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ITEM 32(i) OF

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SNBTS/NIBTS MICROBIOLOGICAL QA GROUPEVALUATION OF ALT TESTING - FINAL REPORT1. INTRODUCTION

This report presents data obtained in a multi-centred evaluation of the Eppendorff Epos system supplied by BDH. This equipment was chosen for evaluation following a preliminary investigation of several systems undertaken by the Glasgow and West of Scotland Blood Transfusion Service.

The system had been demonstrated at Law BTS to members of the Microbiological QA Group and there was general agreement that this machine was likely to prove suitable for routine testing.

BDH supplied each Centre with the complete system including all necessary reagents. A full description of the equipment and reagents supplied can be found in the report by I McVarish and A Barr, November 1987.

2. RESULTS2.1 Ease Of Use

The equipment was found to be simple to use and there was no reason to doubt its reliability. Reproducibility was found to be excellent.

2.2 Inter-Centre Comparability

Each Centre used the same reagents and so the data supplied from each region should be directly comparable. This data is summarised in Table 1. Each Centre supplied data on the proportion of donors tested with ALT values above cut-offs ranging from > 31 iu/L to > 100 iu/L. It will be noted that this data is similar from Centre to Centre.

Further population statistics are available from four Centres who provided information on the mean ALT value and the upper and lower limits of normal. It should be noted that the mean and standard deviations were calculated from the Log of each individual ALT value. The upper and lower limits are calculated as follows:

Lower Limit :- Antilog of (Log Mean - 2 SD)
Upper Limit :- Antilog of (Log Mean + 2 SD)

It will be noted that the upper Limits of normal for each of the four Centres are remarkably similar.

2.3 National Data Compilation

As there was relatively little inter-Centre variation, it was considered reasonable to calculate national data for each parameter. This data is presented in Table 2. The data in this table was calculated from all of the original raw data. Thus, the large number of assays from Glasgow will influence the data more strongly than the lower number of assays performed in Dundee. This is considered the most valid calculation of the premise is accepted that there is no inter-regional variation.

It will be seen from Table 3 that the national mean (calculated from data from four Centres) is 10.2 iu/L. Various cut-off values have been proposed for use when screening blood donors. These have included mean plus 2, 2.25 or 2.5 standard deviations. These cut-off values were calculated from the mean data and are also listed in Table 3.

3. SUMMARY/CONCLUSIONS

- 3.1 If the SNBTS/NIBTS decides to introduce ALT testing, then the Epos system would clearly prove suitable. The purchase of a common system would clearly be of advantage in terms of ensuring comparability of data and ease of establishing National Quality Control Schemes.
- 3.2 There are no apparent inter-regional differences and the establishment of a common cut-off should be a relatively straightforward exercise. A cut-off of mean + 2.5 SD would lead to the exclusion of approximately 1.5% of donations whereas, mean + 2.0 SD would lead to the exclusion of approximately 5%.

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TABLE 1

SUMMARY OF ALT DATA FROM EACH REGION

	C E N T R E					
	GLASGOW	EDINBURGH	NORTHERN IRELAND	DUNDEE	INVERNESS	ABERDEEN
NUMBER TESTED	5,000	1,284	1,706	796	924	1069
MEAN ALT VALUE	7.8	14.8	N/A	N/A	15	17.05
NORMAL RANGE						
LOWER	1.37	4.57	N/A	N/A	4.74	5.7
UPPER	44.7	48.1	N/A	N/A	47.5	45.6
% Above Cut-Off						
> 31 iu/L	10.5	10.5	15.65	11.73	9.2	7.6
> 41	5.3	5.5	6.95	4.73	3.6	3.4
> 51	2.8	3.2	4.05	2.36	1.4	2.5
> 61	1.8	1.9	1.95	1.24	1.0	1.8
> 71	1.1	1.1	1.05	0.49	0.8	1.3
> 81	0.8	0.7	0.75	0.37	0.6	0.7
> 91	0.6	0.7	0.25	0.25	0.2	0.5
> 101	0.4	0.4	0.15	0.25	0.1	0.1

TABLE 2COMBINED ALT DATA FROM ALL CENTRES

NUMBER TESTED	:	10,799
PERCENT > 31 iu/L	:	11.0 %
> 41 iu/L	:	5.2 %
> 51 iu/L	:	2.9 %
> 61 iu/L	:	1.7 %
> 71 iu/L	:	1.0 %
> 81 iu/L	:	0.7 %
> 91 iu/L	:	0.5 %
> 101 iu/mL	:	0.3 %

TABLE 3MEAN ALT DATA FROM 4 CENTRES

NUMBER TESTED	:	8277
"NATIONAL" MEAN	:	10.2 iu/L
LOWER LIMIT OF NORMAL	:	2.3 iu/L
UPPER LIMIT OF NORMAL	:	45.7 iu/L
MEAN + 2 SD	:	45.7 iu/L
MEAN + 2.25 SD	:	55.1 iu/L
MEAN + 2.5 SD	:	64.6 iu/L