creatinine values and recollection of urine samples based on elevated pH creates delays in reporting, ultimately reducing the number of job applicants that can be hired quickly. In cases of elevated pH, research supports that summer heat is the reason for higher urinary pH, not donor malfeasance. A dilute reporting status, which is generally insignificant to an employer seeking a new hire, requires additional specific gravity testing that delays the reporting of sample results.

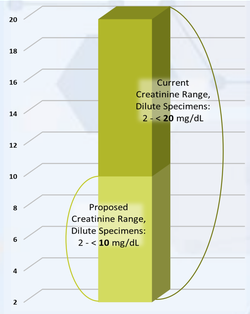
OBJECTIVE

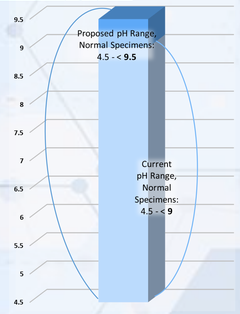
Establish alternative SVT acceptance criteria by creating new acceptability ranges for creatinine and pH. Lowering the threshold for acceptable creatinine values and raising the levels of allowable pH would minimize sample follow-up testing and reduce unnecessary recollections that might otherwise lead to the denial of a job opportunity.

METHODS

A retrospective analysis of millions of samples over more than two years' time was performed to identify trends in creatinine and pH values. Samples were collated by month to determine potential effects of seasonal temperature changes.

Figures A and B: Current and Proposed SVT Acceptance Criteria Ranges for *(Left)* Creatinine and *(Right)* pH





Non-regulated clients were given the opportunity to adopt new SVT acceptance criteria beginning in March of 2023. The creatinine cutoff requiring specific gravity testing and reporting specimens as dilute was reduced to 10 mg/dL from 20 mg/dL. The pH cutoff requiring analysis by pH meter and reporting specimens as invalid or adulterated due to high pH was increased from 9.0 to 9.5.

RESULTS / DISCUSSION

From the retrospective data, specimens having a creatinine concentration less than 20 mg/dL comprised approximately 4.4% of total specimen volume, and 58% of those samples eventually reported as dilute. Samples with a creatinine concentration between 10 and 19.9 mg/dL made up 3.8% of total volume and reported dilute at the rate of 56.9%. Only 0.6% of total specimens had creatinine levels less than 10 mg/dL, and 64.3% of these samples reported as dilute. See Table 1 and Figure C for the division of study specimens by creatinine concentration.

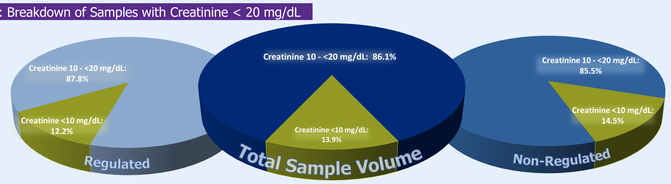
Table 1: Creatinine Concentration Ranges for Study Population from 01/2021 to 08/2023

Regulated Specimens	
Creatinine <20 mg/dL	3.9%
Creatinine 10 - <20 mg/dL	3.4%
Creatinine <10 mg/dL	0.5%
Potential Reduction in Testing	87.8%

TOTAL- Regulated and Non-Regulated	
Creatinine <20 mg/dL	4.4%
Creatinine 10 - <20 mg/dL	3.8%
Creatinine <10 mg/dL	0.6%
Potential Reduction in Testing	86.1%
Potential Savings of >600,000 Specific Gravity Tests	

Non-Regulated Specimens	
Creatinine <20 mg/dL	4.6%
Creatinine 10 - <20 mg/dL	3.9%
Creatinine <10 mg/dL	0.7%
Potential Reduction in Testing	85.5%

Figure C: Breakdown of Samples with Creatinine < 20 mg/dL



Further analysis of samples with creatinine concentrations less than 20 mg/dL revealed that the overall reporting rate of dilute specimens for all samples was 2.5%. While 58% of specimens with creatinine less than 20 mg/dL were ultimately reported as dilute, 84.6% of these samples had creatinine concentrations of 10 mg/dL or greater, and 15.4% had creatinine less than 10 mg/dL. See Figure D for analysis of the study population reporting as dilute, and Figure E for the breakdown of dilute specimens by creatinine concentration range.

Figure D *(Left):* Detail of Total Samples with Creatinine < 20 mg/dL and Specimens Reporting Dilute

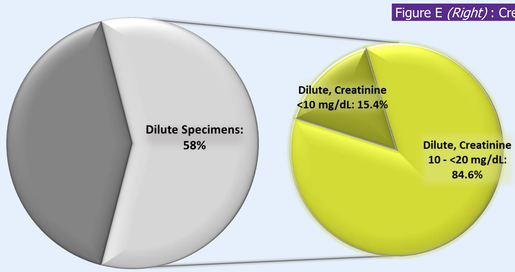
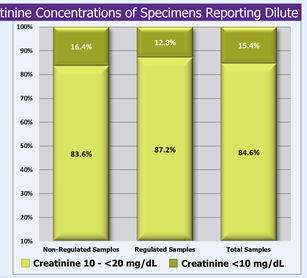
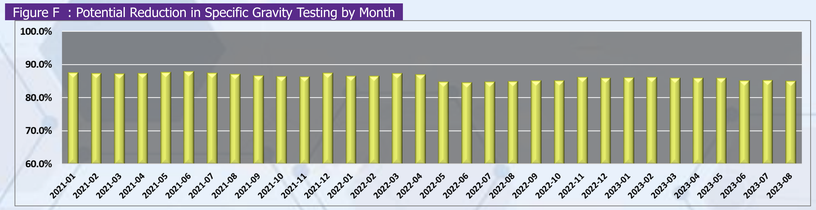


Figure E *(Right)* : Creatinine Concentrations of Specimens Reporting Dilute



Lowering the minimum concentration of "normal" creatinine to 10 mg/dL from 20 mg/dL would potentially cut the number of all samples requiring specific gravity analysis by 86.1%. This difference could mean a reduction in the number of samples being handled by laboratory staff by well over 600,000 annually. Month-to-month, the reduction rate is virtually constant and no substantial affect by seasonal difference in donor hydration is apparent (See Below).

Figure F : Potential Reduction in Specific Gravity Testing by Month



For the almost 10 million samples analyzed for pH from January 2021 to August of 2023, 0.27% had a pH greater than or equal to 9.0. Samples with pH of 9.5 and greater made up 0.10% of the total sample volume. The majority of specimens with pH greater than or equal to 9.0 had a pH less than 9.5, comprising 0.17% of the total specimen volume and 61.7% of samples with "high" pH. See Table 2 and Figure G for detailed categorization of pH results for the study.

Table 2: pH Ranges for Study Population from 01/2021 to 08/2023

Regulated Specimens	
pH ≥ 9.0	0.23%
9.0 ≤ pH < 9.5	0.14%
pH ≥ 9.5	0.09%
Potential Reduction in Recollects	60.8%

TOTAL- Regulated and Non-Regulated	
pH ≥ 9.0	0.27%
9.0 ≤ pH < 9.5	0.17%
pH ≥ 9.5	0.10%
Potential Reduction in Recollects	61.7%
Potential Savings of >16,000 Recollected Samples	

Non-Regulated Specimens	
pH ≥ 9.0	0.32%
9.0 ≤ pH < 9.5	0.20%
pH ≥ 9.5	0.12%
Potential Reduction in Recollects	62.2%

Figure G: Breakdown of Samples with pH ≥ 9.0

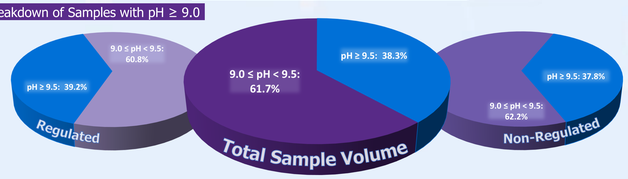
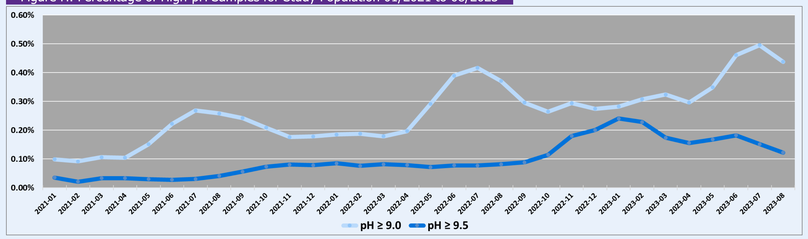
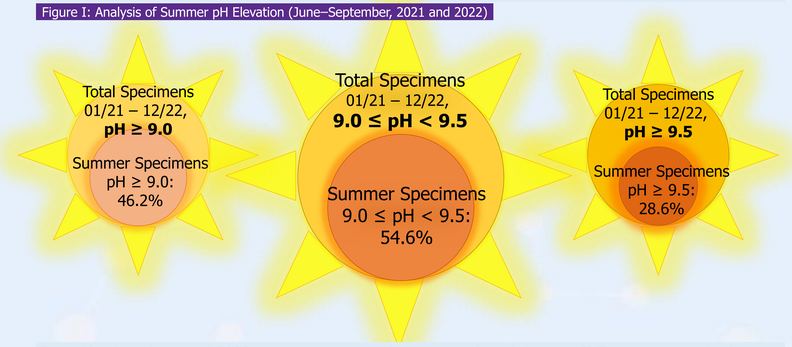


Figure H: Percentage of High-pH Samples for Study Population 01/2021 to 08/2023



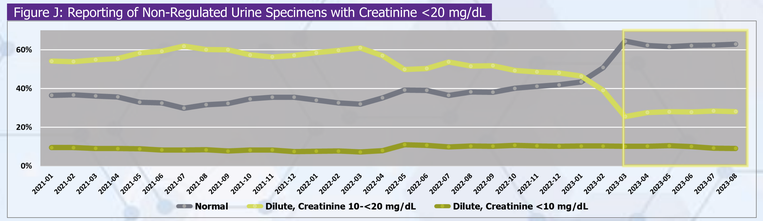
During summer months, from June through September, data showed a dramatic increase in the number of specimens reported invalid due to pH greater than or equal to 9.0 (but less than 11.0). This seasonal increase is observed annually (see Figure H). Considering the data for only the two full years of January 2021 to December 2022, the months of June, July, August, and September ("summer") for both years account for 34.6% of the total sample volume. Interestingly, these 8 months produce 46.2% of the specimens with pH 9.0 and greater for the 24-month time frame. Furthermore, 54.6% of the specimens having pH greater than or equal to 9.0 and less than 9.5 are attributed to these hot-weather months; but only 28.6% of the samples having a pH 9.5 and greater are from June through September, which is 6% lower than the relative volume.

Figure I: Analysis of Summer pH Elevation (June–September, 2021 and 2022)



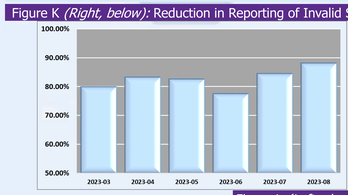
From March to August of 2023, subsequent to the implementation of the new SVT acceptance criteria, about 75% of non-regulated specimen volume consisted of samples from clients who approved of the revised cutoffs for pH and creatinine. During that period, there was a 59% decrease in specific gravity testing for non-regulated sample volume compared to years prior; 84% of specimens with creatinine concentrations less than 20 mg/dL had creatinine greater than 10 mg/dL, which amounted to a savings of nearly 42,000 specific gravity tests (see highlighted region of Figure J below).

Figure J: Reporting of Non-Regulated Urine Specimens with Creatinine <20 mg/dL



With the upper limit of pH acceptability increasing from 9.0 to 9.5, the number of specimens requiring additional testing for elevated pH dropped by 82% for clients electing to use the new SVT ranges (see Figure K). In only 6 months, this change alone prevented more than 2,500 specimens from reporting as invalid; therefore preventing unnecessary sample recollections and allowing thousands of job applicants to join the workforce more quickly.

Figure K *(Right, below):* Reduction in Reporting of Invalid Specimens for Population using the pH 9.5 Cutoff



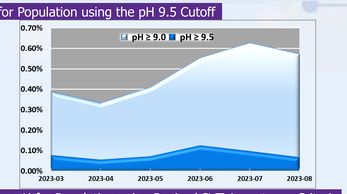


Figure L *(Left, above):* Specimen pH for Population using Revised SVT Acceptance Criteria

CONCLUSION

Alternative SVT criteria is limited to non-regulated urine testing and not applicable to the Federal Drug Testing Program. Because needs may vary by organization and industry, non-regulated substance abuse testing allows employers the customization of drugs and cutoffs in their panels. All SVT criteria changes were approved by clients prior to implementation, offering an additional way to individualize and improve testing programs.

DISCLOSURE

No relevant financial or nonfinancial relationships to disclose.