INT-05: DRUG INTERFERENCE TEST KIT

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ASSURANCE™ DRUG Interference Test Kit INT-05 is for Laboratory Use as part of Interference testing procedures. Interferents available include: METACLOPRAMIDE HCL, PROCHLORPERAZINE, DEXAMETHASONE, CIPROFLOXACIN, FAMOTIDINE, DIPHENHYDRAMINE HCL, FUROSEMIDE, PAMIDRONATE, TAMOXIFEN, EVEROLIMUS, ATORVASTATIN, GABAPENTIN, GLIPIZIDE, and LEVOTHYROXINE. Ethanol, 0.2% DMSO, and/or 0.1N NaOH may be included as blanks (see Table in REAGENTS section.) Components may be purchased individually or in customer-defined combinations.

KIT COMPONENTS AND TYPICAL VALUES

Drug components and concentrations are based on recommendations by the Clinical laboratory Standards Institute (CLSI).[1] The concentrations are 20 times the recommended test concentrations, allowing a 1:20 dilution with serum/urine pool.

Part Number	Name	20X Product Concentration
INT-05MET	Metoclopramide	30 µmol/L
INT-05PRO	Prochlorperazine	53.4 µmol/L
INT-05DEX	Dexamethasone	30.6 µmol/L
INT-05CIP	Ciprofloxacin	604 µmol/L
INT-05FAM	Famotidine	35.6 µmol/L
INT-05DIP	Diphenhydramine	392 µmol/L
INT-05FUR	Furosemide	3620 µmol/L
INT-05PAM	Pamidronate	156.6 µg/mL
INT-05TAM	Tamoxifen	80 µmol/L
INT-05EVE	Everolimus	900 ng/mL
INT-05ATO	Atorvastatin	12000 µg/l
INT-05GAB	Gabapentin	10520 mol/L
INT-05GLI	Glipizide	89.6 mol/L
INT-05LEV	Levothyroxine	25.8 mol/L
INT-05D	0.2% DMSO	As Control
INT-04E	100% Ethanol	As Control
INT-01N	0.1N NaOH	As control

REAGENTS

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

Interferent	Matrix
Metoclopramide	Aqueous
Prochlorperazine	Aqueous, 0.2% DMSO
Dexamethasone	Ethanol
Ciprofloxacin	Aqueous
Famotidine	Aqueous
Diphenhydramine	Aqueous
Furosemide	Ethanol
Pamidronate	Aqueous
Tamoxifen	Ethanol
Everolimus	Ethanol
Atorvastatin	Aqueous, 0.2% DMSO
Gabapentin	Aqueous
Glipizide	0.1N NaOH
Levothyroxine	0.1N NaOH

NONREACTIVE INGREDIENTS

Ethanol, DMSO

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 2 Freeze/Thaw cycles is recommended. **Dexamethasone, Furosemide, Tamoxifen, and Atorvastatin** are sensitive to light and may degrade more quickly than other components. Ensure proper storage and limit exposure time.

LIMITATIONS

- 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.sundiagnostics.us or email support@sundiagnostics.us.

References:

1. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry; Approved Guideline–Second Edition*. CLSI document EP7-A2 (ISBN 1-56238-584-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

Symbols Used			
-20°C -10°C	**Storage Temp**	LOT	**Lot Number**
	Protect from light		**Consult Package Insert**
	Manufacturer	REF	**Reorder Number**
	Expiration	**ASSURANCE™ Interference Test Kit is a general purpose reagent intended for laboratory use. CE marking not required**	