



National Headquarters
Washington, DC 20006

March 4, 1986

Dear John,

In response to your February 17, 1986 query about anti-HBc testing, I am enclosing a copy of a communication issued to all Red Cross regional blood services that indicated that American Red Cross will not make changes in donor testing directives at this time.

We are conducting a review of the subject of anti-HBc/ALT donor testing at national headquarters on March 7, 1986. I'll send you an update on our position after that review.

With best regards,

Sincerely,

GRO-C

S. Gerald Sandler, M.D.
Associate Vice President
Medical Operations

John D. Cash, M.D.
National Medical Director
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American Red Cross

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GRO-C	
ORIGINATOR DR. SANDLER	EXT GRO-C
DATE 2/20/88	TIME

FROM:

S. GERALD SANDLER, M.D., ASSOCIATE VICE PRESIDENT,
MEDICAL OPERATIONS, ARC NHQ

TO:

DIRECTORS; MEDICAL DIRECTORS; ADMINISTRATORS;
DIRECTORS, TECHNICAL SERVICES

RE: ANTI-HBC TESTING

AS ANNOUNCED PREVIOUSLY, NATIONAL HEADQUARTERS HAS CONDUCTED A REVIEW OF CURRENT INFORMATION ON THE SUBJECT OF SURROGATE TESTS (ANTI-HBC/ALT) FOR THE PREVENTION OF NON A, NON B POSTTRANSFUSION HEPATITIS. IN CONSIDERATION OF UNRESOLVED SCIENTIFIC ISSUES THAT WERE RAISED DURING THIS REVIEW, THE AMERICAN RED CROSS WILL NOT INITIATE CHANGES IN BLOOD SERVICES DIRECTIVES FOR TESTING DONATED BLOOD AT THIS TIME. TO CLARIFY THESE ISSUES, NATIONAL HEADQUARTERS STAFF WILL CONTINUE TO WORK WITH FDA OFFICIALS, LEADERSHIP OF OTHER BLOOD COLLECTION ORGANIZATIONS

AND SCIENTISTS IN THE FIELD. ALSO, IN RESPONSE TO A RECOMMENDATION BY THE CENTER DIRECTORS COUNCIL, AN AD HOC PANEL OF REGIONAL BLOOD SERVICES DIRECTORS AND OTHER SCIENTISTS WILL DESIGN RESEARCH STUDIES TO OBTAIN DATA NECESSARY FOR FURTHER PLANNING IN THIS AREA. ROGER Y. DODD, PH.D., HEAD, TRANSMISSIBLE DISEASES LABORATORY, BIOMEDICAL RESEARCH AND DEVELOPMENT, NATIONAL HEADQUARTERS, WILL COORDINATE THIS PROCESS AND WILL REPORT TO REGIONS ON THIS SUBJECT IN THE NEAR FUTURE. SUMMARIES OF RELEVANT DISCUSSIONS AT MEETINGS OF THE CENTER DIRECTORS COUNCIL AND THE FDA BLOOD PRODUCTS ADVISORY COMMITTEE, AS WELL AS A REPORT OF THE SYSTEMWIDE ANTI-HBC STUDY, ARE IN PREPARATION FOR DISTRIBUTION TO REGIONAL BLOOD SERVICES.

WITH REFERENCE TO THE PREPARATION OF OPERATING BUDGETS FOR FY 1986-87, REGIONS SHOULD PREPARE AN ADDENDUM WHICH IDENTIFY THE SURCHARGE LEVEL THAT WOULD BE NECESSARY TO RECOVER EXPENSES RELATED TO SURROGATE TESTING SHOULD ANY CHANGES IN DONOR MANAGEMENT OCCUR WITHIN THE NEXT 16 MONTHS. A GUIDELINE FOR THE PREPARATION OF THIS ADDENDUM WILL BE DISTRIBUTED BY MR. ARNOLD DEBEAUFORT, DIRECTOR, FINANCIAL MANAGEMENT, WITHIN THE NEXT WEEK.

S. GERALD SANDLER, M.D.
ASSOCIATE VICE PRESIDENT

bcc: Med Ops Management Group
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