

NORTH LONDON BLOOD TRANSFUSION CENTRE

MINUTES OF MEETING HELD ON 13TH APRIL 1989

Anti HCV screening with ORTHO ELISA.

IN ATTENDANCE: Mr P Savage
Dr J A Barbara
Dr A Raafat

1. Mr Savage reported that at a recent meeting in Raritan, New Jersey, from which he had just returned, much interest was expressed regarding our protocols; particularly the paired donor recipient study, as similar studies will not be feasible in the US at this stage.
2. He also provided a leaflet entitled "ORTHO HCV anti-body ELISA test system." A copy of this is enclosed. Some of the questions raised at the previous meeting at NLBTC were dealt with in this leaflet.
3. Results of the US Studies.
 - 3.1. Pre clinical studies:
New York study
initial reactive 1.4%
repeat reactive 1.2%
Kansas City 1% (? repeat reactive)
 - 3.2. Clinical Study:- (Alter's panel). (Please see the leaflet.)
About 80% correlation.
4. Significance of Positive anti-HCV test result:-
 - 4.1. Infectivity: it is thought that a positive result denotes infectivity. This is corroborated by Alter's Panel results.
 - 4.2. Protectivity: a positive anti-HCV is probably not analagous to a positive anti-HBS, i.e. it confers no protection against the virus.
 - 4.3 Whether the antibody is directed against the viral capsid or against core antigens is not known.
 - 4.4 No information was available regarding the prognostic implications of a positive result in an individual.
 - 4.5 The degree of correlation with transmission of PTH was dependent on duration of transaminase peak. In 80% of cases where ALT peak was sustained > 1/52 donors with positive anti-HCV were involved.
5. Initial versions of the kit: repeat-reactive rates (see above 3.1).

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6. Equipment:

- 6.1. ORTHO will provide a computer, reader, washer and software.
- 6.2 Although HCV testing should be feasible with other systems, SLT will be employed in this trial site to ensure comparability with US trials.
- 6.3 ORTHO will modify the software according to the recommendations made here (e.g. histogram capability etc).
- 6.4 UK results will be analysed locally and not in USA.

7. Kits:

- 7.1 Although the format is not approved, the possibilities are a) solid plates, b) removable strips, c) removable sections.
- 7.2 Packaging, i.e. number of plates per pack, is also not finalized.
- 7.3 JAB suggested a combination of a) and b) in each pack in the ratio of 5:1.
- 7.4 Wells are flat bottomed (12 x 8 rows).

8. Reproducibility:

US studies showed very good reproducibility between the centres and from lot to lot.

- 9. A new agreement with ORTHO would require all publications of the generated data to be subject to ORTHO's approval although no restrictions are envisaged.
- 10. 2 forthcoming Scientific publications are expected within a month in Science. (N.B. now published: Science, 244, 21 April 89, 359-364.)
- 11. There is no information on the effect of heating on the serum test performance. The UK study might address this, if there are sufficient assays available.
- 12. No difference was found between anti-HCV test results on serum or plasma.
- 13. Only very old samples which have undergone multiple freeze-thaw cycles were unsuitable for testing.
- 14. The cut-off was fairly clear, with only a small number of samples in the grey zone.
- 15. Confirmation:
 - 15.1 A positive result would require re-testing in duplicate.

15.2 CHIRON will devise a protocol for a confirmatory test (? Westernblot, ? RIA) via ORTHO. Exact criteria for access to this test were not defined.

We have the option to have 'positive' and 'borderline' samples sent to CHIRON for further testing.

16. ORTHO will supply a 'one-off' proficiency panel and also a reproducibility panel.

Proficiency panel: 4 negative samples (0.5 ml each)
 4 positive samples (0.5 ml each)

Reproductivity panel: 3 sample dilutions (1 ml each)

In view of the limited quantity of sera available for proficiency and reproducibility panels, it may be worthwhile to supplement these with our own internal Q.C. samples from our donors implicated in transmitting NANBH and possibly from samples of recipients.

17. Kits will be available early in May, but equipment may take longer to arrive.

18. Next meeting date not finalised.

AR/JAB/ME
19th April 1989

DISTRIBUTION: Dr M CONTRERAS
 MR P SAVAGE
 (DR H H GUNSON, for information)
 (DR I FRASER " ")
 (DR D LEE " ")
 (DR RANASINGHE " ")

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