



Simplifying Interference Testing



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ASSURANCE™ RF Interference Test Kit is for Laboratory Use as part of Interference testing procedures. Interferents available include: Rheumatoid Factor (RF) positive plasma at various concentrations. Components may be purchased individually, in customer-defined combinations, or as INT-03 (five vials of RF Interferent, from individual donors, at different concentrations).

KIT COMPONENTS AND TYPICAL VALUES

RF Interferent Lot Number	Expiration Date	Typical Value Rate Nephelometry (Beckman Immage)	Typical Value Immunturbidimetry (Randox)
0108614	2015-03-31	5300 IU/mL	1885 IU/mL
0208614	2015-03-31	3450 IU/mL	1049 IU/mL
0308614	2015-03-31	4830 IU/mL	1921 IU/mL
0408614	2015-03-31	9545 IU/mL	2659 IU/mL
0508614	2015-03-31	9695 IU/mL	2298 IU/mL
ASSURANCE™ RF Interference Test Kit		1 vial at each of 5 concentrations	Reorder Number: INT-03

REAGENTS

This product is prepared from constituents of human origin, as follows:

Component	Origin
RF	Human Plasma

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. Ensure proper storage and limit exposure time.

LIMITATIONS

- Care should be used when evaluating assays for interference using native, human-sourced material.
- Typical concentrations are intended as a guide only.
- INT-03 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 and results reporting spreadsheet are available at www.sundiagnosics.us or email support@sundiagnosics.us.

Symbols Used					
	Biohazard		Lot Number		Expiration
	Manufacturer		Consult Package Insert		Storage Temp
	Reorder Number	Note: ASSURANCE™ RF Test Kit is a general purpose reagent intended for laboratory use. CE marking not required			