

**ASSURANCE™ DRUG Interference Test Kit** is for Laboratory Use as part of Interference testing procedures. Interferents available include: ACETAMINOPHEN, N-ACETYL-CYSTEINE, ACETYLSALICYLIC ACID, AMPICILLIN SODIUM, CEFOXITIN SODIUM, CYCLOSPORINE, DOXYCYCLINE HCL, HEPARIN, IBUPROFEN, LEVODOPA, METHYLDOPA, METRONIDAZOLE, PHENYLBUTAZONE, RIFAMPICIN, and THEOPHYLLINE. Components may be purchased individually, in customer-defined combinations, or as INT-04 (one vial of each component packaged in 2 boxes).

#### KIT COMPONENTS AND TYPICAL VALUES

Drug components and concentrations are based on recommendations by an expert panel<sup>1</sup> and the Clinical laboratory Standards Institute (CLSI).<sup>2</sup> The concentrations are 20 times the recommended test concentrations, allowing a 1:20 dilution with serum/urine pool.

Box	Interferent	Conc.	Volume Per Vial	Reorder Number
1	ACETYLCYSTEINE	60 mg/dL	1 mL	INT-04ACC
1	AMPICILLIN NA	150 mg/dL	1 mL	INT-04AMP
1	CEFOXITIN NA	13,200 mg/dL	1 mL	INT-04CEF
1	DOXYCYCLINE HCL	36 mg/dL	1 mL	INT-04DOX
1	THEOPHYLLINE	120 mg/dL	1 mL	INT-04THE
1	LEVODOPA	15 mg/dL	1 mL	INT-04LEV
1	METHYLDOPA	45 mg/dL	1 mL	INT-04MED
1	METRONIDAZOLE	246 mg/dL	1 mL	INT-04MET
2	ACETYLSALICYLIC ACID	60 mg/dL	1 mL	INT-04ASA
2	IBUPROFEN	438 mg/dL	1 mL	INT-04IBU
2	PHENYLBUTAZONE	642 mg/dL	1 mL	INT-04PHE
2	RIFAMPICIN	96 mg/dL	1 mL	INT-04RIF
2	CYCLOSPORINE	3.6 mg/dL	1 mL	INT-04CYC
2	ACETAMINOPHEN	312 mg/dL	1 mL	INT-04ACM
2	HEPARIN	66,000 U/L	1 mL	INT-04HEP
2	ETHANOL	100%	1 mL	INT-04E
<b>ASSURANCE™ Drug Interference Test Kit</b>			<b>1 vial of each</b>	<b>INT-04</b>

#### PROCEDURAL NOTES

Rifampicin may settle out of solution. Vortex for 10 seconds before use.

#### REAGENTS

This product is prepared from purified chemicals. Human source materials are not used.

Interferent	Matrix	Interferent	Matrix
ACETYLCYSTEINE	Aqueous	ACETYLSALICYLIC ACID	Ethanol
AMPICILLIN NA	Aqueous	IBUPROFEN	Ethanol
CEFOXITIN NA	Aqueous	PHENYLBUTAZONE	Ethanol
DOXYCYCLINE HCL	Aqueous	RIFAMPICIN	Ethanol
THEOPHYLLINE	Aqueous	CYCLOSPORINE	Ethanol
LEVODOPA	Aqueous	ACETAMINOPHEN	Aqueous
METHYLDOPA	Aqueous	HEPARIN	Aqueous
METRONIDAZOLE	Aqueous	ETHANOL	Ethanol

#### NONREACTIVE INGREDIENTS

Ethanol

#### PRECAUTIONS AND WARNINGS

Dispose of all waste material in accordance with requirements of your local waste management regulations.

#### STORAGE AND STABILITY

This product will be stable until the expiration date when stored at -10 to -20°C. After use, refreeze promptly. A maximum of 4 Freeze/Thaw cycles is recommended. **Cefoxitin, Levodopa, Cyclosporine, and Rifampicin** are sensitive to light and may degrade more quickly than other components. Ensure proper storage and limit exposure time.

#### LIMITATIONS

- INT-04 should not be used past the expiration date listed on the kit box. Refer to Interferent vials for expiration of individually purchased components or custom kit configurations.
- If there is evidence of microbial contamination discard the vial.
- This product is not intended for use as a control, standard or calibrator.
- Information gathered from experiments performed using ASSURANCE™ Interference Test Kits should not be used to

adjust patient results. Confirm results with an alternate method when necessary.

Sample Interference Testing procedure (based on CLSI EP-7A guidelines) and results reporting spreadsheet are available at [www.sundiagnosics.us](http://www.sundiagnosics.us) or email [support@sundiagnosics.us](mailto:support@sundiagnosics.us).

#### References:

- Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendations of drugs and their concentrations to be used in drug interference studies. *Ann Clin Biochem* 2001; 38:376-385.
- Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition*. CLSI document EP7-A. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania 2018.
- CLSI. Supplemental Table for Interference Testing in Clinical Chemistry, 1<sup>st</sup> Edition. CLSI Supplement EP37. Clinical and Laboratory Standards Institute, 2018.

Symbols Used			
	Storage Temp		Lot Number
	Protect from light		Consult Package Insert
	Manufacturer		Reorder Number
	Expiration	<b>ASSURANCE™ Interference Test Kit is a general purpose reagent intended for laboratory use. CE marking not required</b>	