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DU PONT FIVE-YEAR Pb STUDY - Pb DETERMINATION QUALITY CONTROL

This letter summarizes the analysis of the urine Pb and blood Pb percent recovery data collected by the Chambers Works Medical Division. These data serve as a quality control check on the Pb determination methods used in analyzing the urine and blood samples collected in the Du Pont Five-Year Pb Study.

No significant trends could be detected in either the urine Pb or the blood Pb percent recovery data. The urine Pb percent recoveries varied from 90 to 98% (average = 93.2%) with the exception of three months (November 1971 77.3%, December 1971 85.2%, February 1972 81.7%), while the blood Pb recoveries varied from 57 to 95% with an average of 81%. It is concluded that there is no evidence in these percent recovery data that significant negative trend in average urine Pb levels in the Du Pont Five-Year Pb Study (see letter from R. D. Snee to M. McLaughlin, "Du Pont Five-Year Pb Study", 9/6/72) can be attributed to differences in the method of urine Pb determination over the five-year period.

ENGINEERING SERVICE DIVISION

R. D. Snee
R. D. Snee
Applied Statistics

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Haskell Laboratory

RDS:chm
Attachments

DU PONT FIVE-YEAR Pb STUDY

Analysis of Urine Pb and Blood Pb Percent Recovery Data

I. Objective

In the analysis of the urine Pb and blood Pb data from the Du Pont Five-Year Pb Study we found a significant negative trend in the average urine Pb levels of the subjects (letter from R. D. Snee to M. McLaughlin, 9/6/72). It's possible that this negative trend may have resulted from differences in laboratory procedures over the five-year period 1967-1972. The percent recovery of the analytical method of urine Pb determination was routinely checked from 9/68-4/72 (Table 1). The percent recovery of the blood Pb analysis was checked less frequently from 8/66 to 4/72 (Table 3). Any significant trends in the urine Pb and blood Pb percent recovery data would be an indication of differences in the analytical method.

II. Statistical Analysis and Results

Time plots of the urine Pb and blood Pb percent recovery data are shown in Figures 1 and 2. The urine Pb recoveries varied from 90 to 98% with the following exceptions (Figure 1).

<u>Month</u>	<u>% Recovery</u>
November 1971	77.3
December 1971	85.2
February 1972	81.7

There were no significant trends. These three abnormal months cannot explain the significant negative trend we observed in the average urine Pb levels. It should be noted also that the standard deviation of replicate urine Pb percent recoveries within a month increased in 1971 and 1972, compared to previous years (Table 2).

There also were no significant trends in the blood Pb percent recovery data (Table 4, Figure 2) which varied from 57 to 95%, with an average of 81%. It is of interest that approximately two-thirds of the variability in blood Pb percent recovery is variation between replicate blood Pb percent recoveries run on the same day (Table 4).

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TABLE 1

Urine Pb Percent Recovery Data

<u>Month</u>	<u>Year</u>	<u>Number of Determinations</u>	<u>Average</u>
9	68	7	95.7
10	68	24	92.8
11	68	16	93.8
12	68	17	91.4
1	69	16	92.2
2	69	29	94.4
3	69	24	93.7
4	69	35	91.6
5	69	21	93.6
6	69	6	91.0
7	69	19	92.7
8	69	20	91.4
9	69	20	91.9
10	69	31	94.1
11	69	24	94.6
12	69	24	96.7
1	70	24	96.2
2	70	26	96.0
3	70	16	94.0
4	70	15	90.3
5	70	17	90.2
6	70	15	96.3
7	70	9	93.1
8	70	---	----
9	70	3	96.0
10	70	7	93.1
11	70	7	95.4
12	70	9	96.0
1	71	11	91.3
2	71	10	94.8
3	71	12	93.7
4	71	14	93.3
5	71	13	93.2
6	71	6	97.7
7	71	7	91.7
8	71	8	91.2
9	71	15	93.7
10	71	12	92.2
11	71	3	77.3
12	71	5	85.2
1	72	7	94.6
2	72	7	81.7
3	72	7	95.7
4	72	8	90.0

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TABLE 2

Urine Pb Percent Recovery Data

<u>Year</u>	<u>Number of Determinations</u>	<u>Average</u>	<u>Standard Deviation (4)</u>
1968 ⁽¹⁾	64	93.0	7.56
1969	269	93.4	5.37
1970 ⁽²⁾	148	94.3	5.86
1971	116	92.4 ⁽⁵⁾	8.73
1972 ⁽³⁾	29	90.5 ⁽⁶⁾	15.11

(1) Based on 4 months of data - September to December

(2) No data for August

(3) Based on 4 months of data - January to April

(4) Standard deviation of replicate determinations within a month

(5) Significantly low because of the low % recoveries in Nov & Dec

(6) Significantly low because of the low % recoveries in Feb

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TABLE 3

Blood Pb Percent Recovery Data

<u>Month</u>	<u>Year</u>	<u>Number of Determinations</u>	<u>Average</u>
8	66	2	82.5
4	67	16	83.2
7	67	4	76.0
2	68 [*]	2	92.5
3	69	15	87.1
4	69	5	95.0
2	71	2	72.0
3	71	4	57.0
6	71	9	74.0
7	71	16	86.4
8	71	9	84.8
10	71	8	76.5
11	71	16	78.6
4	72	11	73.8

Total Number of Determinations = 119

Average Percent Recovery = 81.0

Standard Deviation of Replicate Determinations
on the same day = 12.87

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TABLE 4

Blood Pb Percent Recovery Data

Analysis of Variance

<u>Source</u>	<u>df</u>	<u>SS</u>	<u>MS</u>	<u>F</u>
Total	118	28590.9		
Year-Month	13	6322.2	486.3	1.42
Days (Y-M)	45	12332.5	274.1	1.65*
Replicates	60	9936.2	165.6	

<u>Source</u>	<u>Variance Component</u>	<u>Percent of Total Variation</u>	<u>Standard Deviation</u>
Year-Month	17.6	7.2	4.19
Days	62.1	25.3	7.88
Replicates	165.6	67.5	12.87
Total	245.3	100.0	

*Significant at the .05 probability level

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N 27020.06 URINE Pb % RECOVERY DATA

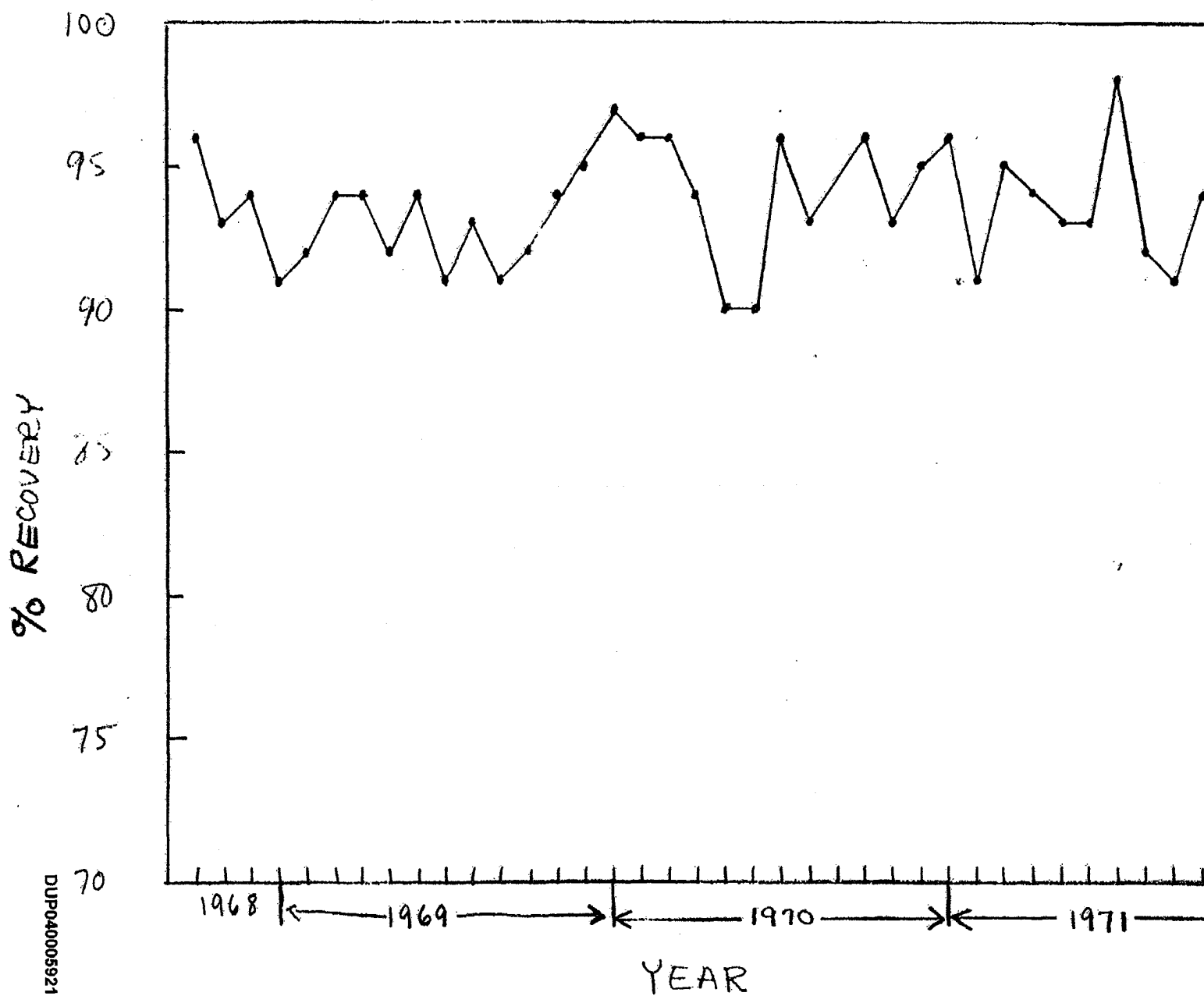
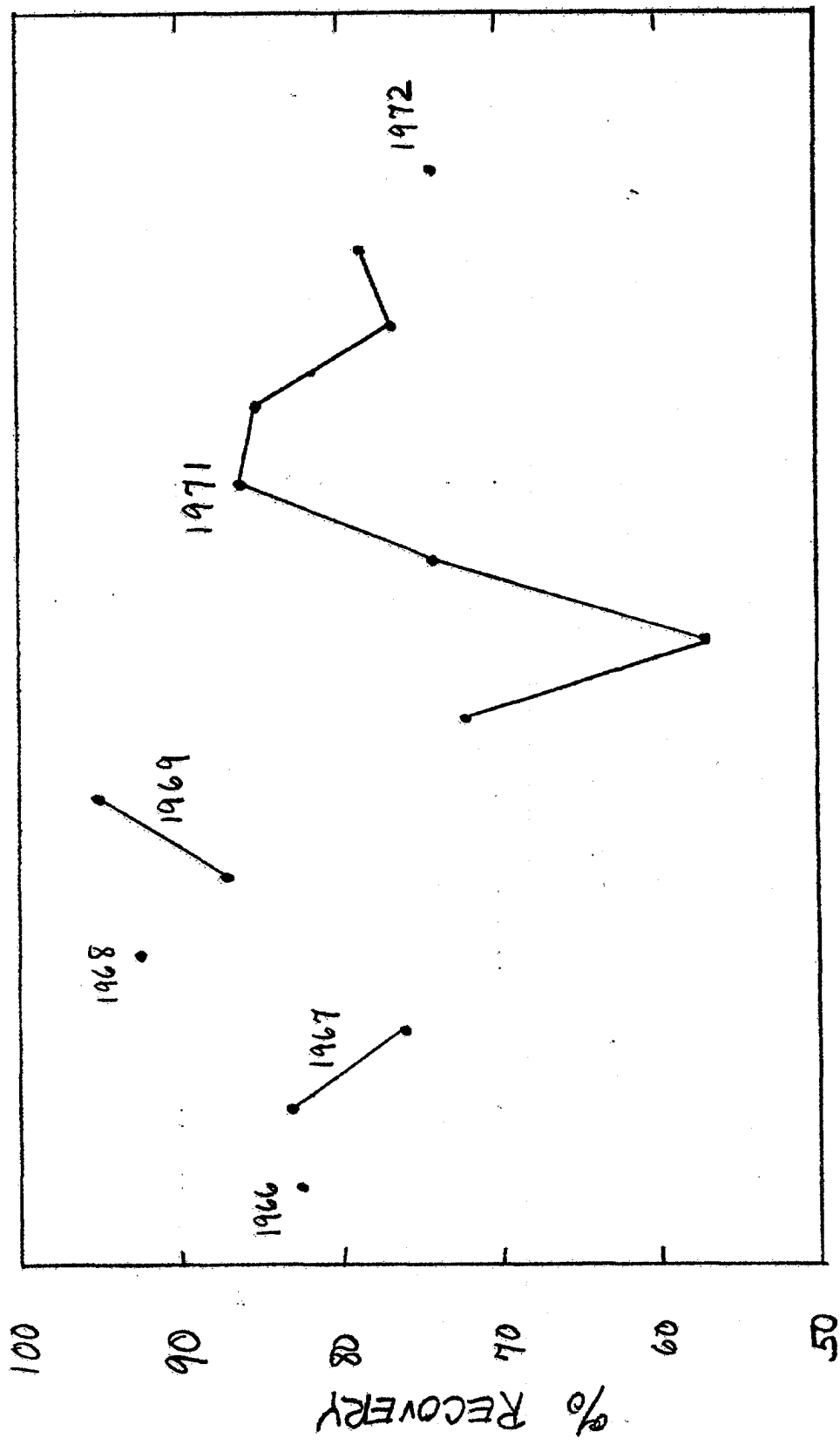


FIGURE 2

BLOOD Pb % RECOVERY DATA



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