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ASSURANCE™ HAMA Interference Test Kit is for Laboratory Use as part of Interference testing procedures. Interferents available include: Human Anti-Mouse Antibody (HAMA) positive serum at various concentrations. Components may be purchased individually, in customer-defined combinations, or as INT-02 (five vials of HAMA Interferent, from individual donors, at different concentrations).

KIT COMPONENTS AND TYPICAL VALUES

ASSURANCE™	1 vial of HAMA-	Reorder Number:	
HAMA	positive human	INT-02HAMA	
Interferent	serum		
ASSURANCE™	5 vials	Reorder Number:	
HAMA	1 each of 5	INT-02	
Interference	individual HAMA-		
Test Kit	positive Serum		
	Samples		

REAGENTS

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

Component	Origin	
HAMA	Human Serum	

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.
- INT-02 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.sundiagnostics.us or email support@sundiagnostics.us.

⊗	Biohazard	LOT	Lot Number
Ţ <u>i</u>	Consult Package Insert	-20°C \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Storage Temp
ш	Manufacturer	REF	Reorder Number
Σ	Expiration		