



# Sun Diagnostics, LLC. 60 Pineland Drive Brunswick Hall, Suite 322 New Gloucester, ME 04260

Toll free: 1-877-786-3424 www.sundiagnostics.us

ASSURANCETM 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

Interference Test Kit		at each of 5 concentrations	INT-03
ASSURANCE™ RF		1 vial	Reorder Number:
0523518	2020-02-29	1,740 IU/mL	1,676 IU/mL
0423518	2020-02-29	1,770 IU/mL	2,195 IU/mL
0323518	2020-02-29	1,710 IU/mL	2,010 IU/mL
0223518	2020-02-29	1,830 IU/mL	1,915 IU/mL
0123518	2020-02-29	1,820 IU/mL	2,002 IU/mL
Lot Number		(Beckman Immage)	(Randox)
Interferent	Date	Rate Nephelometry	Immunoturbidimetry
RF	Expiration	Typical Value	Typical Value

#### 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 biohazardous. 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 <a href="https://www.sundiagnostics.us">www.sundiagnostics.us</a> or email <a href="mailto:support@sundiagnostics.us">support@sundiagnostics.us</a>.

Symbols Used							
<b>⊗</b>	Biohazard	LOT	Lot Number	Ω	Expiration		
<b></b>	Manufacturer		Consult Package Insert	-20°C -10°C	Storage Temp		
REF	Reorder Number	Note: ASSURANCE™ RF Test Kit is a general purpose reagent intended for laboratory use. CE marking not required					