



Ortho Diagnostic Systems Limited

a ~~Johnson & Johnson~~ company

Enterprise House, Station Road
Loudwater, High Wycombe
Bucks HP10 9UF

Telephone: High Wycombe (0494) 442211
Facsimile: High Wycombe (0494) 461006
Telex: 837884

Registered in England No. 688260
Registered Office: Address as shown
*Trademark

11th January, 1991

Dear Dr. Barbara,

In order that I can ship you the Second Generation RIBA-HCV assay for clinical evaluation, I am required by the U.S. Food and Drug Administration to have you sign and return the attached declaration.

Could you please return this to me as soon as possible in order that I can arrange shipment.

Yours sincerely

GRO-C

PETER SAVAGE
Marketing Manager -
Infectious Diseases/Immunology

Enclosed:

MAIN/ 1551

~~NLN/ 9084~~

NHBT0000191_011_0001



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PLEASE TYPE OR PRINT CLEARLY

DECLARATION OF USE

RIBA-HCV Test System

Customer Telephone Number: GRO-C Ortho Customer#:.....

Researcher's Name: . Dr. J. A. J. BARBARA

Researcher's Title: North London *Head of Microbiology*

Institution: Blood Transfusion Centre,
Colindale Avenue,
London NW9 5BG

Address:

Telephone: *on am*

I, *JOHN BARBARA* (researcher), representing
NBCTC (name if institution),

understand that RIBA HCV TEST SYSTEM, SECOND GENERATION has not been approved by the U.S. Food and Drug Administration, and hereby agree to follow all applicable federal rules and regulations pertaining to the use of "Research Use Only" test kits. I agree that this product will be used only for research purposes, and the research nature of the product, and test data resulting from its use, will be clearly indicated on all data reports. I further understand that data collected from the use of this product must be made available to the U.S. Food and Drug Administration and/or Ortho Diagnostic Systems Inc. if requested. Ortho Diagnostic Systems Inc. reserves the right to discontinue supplying "Research Use Only" product if the above guidelines are not followed.

INVESTIGATOR (print or type): *DR. J. BARBARA*

(sign): GRO-C Date: *14 MAY 91*

Expected usage. ☒ Tests per month: *?*

Brief description of study objectives:

Comparison of effectiveness of 1st & 2nd generation RIBAs