

Interferences from Endogenous and Exogenous Substances

Interferences from Endogenous Substances

(Substances produced or originating from within the body)

| Interfering Compound* | Clinical Significance | Physiological Levels (upper limit of normal) | Test Conc. | ONE TOUCH® Profile ONE TOUCH® Basic ONE TOUCH® II Hospital | SureStep® SureStep®Pro |
|-----------------------|--|---|------------|---|---|
| Bilirubin | A degradation product of heme that is excreted by the liver. Bilirubin is used to assess liver function. Increased levels are seen in liver cell damage due to inflammation, toxicity, or cancer. Increased levels are also seen with biliary tree obstruction. In infants, even in the absence of disease, the concentration of bilirubin increases following birth. The concentration peaks about the third to fifth day of life. | <i>Adults</i> 1.2 mg/dL (total) 0.2 mg/dL (conjugated) <i>Neonates</i> 12 mg/dL (total) | 20 mg/dL | NO INTERFERENCE at physiological levels up to test concentration | NO INTERFERENCE at physiological levels up to test concentration |
| Cholesterol | A substance (lipid) widely distributed in animal tissues; also found in egg yolks, various oils, fats, brain and spinal cord nervous tissue, the liver, the kidneys, and the adrenal glands. Cholesterol can be made by the liver or taken in through the diet. It is important in the synthesis of various hormones. Elevated blood cholesterol levels constitutes an increased risk of developing heart disease. | 300 mg/dL | 500 mg/dL | NO INTERFERENCE at physiological levels up to test concentration | NO INTERFERENCE at physiological levels up to test concentration |
| Creatinine | Produced by the muscle, creatinine is a measure of kidney function. Increased levels are found in advanced stages of renal disease. | 1.5 mg/dL | 30 mg/dL | NO INTERFERENCE at physiological levels up to test concentration | NO INTERFERENCE at physiological levels up to test concentration |
| Triglycerides | Compounds made of fatty acid molecules that constitute the storage form of lipid (fat). Triglycerides are the main energy reserve of the body. | 190 mg/dL | 3000 mg/dL | NO INTERFERENCE at physiological levels and levels ≤ 2500 mg/dL | NO INTERFERENCE at physiological levels up to test concentration |
| Uric Acid | Increased levels are seen in Gout, kidney failure, leukemia, and various types of cancer. Gout is caused by excessive amounts of uric acid in the blood. Urate crystals deposit in and around joints. Gout takes the form of acute arthritis and is marked by joint inflammation. Any joint may be affected but gout usually starts in the knee or foot. | 7 mg/dL | 20 mg/dL | NO INTERFERENCE at physiological levels up to test concentration | NO INTERFERENCE at physiological levels up to test concentration |

* As suggested by the Food and Drug Administration, Center for Devices and Radiological Health, document "Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostics Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology" 02/28/97.

^a Physiological level defined by the National Committee for Clinical Laboratory Standards. Interference Testing in Clinical Chemistry. Proposed Guidelines. NCCLS Document EP7-P, Vol. 6 No. 13.

See other side for exogenous substances.

Interferences from Exogenous Substances

(Substances originating from outside the body such as therapeutic agents or vitamins)

| Interfering Compound* | Clinical Significance | Therapeutic Levels | Test Conc. | ONE TOUCH® Profile ONE TOUCH® Basic ONE TOUCH® II Hospital | SureStep® SureStep®Pro |
|---------------------------------------|--|--|--------------------|---|---|
| Acetaminophen | Analgesic (relieving pain) but lacks anti-inflammatory properties. | 1–2 mg/dL ^a >15 mg/dL (toxic) >150 mg/dL (lethal) | 20 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Ascorbic Acid (Vitamin C) | Daily allowance of Vitamin C is 50–60 mg/day. It is necessary for collagen formation in connective tissue and required for maintaining the integrity of tissue, especially capillary walls. Although the effectiveness of Vitamin C for the prevention and treatment of the common cold has not been confirmed, some feel that Vitamin C may decrease the severity of cold symptoms. | 0.8–1.2 mg/dL ^a | 3 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Dopamine | Used in the treatment of some types of shock (cardiogenic, anaphylactic, and septic), profound hypotension, and severe heart failure. <i>Dopamine is also an endogenous compound present at physiological levels <87 pg/mL.</i> | Drug is usually diluted to 0.4–1.6 mg/dL and administered IV at a rate of 2–5 ug/kg per minute. ^b | 13 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels and levels <6 mg/dL; interference only at super therapeutic levels |
| Ephedrine | Used primarily as a nasal decongestant and in the treatment of asthma. | 0.005–0.01 mg/dL ^c >0.2 (toxic) | 10 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Gentisic Acid | Oxidative metabolite (breakdown product) of salicylate. Represents 1% of total breakdown products. | 3.5–5.0 mg/dL ^a | 50 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels and levels <10 mg/dL; interference only at super therapeutic levels |
| Ibuprofen | Non-Steroidal Anti-Inflammatory Drug (NSAID): suppresses signs and symptoms of inflammation, and reduces pain of mild to moderate intensity (analgesic). | 0.5–4.2 mg/dL ^a | 40 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| L-Dopa (Levo-Dopa) | Used in the treatment of Parkinson's Disease. Parkinson's disease is a chronic nervous disease defined by a fine, slowly spreading tremor, and muscular weakness and rigidity. | 0.02–0.3 mg/dL ^d at steady state during chronic 3–8 g PO dose | 100 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels and levels <20 mg/dL; interference only at super therapeutic levels |
| Methyl Dopa | Used as an antihypertensive (an agent that prevents or controls high blood pressure). | 0.1–0.5 mg/dL ^a >1.0 (toxic) | 2.5 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Salicylate (aspirin) | Active metabolite of aspirin. Non-Steroidal Anti-Inflammatory Drug (NSAID): suppresses signs and symptoms of inflammation, and reduces pain of mild to moderate intensity (analgesic). | 15–30 mg/dL ^a >40 (toxic) | 50 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Tetracycline | Most typical "broad-spectrum" antibiotic used in the treatment of a variety of bacterial infections. | 0.4 mg/dL ^a | 4 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Tolazamide (Tolamide, Tolinase) | Sulfonylurea or oral hypoglycemic which stimulates insulin secretion from the pancreas and increases the sensitivity of tissues to insulin. Controls hyperglycemia in persons with Type 2 diabetes who cannot achieve appropriate control with changes in diet. Duration of action: 10–14 hours. | 2.0–2.5 mg/dL ^d | 100 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Tolbutamide (Oramide, Orinase) | Sulfonylurea or oral hypoglycemic which stimulates insulin secretion from the pancreas and increases the sensitivity of tissues to insulin. Controls hyperglycemia in persons with Type 2 diabetes who cannot achieve appropriate control with changes in diet. Duration of action: 6–12 hours. | 5.3–10 mg/dL ^a >64 mg/dL (toxic) | 100 mg/dL | NO INTERFERENCE at therapeutic levels up to test concentration | NO INTERFERENCE at therapeutic levels up to test concentration |
| Preservatives | | | | | |
| Sodium Fluoride | Gray Top Tube; a 7 mL tube contains 17.5 mg sodium fluoride. | 500 mg/dL ^a | Blood drawing tube | Low glucose results | Produced strong negative effect |
| Sodium Citrate | Light Blue Top Tube; contains 0.105M (3.2%) or 0.129M (3.8%) sodium citrate. | 500 mg/dL ^a | Blood drawing tube | NO INTERFERENCE | NO INTERFERENCE |
| EDTA (K+) | Lavender Top Tube; a 10 mL tube contains 17.55 mg potassium EDTA. | 400 mg/dL ^a | Blood drawing tube | NO INTERFERENCE | NO INTERFERENCE |

* As suggested by the Food and Drug Administration, Center for Devices and Radiological Health, document "Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostics Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology" 02/28/97.

Therapeutic level defined by:

^a the National Committee for Clinical Laboratory Standards. Interference Testing in Clinical Chemistry. Proposed Guidelines. NCCLS Document EP7-P, Vol. 6 No. 13; ^b Goodman and Gilman's: The Pharmacological Basis of Therapeutics, 8th edition; ^c Tietz Textbook of Clinical Chemistry, 2nd edition; ^d Mayo Laboratory, Rochester, MN.