ASSURANCE™ INTERFERENCE TEST KIT

Sun Diagnostics

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ASSURANCE™ Interference Test Kit is for Laboratory Use as part of Interference testing procedures. Interferents available include: TRIGLYCERIDE-RICH LIPOPROTEINS, HEMOLYSATE, TOTAL PROTEIN, CONJUGATED BILIRUBIN, UNCONJUGATED BILIRUBIN., and 0.1N NaOH as the base for Unconjugated Bilirubin. Components may be purchased individually, in customer-defined combinations, or as INT-01 (one vial of each component).

KIT COMPONENTS AND TYPICAL VALUES

Interferent	Typical Concentration	Volume Per Vial	Reorder Number
Triglyceride-rich lipoproteins	>15,000 mg/dL	1 mL	INT-01T
Hemolysate	>10,000 mg/dL hemoglobin	1.4 mL	INT-01H
Protein	>10 g/dL albumin >10 g/dL γ-globulins	1.4 mL	INT-01P
Conjugated Bilirubin	>400 mg/dL	1 mL	INT-01B
Unconjugated Bilirubin	>400 mg/dL	1 mL	INT-01BU (Includes Unconjugated bilirubin and NaOH)
NaOH (for Bu; spike into control pool)	0.1N	1 mL	
ASSURANCE™ Interference Test KIt		**1 vial of each component**	**INT-01**

REAGENTS

This product is in part prepared from purified chemicals and constituents of human origin, as follows:

Component	Origin
Triglyceride-rich lipoproteins	Human
Red blood cell hemolysate	Human
Albumin	Human
Gamma Globulins	Human
Conjugated Bilirubin	Purified Chemical
Unconjugated Bilirubin	Porcine
NaOH	Purified Chemical

NONREACTIVE INGREDIENTS

None

PRECAUTIONS AND WARNINGS

WARNING: Potentially Bio-hazardous

Human source material is considered potentially bio-hazardous. This material was tested for communicable diseases (HIV, Hepatitis B and Hepatitis C) with kits approved by the FDA (where available) and found to be negative (non-reactive). Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

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

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. Bilirubin is sensitive to light and oxygen and may degrade more quickly than other components. Ensure proper storage and limit exposure time.

Symbols Used			
	Biohazard	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**	
-10°C -20°C	**Storage Temp**		

LIMITATIONS

- Care should be used when evaluating assays for interference using native, human-sourced materials:
  - Triglyceride-rich lipoprotein (TRL) material may contain background constituents, such as sucrose or glucose, which may react with glucose assays and erroneously indicate interference from TRL.
  - Human albumin may bind cations (such as calcium, sodium, potassium, or magnesium), iron, thyroxine, fatty acids, bilirubin, and homocysteine.
  - Drug and drug metabolites may bind to albumin, gamma-globulins, and lipoproteins.
- Typical concentrations are intended as a guide only. **Laboratory should determine actual values before proceeding with interference experiment(s).**
- INT-01 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 Kit 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), dilution calculator and results reporting spreadsheet are available at www.sundiagnostics.us or email support@sundiagnostics.us.