

## **HemataSTAT TECHNOLOGY**

**ABSTRACT - Morristown Memorial Hospital, Morristown, New Jersey**

The Separation Technology (STI) HemataSTAT system for measurement of whole blood hematocrits was evaluated by a third party at the Morristown Memorial Hospital, Morristown New Jersey in May of 1988. This evaluation was a comparison of the STI angle technology to a reference NCCLS hematocrit centrifuge. Samples were taken from sixty-five patients and outliers were excluded. Measurements were taken from the middle as well as both ends of the angle formed by the red blood cell and plasma interface.

The study demonstrated that the observation at the middle of the RBC plasma interface provided the optimum point of measurement. Incomplete packing of the red blood cells is corrected by a fixed factor.

The results of the comparison of the STI angle technology to a reference NCCLS hematocrit centrifuge was excellent. There was a strong correlation ( $r=0.9978$ ) between the HemataSTAT centrifuge and the NCCLS reference centrifuge. Precision was typically under a 1% CV. The short time of centrifugation and the quiet operation of the centrifuge were also notable.

STI CLINICAL STUDY – MORRISTOWN MEMORIAL HOSPITAL

NCCLS Reference HCT V.S. STI Angle Centrifuge HCT

May 1998

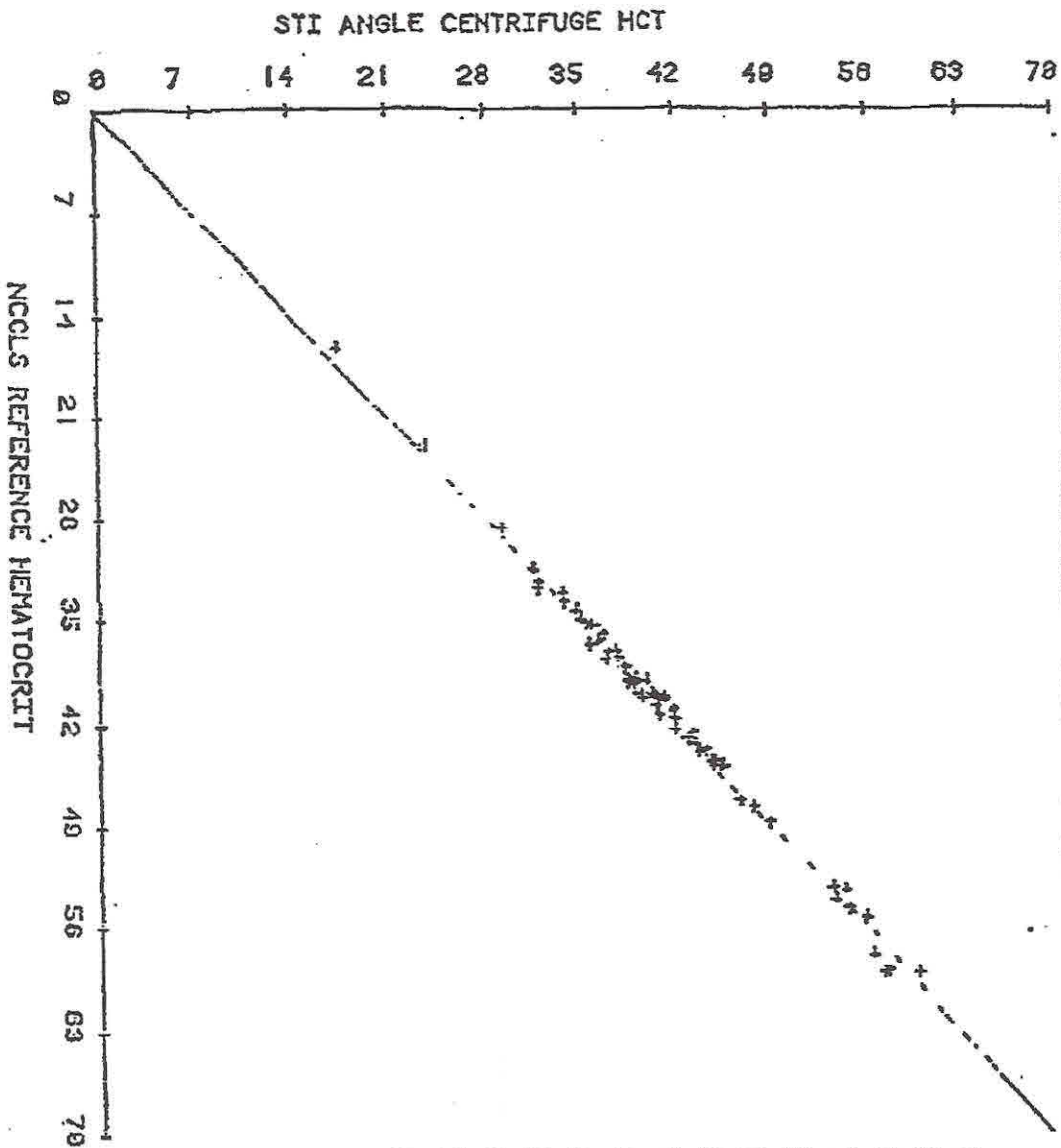
TABLE I

STI ANGLE CENTRIFUGE WITHIN RUN PRECISION: ALGORITHM CORRECTED RESULTS  
One Minute

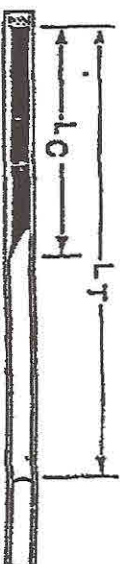
|              | $L_A/L_T \approx 0.920$ | $L_B/L_T \approx 0.886$ | $L_C/L_T \approx 0.852$ |
|--------------|-------------------------|-------------------------|-------------------------|
| Sample No. 1 |                         |                         |                         |
| $\bar{x}$    | 23.2                    | 23.9                    | 24.2                    |
| SD           | 0.54                    | 0.54                    | 0.51                    |
| % CV         | 2.31                    | 2.26                    | 2.09                    |
| Sample No. 2 |                         |                         |                         |
| $\bar{x}$    | 34.8                    | 35.3                    | 35.4                    |
| SD           | 0.21                    | 0.21                    | 0.25                    |
| % CV         | 0.60                    | 0.60                    | 0.73                    |
| Sample No. 3 |                         |                         |                         |
| $\bar{x}$    | 40.6                    | 40.4                    | 40.4                    |
| SD           | 0.34                    | 0.31                    | 0.22                    |
| % CV         | 0.83                    | 0.78                    | 0.55                    |
| Sample No. 4 |                         |                         |                         |
| $\bar{x}$    | 53.6                    | 53.2                    | 52.7                    |
| SD           | 0.17                    | 0.15                    | 0.12                    |
| % CV         | 0.31                    | 0.29                    | 0.23                    |

Plot 1

STI HCT CLINICAL STUDY - MORRISTOWN MEMORIAL HOSPITAL  
NCCLS REFERENCE HEMATOCRIT V.S. STI ANGLE CENTRIFUGE HCT



R = .9973738  
SLOPE = .9838631  
INTERCEPT = .7124324  
TOTAL POINTS = 65  
POINTS ON PLOT = 65  
DATA PLOTTED : 05/11/86  
X MEAN = 41.40302  
Y MEAN = 41.52683  
S.D. OF X = 8.208888  
S.D. OF Y = 8.097406  
MAXIMUM X = 50.20769  
MINIMUM X = 16.27655  
MAXIMUM Y = 60.03458  
MINIMUM Y = 17.46726



Spin time = 1 minute  
ALL STI results obtained  
with Digital Reader  
STI HCT = 0.852  $L_c/L$

PLOT 2 Measured to MIDDLE of angle

| ENTRY # | NCCLS    | STI      | STD   | CV    |
|---------|----------|----------|-------|-------|
| 1       | 33.88788 | 33.56742 | 0.227 | 0.672 |
| 2       | 38.34871 | 38.25109 | 0.069 | 0.180 |
| 3       | 39.22024 | 38.25541 | 0.682 | 1.761 |
| 4       | 41.44796 | 40.85953 | 0.416 | 1.011 |
| 5       | 33.02924 | 32.35369 | 0.478 | 1.461 |
| 6       | 39.19848 | 38.43724 | 0.538 | 1.387 |
| 7       | 37.80714 | 36.73380 | 0.759 | 2.036 |
| 8       | 39.38761 | 39.27423 | 0.080 | 0.204 |
| 9       | 40.24944 | 40.11937 | 0.092 | 0.229 |
| 10      | 39.05461 | 39.07311 | 0.013 | 0.033 |
| 11      | 16.27655 | 16.13879 | 0.097 | 0.601 |
| 12      | 35.11948 | 34.96670 | 0.106 | 0.308 |
| 13      | 32.62593 | 31.50075 | 0.796 | 2.481 |
| 14      | 28.77170 | 27.95642 | 0.576 | 2.032 |
| 15      | 35.43503 | 34.70972 | 0.513 | 1.462 |
| 16      | 39.31786 | 38.89091 | 0.302 | 0.772 |
| 17      | 31.66553 | 32.02864 | 0.257 | 0.806 |
| 18      | 36.63004 | 36.51122 | 0.084 | 0.230 |
| 19      | 37.22646 | 37.54564 | 0.226 | 0.604 |
| 20      | 36.81902 | 35.65637 | 0.822 | 2.269 |
| 21      | 37.37276 | 36.50832 | 0.611 | 1.655 |
| 22      | 36.18534 | 36.53511 | 0.247 | 0.680 |
| 23      | 31.55620 | 31.04052 | 0.365 | 1.165 |
| 24      | 44.58568 | 44.95178 | 0.259 | 0.578 |
| 25      | 39.24197 | 39.59363 | 0.249 | 0.631 |
| 26      | 44.88169 | 45.68168 | 0.566 | 1.249 |
| 27      | 44.55740 | 45.26448 | 0.500 | 1.113 |
| 28      | 43.12314 | 42.71860 | 0.286 | 0.666 |
| 29      | 42.73396 | 42.56784 | 0.117 | 0.275 |
| 30      | 40.01418 | 39.67686 | 0.230 | 0.699 |
| 31      | 40.30784 | 41.18905 | 0.623 | 1.529 |
| 32      | 47.20375 | 47.43829 | 0.166 | 0.350 |
| 33      | 40.21282 | 39.91452 | 0.211 | 0.526 |
| 34      | 33.34998 | 33.85367 | 0.356 | 1.060 |
| 35      | 35.51656 | 35.44418 | 0.051 | 0.144 |
| 36      | 44.83120 | 44.87894 | 0.034 | 0.075 |
| 37      | 42.53215 | 41.84570 | 0.485 | 1.151 |
| 38      | 43.89015 | 44.16131 | 0.192 | 0.436 |
| 39      | 44.01328 | 44.17361 | 0.113 | 0.257 |
| 40      | 43.49045 | 44.04094 | 0.389 | 0.889 |
| 41      | 40.34260 | 41.32479 | 0.695 | 1.701 |
| 42      | 48.78049 | 49.26429 | 0.342 | 0.698 |
| 43      | 40.32101 | 41.35875 | 0.734 | 1.797 |
| 44      | 40.06775 | 39.95771 | 0.078 | 0.194 |
| 45      | 44.98841 | 44.87218 | 0.082 | 0.183 |
| 46      | 40.16861 | 40.59628 | 0.302 | 0.749 |
| 47      | 40.91802 | 40.93240 | 0.010 | 0.025 |
| 48      | 34.44698 | 34.32602 | 0.086 | 0.249 |
| 49      | 41.79375 | 41.53869 | 0.180 | 0.433 |
| 50      | 41.26214 | 41.75604 | 0.349 | 0.841 |
| 51      | 37.74982 | 37.70710 | 0.030 | 0.080 |
| 52      | 23.11964 | 22.71691 | 0.285 | 1.243 |
| 53      | 41.18182 | 41.54931 | 0.260 | 0.628 |
| 54      | 40.29589 | 40.78570 | 0.346 | 0.854 |
| 55      | 47.63585 | 48.52831 | 0.631 | 1.312 |
| 56      | 54.19355 | 54.28515 | 0.065 | 0.119 |
| 57      | 53.39731 | 53.50130 | 0.074 | 0.138 |
| 58      | 59.02627 | 58.30466 | 0.510 | 0.870 |
| 59      | 55.55298 | 56.84950 | 0.210 | 0.376 |
| 60      | 63.69508 | 64.13265 | 0.380 | 0.706 |
| 61      | 58.02276 | 56.91993 | 0.780 | 1.357 |
| 62      | 54.77968 | 55.34605 | 0.400 | 0.727 |
| 63      | 59.13660 | 58.95001 | 0.132 | 0.223 |
| 64      | 59.20769 | 60.42051 | 0.858 | 1.434 |
| 65      | 55.34459 | 56.51386 | 0.827 | 1.478 |

Regression Output:

|                     |          |
|---------------------|----------|
| Constant            | -0.91712 |
| Std Err of Y Est    | 0.565602 |
| R Squared           | 0.995612 |
| R                   | 0.997804 |
| No. of Observations | 65       |
| Degrees of Freedom  | 63       |
| X Coefficient(s)    | 1.021848 |
| Std Err of Coef.    | 0.008546 |

X MEAN: 41.48383  
Y MEAN: 41.47303  
SD OF X: 8.27253  
SD OF Y: 8.47187  
MAX X: 59.20769  
MAX Y: 60.42051  
MIN X: 16.27655

# STI HCT CORRELATION

PLOT 2-Middle of Angle

