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Authors

Godwin, Zachary

Lima, Kelly

Greenhalgh, David

et al.

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A Retrospective Analysis of Clinical Laboratory Interferences Caused by Frequently Administered Medications in Burn Patients

Zachary Godwin, BS¹, Kelly Lima, BS¹, David Greenhalgh, MD, FACS², Tina Palmieri, MD, FACS, FCCM², Soman Sen, MD, FACS², and Nam K. Tran, PhD, MS, FACB¹

¹Department of Pathology and Laboratory Medicine, University of California, Davis, School of Medicine, Shriners Hospital for Children of Northern California

²Division of Burn Surgery, Department of Surgery University of California, Davis, School of Medicine, Shriners Hospital for Children of Northern California

STRUCTURED ABSTRACT

Objective—The goal of this study is to quantify the number of medications administered to burn patients and identify potential drugs interfering with laboratory testing.

Methods—We reviewed the medical records of 12 adult (age 18 years) burn patients with 20% total body surface area (TBSA) burns from an existing glucose control database at our institution. Dose, interval, and route of medications administered from admission to discontinuation of intensive insulin therapy were recorded. Interfering drugs were identified based on established clinical chemistry literature.

Results—The retrospective cohort of adult burn patients exhibited a mean (SD) age of 37.9 (3.0) years. Mean TBSA burn was 51.3 (9.3) %. Disease severity determined by the average multiple organ dysfunction score was 5.4 (0.2). Mean and median medications administered per day were 42.1 (9.5) and 49 (with a daily range of 0 to 65) respectively. A total of 666 potential laboratory test interferences caused by medications were identified. There were 261 different effects (*e.g.*, increased glucose, decreased potassium). Multiple interferences, 71.0% (475/666), were caused by more than one medication.

Conclusions—Investigation of the number of medications administered to a burn patient and delineation of potential laboratory test interferences has not been conducted in burn patients. Given the substantial number of medications administered to burn patients, physicians and laboratory personnel should work together to identify potential interferences and define appropriate countermeasures while enhancing the laboratorians understanding of this unique population. This synergistic partnership can lead to intelligent support tools and potentially autocorrecting instruments.

Corresponding Author: Zachary R. Godwin, BS 3435 Tupper Hall, Department of Pathology and Laboratory Medicine, University of California, Davis, School of Medicine, Davis, CA 95616, Phone: 530-752-8471, Fax: 530-752-4548, zrgodwin@ucdavis.edu.

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Keywords

Medication; Burn; Interference; Clinical; Laboratory; Testing

INTRODUCTION

Burn patients represent a high-risk critically ill population. Treatment of severe burns is a multifaceted process where burn physicians must manage not only the burn injury, but also determine the appropriate volume of fluid resuscitation, assess organ dysfunction severity and functionality, calculate nutrition requirements, and monitor for signs of potential infections. [1] Medications are instrumental in treating the litany of medical complications found in burn patients and routine laboratory testing provides important objective means to do so. Unfortunately many of these medications can interfere with laboratory testing by altering the correct results, thus impairing clinical decision-making. [2]

Intensive pharmacotherapy is common in burn care. An example of burn specific pharmacotherapy interfering with laboratory testing has been recently recognized during high dose ascorbic acid therapy. [3,4] During acute burn shock patients are resuscitated using the Parkland formula. [5,6] Patients who do not respond to standard resuscitation protocols are at risk of volume overload, which has been shown to lead to extremity or abdominal compartment syndrome as well as acute respiratory distress syndrome. [7–9] Pharmacotherapy using high dose ascorbic acid (*i.e.*, vitamin C) has been proposed to reduce fluid requirements during burn shock. [10,11] Ascorbic acid is a strong antioxidant and has been known to interfere with electrochemical reactions in a variety of laboratory tests including those for glucose, urinalysis, and creatinine. [3,12]

The myriad administered medications necessitate routine monitoring of drug-to-drug interactions by hospital pharmacists. [13] While this prevents adverse reactions within the patient, it does nothing for clinical laboratory testing. As seen with high dose ascorbic acid therapy, medications may have unintended effects on laboratory tests. These effects are well documented within the clinical laboratory community. [12,14] To our knowledge, medications administered in burn patients during high-risk time periods correlated with the number of potential laboratory testing interferences (Table 1) present is not a well-studied interaction. The goal of this study is to quantify the number of medications administered to burn patients during this phase, identify potential drug interferences that may impact routine laboratory results, and provide recommendations to improve the safety of laboratory testing in burn patients.

METHODS

We conducted a retrospective chart review that was approved by our institutional review board. This review examined the medical records of 12 adult (age 18 years) burn patients with 20% total body surface area (TBSA) burns admitted to our facility from 2011 to 2012. Eligible patients required intensive insulin therapy (IIT) at admission and were part of an existing glycemic control database, which encompassed medical data from admission until the conclusion of IIT. Patient data was stratified into three groups: (a) 20 to 30%, (b)

31 to 60% and (c) 60 to 98% TBSA. Demographics and mortality data was collected. Daily multiple organ dysfunction score (MODS) was also included in our dataset. Medications dose, interval, and route of administration from the time of admission to discontinuation of intensive insulin therapy were recorded. Dosing in particular is included given the dose-dependent relationship of drug interferences on laboratory testing. The admission and intensive insulin therapy phases of burn care serve as high-risk time periods for these patients. Types of laboratory tests (*i.e.*, complete blood count, basic metabolic panel, comprehensive metabolic panel, blood gases, and urinalysis) were also documented. Interfering substances were defined as compounds that cause inaccurate results for laboratory tests and were identified based on established clinical laboratory reference documentation. [14] Parametric data analysis was performed using MiniTab software (MiniTab, Inc., State College, PA). The 2-sample *t*-test compared independent means and repeated measures one-way analysis of variance (ANOVA) compared means between the three burn groups. Post-hoc pairwise comparisons via the Tukey's HSD test were used for statistically significant ANOVA results. Tests for normality (Shapiro-Wilk) and nonparametric data analysis were performed using R statistical software (www.r-project.org). The Friedman test with repeated measures compared medians between the three burn groups.

RESULTS

Patients had a mean (SD) age of 37.9 (3.0) years, mean TBSA burn of 51.3% (9.3) and mean Multiple Organ Dysfunction Score (MODS) or 5.4 (0.2). Mortality was 8.3% (1/12 patients). Age, burn size, and MODS were similar ($P > 0.05$) between the three patient groups. Mean medications administered per day were 42.1 (9.5), and median medications administered were 49 with a daily range of 0 to 65 across all patients. A total of 666 potential interferences caused by medications administered were analyzed during intensive insulin therapy. Of these interferences, 261 were reported to have single discrete effects (*e.g.*, increased glucose). Multiple potential interferences, 71.0% (475/666), were caused by more than one administered medication. Clinically significant drug interferences on laboratory testing were documented in two patients. Both cases involved high dose ascorbic acid during acute burn resuscitation. The interference resulted in significant and erroneous increases in (mean [SD] bias: 84.5 [25.2] mg/dL, $P < 0.001$) point-of-care glucose meter results when compared to clinical laboratory methods unaffected by ascorbic acid therapy.

The most common sample types (*i.e.*, serum, plasma, and urine specimens) were affected the most by drug interferences (Figure 1). When the mean medications per day were compared across the three different burn size groups (Figure 2), no statistically significant difference ($P = 0.313$) in mean medications per day relative to burn size was observed. Performing the Shapiro-Wilks test for normality revealed the data in both the 20 to 30% and 31 to 60% groups were normally distributed, however the data in the 61 to 98% group was slightly skewed. Nonparametric analysis revealed a statistically significant ($P < 0.001$) increase in median medications per day with respect to increase in burn size. Additionally, no statistically significant difference in the number of medications administered at either admission ($P = 0.247$) or the end ($P = 0.483$) of intensive insulin therapy was found.

DISCUSSION

Treatment of burn patients requires a multitude medications and laboratory tests. Six hundred and sixty six potential interferences caused by medications administered at a mean rate of 42.1 (9.5) medications per day is a startling statistic. However, each of these medications serves a crucial purpose to ensure patients receive the best possible care. The potential impact of interfering substances on medical testing is well known in the field of laboratory medicine as shown by the volumes of reference material available to hospital laboratories and the rigorous validation of new medical tests through the United States Food and Drug Administration (FDA). Unfortunately, new drugs and laboratory tests are developed daily – making evaluation prior to clinical application for every drug and every test unrealistic.

Grouping patients into the 20 to 30%, 31 to 60%, and 61 to 98% TBSA stratifications allowed us to represent three at-risk populations. Intriguingly we found that this stratification of burn size did not reveal any significant differences in the mean number of medications administered per day. While we identified a significant difference in the median medications administered per day, nonparametric tests are more susceptible to Type I error (*i.e.*, falsely accepting the alternative hypothesis when the null hypothesis is true). Mortality and disease severity have been shown to increase with burn size, thus one would assume clinical complications requiring medication therapy or treatment would also increase. [15] However, there are few studies investigating this interesting topic. Further studies with larger sample sizes should ultimately be conducted to further explore the relationship of medication frequency and its relation to patient outcomes.

Beyond the few examples of medications that result in dangerous erroneous laboratory measurements including the two cases encountered in this retrospective review, most manufacturer, FDA, and peer-reviewed literature reports mild to moderate effects by the majority of interfering substances which may be statistically significant, but perhaps not clinically significant. Those that are clinically significant can unfortunately put patients at risk for dangerous glycemic excursions and poor outcomes. Based solely on ascorbic acid interference, the observed glucometer bias of 84.5 mg/dL places patients at risk for hypoglycemia. [3] Additional medications being present in the patients system can further exacerbate this effect including hydroxycobalamin, which are increasingly being used in burn patients with suspected cyanide poisoning. [16] When taking into account the increasing number of medications released to market annually and the resulting increase in new medication interactions; the subject of medication interference is clearly an exponentially growing matter. [17]

Burn physicians, pharmacists, nurses, and laboratorians cannot maintain an ever-expanding list of complex pharmacological interactions relative to clinical laboratory analyses. The role of laboratory medicine in burn care could prove valuable and improve not only the quality of care, but also the safety of medical testing. Enhanced understanding of burn physiology by laboratory experts with close partnerships with burn critical care specialists enables quick recognition of potential interferences and development of diagnostic solutions in this high-risk population. At our institution, the burn care team works closely with our laboratory

colleagues. This partnership has gone as far as to develop a rapid and dynamic system to obtain suspected interfering medications from the pharmacy to conduct real-time testing, confirm interferences, and quickly establish immediate solutions such as “priority one” plasma glucose testing in response to ascorbic acid interference on glucose meters. To date, the system has proven invaluable in identifying interfering substances including from the aforementioned high dose ascorbic acid therapy.

The reliance on human recognition of interfering substances is unfortunately not ideal. An innovative solution could lay in the use of electronic decision support tools. With the proliferation of electronic health record (EHR) and laboratory information systems (LIS), electronic decision support may provide unique opportunities to improve the safety of laboratory testing in high-risk patients. Medication administration records (MAR) within an EHR keep track of all the pertinent medication data. Laboratory test orders are sent via the EHR and are received by the LIS. Unfortunately, all three systems do not communicate effectively with one another and may not even display similar data. To this end, we recommend the creation of an automated tool within the EHR to act as a mediator between MAR and LIS that warns physicians about test results that may be affected by a currently administered medication.

While an upgrade to EHR systems would greatly enhance the quality of care for burn patients and other critically ill populations, we suggest going beyond EHR alerts. Ultimately *in vitro* diagnostics companies should develop laboratory tests that are robust to interfering substances. Similar endpoints have already been achieved for blood glucose monitoring systems (BGMS). Recent BGMS’s are designed to accurately measure blood glucose and automatically correct for interfering substances such as maltose, galactose, ascorbic acid, hematocrit, and high oxygen tension. [3,18,19] Enhanced performance of an autocorrecting BGMS during high dose ascorbic acid therapy, for example, was reported previously by our clinical studies in adult and pediatric burns and highlighting the value of robust biosensors for critical care. [3,20]

Limitations to our study include a small sample size of 12 patients. Additionally, the study was retrospective and at a single center. The use of medications and laboratory tests may vary between institutions. Lastly, our assessment focused from the time of admission until the conclusion of intensive insulin therapy.

CONCLUSIONS

The clinical impact of interfering substances on medical testing is well documented in laboratory medicine. These interferences have been shown to lead to erroneous measurements and impact patient care. Our study described the number of medications administered to burn patients and detailed potential laboratory test interferences that may lead to erroneous measurements. We recommend burn physicians work with laboratory personnel to identify potential interferences and define appropriate countermeasures. In parallel, laboratory personnel should work with burn care experts to improve their understanding of this unique critically ill population. Lastly, the development of intelligent electronic healthcare support tools capable of flagging potentially interfering drugs and

autocorrecting biosensors could perhaps one day adjust the values in the presence of interfering substances with no intervention needed.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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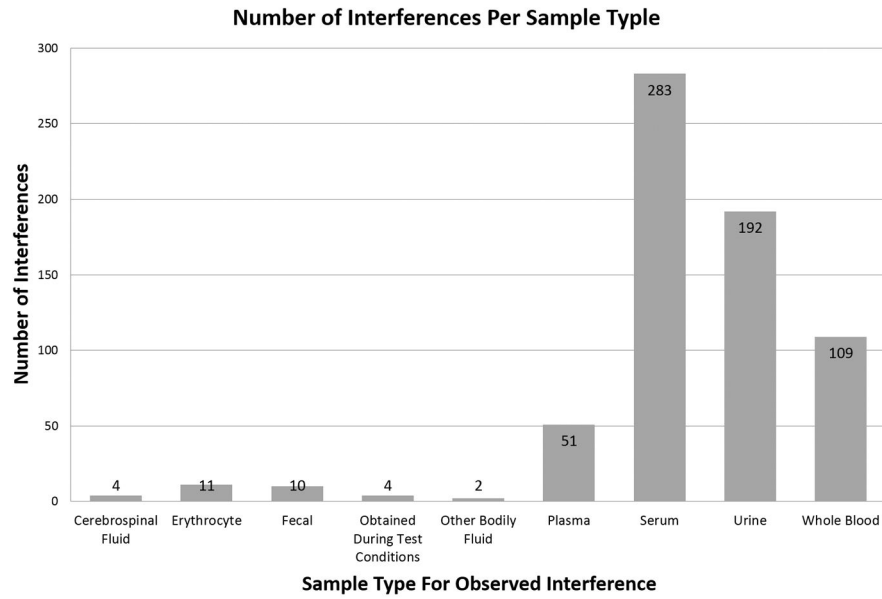
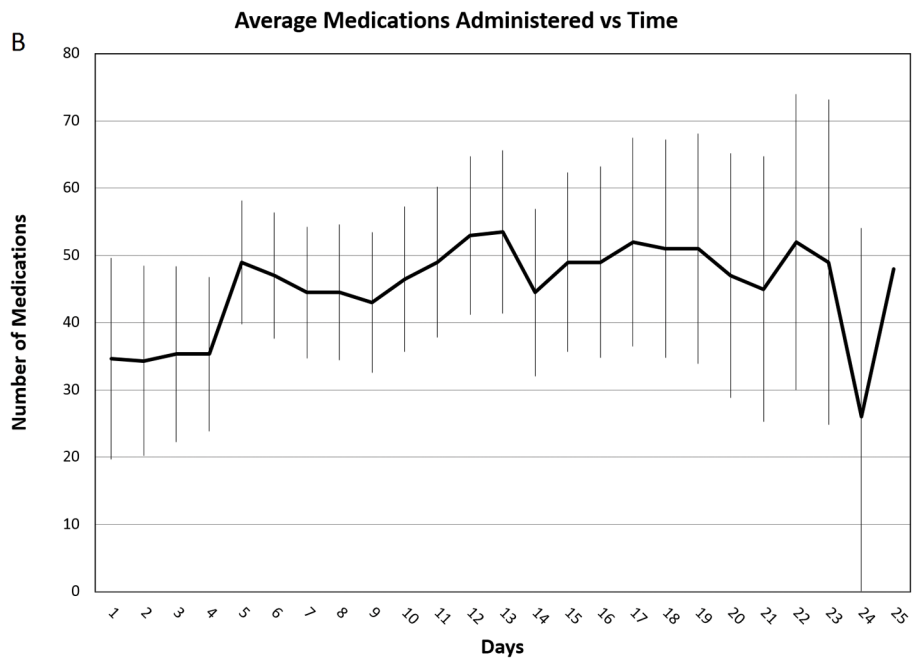
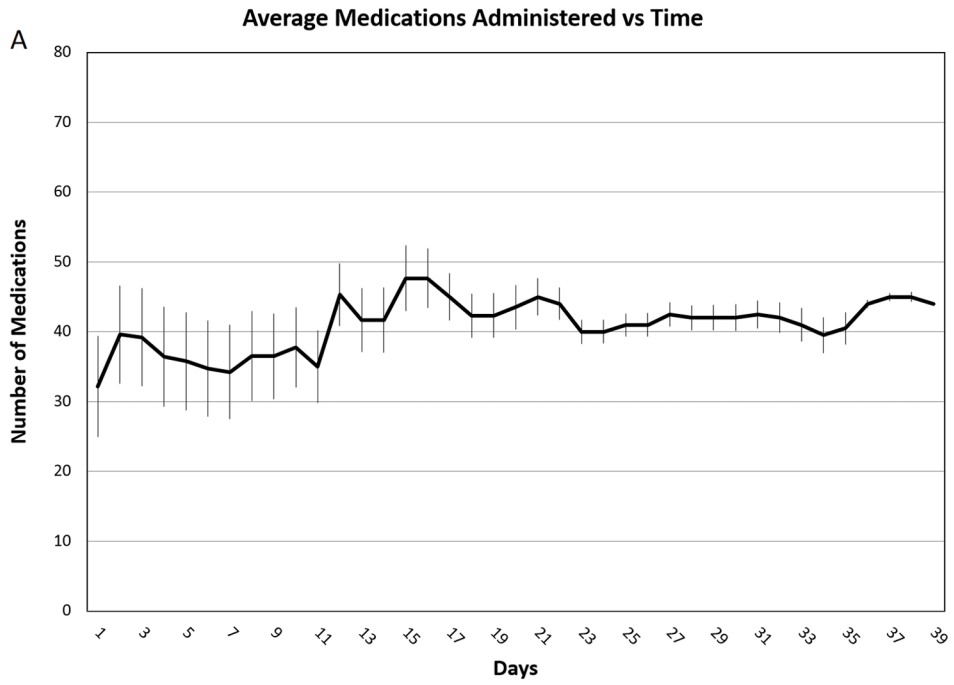


Figure 1. Number of Interferences per Sample Type

Illustrates the distribution of interferences amongst observed sample types. The most commonly used clinical samples types were found to contain the highest abundance of interferences. “Erythrocyte” refers to direct interference effects observed in red blood cells. “Obtained during test conditions” refer to interferences not seen clinically but observed in laboratory test conditions.



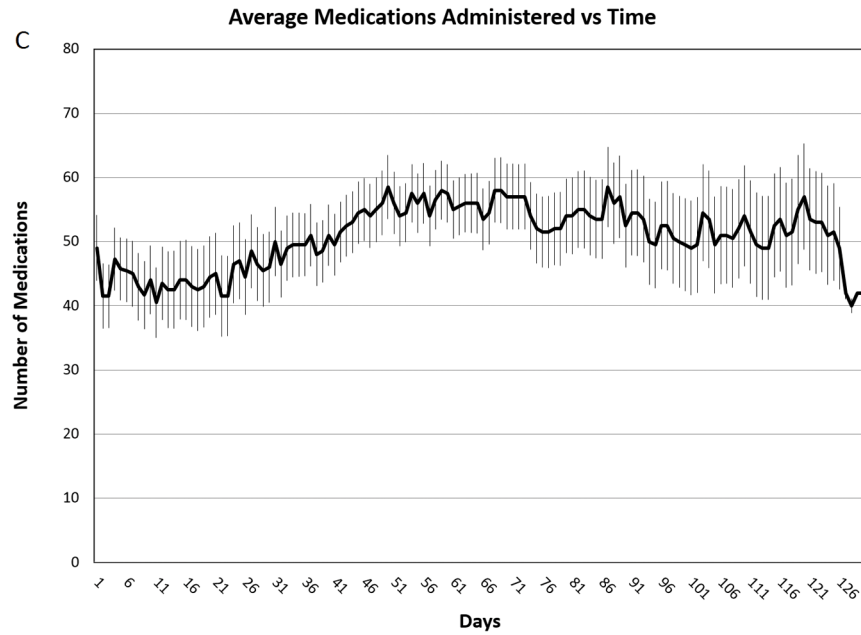


Figure 2. Average Medications Administered vs. Time
 Average medications administered per day throughout the course of intensive therapy. **Panel A:** Patients with 20–30% TBSA burns (n=5). **Panel B:** Patients with 31–60% TBSA burns (n=3). **Panel C** Patients with 61–98% TBSA burns (n=4). The error bars indicate standard deviations.

Table 1

Laboratory Interferences Caused by Administered Medications

Drug	Sample Type	Interference	Laboratory Effect
Acetaminophen	Serum	Uric Acid ↑	Falsely High Values With Phosphotungstate Methods
	Urine	Uric Acid ↑	Falsely High Values With Phosphotungstate Methods
Acetylsalicylic Acid	Cerebrospinal Fluid	Protein ↑	False + with Folin-Ciocalteu Reagent
	Serum	Albumin ↓	Decreased Dye Binding Capacity
	Serum	Barbiturate ↑	May Interfere with UV Spectrophotometry
	Serum	Calcium Bilirubin ↓	Depresses Fluorescence of Calcein Method
	Serum	Cholesterol ↑	Alleged Effect
	Serum	Uric Acid ↑	Acts as Reducing Substance with Non-Specific Methods
	Urine	Acetoacetate ↑	Reacts with Gerhardt Ferric Chloride Procedure
	Urine	Catecholamines ↑	Interfering Fluorescence in Many Procedures
	Urine	Dihydroxyphenylalanine Screen +	Light Amber Color Produced
	Urine	Fouchet Test +	Produces Purple Color
	Urine	Glucose ↓	Glucose Oxidase Methods Inhibited by Gentisic Acid
	Urine	Homogentisic Acid ↑	Interferes with Measurement Procedure
	Urine	Ketones ↑	Reddish Color with Gerhardt's Test
	Urine	Phenylketones +	Purple with Ferric Chloride, Purple with Phenistix
	Urine	Protein ↑	Interference with Folin-Ciocalteu Reaction
	Urine	Sugar ↑	False + with Clinitest or Benedict's
	Urine	Uric Acid ↑	Acts as Reducing Substance with Non-Specific Methods
	Urine	UA Sugar ↑	Conjugate May React with Benedict's
	Urine	Vanillylmandelic Acid ↑	Interferes with Fluoro-, Colorimetric Procedures
	Urine	17 Hydroxy Corticosteroids ↓	Conjugate Inhibits B-Glucuronidase, Dose > 4.8g/day
Albumin	Cerebrospinal Fluid	Protein ↓	Turbidity < Globulins With Sulfosalicylic Acid
	Serum	Thymol Turbidity ↑	If High
Ascorbic Acid	Fecal	Occult Blood Negative	Interferes with Analytic Methods
	Plasma	Catecholamines ↑	Concentrated Solutions Cause Striking Fluorescence
	Serum	Bilirubin ↑	At Therapeutic Concentration May Affect Sequential Multiple Analyzer 12/60 Method
	Serum	Creatinine ↑	Chromogenicity in Color Reaction (Acts as Reducing Agent)
	Serum	Glucose ↓	Slight Effect With Coupled Glucose Oxidase Method

Drug	Sample Type	Interference	Laboratory Effect
	Serum	Glucose ↑	At 1 mmol/L Affects Sequential Multiple Analyzer 12/60 Method
	Serum	Glucose ↑	Affects Alkaline Perricyanide Methods
	Serum	Lactic Dehydrogenase ↓	At Therapeutic Concentration May Depress Sequential Multiple Analyzer 12/60 Value
	Serum	SGOT↑	At 1 mmol/L Affects Sequential Multiple Analyzer 12/60 Method
	Serum	Uric Acid ↑	Measured as Reducing Substance
	ODTC	Protein ↑	Reacts With Folin-Ciocalteu of Lowry Procedure
	Urine	Creatine ↑	Acts as Reducing Agent
	Urine	Glucose ↓	Impaired Color Development of Chromogen in Glucose Oxidase Method
	Urine	Porphobilinogen ↓	Inhibition of Color Develop if No Prior Separation
	Urine	Sugar ↑	False + With Benedict's and Clinitest
	Urine	Uric Acid ↑	Measured as Reducing Substance
	Urine	UA Glucose ↓	May Inhibit Testapea and Clinistix
	Urine	UA Hemoglobin ↓	In Large Amounts Inhibits Guaic Test
	Urine	17 Hydroxy Corticosteroids ↑	Interferes With Method of Reddy
Calcium Gluconate	Serum	Magnesium ↓	False ↓ if Measured by Titan-Yellow
	Urine	Magnesium ↓	False ↓ if Measured by Titan-Yellow
	Urine	17 Hydroxy Corticosteroids ↓	Reduced Value Reported in a Single Case
Chloral Hydrate	Serum	Urea Nitrogen ↑	Reacts with Nessler Reaction
	Urine	Catecholamines ↑	Interferes with Fluorometric Procedures
	Urine	UA Sugar ↑	Excreted as Glucuronide, Reduces Benedict's
	Urine	17 Hydroxy Corticosteroids ↑	Interferes with Porter-Silber Reaction
Chlorpromazine	Cerebrospinal Fluid	Protein ↑	Reacts as if Phenol with Folin-Ciocalteu Reagent
	Serum	Glucose ↑	Abnormally High with Repeated Doses
	Serum	Vitamin B12 ↓	Possible Inhibition Effect on Some Strains of E. Gracilis
	ODTC	Urea Nitrogen ↑	Produces Turbidity with Berthelot's Reagent
	Urine	Metanephrines Total ↑	Interference in Pisano Procedure
	Urine	Phenylketones +	Light Purple with Ferric Chloride, Same with Phenistix
	Urine	Porphobilinogen ↑	Reacts with Ehrlich's Aldehyde Reagent
	Urine	Pregnancy Tests +	Gives False + with Frog, Rabbit and Immunology Test
	Urine	UA Bile ↑	Alleged Interference with Bili-Labstix
	Urine	UA Protein ↑	Affects Turbidity Tests For Up to 3 Days

Drug	Sample Type	Interference	Laboratory Effect
Copper	Urine	Urobilinogen ↑	Reacts with Ehrlich's Aldehyde Reagent
	Urine	17 Ketogenic Steroids ↑	Interferes with Zimmerman Reaction
	Urine	17 Ketosteroids ↑	Interferes with Zimmerman Reaction
	Urine	17 Hydroxy Corticosteroids ↑	Interferes with Porter-Silber Reaction
	Urine	5 Hydroxy Indoleacetic Acid ↓	Interferes with Method of Goldenberg
	Serum	Acid Phosphatase Total ↓	Cupric Ions Inhibit Red Cell Enzyme
	Serum	Calcium ↑	Interferes with Ethylenediaminetetraacetic Acid Titration Procedures
	Serum	Protein-Bound Iodine ↓	As Contaminant of Water May Affect Analysis
	Serum	Sodium ↑	May Interfere with Flame Photometry
	Urine	UA Color ↑	Blue Diapers (Alkaline Urine on Copper Fastenings)
Diazepam	Urine	UA Hemoglobin ↑	False + with Guaiac and Benzidine Tests
	Serum	Dihydroxyphenylalanine Screen Test +	Very Slight Purple Color Produced
	Urine	17 Ketosteroids ↓	Slight Effect on Zimmerman Reaction in Vitro
	Urine	17 Hydroxy Corticosteroids ↑	Moderate Effect with in Vitro Test
	Urine	Urobilin ↑	Produces Yellow-Green Fluorescence
	Whole Blood	Sedimentation Rate ↓	High Blood Sugar Lowers Sedimentation Rate
	Serum	Creatinine ↑	Interferes with Jaffe Reaction
	Serum	Osmolality ↑	Osmotically Active Constituent in Samples
	Serum	Uric Acid ↑	Reducing Substance Reacts with Phosphotungstate
	Urine	Estriol ↓	Interference with Gas Liquid Chromatography Method
Glucose	Urine	Osmolality ↑	Osmotically Active Constituent in Samples
	Urine	Xylose Excretion ↑	Interferes with Bromoaniline Procedure if Over 2g/100mL
	Urine	17 Ketogenic Steroids ↓	Interferes with Norymberski Reaction
	Urine	17 Ketosteroids ↓	Interferes with Zimmerman Reaction
	Plasma	Ammonia ↑	Contains Variable Amounts of Ammonium Salts
	Plasma	Corticosteroids ↑	If Contaminated by Impurities
	Plasma	Insulin ↓	Effect in Heparinized Plasma and Serum
	Plasma	Insulin ↑	Spuriously High Values Reported For Immunoassay
	Serum	Albumin ↑	Promotes Binding of Haba Dye to Globulins
	Serum	Bromosulphthalein Retention ↑	Color Intensity ↑ in Serum, Wavelength Shifted
Heparin	Serum	Calcium ↓	Interferes with EDTA and Fluorometric Methods

Drug	Sample Type	Interference	Laboratory Effect
	Serum	Calcium ↑	If Calcium Salt Used May Affect Result
	Serum	Creatine Phosphokinase ↓	Reported Effect
	Serum	Hydroxybutyric Dehydrogenase ↓	Significant Inactivation
	Serum	Lipoprotein Electrophor +	Alters Electrophoretic Pattern
	Serum	Phosphate ↑	Phosphate Contamination of Heparin Reported
	Serum	Sodium ↑	If Sodium Salt Used May Affect Result
	Serum	Thymol Turbidity ↑	Affects Physico-Chem Properties Altering Turbidity
	Serum	Zinc Sulfate Turbidity ↑	Affects Physico-Chem Properties
Hydroxyzine	Urine	17 Ketogenic Steroids ↑	Interferes with Zimmerman Reaction
	Urine	17 Hydroxy Corticosteroids ↑	Interferes with Porter-Silber Reaction
Lidocaine	Cerebrospinal Fluid	Protein ↑	Reacts with Folin-Ciocalteu Reagent
Magnesium Salts	Serum	Alkaline Phosphatase ↑	Activators of Enzyme in Laboratory Procedures
	Serum	Calcium ↑	Measured as Calcium in Some Ethylenediaminetetraacetic Acid Procedures
Mannitol	Serum	Phosphate ↓	Inhibition of Color Development
Metronidazole	Urine	UA Color ↑	Brown Color Probably Due to Metabolite
	Urine	Alkaline Phosphatase ↓	Interference with Determination Method
Nitrofurantoin	Urine	Lactic Dehydrogenase ↓	Interference with Determination Method
	Urine	Sugar ↑	Metabolites May Reduce Benedict's, Yield False +
	Urine	UA Color ↑	Brown, Yellow Color
Phenols	Urine	Phenylketones +	Violet with Ferric Chloride, Nil With Phenistix
	Urine	UA Color ↑	Dark Green to Brownish Black on Standing
Potassium	Serum	Calcium ↑	Affects Flame Photometry if Poor Instrument
	Serum	Sodium ↑	Affects Flame Photometry if Poor Instrument
Prochlorperazine	Urine	Phenylketones +	Light Purple with Ferric Chloride, Same with Phenistix
	Urine	17 Hydroxy Corticosteroids ↑	Interferes with Porter-Silber Reaction
Promethazine	Urine	Pregnancy Tests Negative	False Negative with Porter-Silber Reaction
	Urine	Pregnancy Tests +	False + with Gravindex
	Urine	17 Hydroxy Corticosteroids ↑	Interference With Porter-Silber Reaction
	Urine	5 Hydroxy Indoleacetic Acid ↓	Interference with Nitrosophthol Methods
	Urine	UA Protein ↑	False + with Labstix Due to High pH
Sodium Chloride	Serum	Bilirubin ↓	Inhibition of Diazo Test Reported

Drug	Sample Type	Interference	Laboratory Effect
Vitamin A	Serum	Bilirubin ↑	Interferes with Analysis
	Serum	Cholesterol ↑	Interferes with Zlatkis-Zak Reaction
	Serum	Direct Bilirubin ↑	Interferes with Analysis
Zinc	Urine	Magnesium ↑	Measured by Fluorometric Method of Schachter
Zinc Salts	Serum	Alkaline Phosphatase ↓	Inhibitors of Enzyme in Laboratory Procedures

SGOT: Serum Glutamic-Oxalacetic Transaminase; SGPT: Serum Glutamic-Pyruvic Transaminase; UA: Urinalysis; G6PD: Glucose-6-Phosphate Dehydrogenase; RBC: Red Blood Cell; ODTC: Obtained During Test Conditions; + = Positive