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SURVEY MDL/2

PROSPECTIVE LONGITUDINAL EPIDEMIOLOGICAL SURVEY OF
CLEAN-UP WORKERS AT WORK FROM 1980 IN HIGH-CONTAMINATED
A ZONE

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REPORT ON SURVEY MDL/2

PROSPECTIVE LONGITUDINAL EPIDEMIOLOGICAL SURVEY OF CLEAN-UP WORKERS AT WORK FROM 1980 IN HIGH-CONTAMINATED A ZONE.

INTRODUCTION

In A zone contaminated by high level of TCDD following the ICMESA accident the clean-up operations started in the summer of 1980. The existence of a real risk for clean-up workers is demonstrated by the experience accumulated in the last years as a result of similar operations at various European industrial plants in Europe.

Four years after the contamination episode at the Badische und Soda Fabrik (BASF) (two years after the reopening of the plant a new case of poisoning occurred in a worker who had been repairing an autoclave; during the operation he had several times lifted his protective mask to wipe off the sweat. Four days later dermatological manifestations and neurological symptoms appeared; six months later he was admitted to hospital for pancreatitis and hepatomegaly; nine months later he died; pancreatic necrosis, liver abscesses and chloracne on the trunk were found at necropsy

The clean-up procedures at the Coalite plant in England were inadequate: after the clean-up, 79 cases of chloracne occurred in workers not exposed at the time of the accident.

Numerous cases of chloracne developed among workers engaged on the initial clean-up at the Philips plant in Holland. In the subsequent dismantling of the plant strict personal protection was enforced among the workers, who had to wear ventilated overalls, and a clinical surveillance program was set up centered on the evaluation of biochemical parameters before the event and subsequently at regu

lar intervals. No major deviations from normal values were observed in the ten workers who complied consistently with the prevention procedures. In two other workers who had been sent to the contaminated zone to dilute the contents of some tanks with water and who had worn on the overalls correctly one or more liver function parameters were found to be abnormal eleven weeks later; the values slowly normalised in the weeks that followed. In no case were there dermatological manifestations. The Philips researchers concluded that the working methods were effective in preventing exposure to TCDD.

Notwithstanding the vast quantity of data on TCDD that has accumulated since the Philips episode, a public health surveillance program still has to be based on the observation of biological parameters whose behavior may indirectly reveal exposure to the poison by showing its early effects (early effect indicators). Direct monitoring of the intake of the poison (dose indicator), up to now imply the biopsy of adipose tissue and it is not proposable as a continuous monitoring of groups of active workers in a plan of public health surveillance.

2 - METHODS

2.1 Objectives

The general objective of the survey was to gauge the efficiency of the safety measures taken during the clean-up of areas A1-A5. The safety measures were taken to prevent any significant exposure to the poison but, going by previous experience, possible exposure could not be excluded.

2.2 General design of the study

The design was that of a prospective controlled study (almost like a trial) comparing clean-up workers and reference groups. The parameters of interest (essentially clinical signs and symptoms, biochemical parameters) were measured before, during and after the period of potential exposure, in both groups (Fig. 1).

2.3 Population under study

The groups under study were selected at the preplacement examination. The subjects were sent by the firm handling the clean-up to Desio Hospital. None had previously been engaged on clean-up operations.

The preplacement examination took place in two stages: first 35 clean-up workers were selected and then a month later another 37 subjects were chosen, 36 as controls and 1 as a clean-up worker.

2.4 Preplacement examination. Data collection.

For every subject the preplacement examination included:

- 2.4.1 Interview-questionary
- 2.4.2 History and physical examination
- 2.4.3 Laboratory tests
- 2.4.4 Lung function test
- 2.4.5 Neurological examination, nerve conduction velocity and Electromyography (EMG)
- 2.4.6 Electrocardiogram (ECG)
- 2.4.7 Chest X-ray

2.4.1 Interview-questionary

The main purpose was to obtain informations for the comparison of the clean-up workers with the controls.

The interview-questionary was administered by two trained interviewers at the time of the medical examination. The questions included: universal variables (like years of schooling, marital status, telephone, working history), habit (drinking, smoking), drugs intake, family history and personal history with special reference to liver disease and skin diseases.

A copy of the questionnaire form is attached in Appendix A.

2.4.2 The history was taken and the physical examination done by occupational health specialists of the Occupational Health Service of Desio Hospital.

A copy of the case record form used is attached in Appendix B

2.4.3 Laboratory tests

The following tests were done:

- 1 - Glutamic oxalacetic transaminase (SGOT or AST)
- 2 - Glutamic pyruvic transaminase (SGPT or ALT)
- 3 - Alkaline phosphatase (AP)
- 4 - Gamma glutamyl transpeptidase (GGT)
- 5 - Bilirubin
- 6 - Cholesterol
- 7 - Triglycerides
- 8 - Surface antigen of hepatitis B Virus (HBsAg)
- 9 - Electrophoresis of serum proteins
- 10 - Blood cells count plus platelets and differential
- 11 - Total urinary porphyrins
- 12 - Urinary delta-aminolevulinic acid (ALA-U)

Most of the parameters were chosen because TCDD is hepatotoxic and affects the lipid metabolism. An increase in SGOT-SGPT is to be regarded as an indicator of cytolysis, an increase in GGT as an indicator of enzyme in

duction and an increase in AP as an indicator of biliary stasis.

The urinary porphyrins were determined because TCDD is known to exert a porphyrogenic effect.

2.4.4 Lung function test

2.4.5. Neurological examination, nerve conduction velocity, EMG

2.4.6 Electrocardiographic examination

2.4.7 Chest X-ray examination

2.5 Selection of groups of clean-up workers and controls

The criterium of eligibility was the fitness of the following parameters:

- 1 Males between 18 and 55 years old
- 2 No clinical signs of acute or chronic diseases such as viral hepatitis, diabetes, chronic liver disease, skin disease, etc.
- 3 Results within the normal range for the following laboratory tests: SGOT, SGPT, GGT, AP, Serum bilirubin, RBC, hematocrit, hemoglobin, WBC and differential counts, platelets, urinary porphyrins
- 4 No clinical or instrumental signs of peripheral nervous system
- 5 Normal ventilatory function test.

Out of 112 candidates only 72 were found eligible for the clean-up work and entered the study.

Grounds for exclusion were medical problems (liver disease, abnormal values in laboratory tests), problems relating to the nature of the work (abnormalities of ventilatory function with reduced tolerance to the wearing of a mask).

2.6 Periodic examinations

According to the protocol, every subject had to be examined every 6 months. Moreover, by regional law the clean-up workers had to be examined every 30 working days until the end of the

job. The periodic examinations included physical examination and laboratory test as required for the preplacement examination.

2.7 Final tests

The final tests were done 6 and 12 months after completion of the clean-up job.

2.8 Data analysis

Given the sample size the power of the tests used was estimated and proved to be adequate for the design of the study. The frequency distribution for the demographic and other variables (Table 1) was reported. For comparing this distribution the chi-squared test for independent samples was used. For the comparison of the continuous variates (Figs. 3-26) one- and two-way variance analysis was used, by group (clean-up and reference workers) and by test (tests done at successive examinations), using the SPSS program. All tests were rated significant if the probability depending on chance was less than 0.05% (with two tails).

Discriminant analysis was done with a program developed by Davies. The logic of the discriminant approach lies in the fact that significant differences could be identified for the entire battery of tests used, where for a single test no significant difference emerges.

RESULTS

The results of the preplacement examination and of the first 4 periodic examinations are reported here. The results will also be shown for the subset of individuals which underwent all the periodic tests.

The data are also presented according to the number of hours worked. The time trend of six selected parameters for each worker is also indicated.

3.1 Response

The outline of the study design and follow-up response are shown in Fig. 1.

During the follow-up two of the exposed workers died in a road accident. One missed out after the first follow-up and yet another one after the second. Another four failed to attend for the fourth follow-up.

In the reference group the response rate was low: five failed to attend for the first follow-up, seven for the second and third and another six for the last (response rate = 65%).

Among the clean-up workers the response rate was 100% of those present on the job, who needed to comply with periodical control and to be passed fit to continue working.

The fall in the response rate at the last follow-up was due to ex clean-up workers (those who had for various reasons given up working in the zone). In the reference group the low response rate was due to distance from the place of residence or to emigration to other areas. One control subject after the first follow-up was included among the clean-up workers and from that date he was excluded from the data analysis.

3.2 Base data

3.2.1 Interview-questionary

One of the clean-up workers and four of the controls were not interviewed. Inter-group comparability in respect of certain characteristics is indicated in Table 1. Age, education, marital status, smoking, drinking, previous exposure to hepatotoxic substances and history of skin dis-

ease presented fairly similar distributions in the two groups. Significant differences were found in respect of history of liver disease and possession of a telephone at home, which proved to be more frequent in the reference group.

3.2.2 Laboratory data

Of the laboratory tests done those most relevant for statistical analysis are the ones that, according to the scientific literature, seem to be correlated with exposure to TCDD, viz. urinary porphyrins, liver enzymes, serum cholesterol and triglycerides. The results of the WBC, platelet, serum protein, albumin and gamma globulin tests are also presented. At the preplacement examination no significant difference was found in the variables studied, except for alkaline phosphatase, the mean value of which was higher in the reference group.

3.3 Follow-up results

During the follow-up period nine workers left the job for reasons unrelated to health. Five workers were rated no longer fit and were dismissed. The grounds for unfitness were:

- 1 - in subject 12 abnormal SGOT (42 mU/ml) and SGOT (75 mU/ml) values in two tests, in October and December 1981; these values returned to normal in subsequent tests.
- 2 - in subject 13 severe hypertension (195-125 mmHg).
- 3 - in subject 14 a slight increase in GGT.
- 4 - in subject 16 persistent presence of HBsAg.
- 5 - in subject 27 use of antiepileptic drugs.

These subjects continued to attend for follow-up examinations according to the program for ex clean-up workers. Another subject gave up the job a few days after starting because he could

not stand the mask and was lost to follow-up.

3.3.2 Clinical evaluation

No case of skin or neurological disease occurred. Clinical examination revealed nothing noteworthy. The percentage of subjects with hepatomegaly did not differ significantly in the two groups; the higher percentage among the clean-up workers might be due to the fact that the doctors were not "blind" (Fig. 2). No significant difference emerged in respect of weight variations.

3.3.3 Laboratory data

The analysis was done separately for all the cases in the follow-up period and for a subset of subjects whose data were available for all the periodic examinations (except the last).

Dispersion charts for 10 out of 14 laboratory tests in the first four examinations are shown in Figs. 3-26 together with the means and standard deviations.

3.3.3.1 Urinary porphyrins (Figs. 3 and 4)

No significant difference was found between the two groups at successive tests but a significant difference was found for both groups between tests done successive times. But the values were within normal limits, well below threshold values. The same results appeared for the subset of subjects always present.

3.3.3.2 SGOT - SGPT (Figs. 5,6,7,8)

No significant difference was found, except for SGOT at third follow-up, when the mean value of the exposed (17.75 mU/ml) was higher than in the non exposed (14.28); this difference was also significant within the subgroup of ever-present subjects.

3.3.3.3 Alkaline phosphatase (Figs. 9-10)

The significant difference observed in the baseline test disappeared in subsequent tests.

3.3.3.4 Gamma GT (Figs. 11-12)

No significant difference was found between the two groups in the successive tests but a significant difference did emerge for both groups between successive tests.

3.3.3.5 Bilirubin (Figs. 13-14)

Serum total bilirubin behaved in the same way as GGT.

3.3.3.6 ALA-U (Figs. 15-16)

The same applies to ALA-U.

3.3.3.7 Cholesterol and triglycerides (Figs. 17-18-19-20)

No difference was observed.

3.3.3.8 Other laboratory tests

A significantly lower WBC count was found in the clean-up workers at first follow-up (Figs. 21 and 22) and the same applies to platelets (Fig. 23). The serum total protein value was higher than in the controls (Fig. 24) and a lower mean serum albumin (Fig. 25) in the clean-up workers in the preplacement examination only in the subgroup of the ever-present. A significantly higher gamma globulin value (Fig. 26) was found in the clean-up workers at second follow-up.

3.3.3.9 Analysis of the binary data

In order to identify deviations from the normal values, some variables were converted into binary data, above or below the threshold used at the preplacement examination. The frequency of outside range values was too low for statistical analysis: no noteworthy difference in the percentages of abnormal values was

3.3.3.10 Discriminant analysis

The dispersion chart of the scores obtained by discriminant analysis of the values of eleven laboratory tests is shown in Fig. 37. No significant discriminant function was identified.

3.4 On-job hours and laboratory tests

The clean-up workers were divided into three subgroups by the number of hours worked in zone A at the time of the second follow-up. Seven had worked less than 200 h, nine from 201 to 400 h and twenty more than 400 h. No significant difference in the mean values of the lab tests was found at the first and second follow-up (Table 2).

3.5 Individual assessment of the clean-up workers

It must be stressed that, while the program of tests for the reference group envisaged an examination every six months, the clean-up workers underwent medical checks every 30 days as long as they continued on the job. The number of examinations of this group was between 2 and 20 (mean 12.41). In the foregoing analysis we have considered only the five for which the control data are also available. Figs. 38 to 73 show the time trends of six selected parameters (porphyrins, SGOT, AP, GGT, cholesterol and triglycerides) for each worker.

The analysis of the test shows that in ten cases (nos. 4, 10, 16, 20, 22, 23, 27, 31, 32 and 35) no variables increased by more than 100% of the baseline value during the follow-up period; in thirteen cases (nos. 1, 2, 3, 5, 6, 14, 15, 18, 19, 25, 29, 30 and 33) there was an increase of more than 100% in at least one parameter but always within the normal range. In another thirteen cases (nos. 7, 8, 9, 11, 12, 13, 17, 21, 24, 26, 28, 34, 36) there was an increase of more than 100% in at least one parameter with values beyond the nor-

range: in six cases the increase was in the triglycerides, in three in alkaline phosphatase, in one the urinary porphyrins and triglycerides, in one case transaminase and triglycerides and in one case GGT.

CONCLUSIONS

The program of surveillance for the clean-up workers in area A1-A5 of Seveso was undertaken to check the efficiency of the safety measures taken during the clean-up operation started in May 1980. The principal conclusions are:

1. During the follow-up period no case of clear clinical disease that could be attributed to TCDD (chloracne, peripheral neuropathy, liver disease, etc.) occurred.
2. Of the five workers rated unfit after the commencement of the job one had abnormal liver enzyme values in two tests, which subsequently normalised. There was no known cause of the increase and so a transient effect of TCDD exposure cannot be excluded, although the contemporaneous weight gain (more than 15 kg) may suggest nutritional causes.
3. No definite difference between clean-up workers and controls was found in respect of the laboratory tests. The same conclusion was reached when the data were treated as binary data and discriminant analysis was applied to 13 lab test variables.
4. The analysis of the time trends of six variables in the clean-up workers shows that some variations occurred in the triglycerides; these are, however, more likely to be due to biological variability or to insufficient precision in analysis.

In sum, the survey failed to show biologically significant features

such as to suggest that the workers engaged on the clean-up operations in the highly contaminated zones can have absorbed TCDD. The safety measures adopted seem to have provided effective protection for the workers.

Desio, 30 July 1983.

TABLE 1. Distribution of Demographic and Other Variables in Clean-up and Reference Groups

| Characteristics | Clean-up Workers | Reference Workers |
|--|-----------------------------------|-------------------|
| <u>Mean Age</u> | 31.2 | 32.7 |
| | $t = .74$ | |
| <u>Education</u> (Years completed) | | |
| 0-5 | 13 | 19 |
| 6-9 | 15 | 10 |
| 10+ | 7 | 3 |
| | $\text{Chi sq}_2 = 3.59$ $2df$ | |
| <u>Marital Status</u> | | |
| Never Married | 13 | 19 |
| Married | 15 | 10 |
| Separated, Divorced | 2 | 0 |
| Widowed | | |
| | $\text{Chi sq}_2 = 3.54$ $2df$ | |
| <u>Smoking Habit</u> (Cigarettes/day) | | |
| Non-smoker | 11 | 8 |
| Ex-smoker | 2 | 5 |
| Less than 20 | 11 | 7 |
| 20 or more | 11 | 12 |
| | $\text{Chi sq}_3 = 2.56$ $3df$ | |
| <u>Alcohol Consumption</u> (cc./day) | | |
| 0 | 7 | 6 |
| Less than 40 | 9 | 12 |
| 40 or more | 19 | 14 |
| | $\text{Chi sq}_2 = 1.13$ $2df$ | |
| <u>Previous Exposure to Hepatotoxic Substances</u> | | |
| Yes | 3 | 7 |
| No | 32 | 25 |
| | $\text{Chi sq}_1 = 2.33$ $1df$ | |

TABLE 1. Distribution of Demographic and Other Variables
(Continued) in Clean-up and Reference Groups

| Characteristics | Clean-up Workers | Reference Workers |
|--|-------------------------------|----------------------|
| <u>Telephone at Home</u> | | |
| Yes | 13 | 21 |
| No | 22 | 11 |
| | Chi sq _{1df} = 5.43* | |
| <u>History of Dermatitis</u> | | |
| Yes | 6 | 9 |
| No | 29 | 23 |
| | Chi sq _{1df} = 1.16 | |
| <u>History of Liver Enlargement</u> | | |
| Yes | 4 | 12 |
| No | 29 | 23 |
| | Chi sq _{1df} = 6.25* | |
| <u>Past Physician's Warning on Liver Disease</u> | | |
| Yes | 4 | 4 |
| No | 32 | 28 |
| | Chi sq _{1df} = .03 | |

*Significant at p less than .05

Table 2 Results of various laboratory tests (mean and standard deviation) at the pre-employment examination, after 3 and 9 months in the decontamination workers, divided according to the number of hours spent in A1, A2 zones.

| Number of hours | less than 200 | | | from 201 to 400 | | | more than 400 | | |
|---|-------------------|---------------------------|---------------------------|-------------------|---------------------------|---------------------------|-------------------|---------------------------|-----------------------|
| | pre-empl.ex. | 3 rd month ex. | 9 th month ex. | pre-empl.ex. | 3 rd month ex. | 9 th month ex. | pre-empl.ex. | 3 rd month ex. | 9 th month |
| Total urinary porphyrine ($\mu\text{g/g creat.}$) | 71.17 (24.10) | 89.20 (42.20) | 60.43 (16.67) | 93.67 (54.55) | 75.09 (31.54) | 81.00 (21.95) | 96.44 (44.29) | 70.55 (38.64) | 66.95 (27.1) |
| SGOT (U/L) | 20.71 (4.11) | 10.83 (6.05) | 10.29 (4.88) | 15.56 (2.70) | 14.67 (2.12) | 12.67 (3.24) | 15.20 (3.02) | 14.75 (4.68) | 13.50 (3.8) |
| SGPT (U/L) | 23.71 (6.32) | 20.33 (3.67) | 19.14 (6.72) | 16.78 (5.83) | 14.89 (3.10) | 12.00 (2.86) | 17.70 (4.07) | 19.35 (8.05) | 16.80 (6.1) |
| Alkaline phosphatase (U/L) | 23.86 (5.93) | 34.03 (8.18) | 27.71 (5.02) | 34.67 (11.28) | 37.11 (6.45) | 33.56 (7.04) | 27.20 (6.71) | 32.15 (7.51) | 20.70 (7.1) |
| Gamma-Gl (U/L) | 30.00 (10.07) | 31.67 (12.14) | 26.29 (10.87) | 18.78 (12.36) | 23.11 (12.08) | 20.56 (7.62) | 17.95 (8.01) | 20.85 (7.29) | 18.05 (7.1) |
| Total Bilirubin (mg/dl) | .73 (.13) | .58 (.16) | .67 (.18) | .66 (.18) | .62 (.17) | .59 (.15) | .66 (.13) | .65 (.12) | .57 (.11) |
| PTT (sec) | 27.25 (2.43) | 27.58 (3.22) | 29.67 (3.27) | 27.06 (1.71) | 26.29 (2.21) | 29.59 (2.57) | 25.55 (2.33) | 26.68 (2.80) | 28.77 (1.1) |
| Hemoglobin (g/dl) | 15.80 (.68) | 15.93 (.74) | 16.31 (.58) | 16.06 (.90) | 16.01 (.82) | 16.51 (.81) | 15.64 (.73) | 15.65 (.76) | 16.16 (.9) |
| WBC ($\times 10^3/\text{mm}^3$) | 6.46 (1.69) | 7.15 (2.48) | 6.06 (1.85) | 6.73 (1.30) | 6.67 (2.25) | 6.81 (1.72) | 6.89 (1.19) | 6.97 (1.50) | 6.16 (1.1) |
| Platelets ($\times 10^3/\text{mm}^3$) | 216.14 (47.34) | 230.17 (43.86) | 222.00 (40.85) | 200.89 (42.51) | 209.56 (44.51) | 208.78 (36.77) | 193.25 (34.68) | 205.20 (67.36) | 196.20 (38) |
| Albumin (g/dl) | 4.80 (.22) | 4.97 (.45) | 4.98 (.36) | 4.62 (.33) | 4.96 (.44) | 4.29 (.18) | 4.70 (.33) | 4.78 (.36) | 5.05 (.1) |
| Gamma-Globulin (g/dl) | 1.02 (.12) | .96 (.12) | .94 (.11) | 1.22 (.17) | 1.17 (.22) | 1.15 (.12) | 1.21 (.20) | 1.18 (.20) | 1.16 (.1) |
| Cholesterol Serum Level (mg/dl) | 242.43 (68.38) | 223.50 (57.68) | 215.71 (63.50) | 184.78 (33.24) | 192.78 (30.89) | 192.09 (26.56) | 174.11 (25.22) | 179.60 (23.81) | 183.80 (25) |
| Triglyceride (mg/dl) | 148.43 (50) | 155.17 (57.22) | 131.00 (24.15) | 112.56 (38.85) | 109.56 (46.55) | 138.56 (28.42) | 101.37 (42.36) | 96.35 (86.29) | 134.30 (5) |

FIG. 1 OUTLINE OF THE STUDY DESIGN AND FOLLOW-UP RESPONSE AMONG CLEAN-UP AND REFERENCE GROUPS

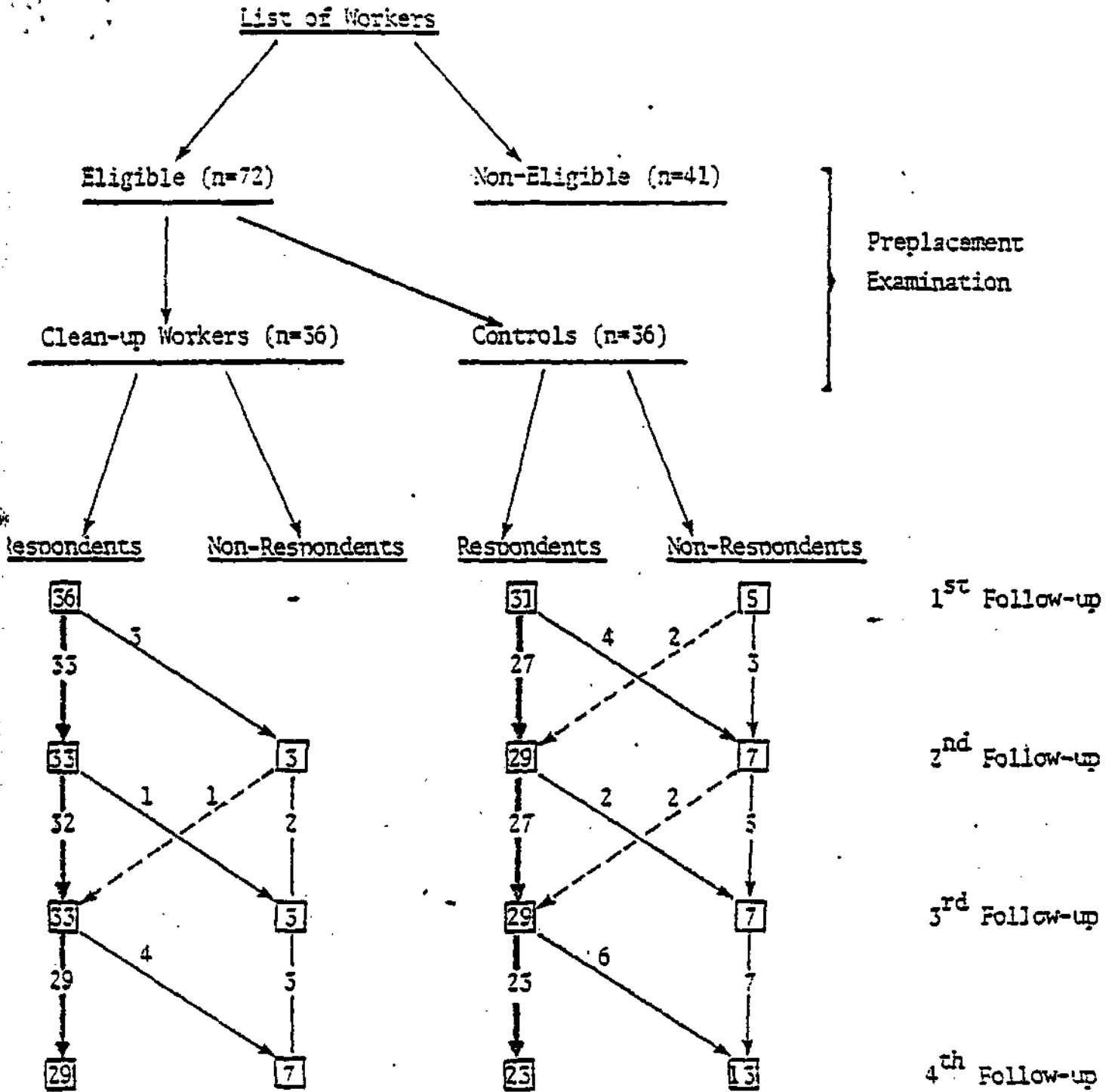


FIG.2 PROPORTION OF LIVER ENLARGEMENT AMONG CLEAN-UP AND CONTROLS.

CLEAN-UP
WORKERS

CONTROLS

—————

.....

% Liver Enlargement (1 cm. or+).

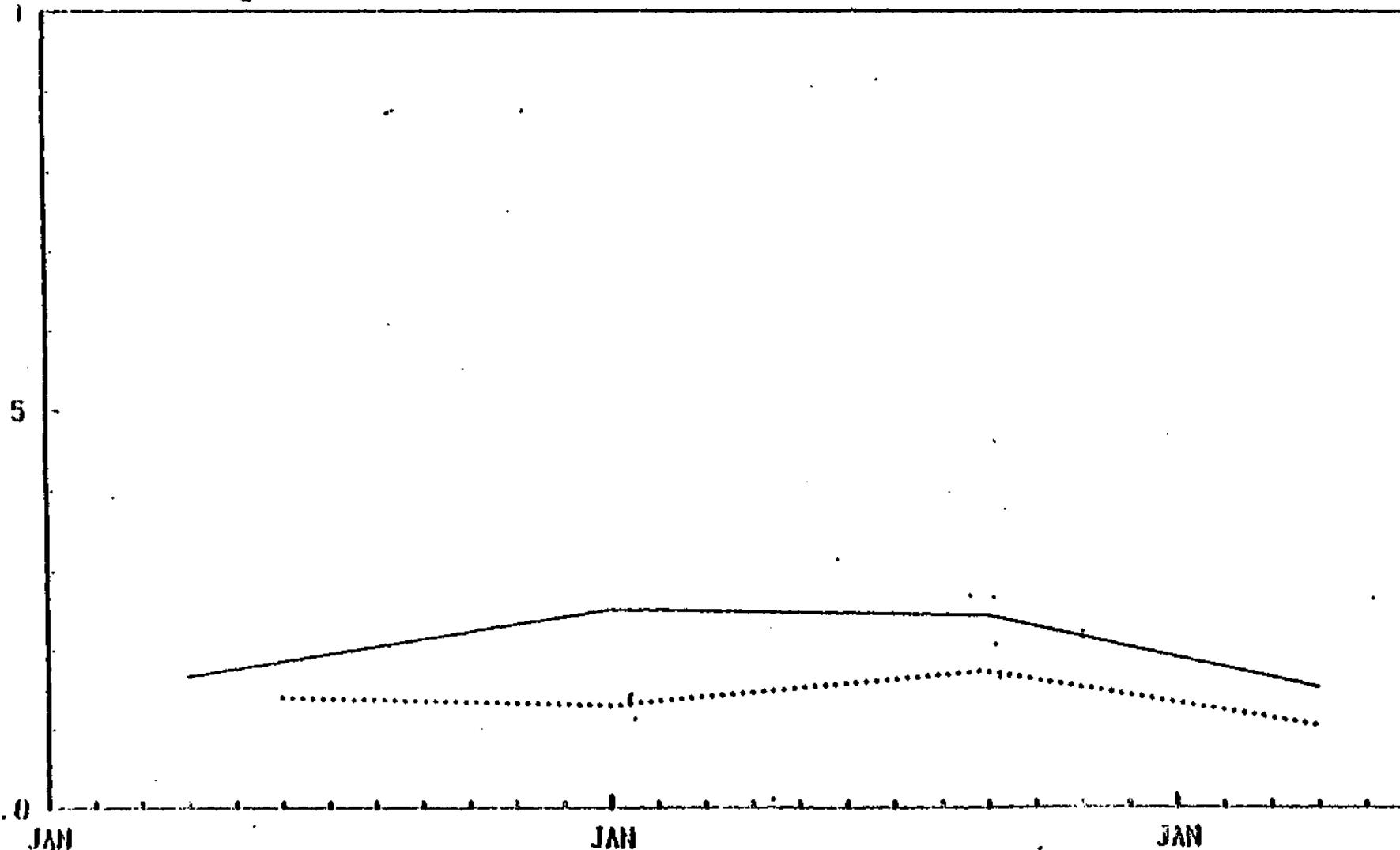


Fig. 3 URINARY PORPHYRINS VALUES
 in clean-up and reference groups

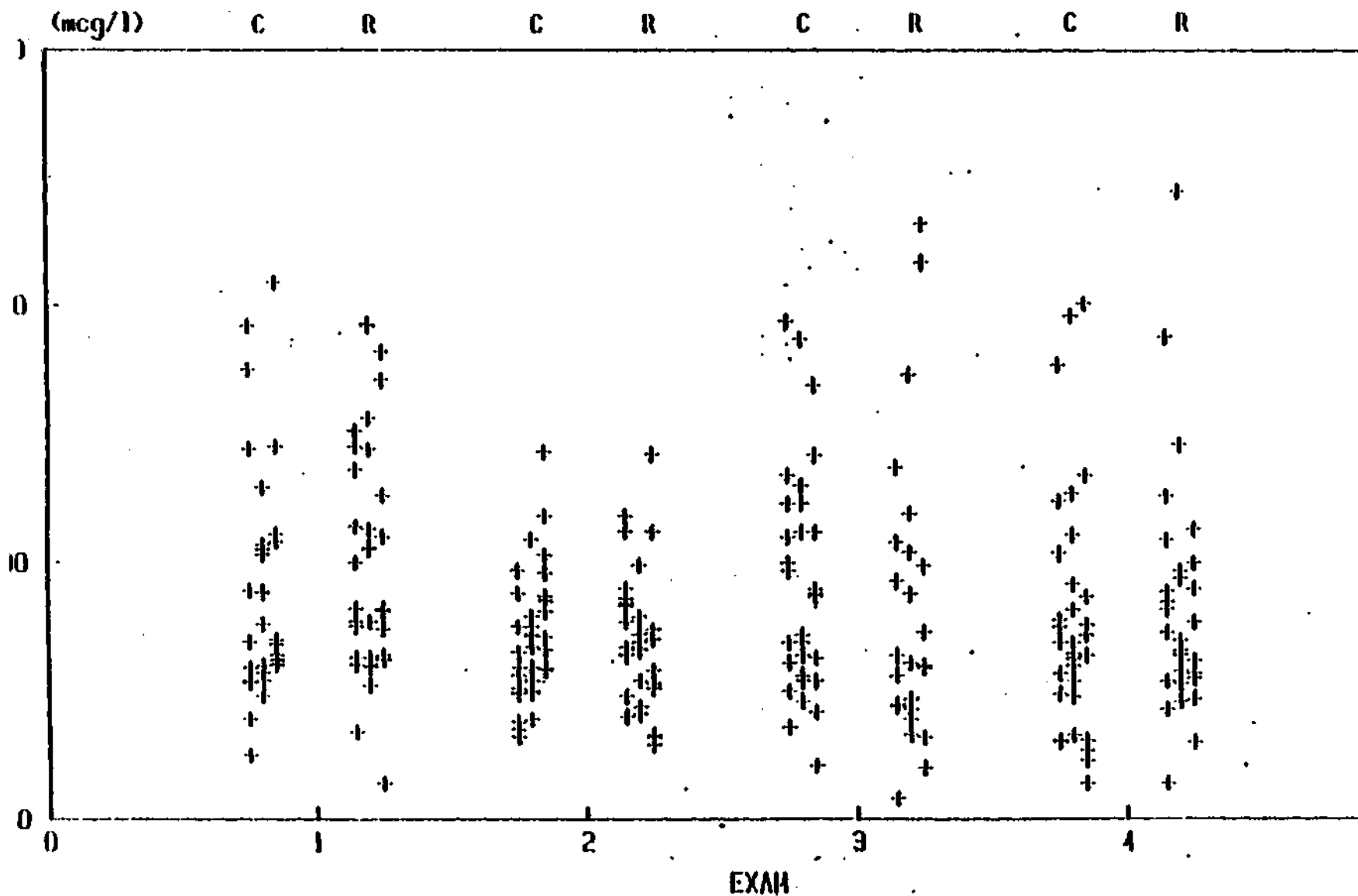
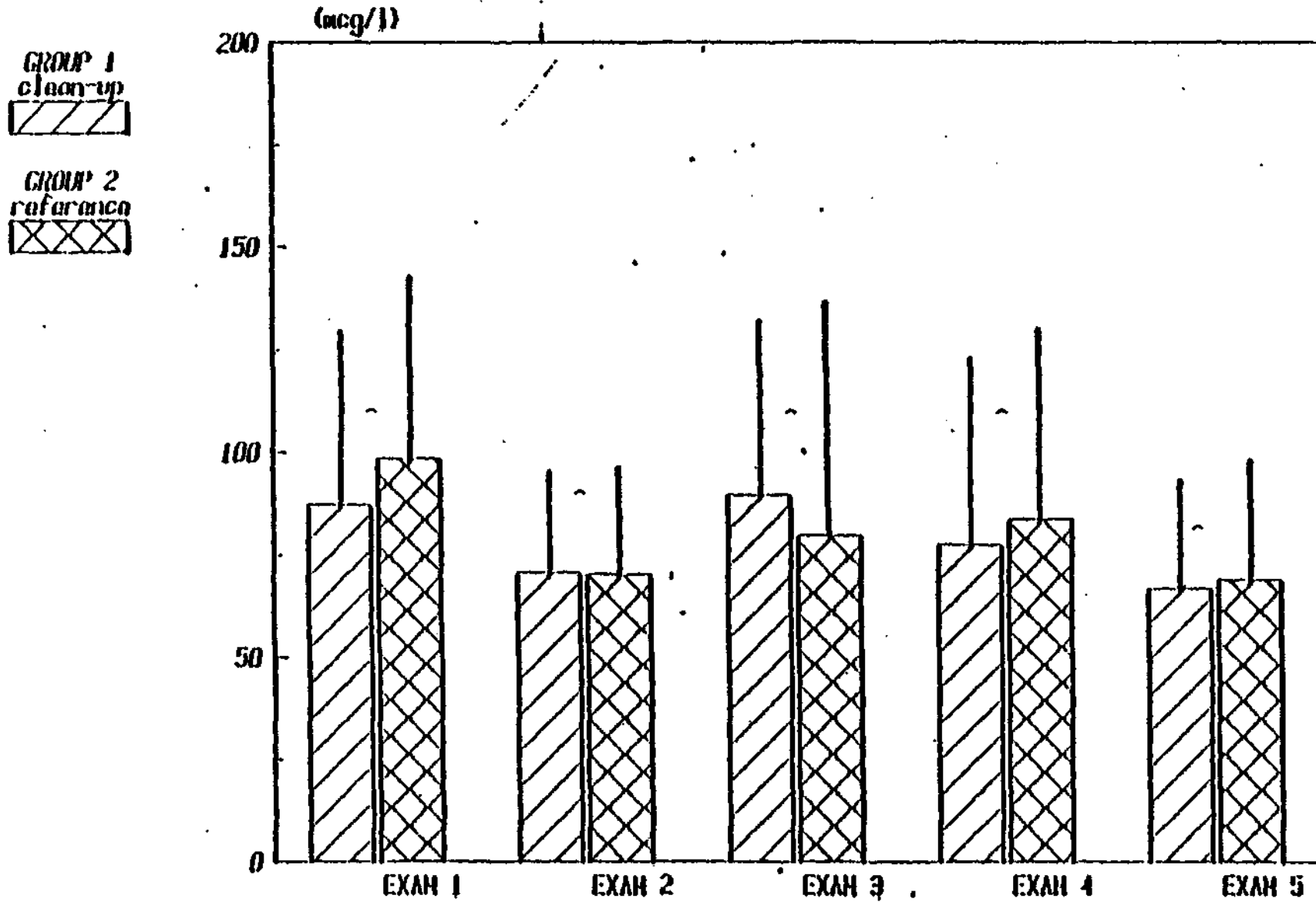


Fig.4 URINARY PORPHYRINS (mean+sd)
in clean-up and reference groups



* Significant between-exams mean difference.

Fig. 5 S G O I values
in clean-up and reference groups

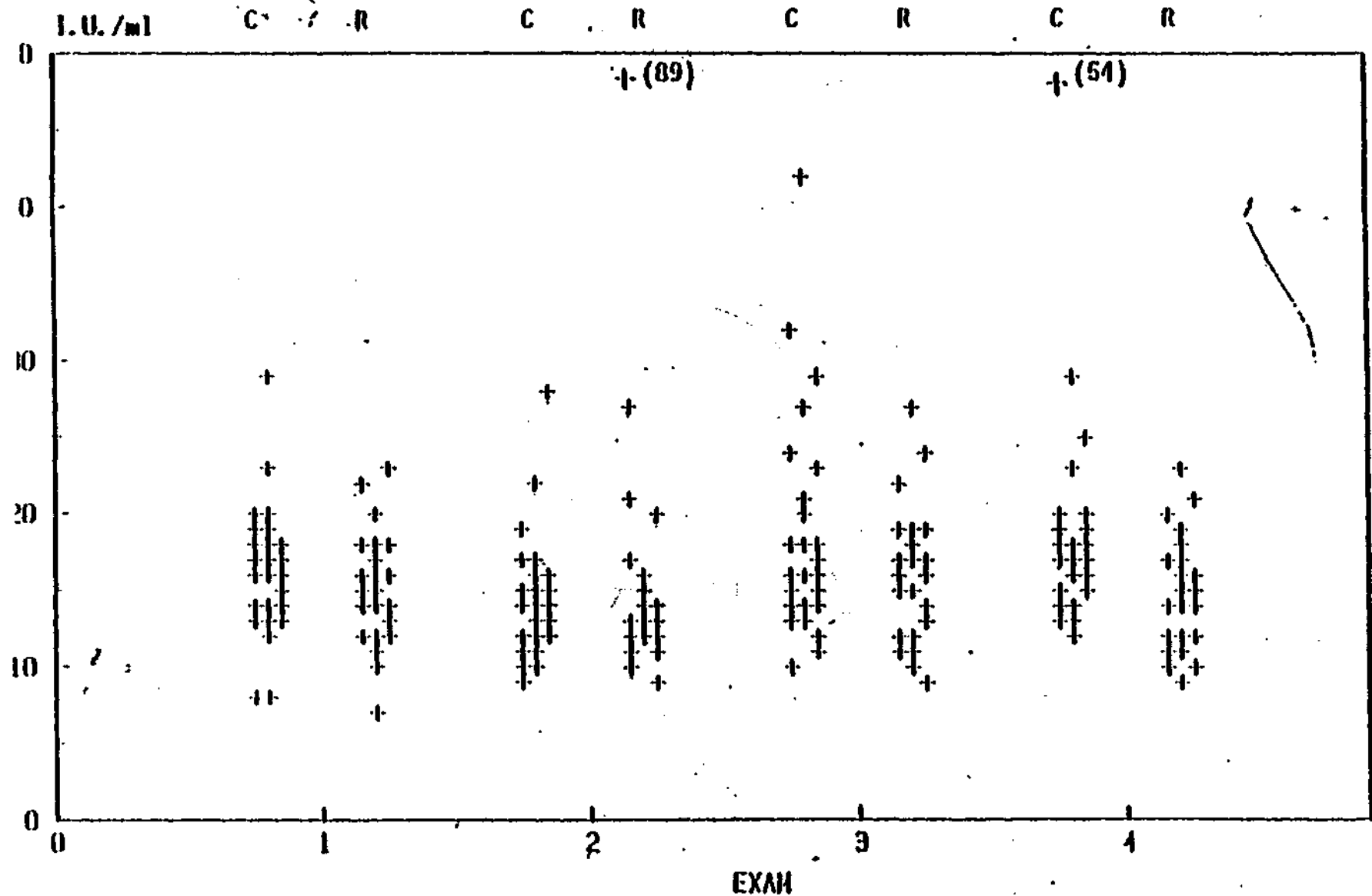
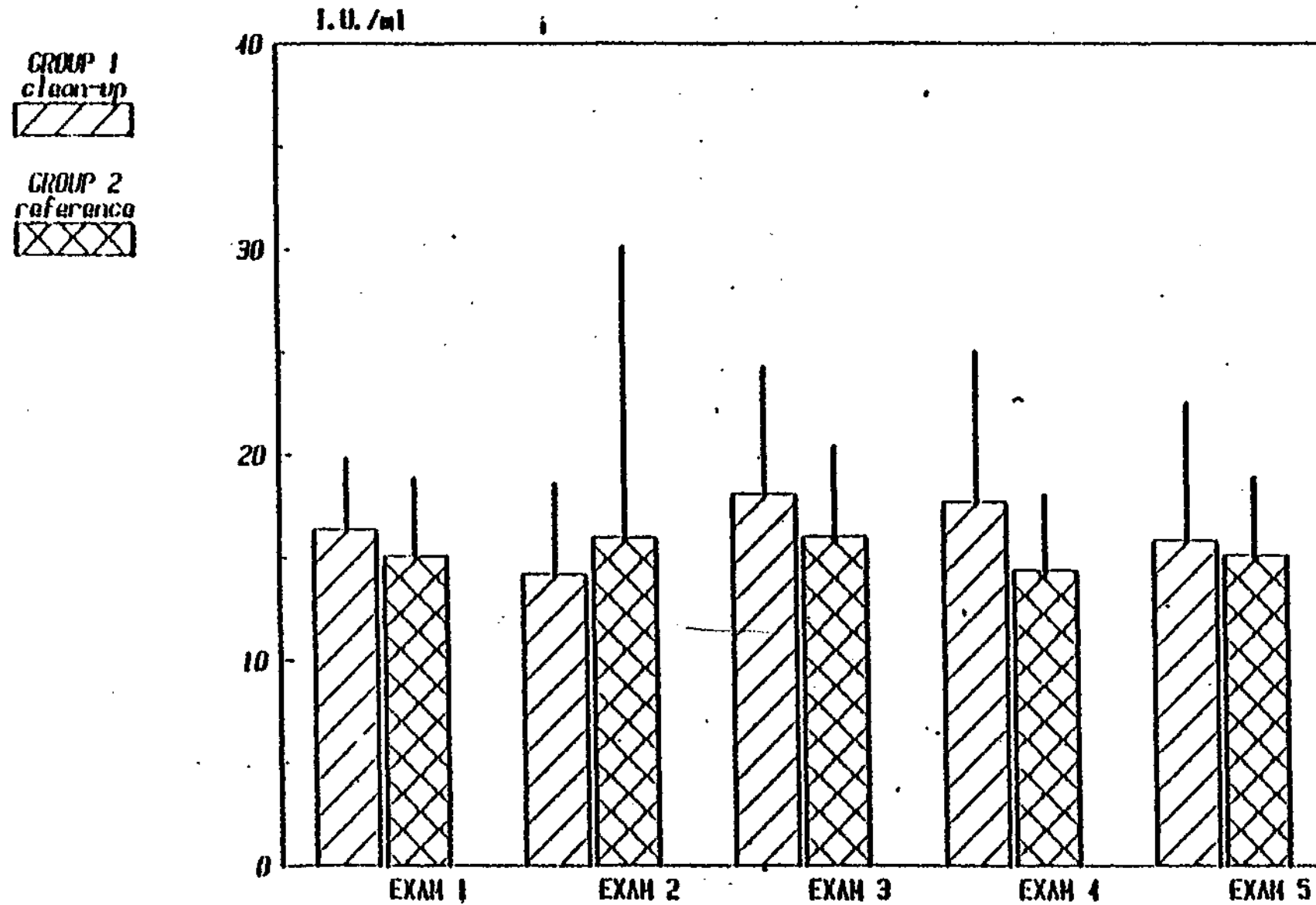


Fig. 6 S. G. O. T. (mean+sd)
in clean-up and reference groups



* Significant between-groups mean difference.

Fig.7 S G P T values
in clean-up and reference groups

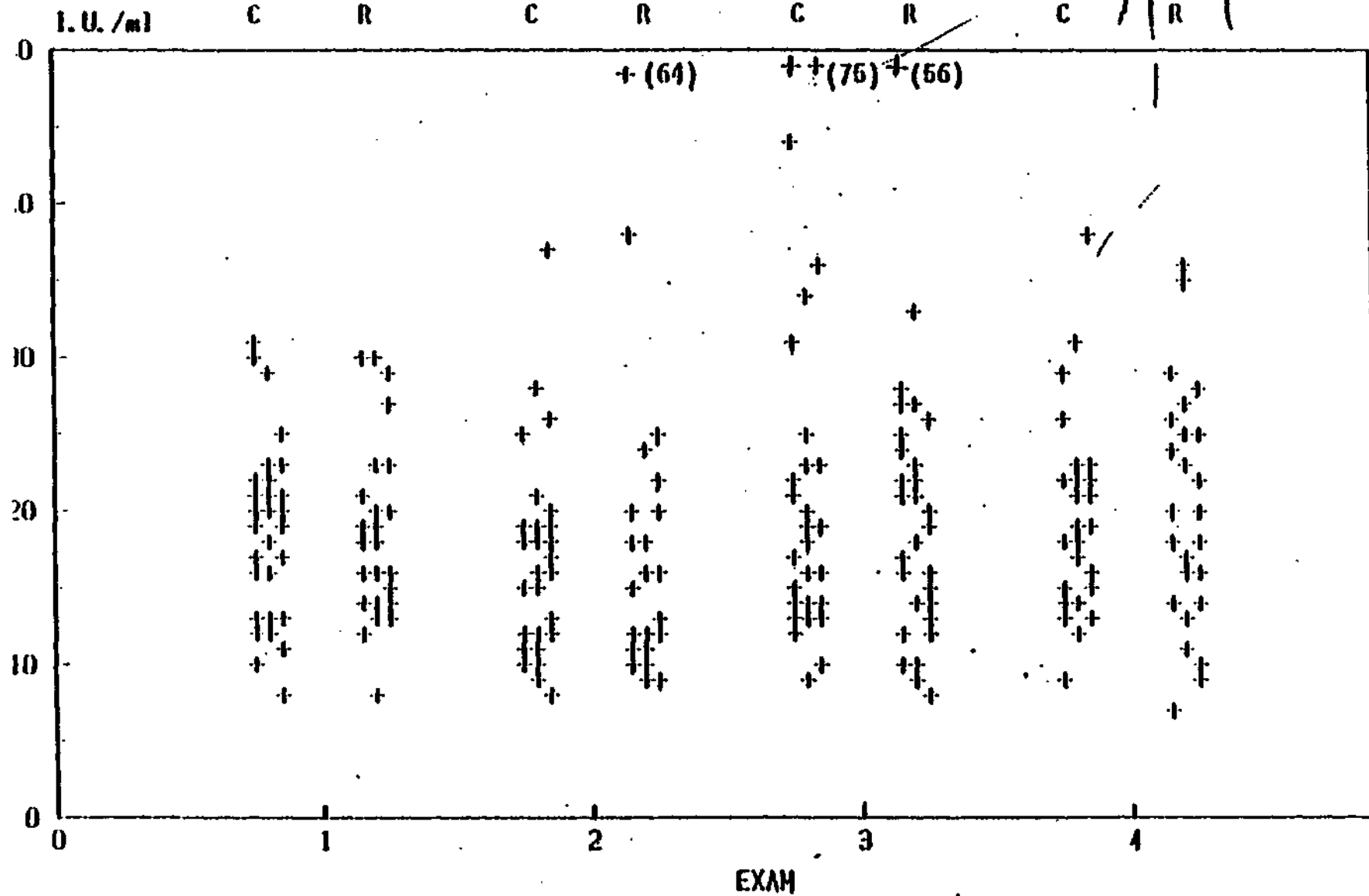


Fig.9 ALKAL. PHOSPHATASE value
in clean-up and reference groups

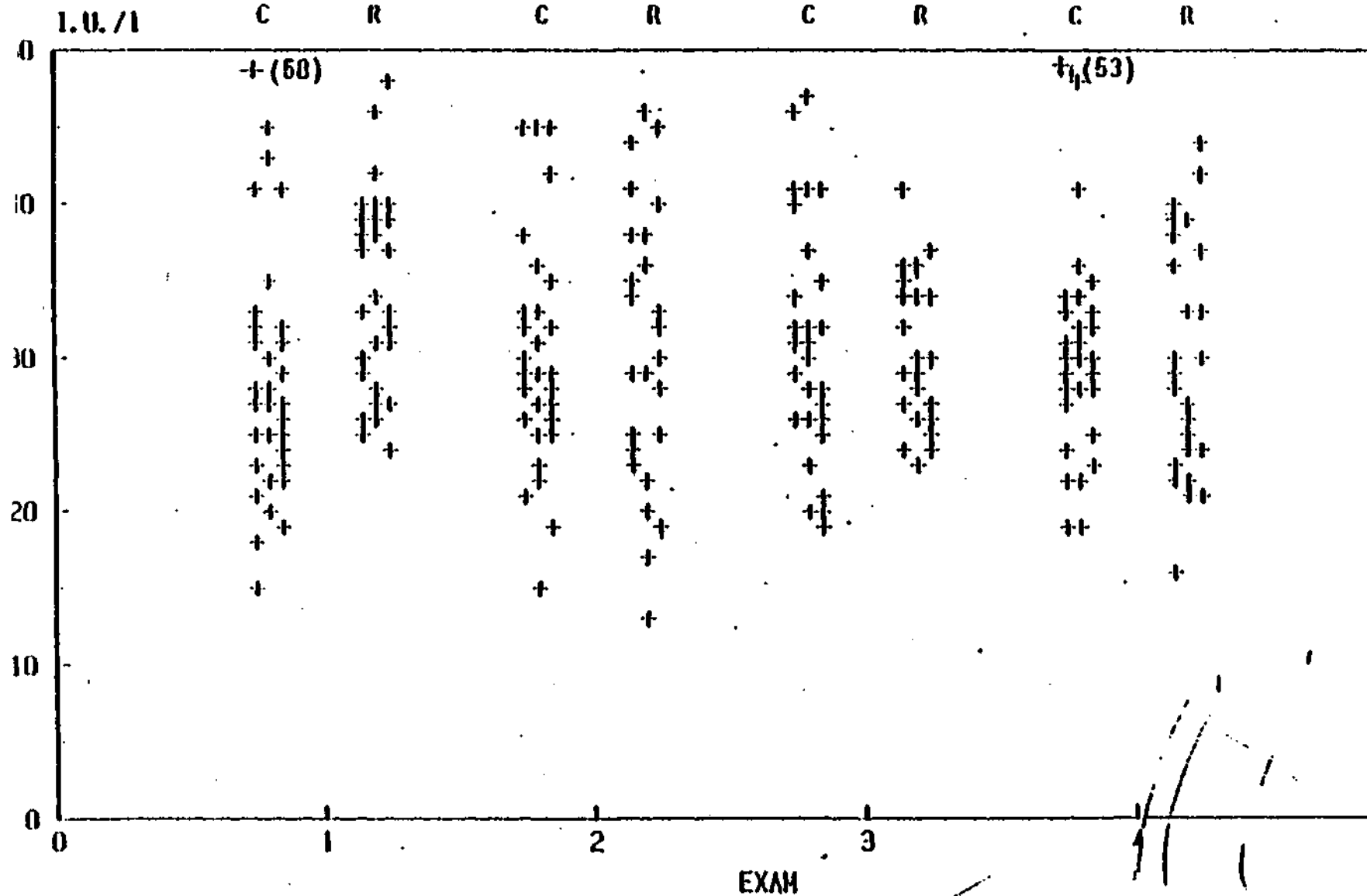


Fig.8 S.G.P.T. (mean+sd)
in clean-up and reference groups

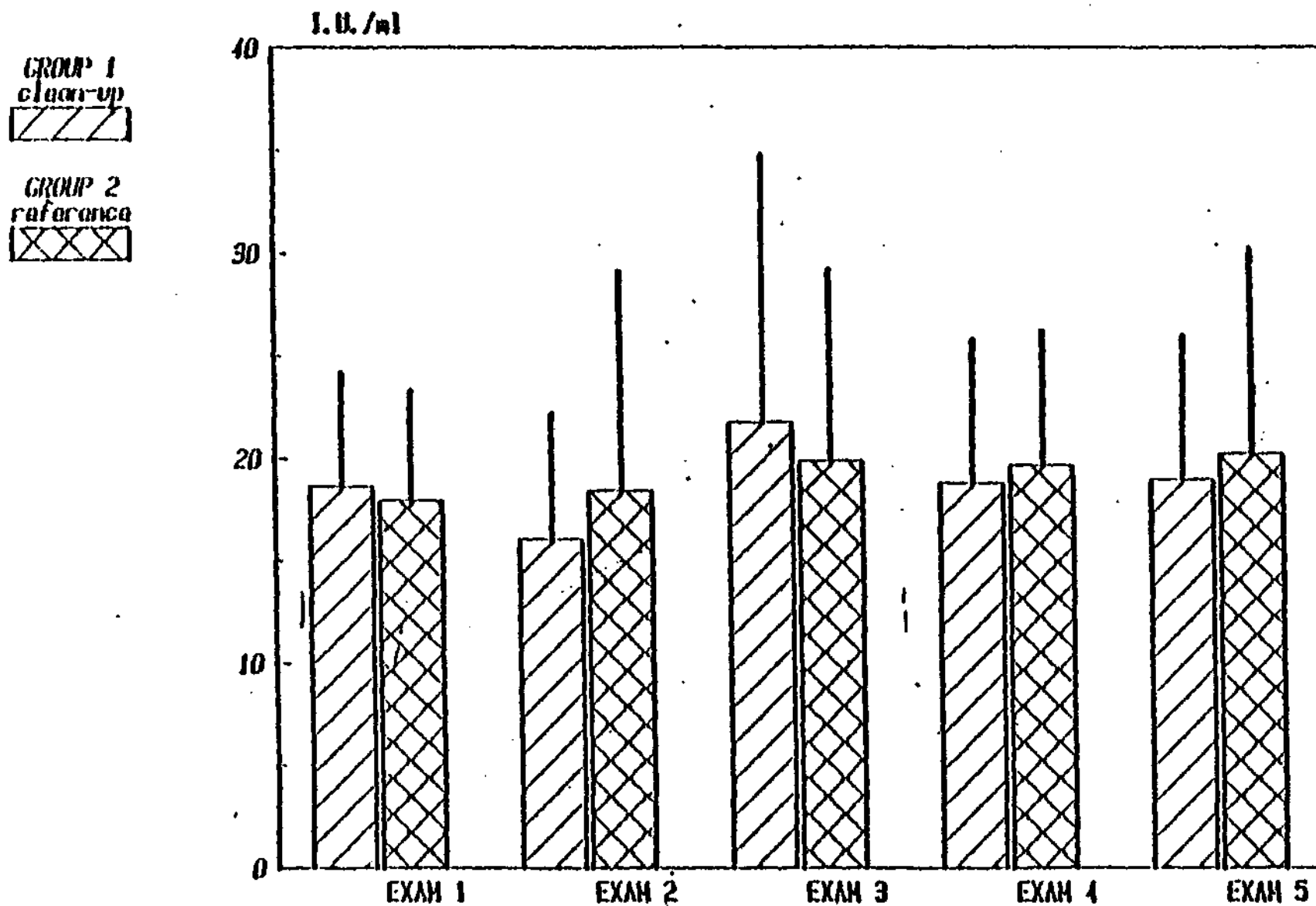
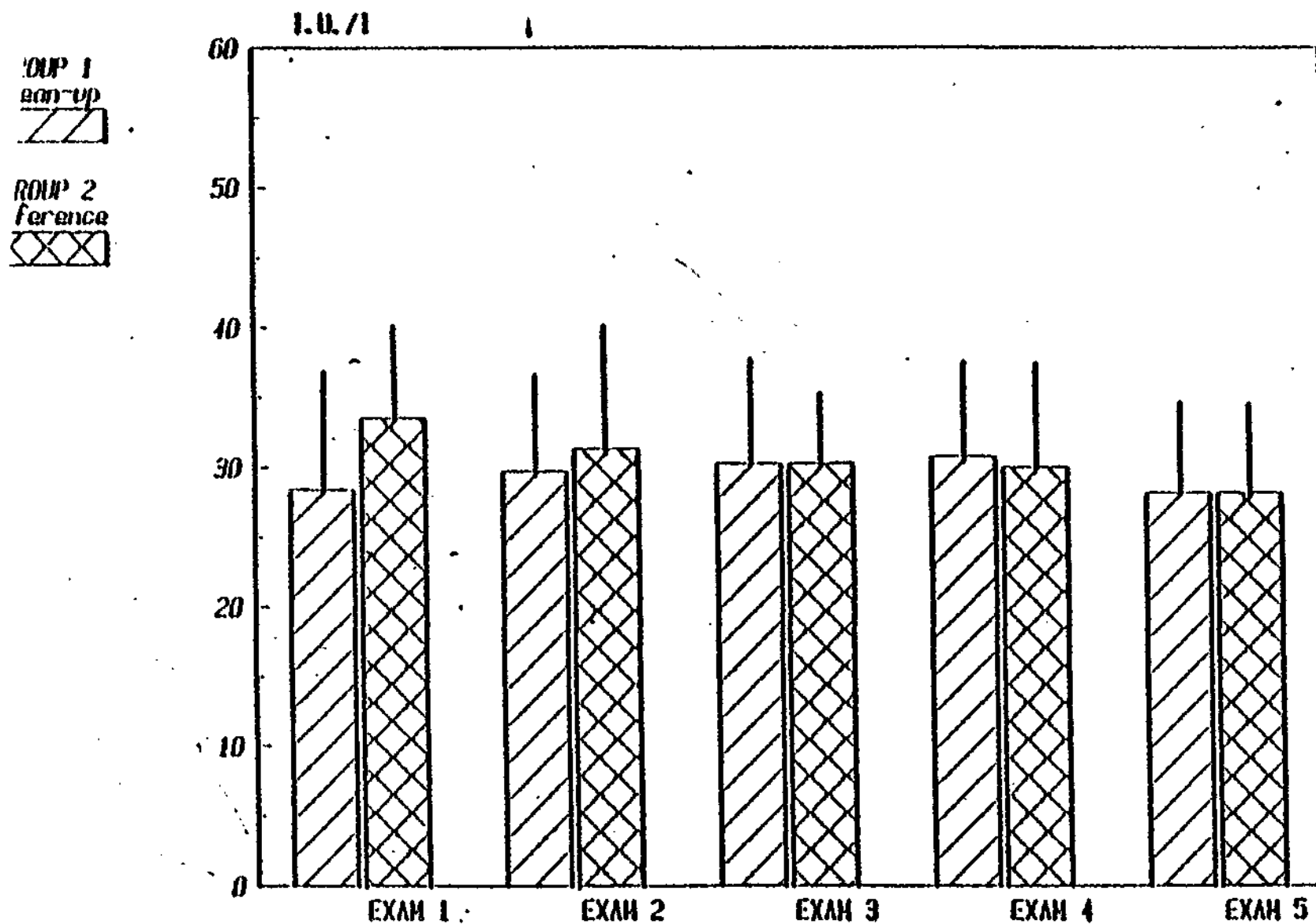


Fig. 10 ALKAL. PHOSPHATASE (mean±sd)
in clean-up and reference groups



^ Significant between-groups post-difference.

Fig. 11 G G T P values
in clean-up and reference groups

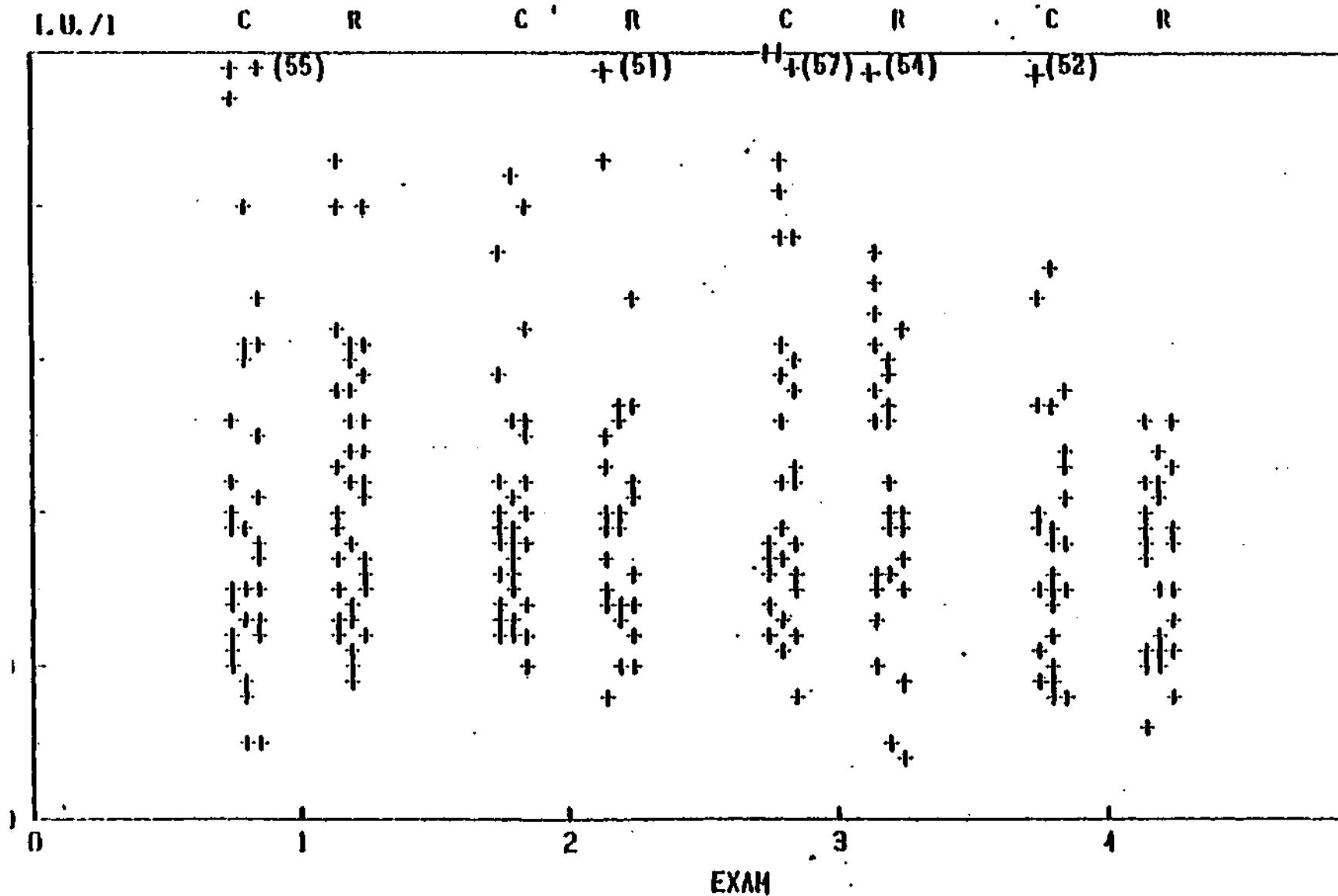
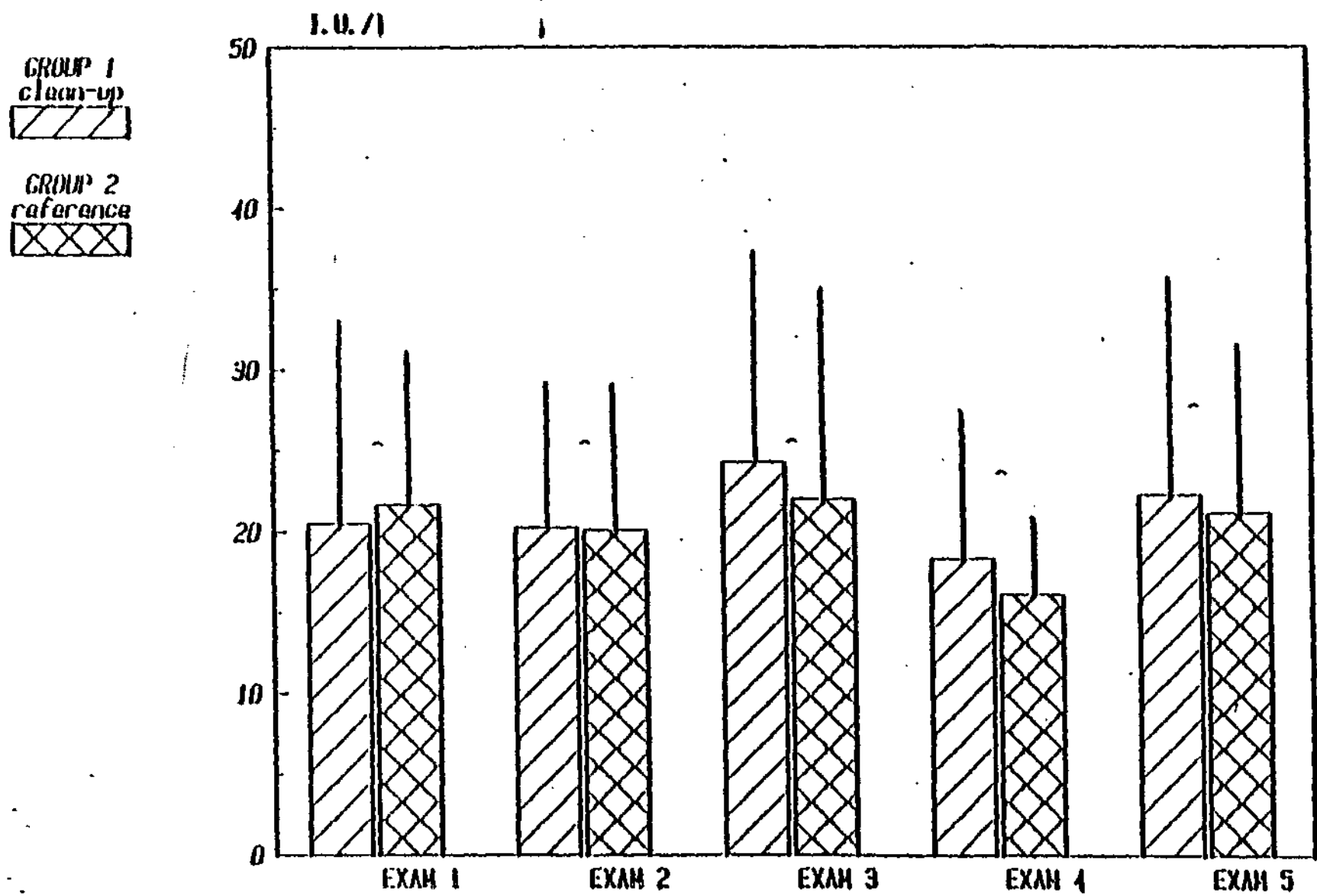


Fig. 12 G, G. T, P. (mean+sd)
in clean-up and reference groups



^ Significant between-exam mean difference.

FIG. 13 BILIRUBIN values
in clean-up and reference groups

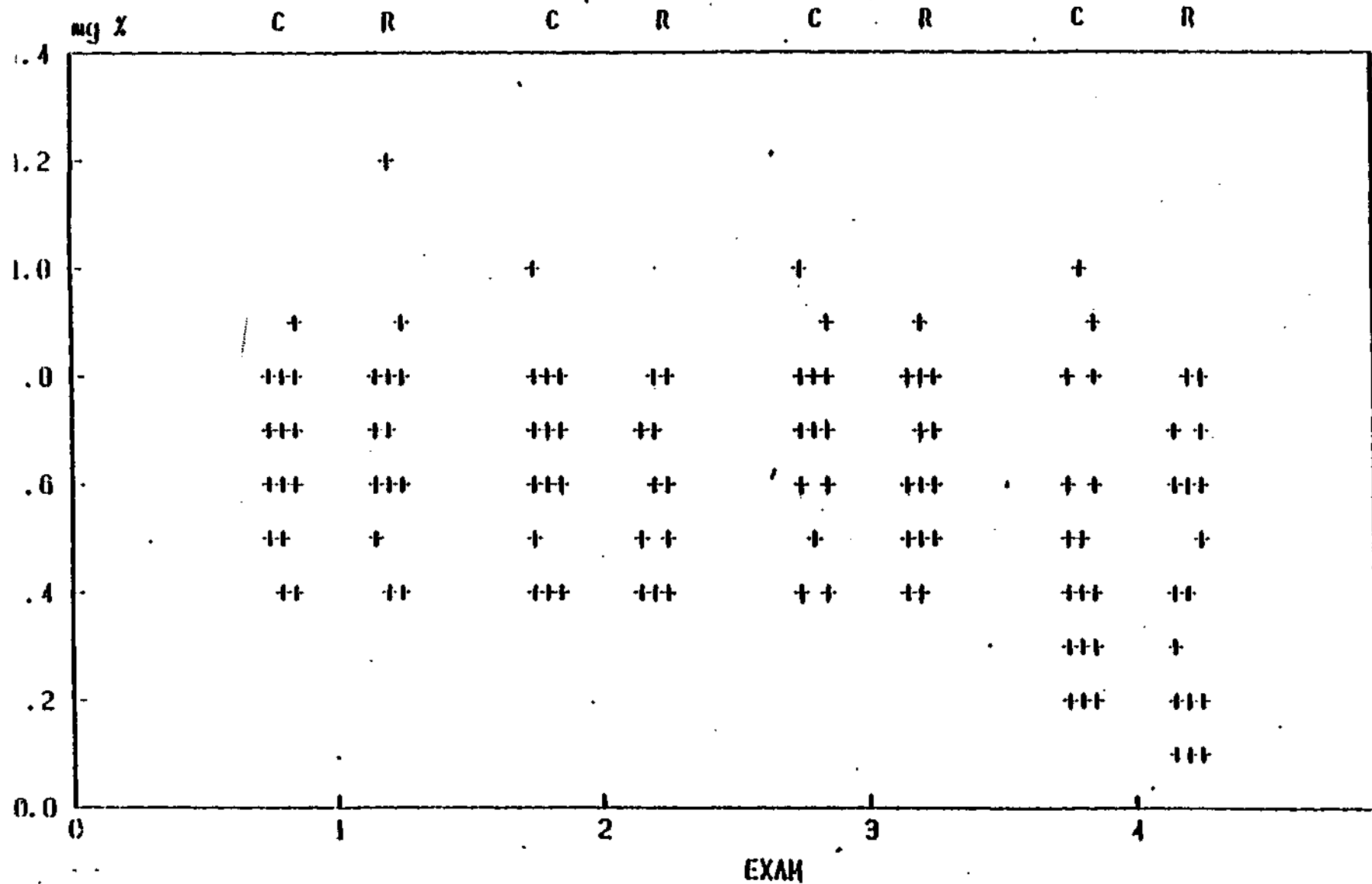
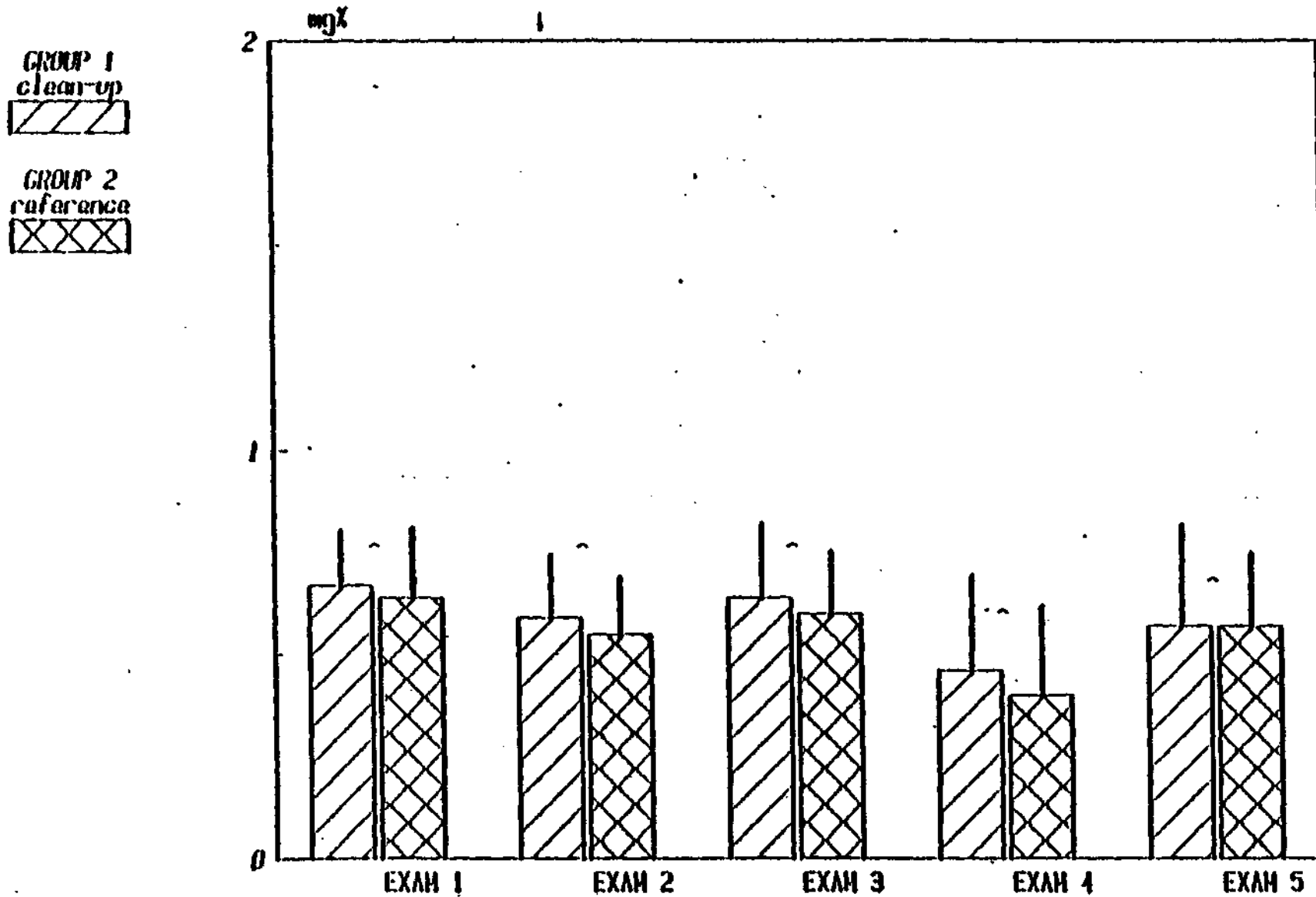


Fig.14 BILIRUBIN (mean±sd)
in clean-up and reference groups



~ Significant between-exams mean difference.

Fig. 15 U - ALA values
in clean-up and reference groups

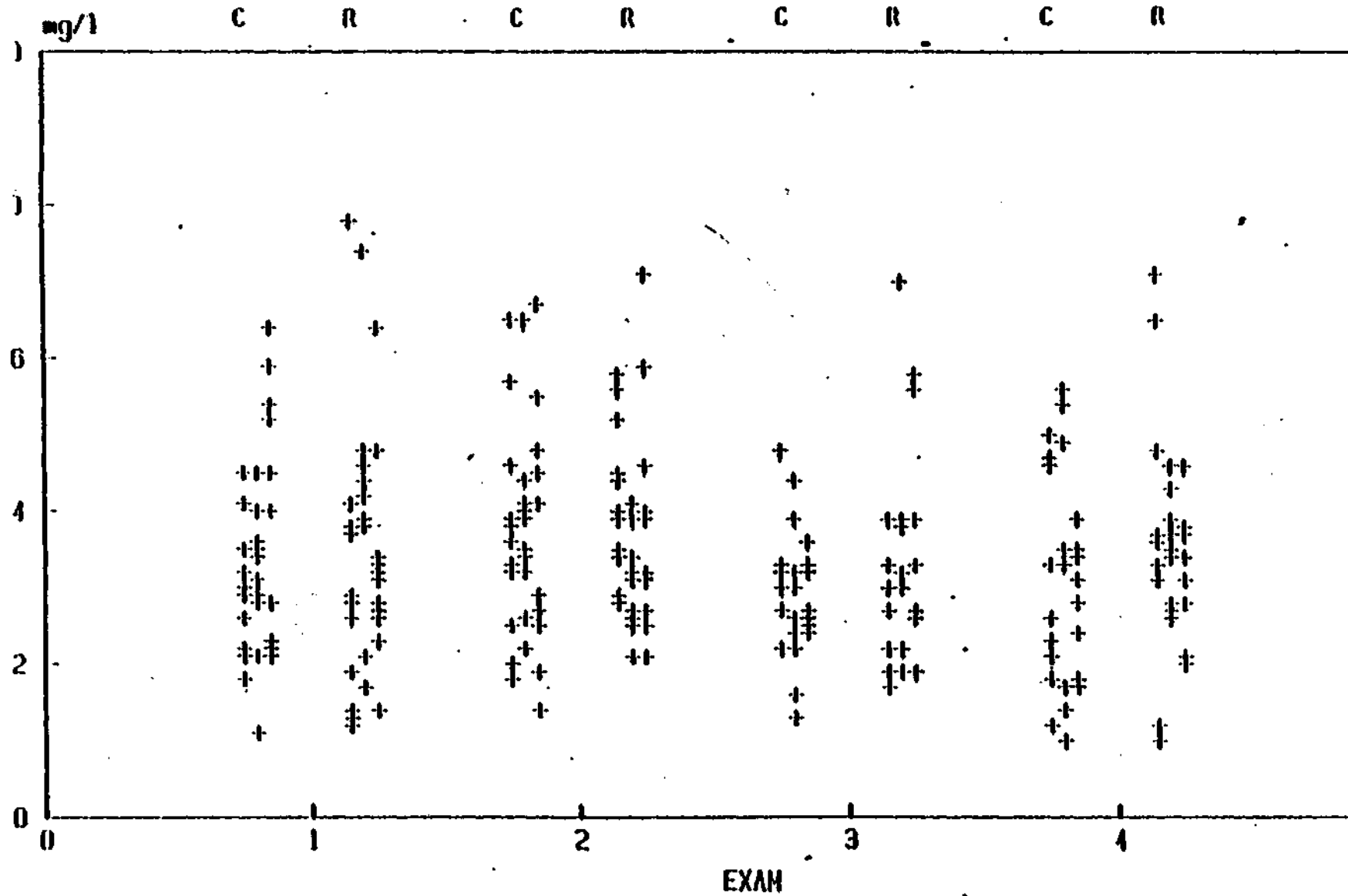
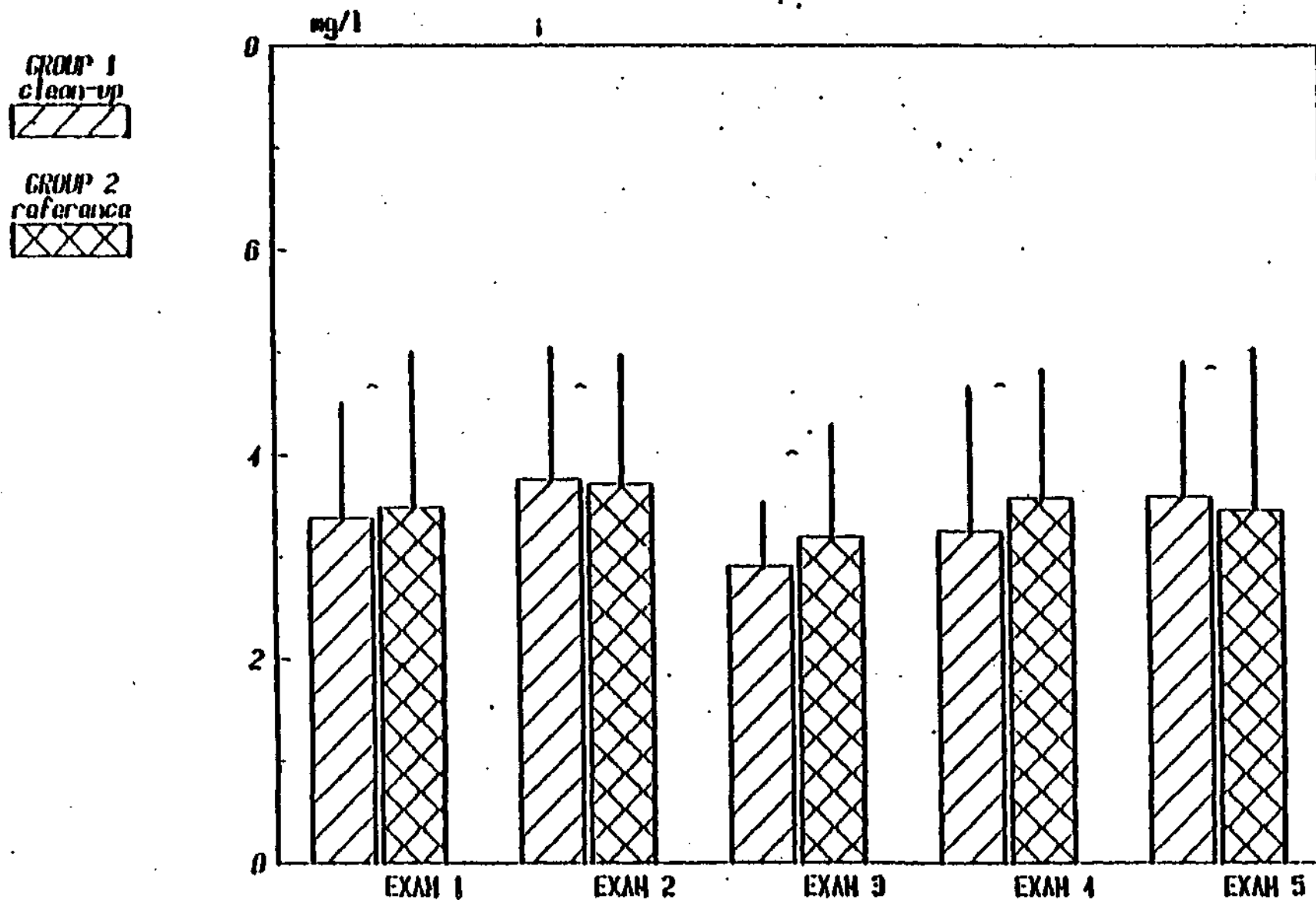


Fig. 16 U - A L A (mean+sd)
in clean-up and reference groups



~ Significant between-exams mean difference.

Fig. 17 CHOLESTEROL values
in clean-up and reference groups

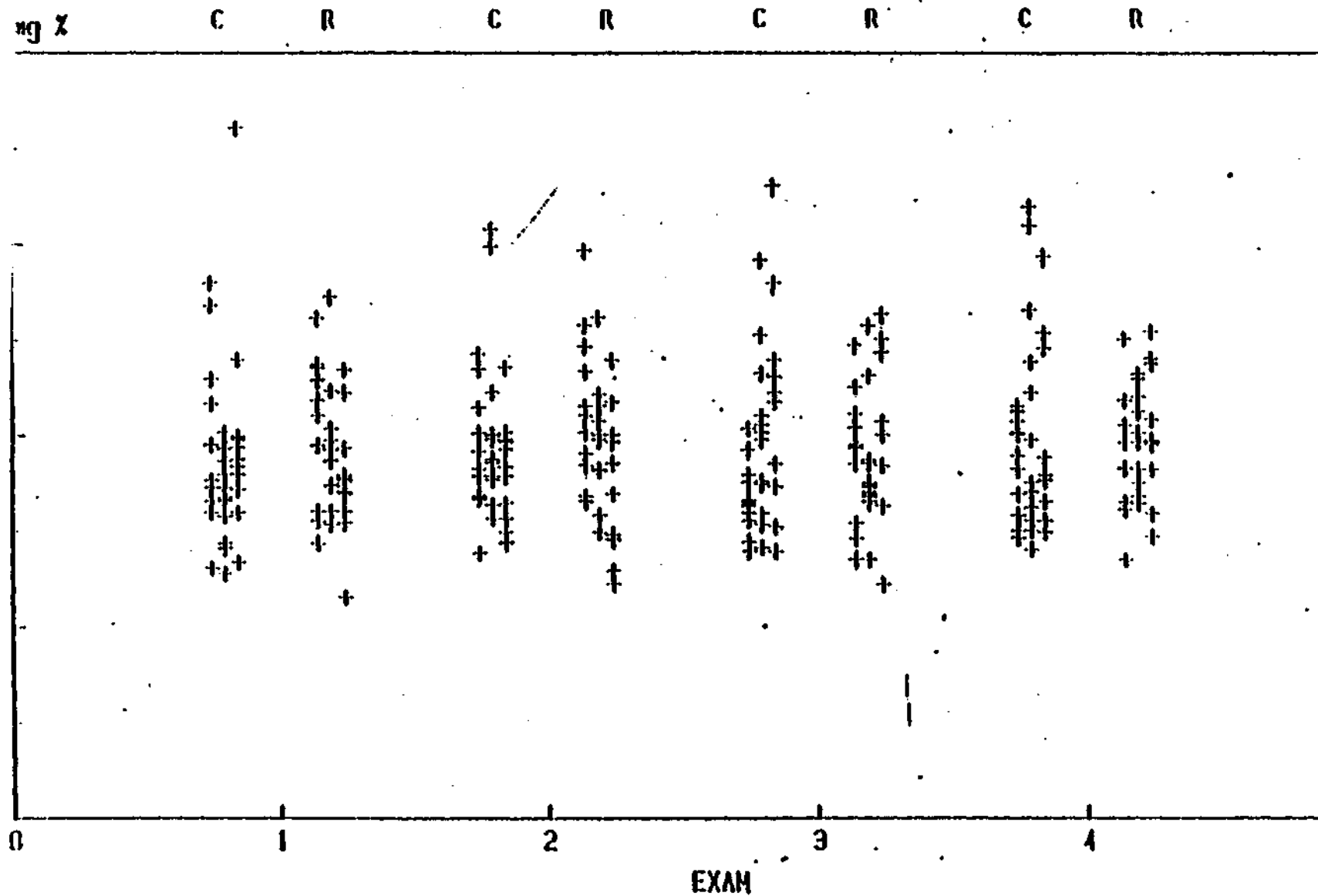


Fig. 18 CHOLESTEROL (mean±sd)
In clean-up and reference groups

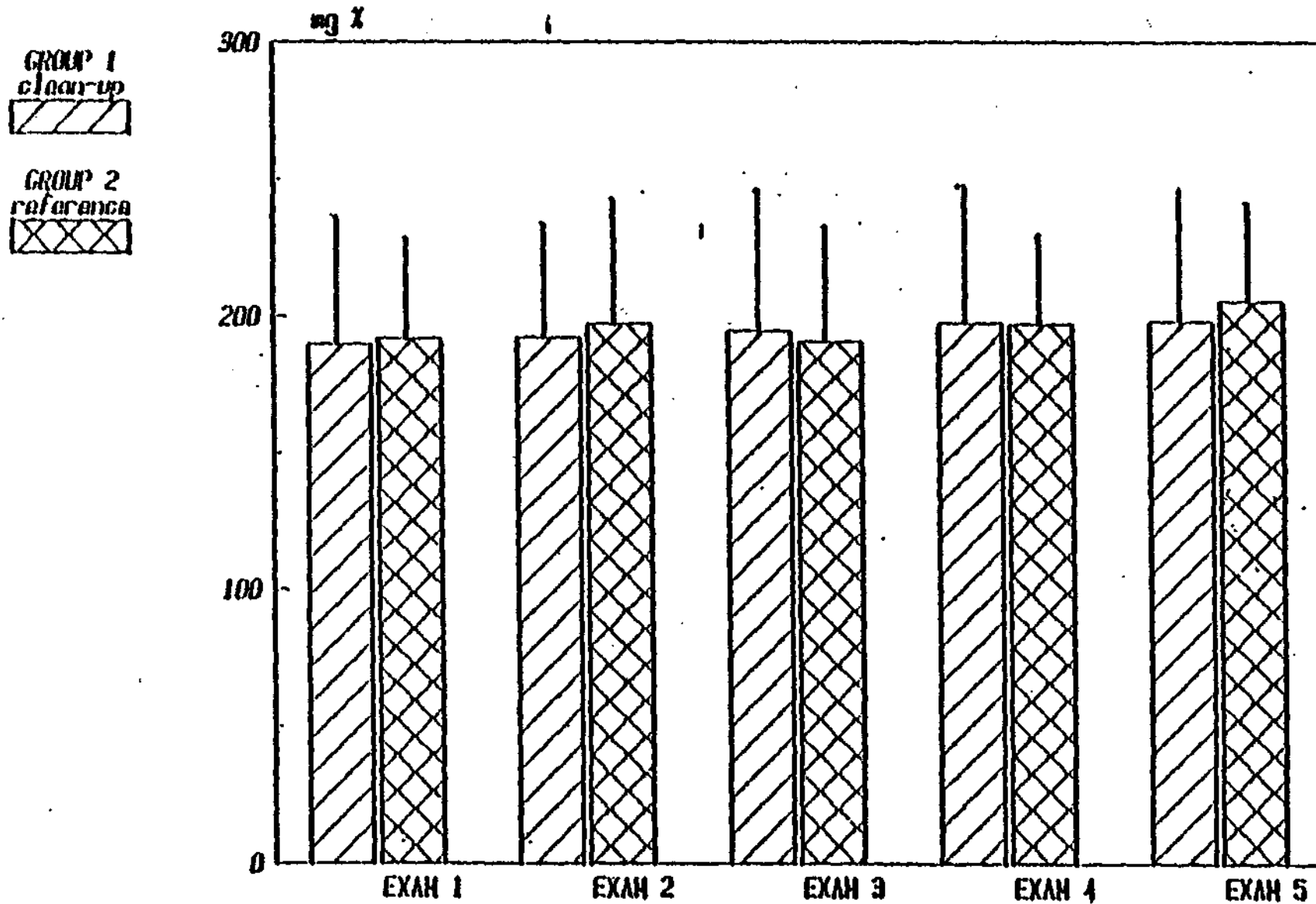


Fig. 19 TRIGLYCERIDES values
in clean-up and reference groups

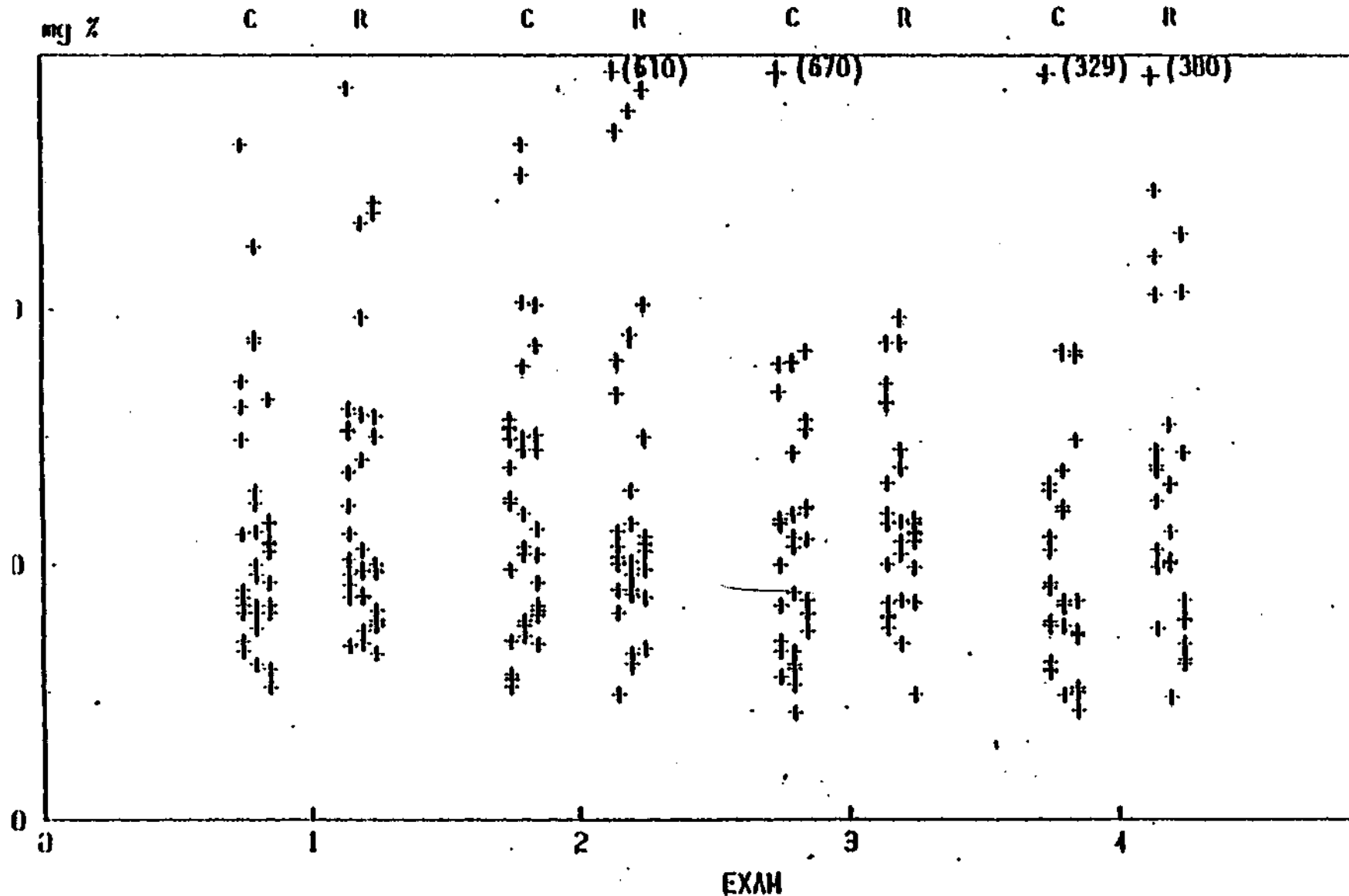


Fig.20 TRIGLYCERIDES (mean±sd)
in clean-up and reference groups

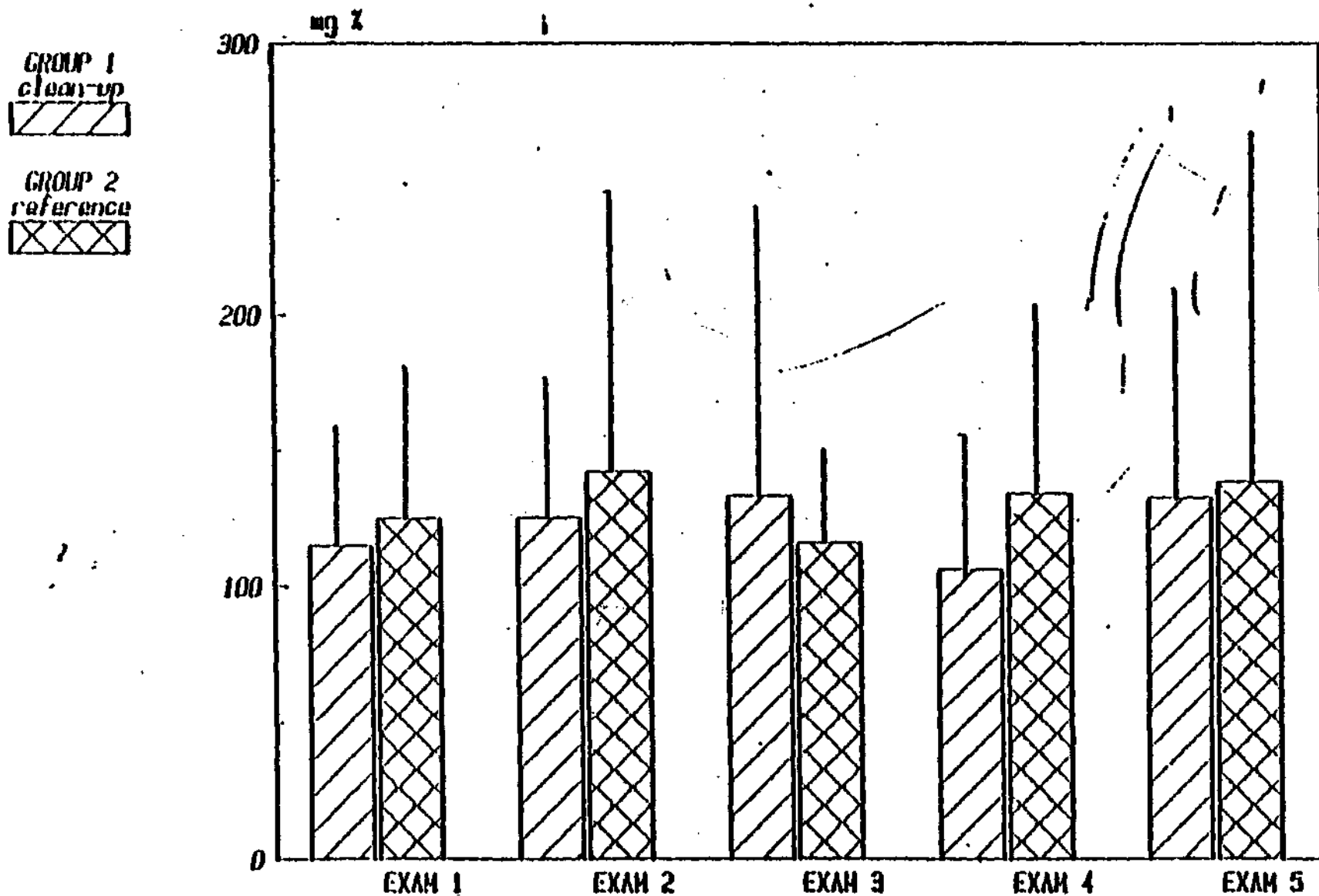


Fig.21 LEUKOCYTES values
in clean-up and reference groups

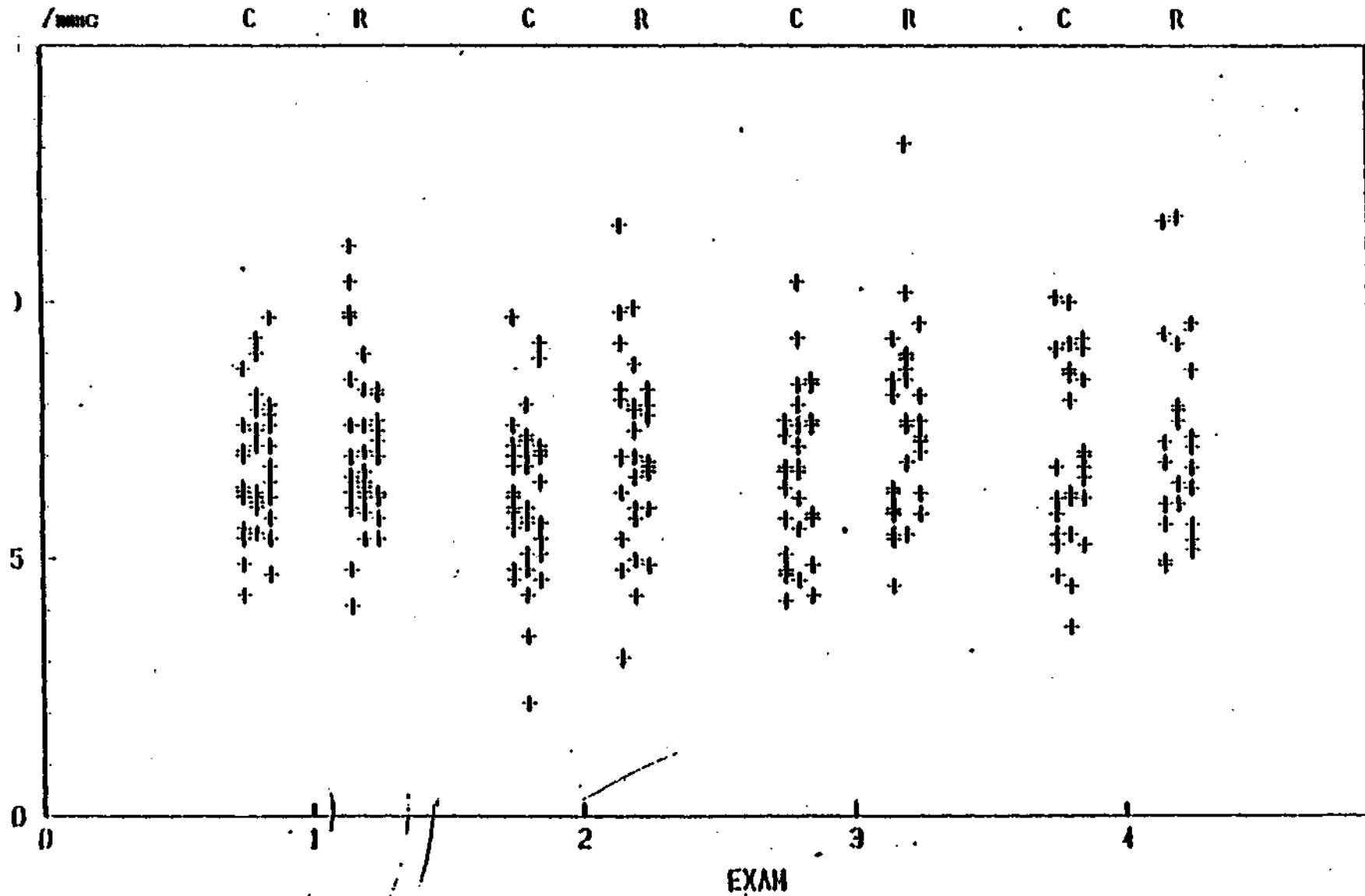
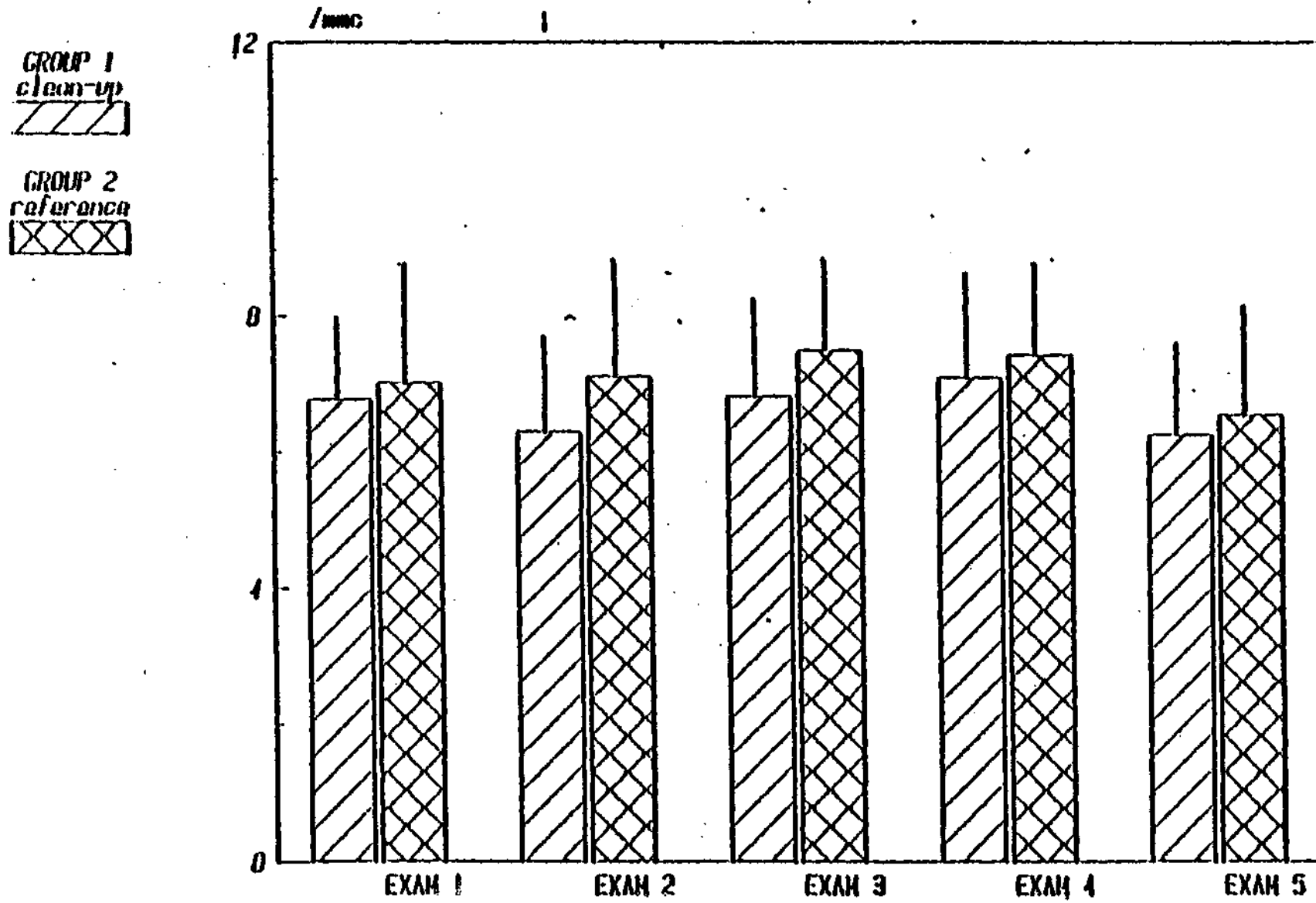
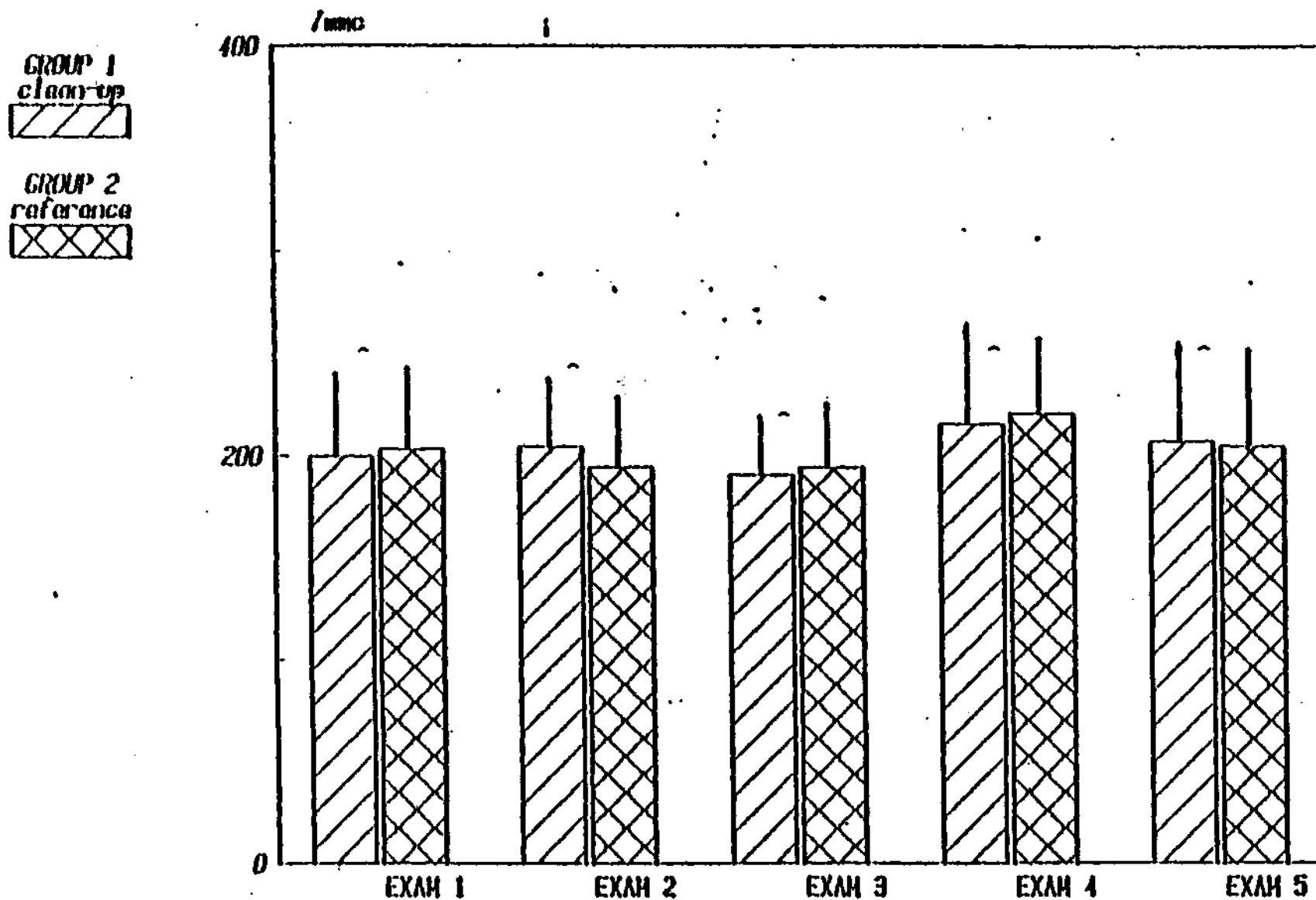


Fig.22 LEUKOCYTES (mean±sd)
in clean-up and reference groups



~ Significant between-groups mean difference.

Fig.23 PLATELETS (mean±sd)
in clean-up and reference groups



~ Significant between-exams mean difference.

Fig.24 SERUM PROTEINS (mean±sd)
in clean-up and reference groups

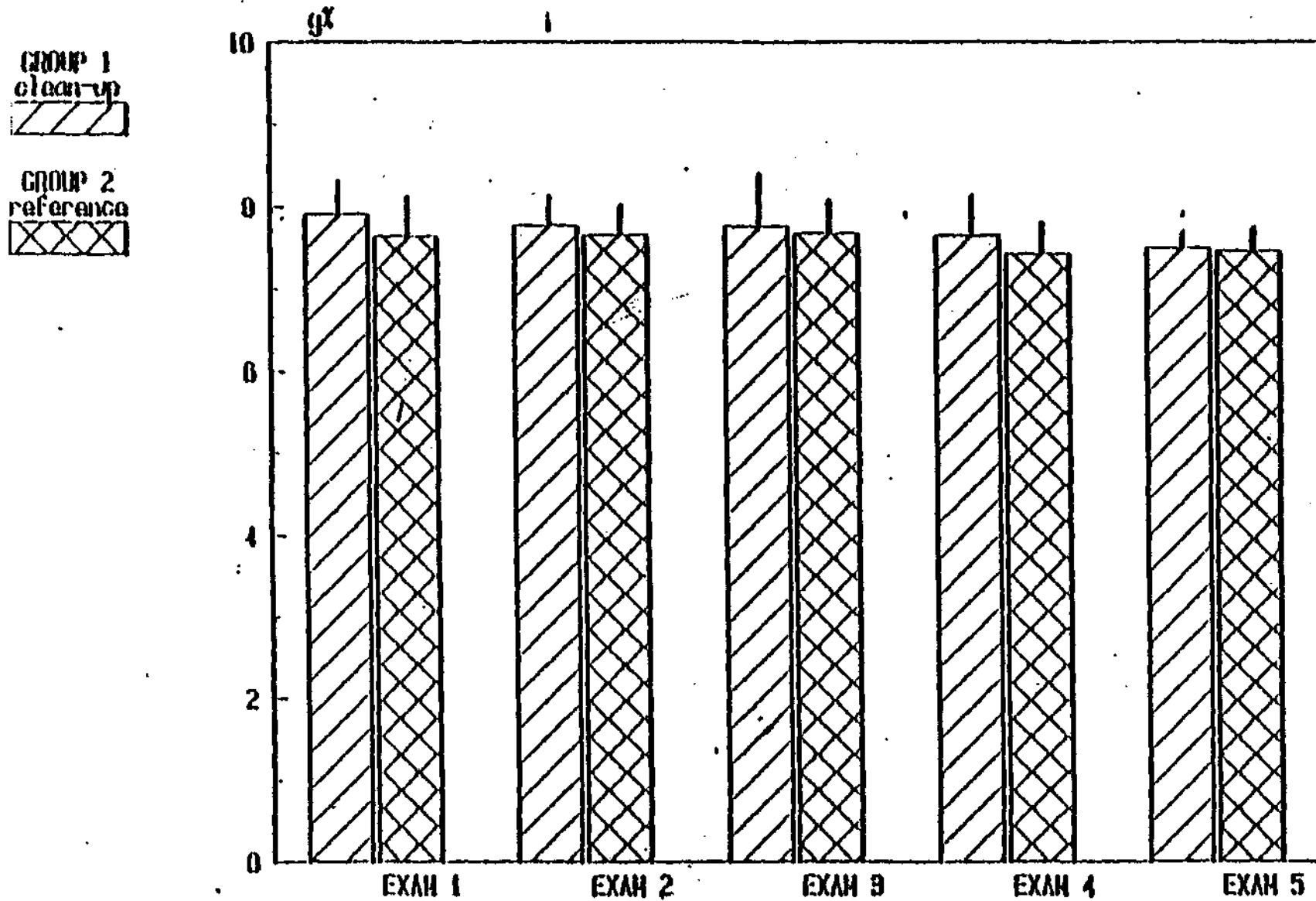


Fig. 25 ALBUMIN (mean±sd)
in clean-up and reference groups

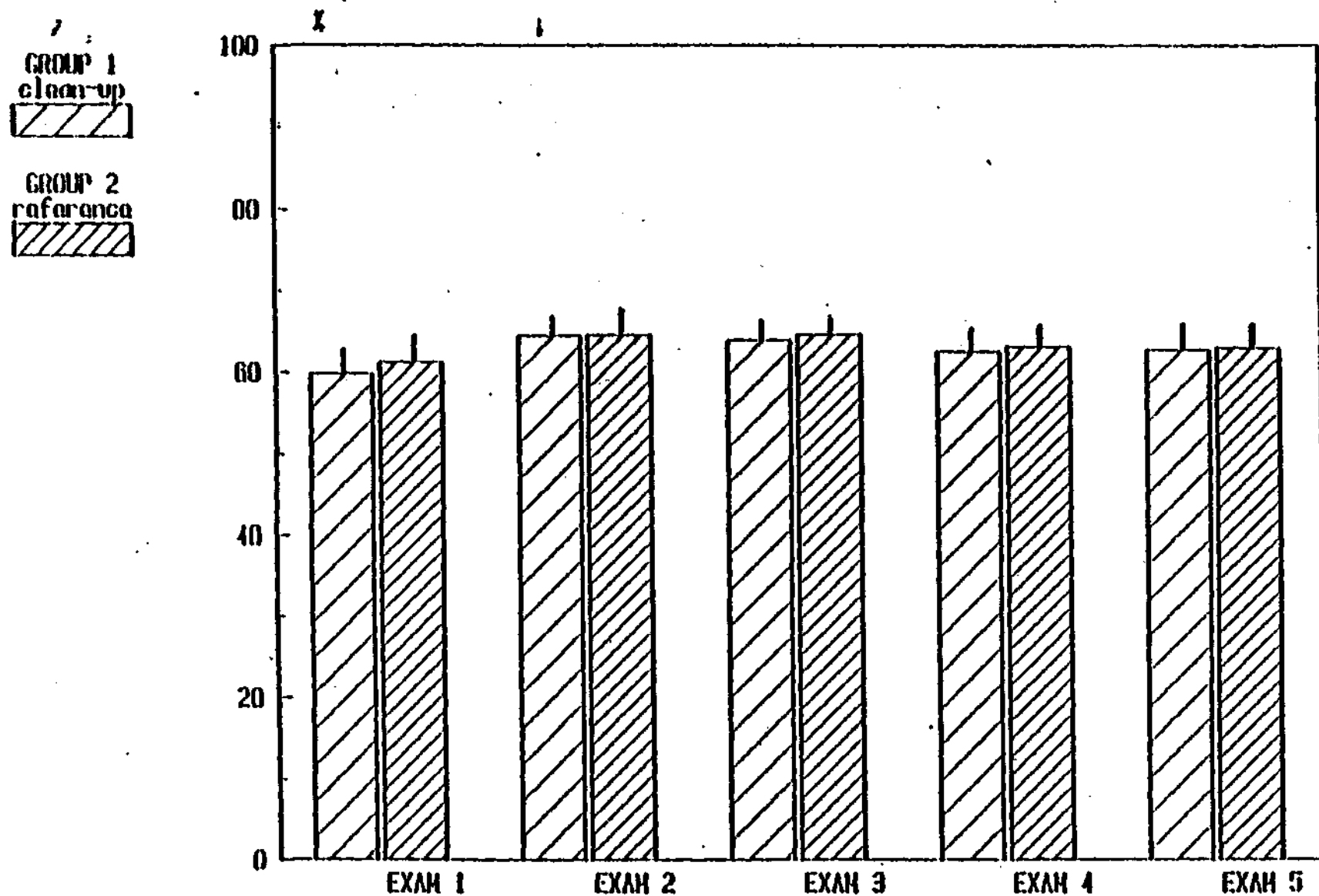
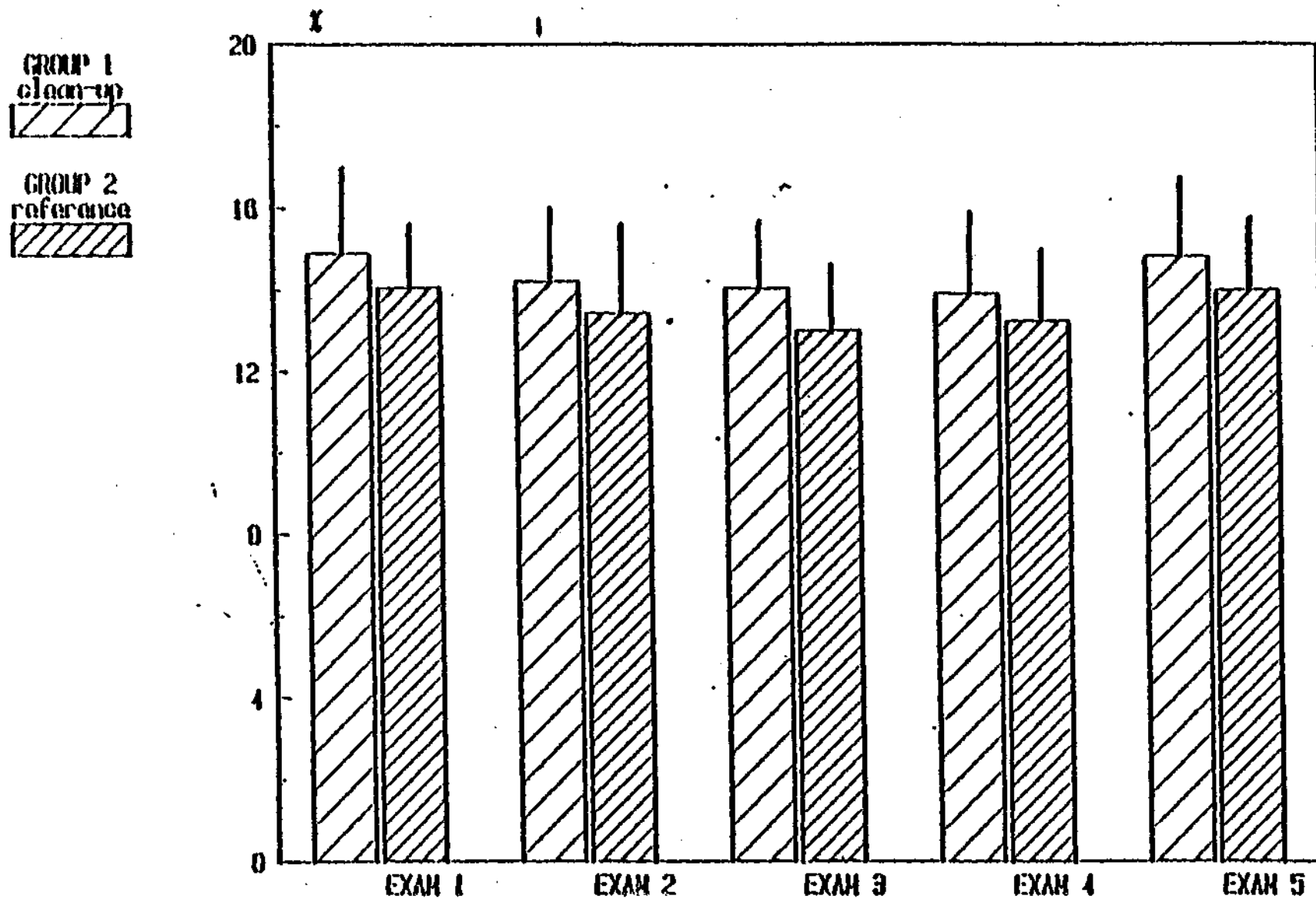


Fig. 26 γ GLOBULINS (mean+sd)
in clean-up and reference groups



* Significant between-groups mean difference.

fig. 27 PORPHYRIN PATTERN IN CLEANUP AND CONTROLS, BY EXAM (CUT-OFF=250)

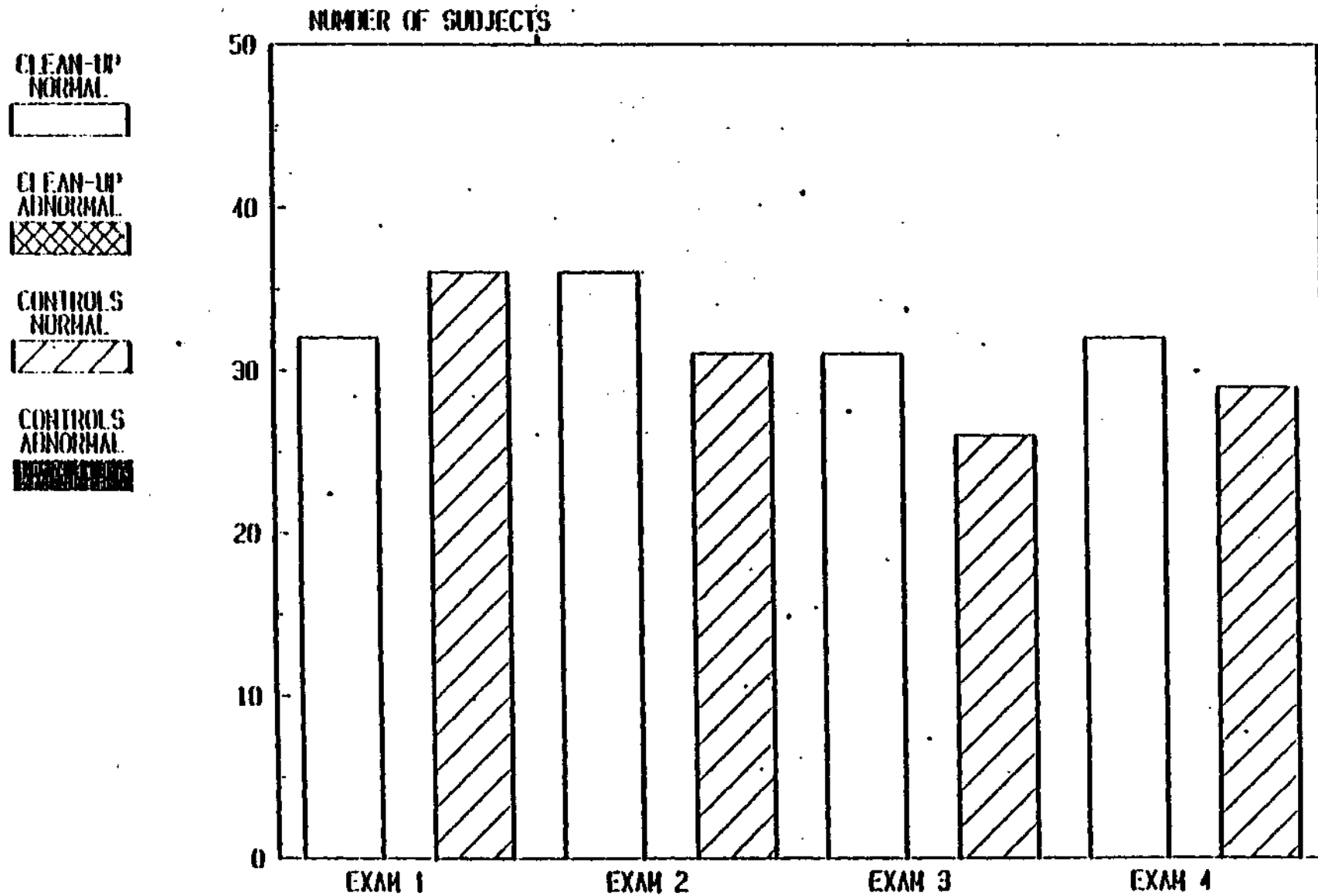


fig.28 SCOT PATTERN IN CLEAN-UP AND CONTROLS, BY EXAM (CUT-OFF=40)

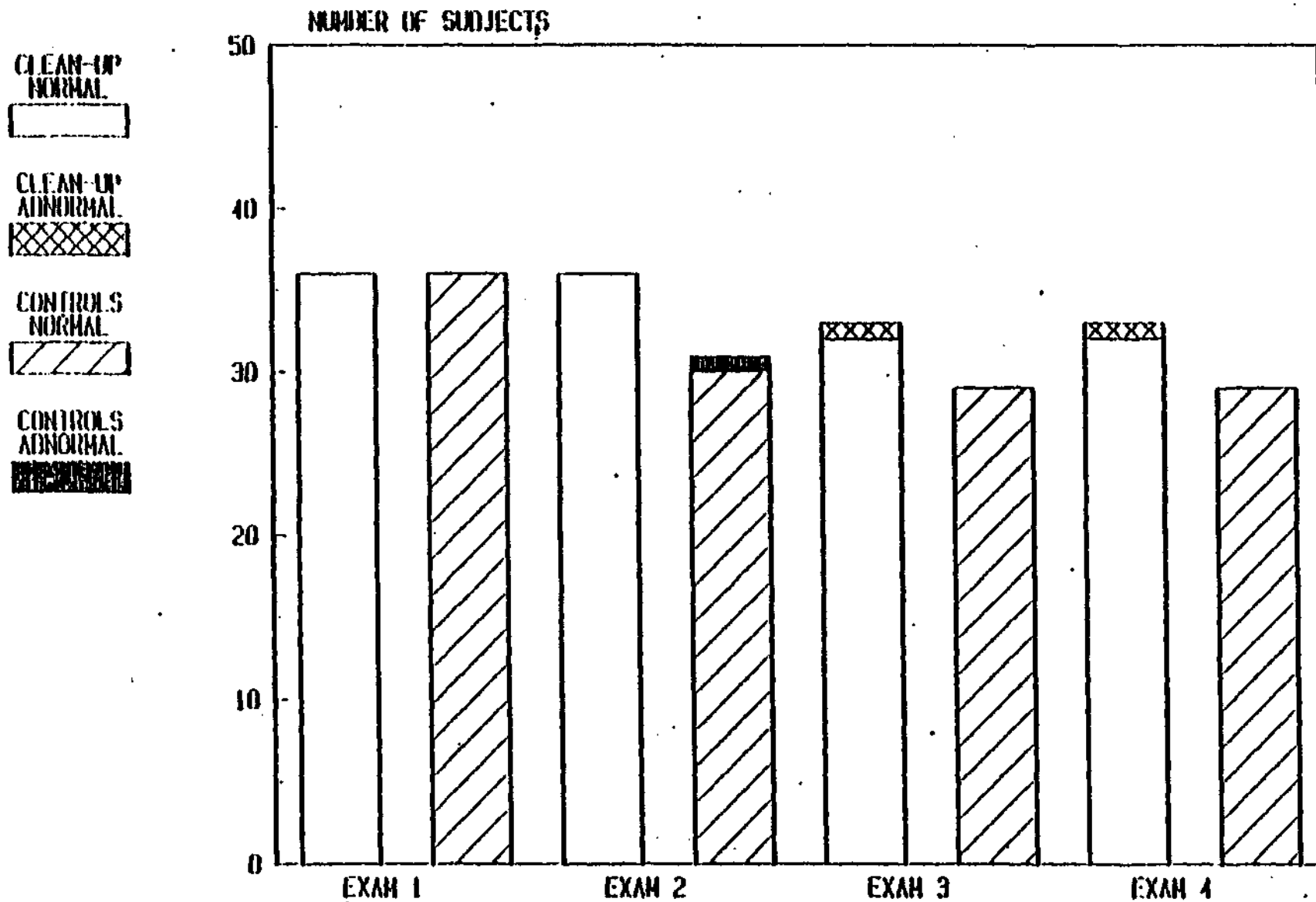


fig. 29 SGPT PATTERN IN CLEAN-UP AND CONTROLS, BY EXAM (CUT-OFF=42)

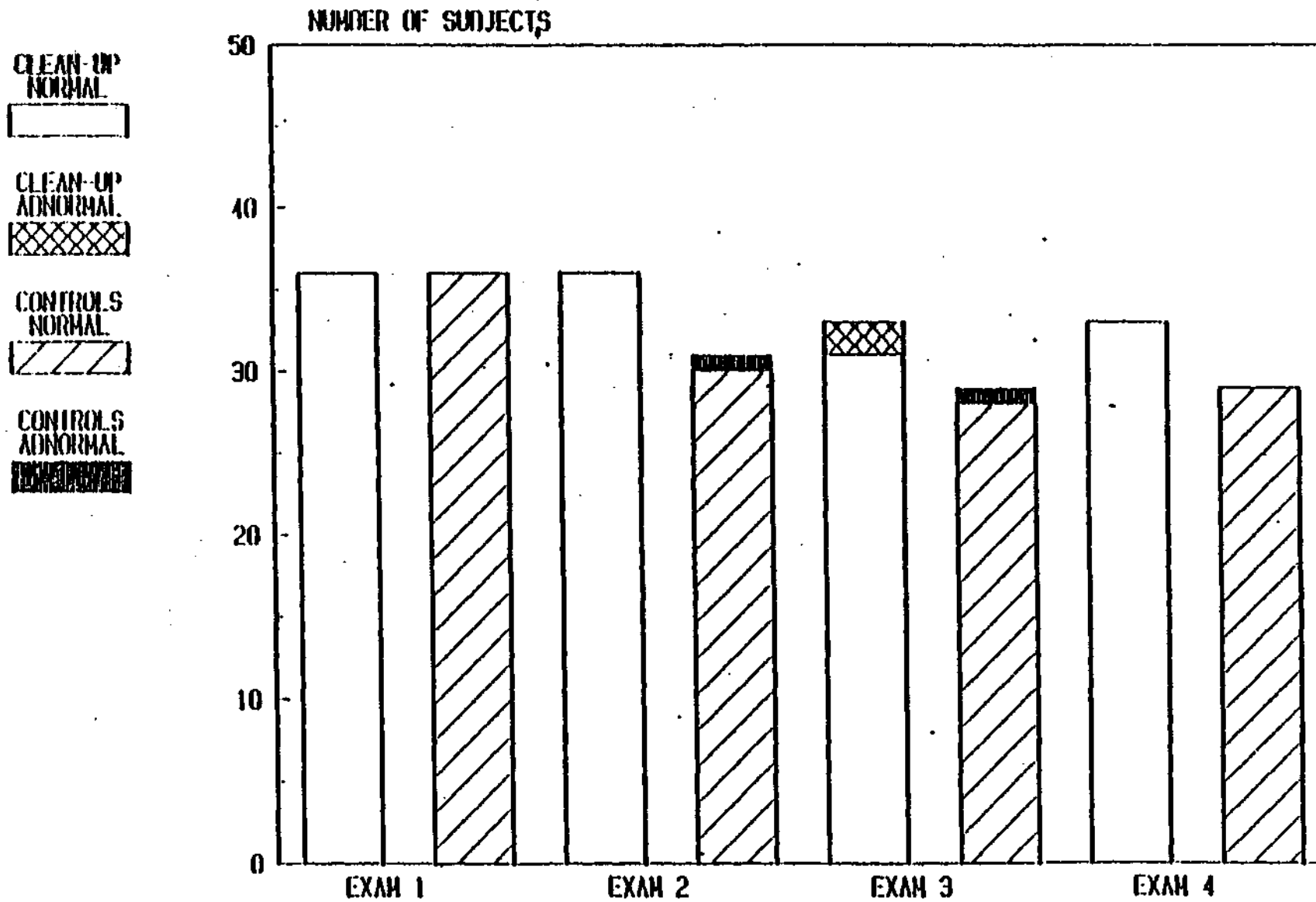


Fig. 30 A. P. PATTERN IN CLEANUP
AND CONTROLS, BY EXAM (CUT-OFF=50)

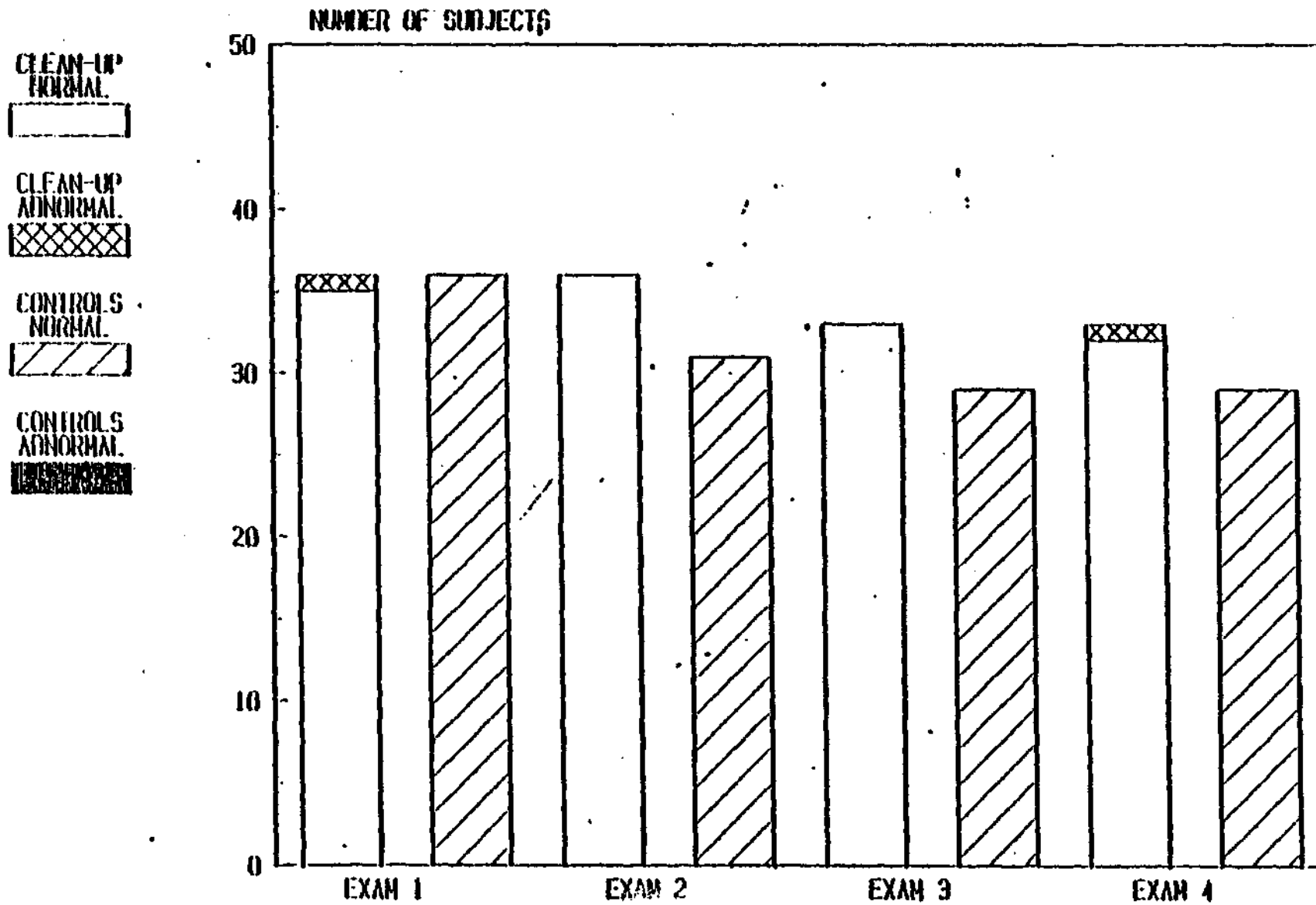


Fig. 31 GGTP-PATTERN IN CLEANUP
AND CONTROLS, BY EXAM (CUT-OFF=50)

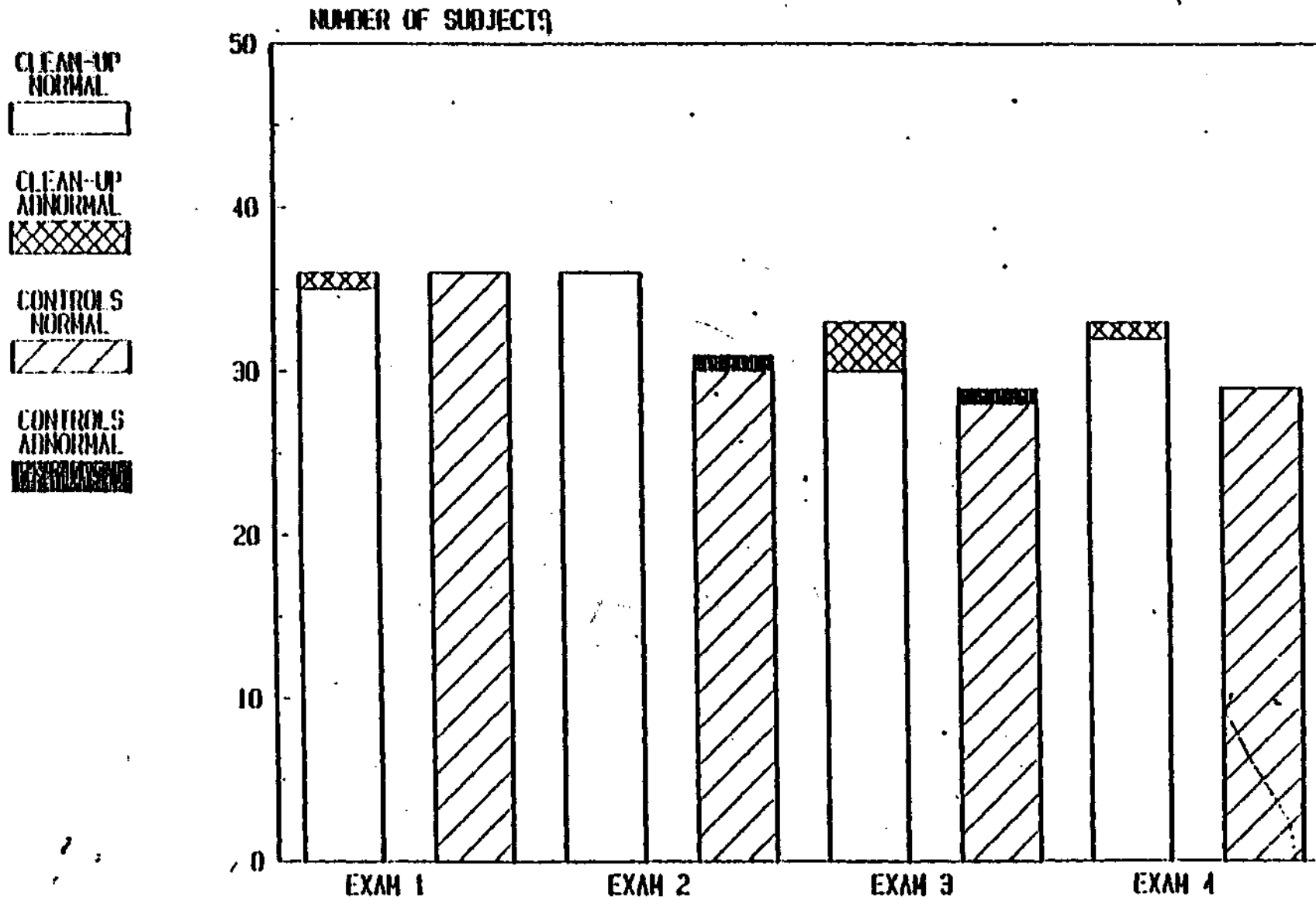


Fig.32 BILIRUBIN IN CLEAN-UP AND CONTROLS, BY EXAM (CUT-OFF=1.4)

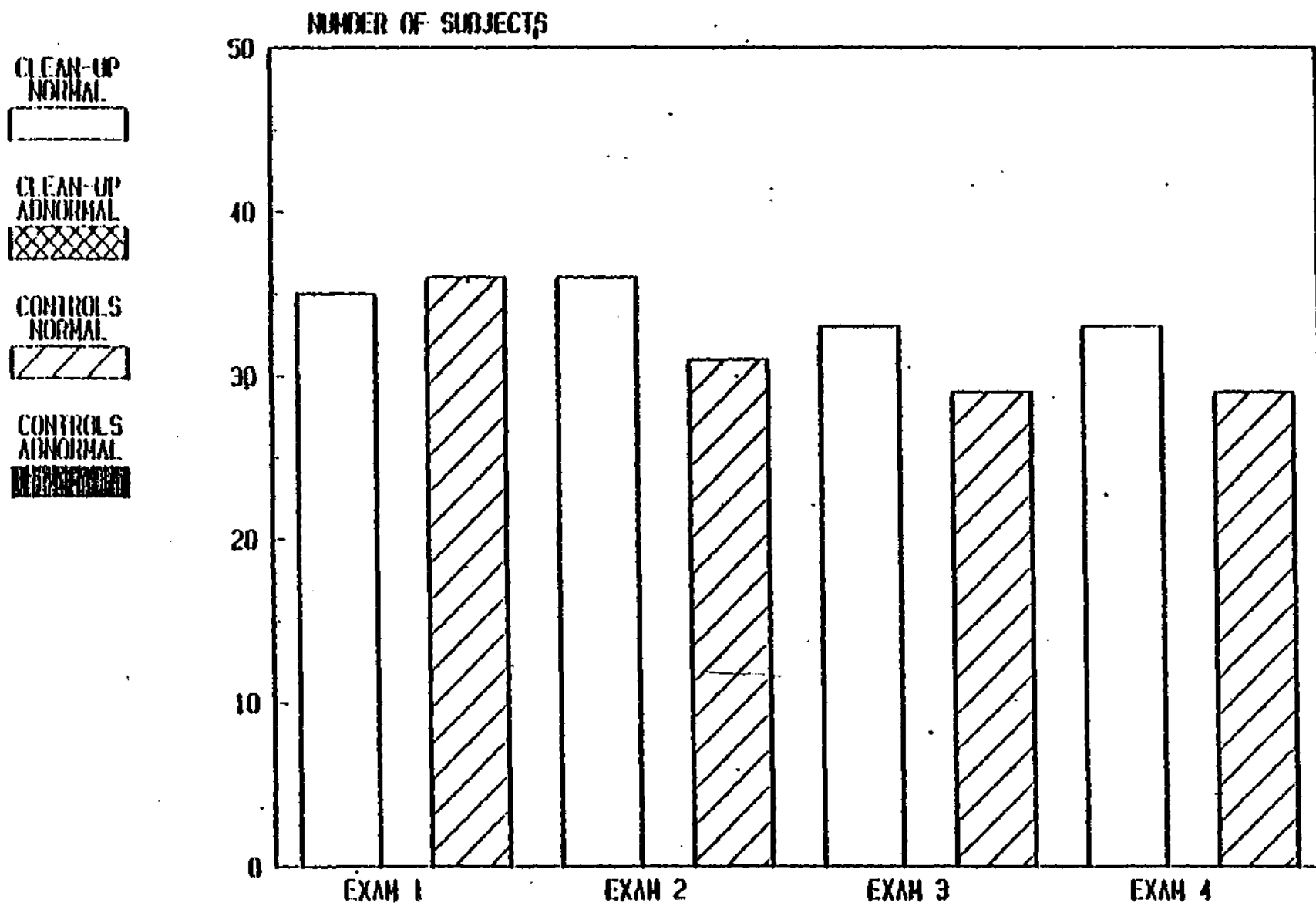


Fig. 33 WBC PATTERN IN CLEAN-UP
AND CONTROLS, BY EXAM (CUTOFF=3.5)

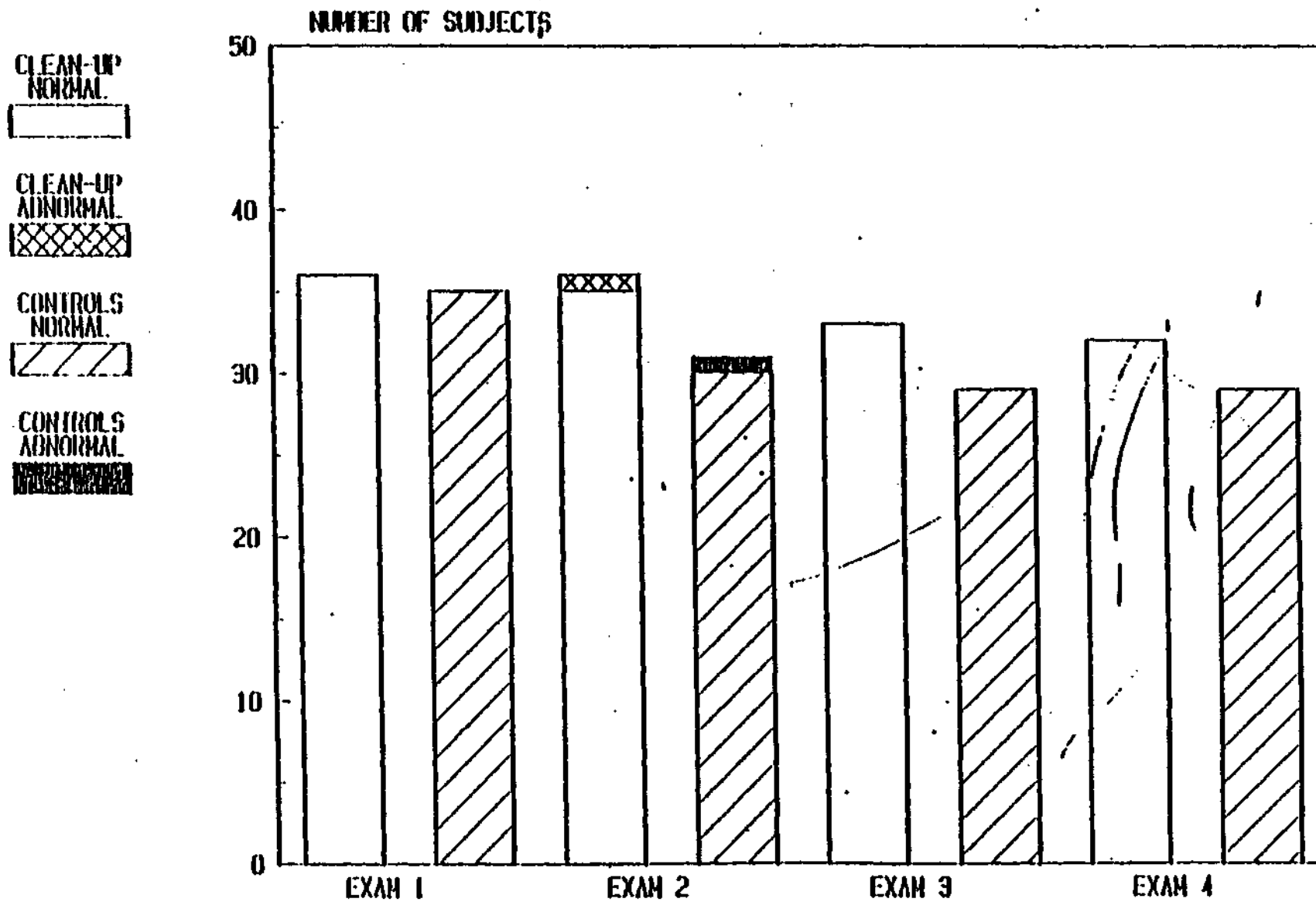


fig.34 U - ALA PATTERN IN CLEAN-UP AND CONTROLS, BY EXAM (CUT-OFF=6)

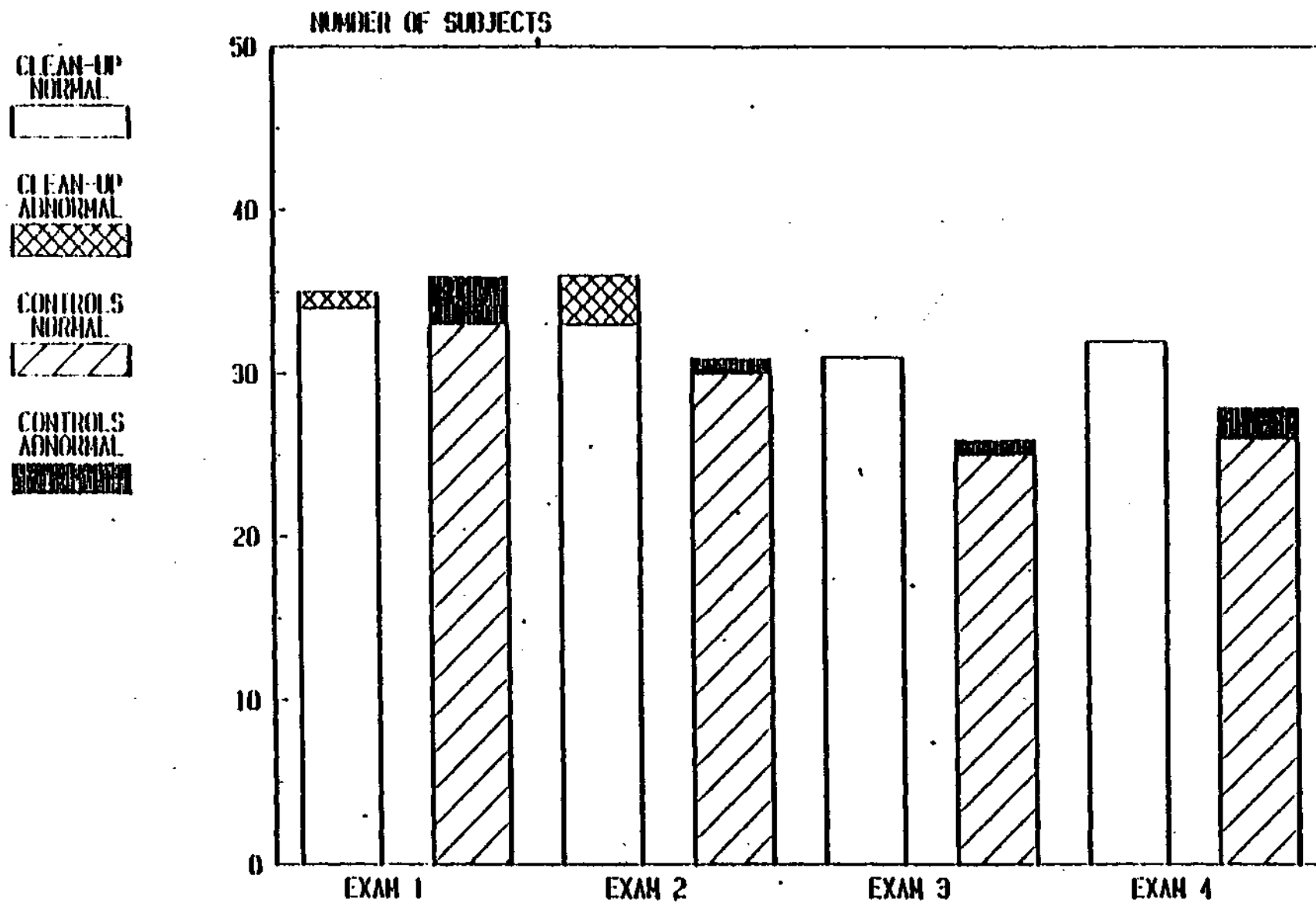


Fig. 35 CHOLESTEROL IN CLEANUP
AND CONTROLS, BY EXAM (CUTOFF=270)

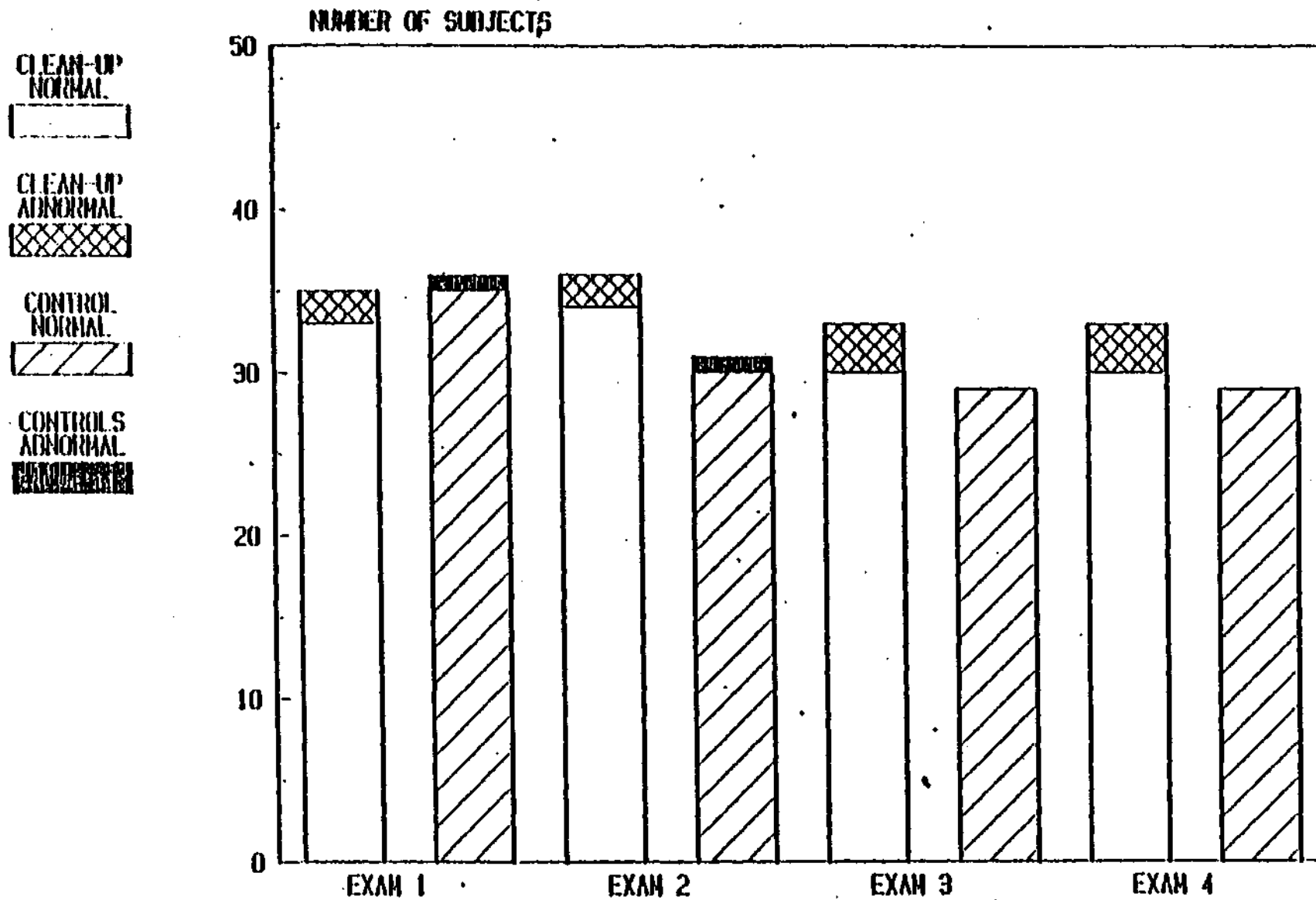
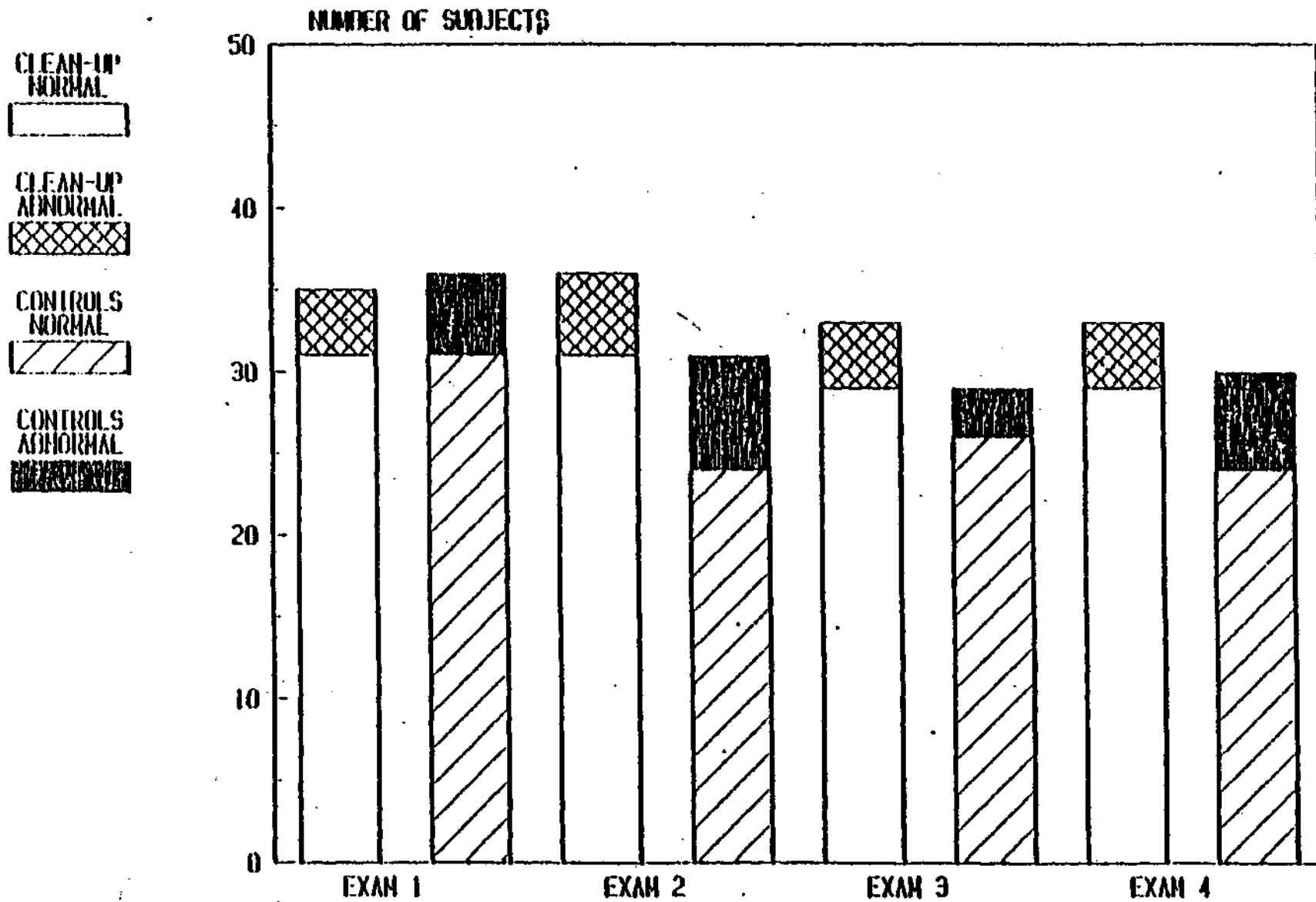


Fig. 36 TRIGLYC. IN CLEAN-UP AND CONTROLS, BY EXAM (CUT-OFF=180)



ON 13 LABORATORY TESTS IN CLEAN-UP AND REFERENCE GROUPS, BY EXAM.

CLEAN-UP
WORKERS

REFERENCE

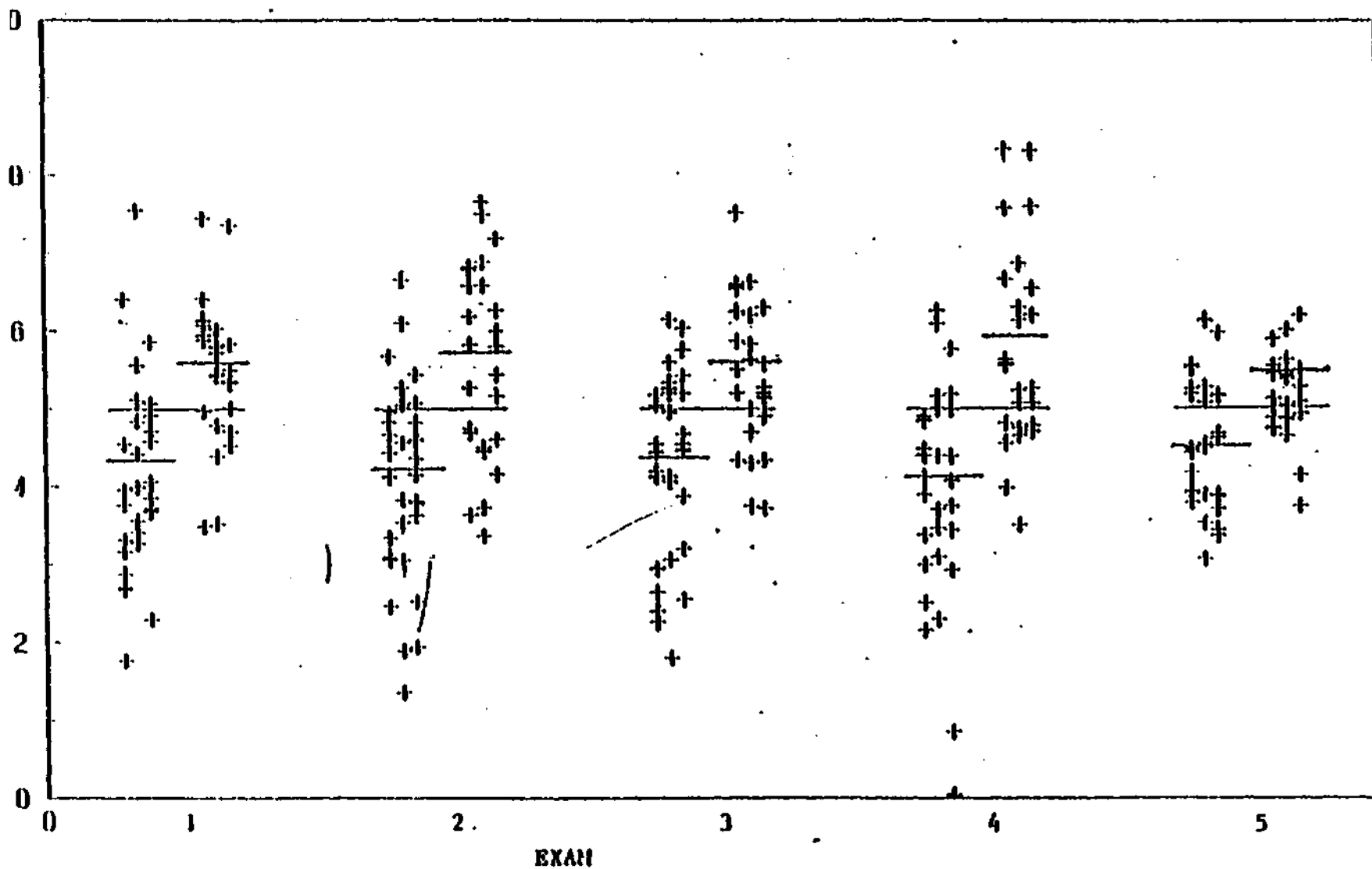


Fig. 38 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER # 1: S.P., 25 yrs

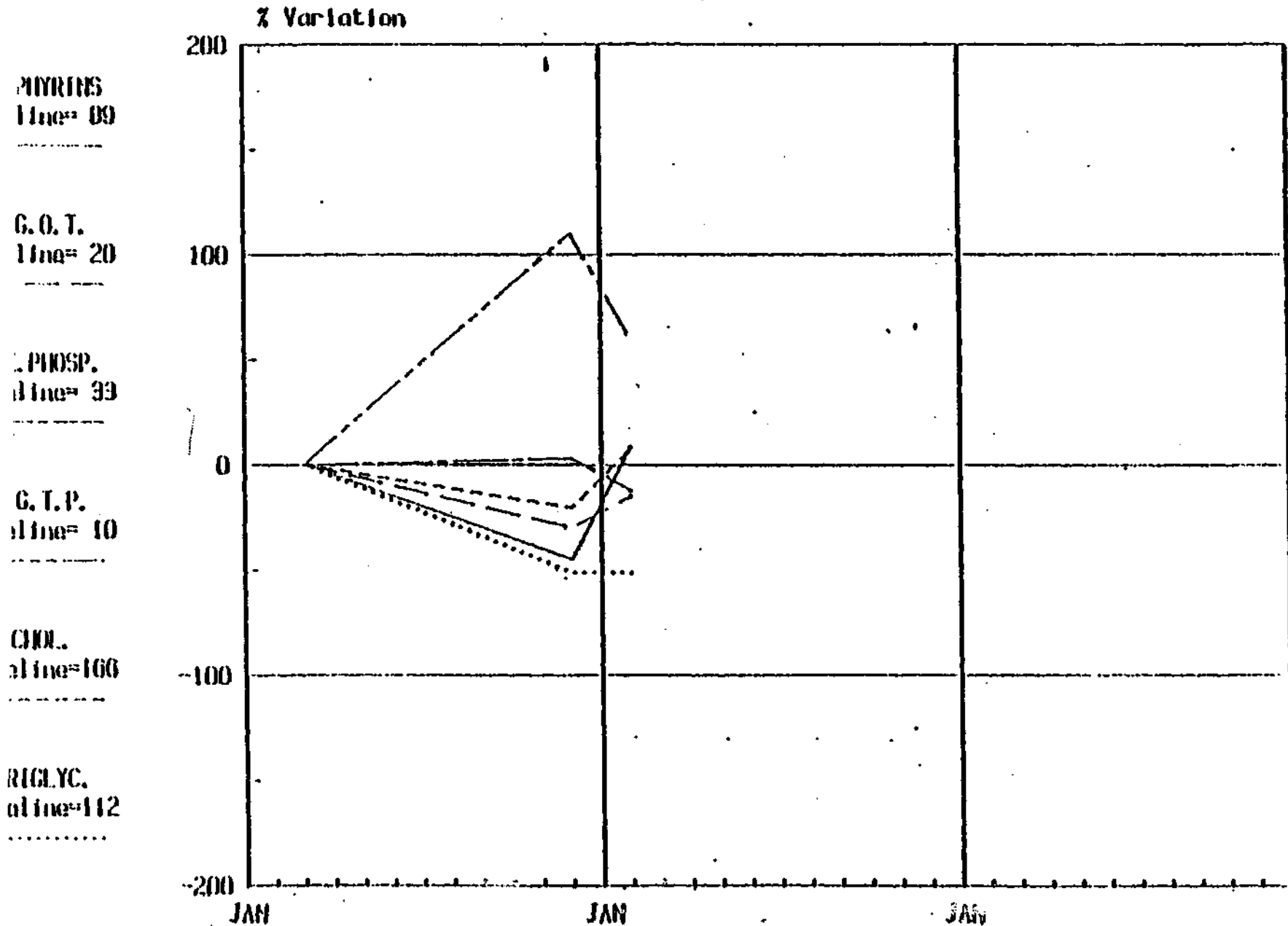


Fig. 39 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER # 2: G.G., 32 yrs

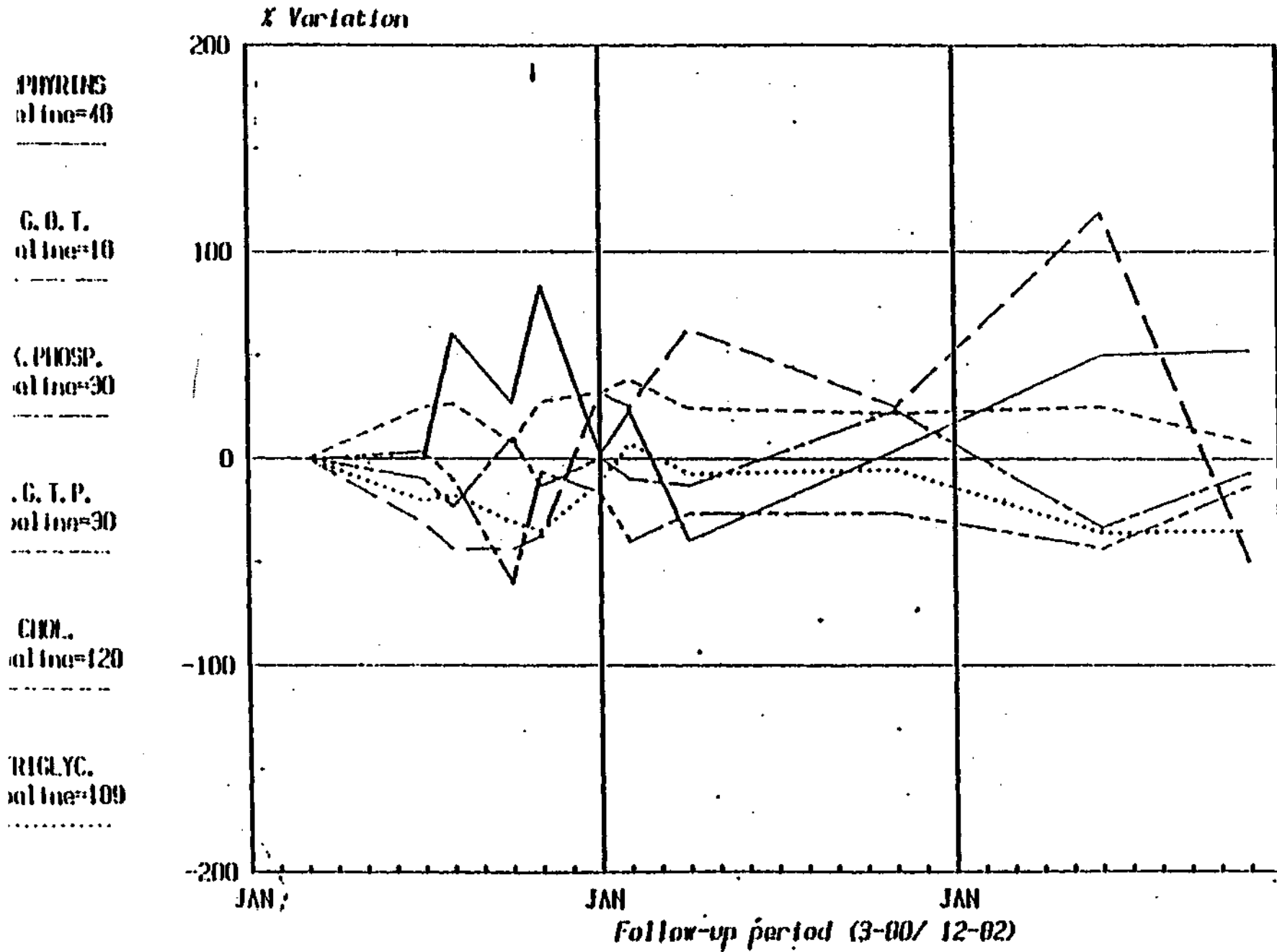


Fig. 40 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #3: V.F., 39 yrs

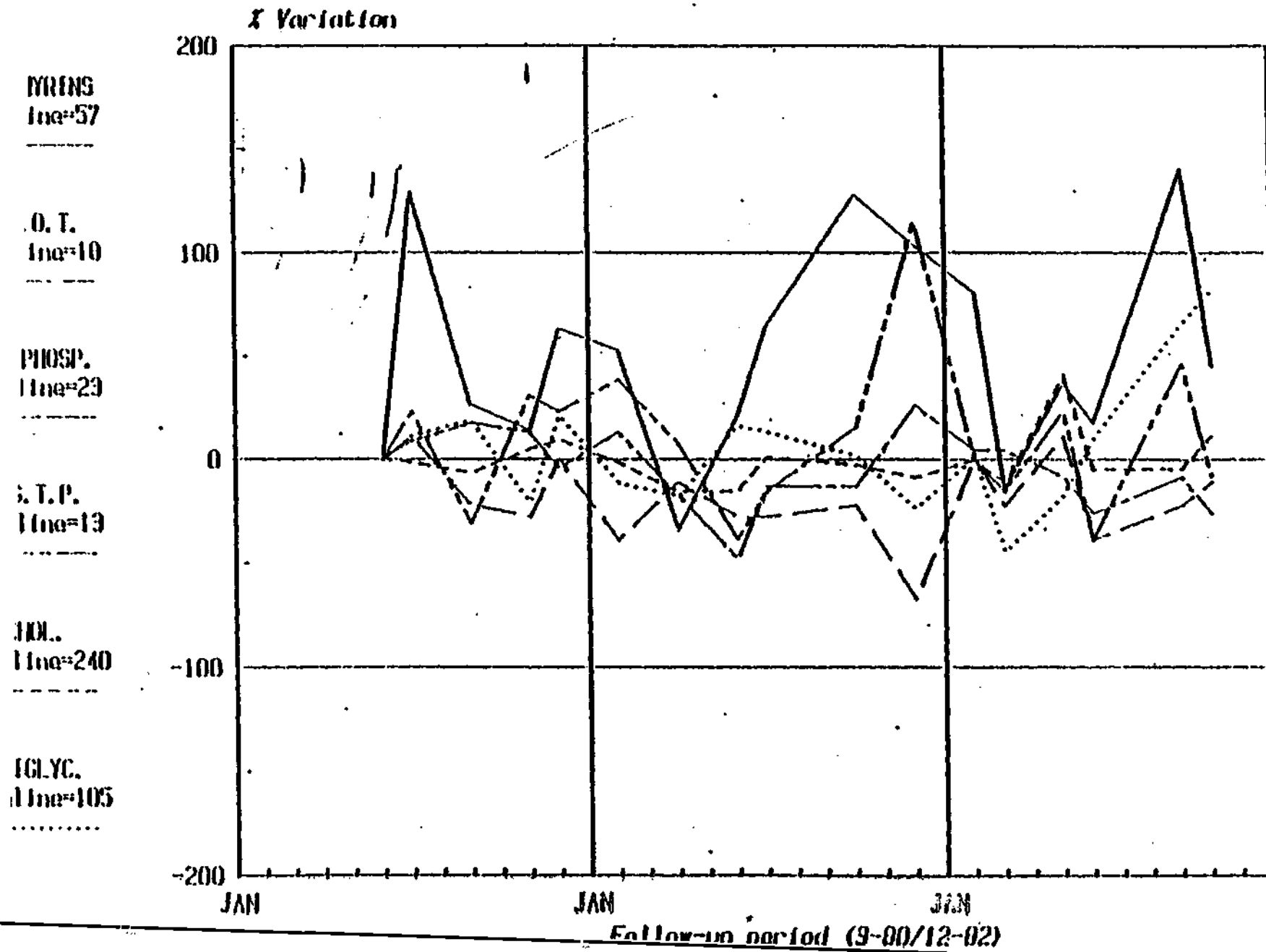


Fig. 41: TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER # 4: P.V., 34 yrs

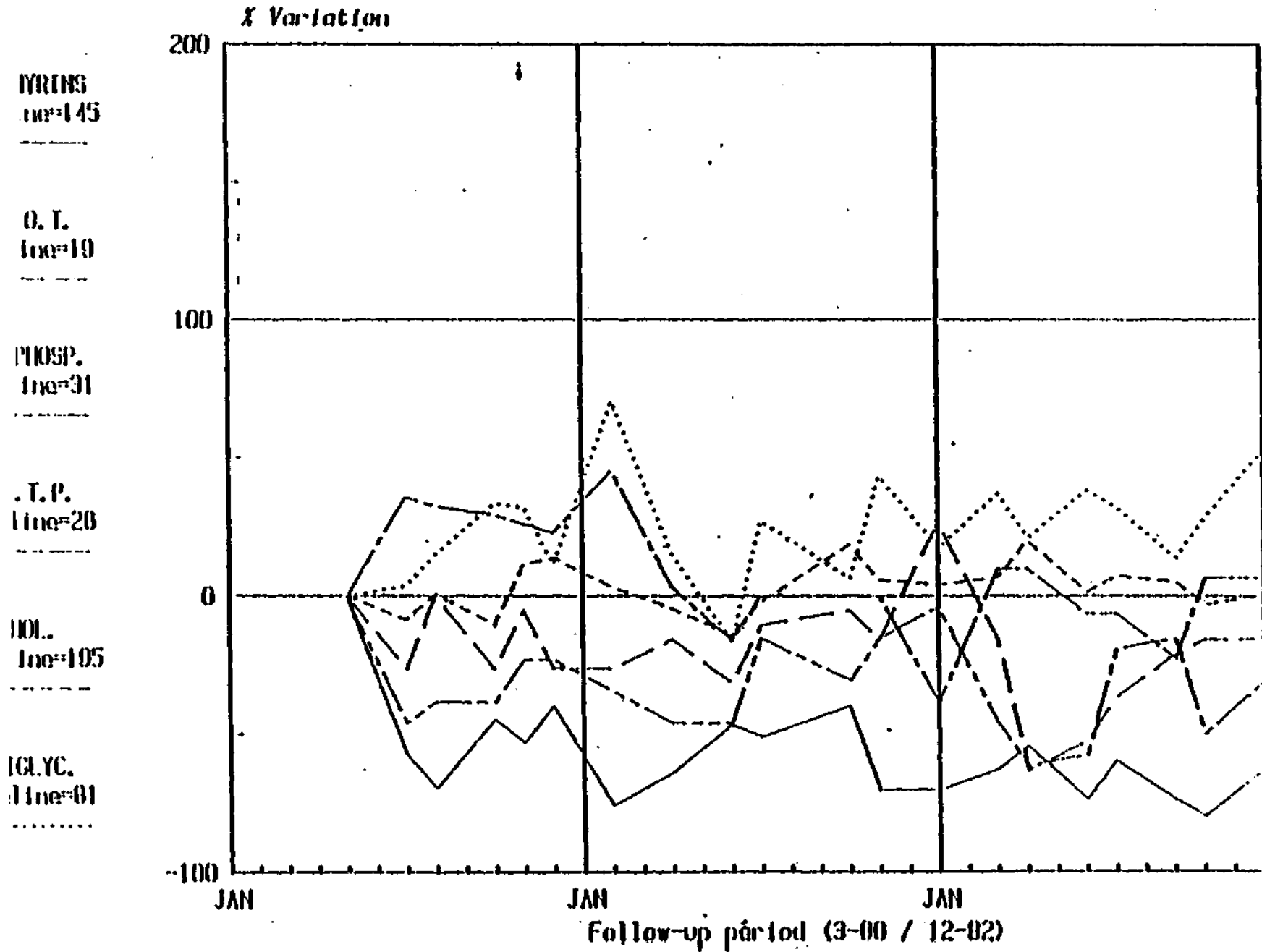


Fig. 42. TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #5: I.S., 41 yrs

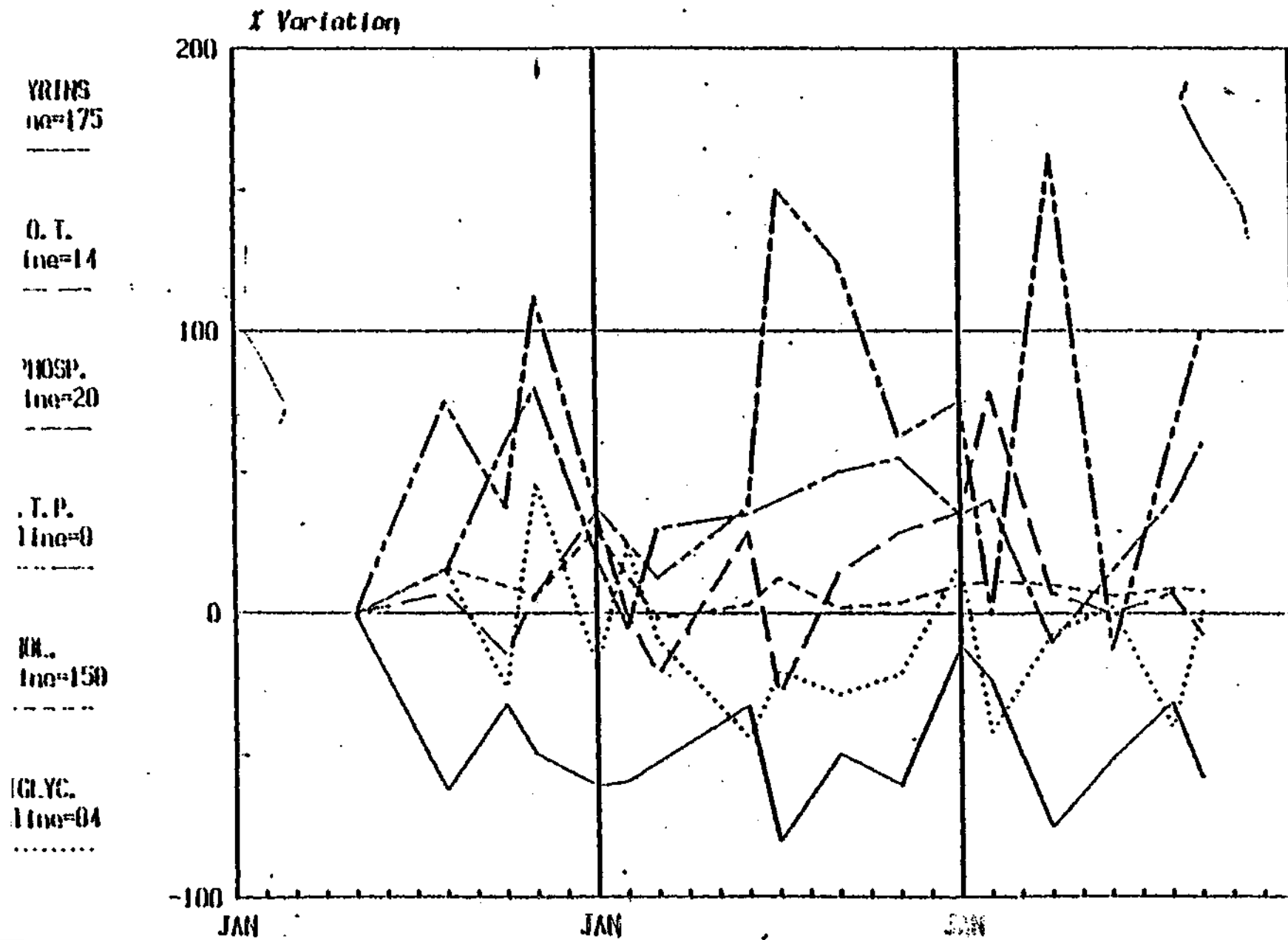


Fig. 43. TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #6: V. C., 27 yrs

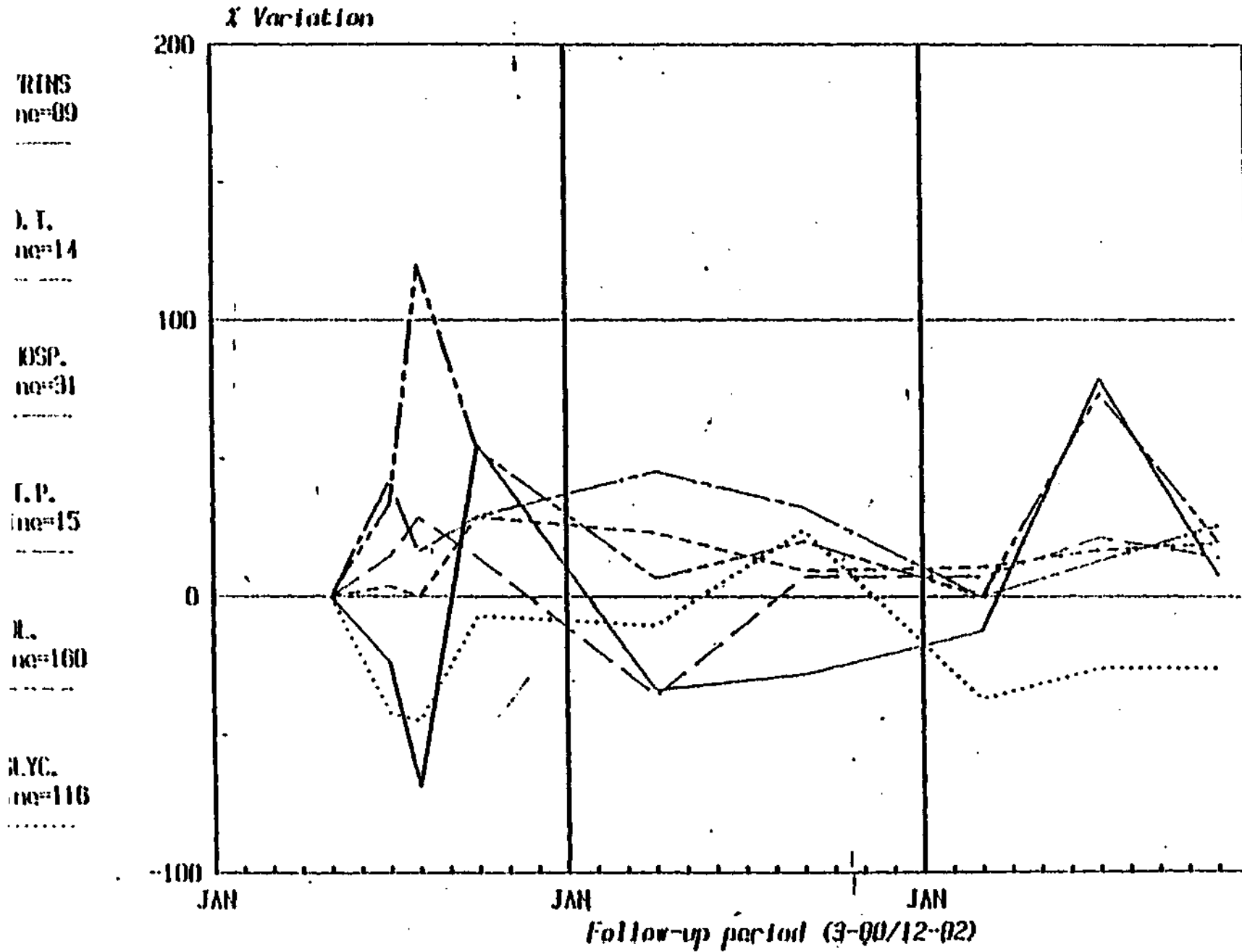


Fig. 44 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #7: G. N., 26 yrs

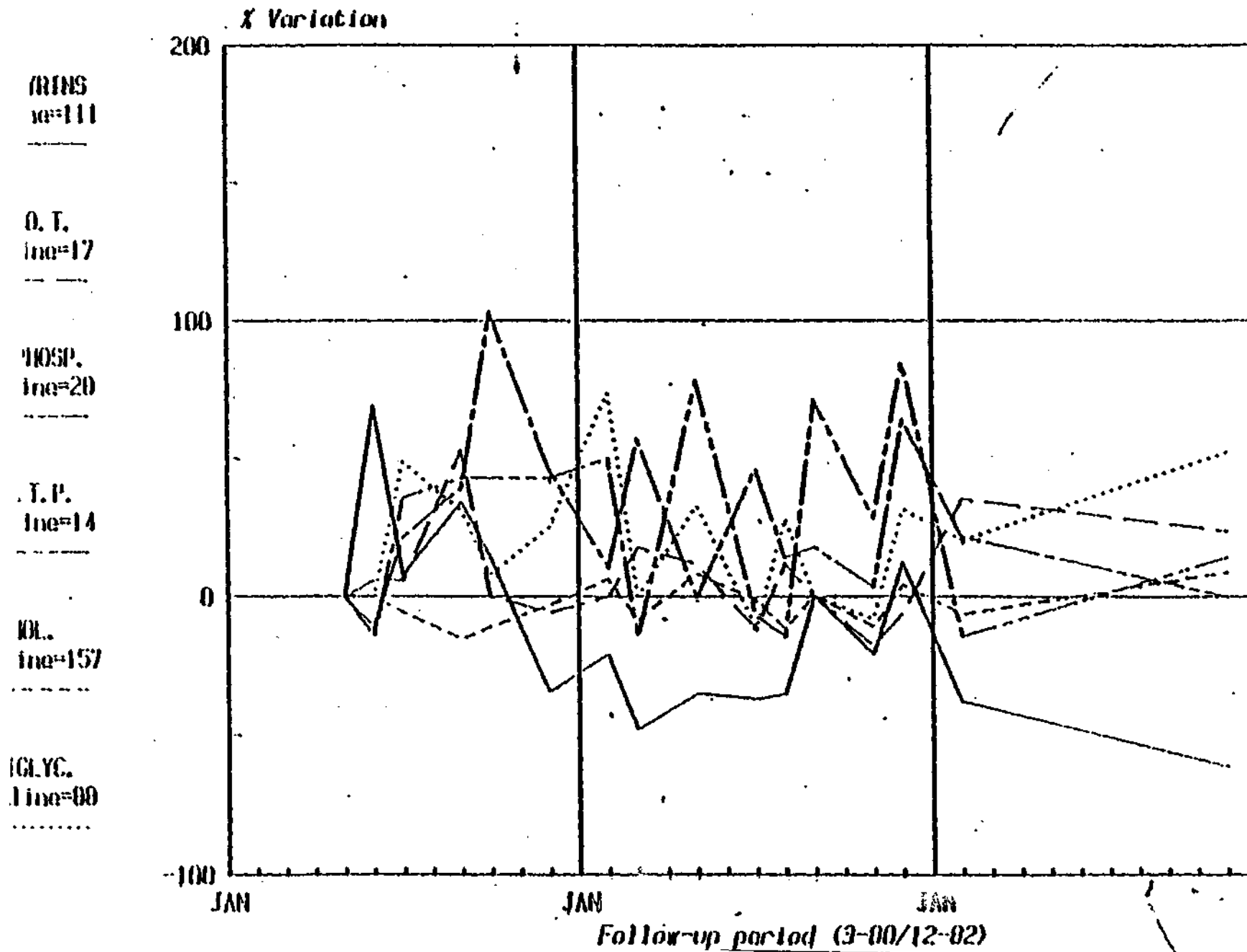


Fig. 46 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #9: C. Z., 29 yrs.

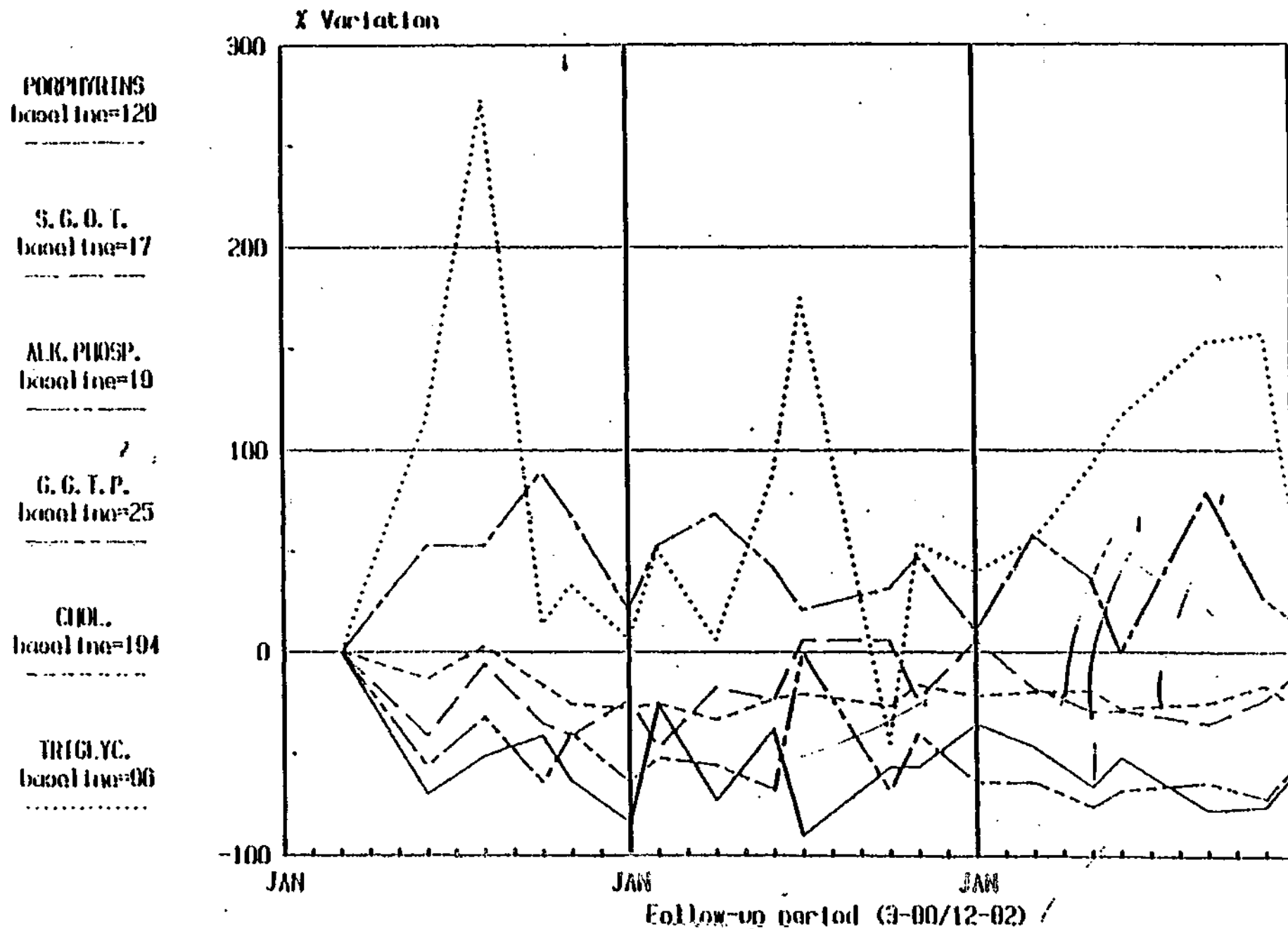


Fig. 47 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #10: F.L., 39 yrs.

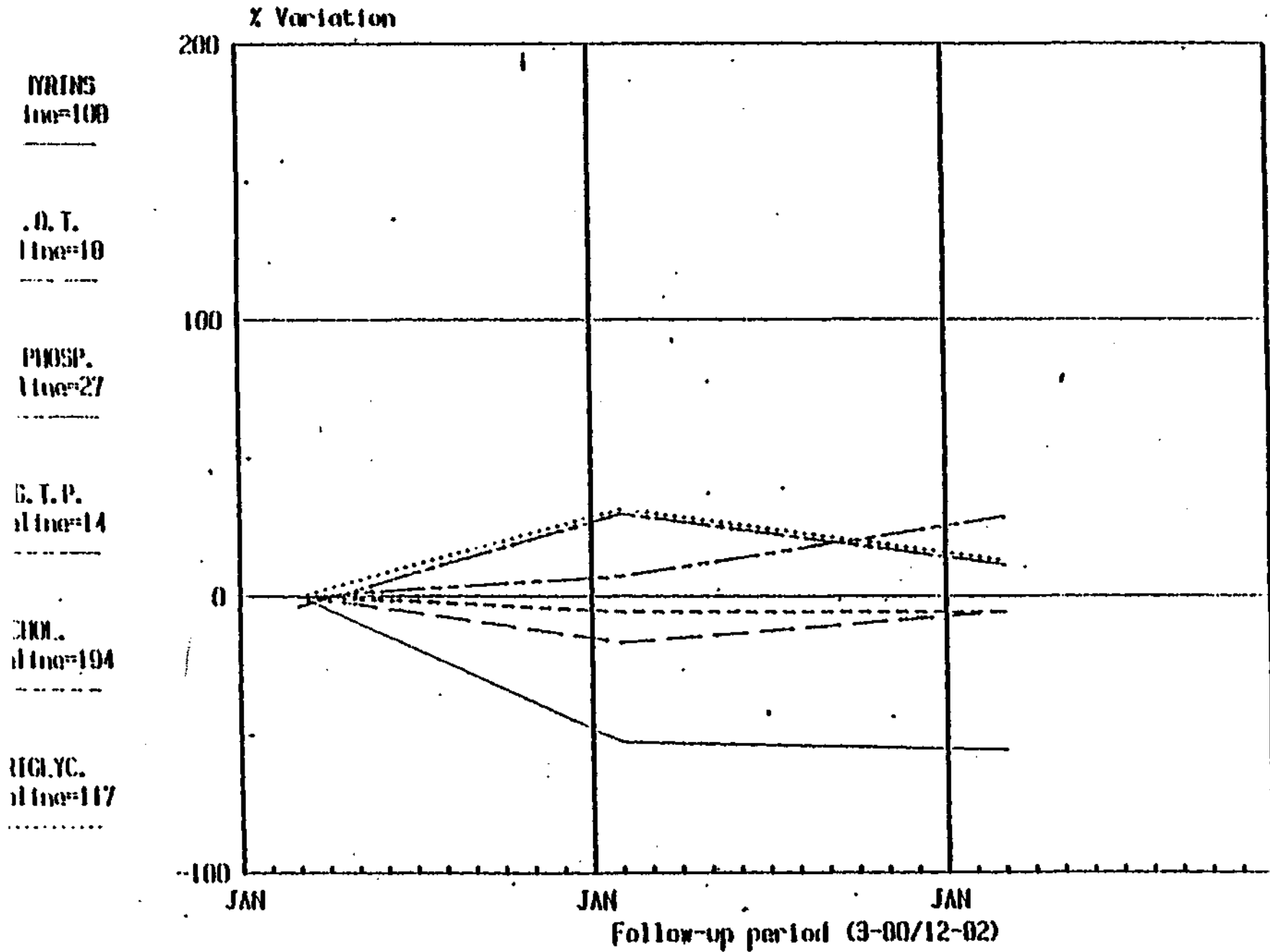


Fig. 48 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #11: L.A., 30 yrs.

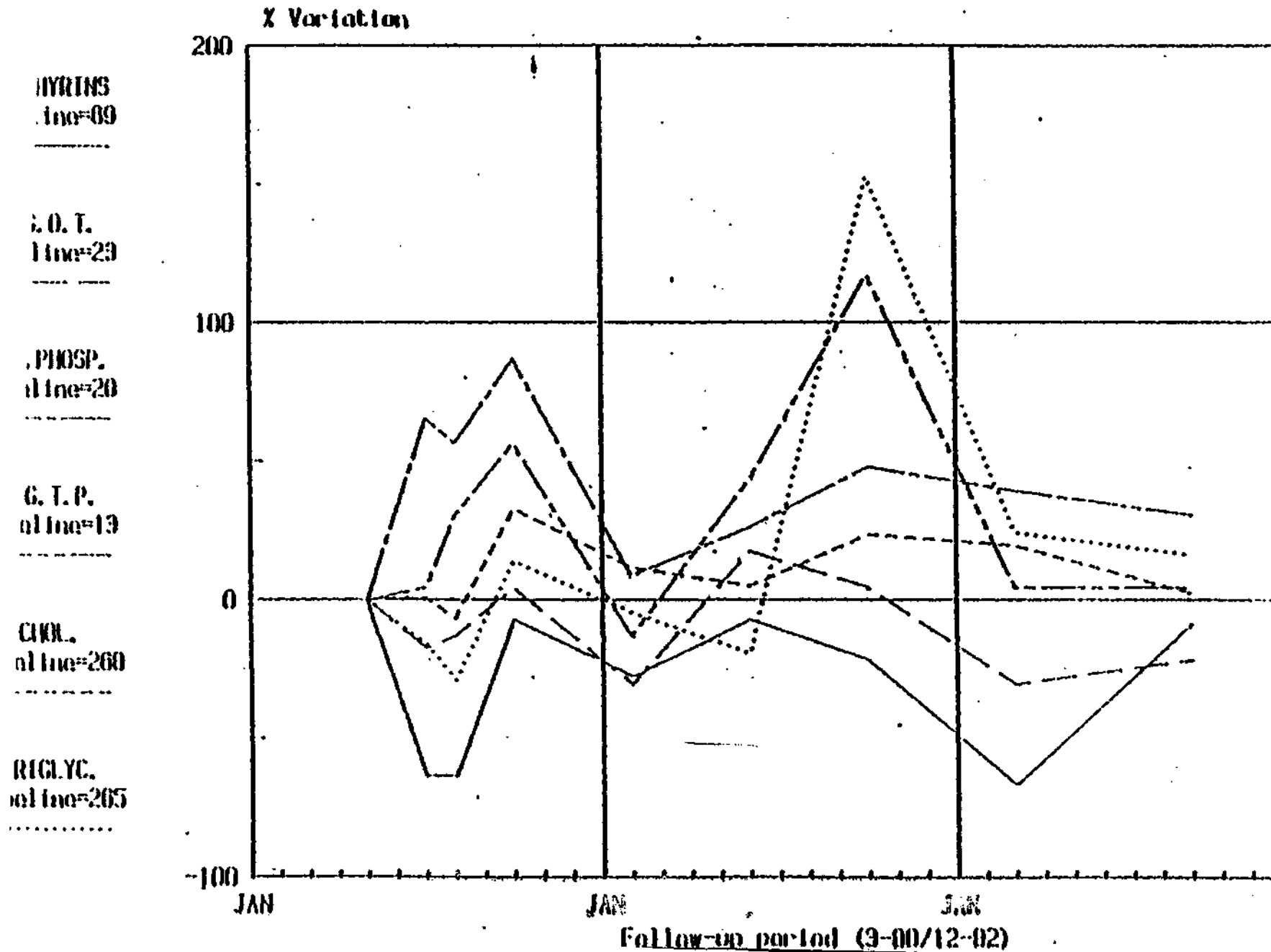


Fig. 49 TIME TRENDS OF 6 PARAMETERS IN CLEAN-UP WORKER #12; M.R., 24 yrs.

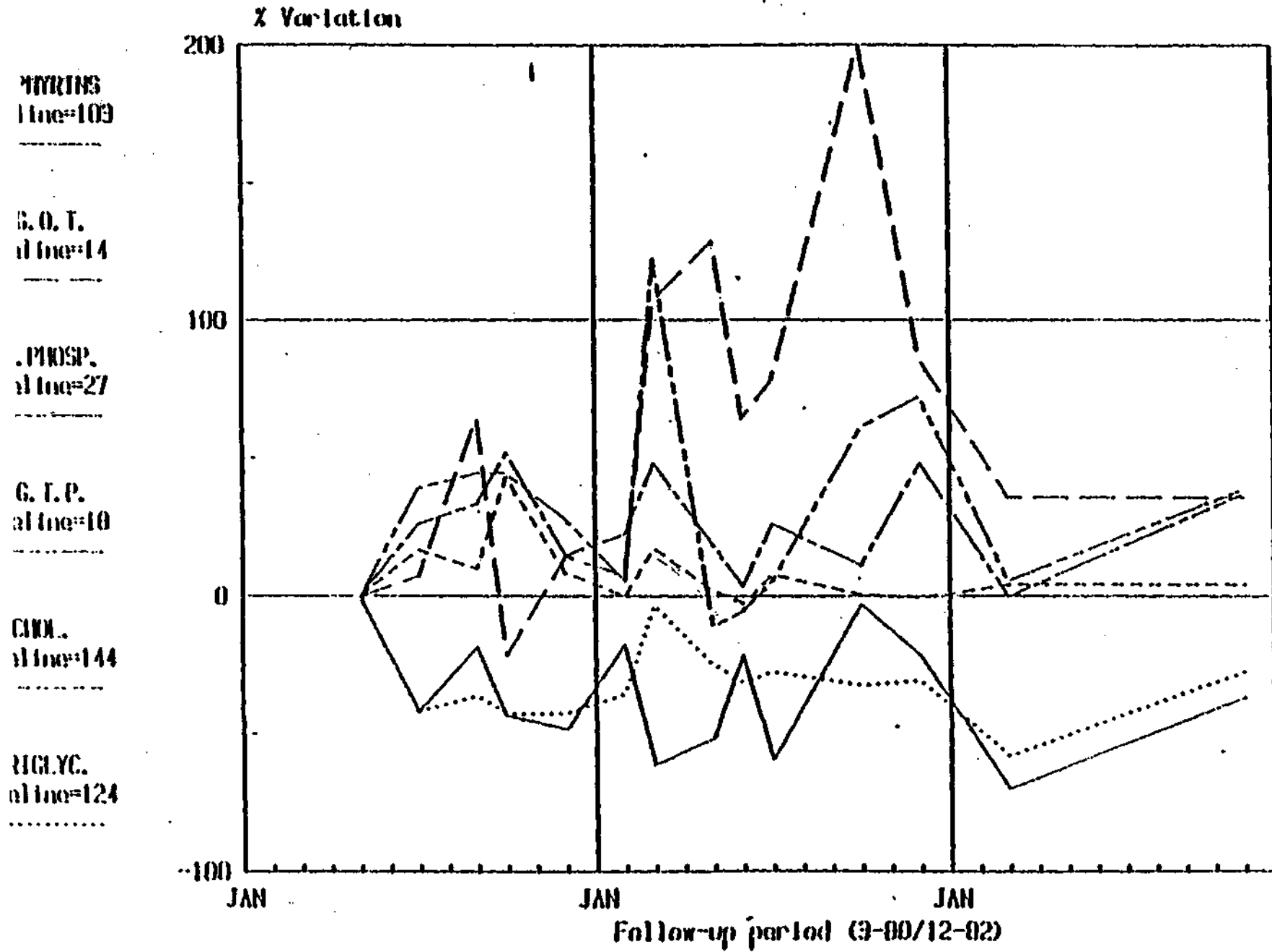


Fig. 50 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #13; A.F., 46 yrs.

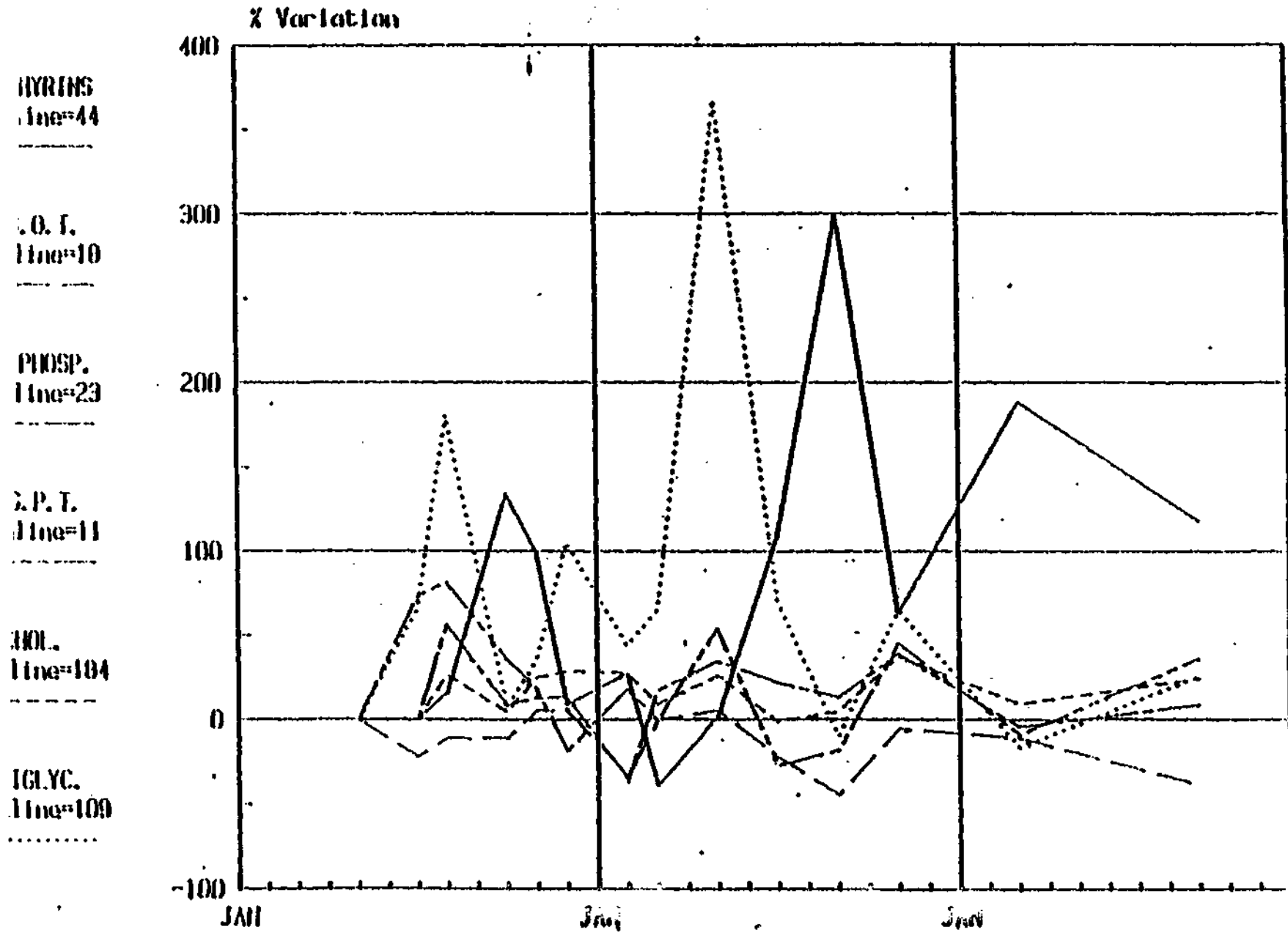


Fig. 51 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #14: G. C., 44 yrs.

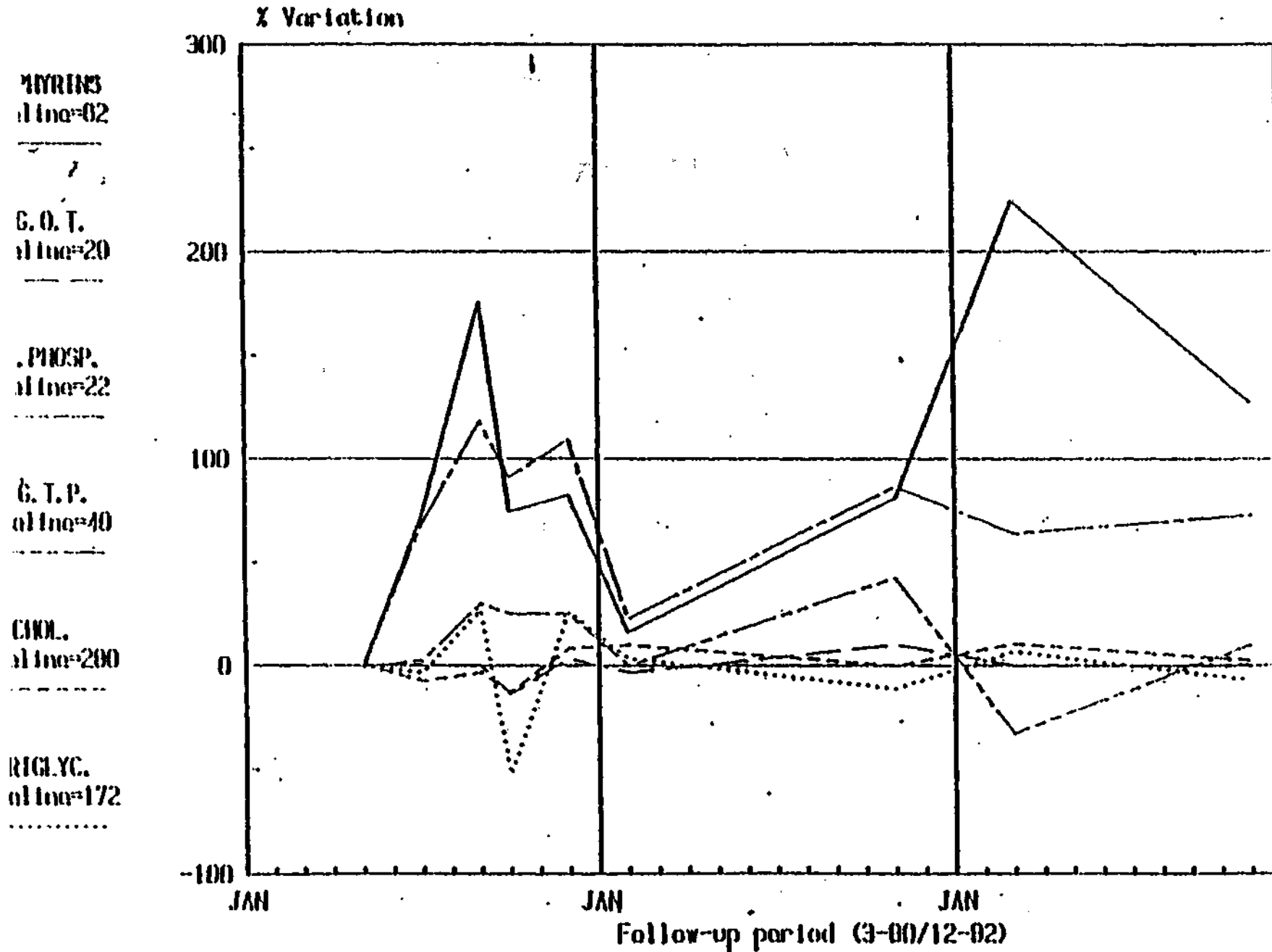


Fig. 52. TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #15; S. G., 24 yrs.

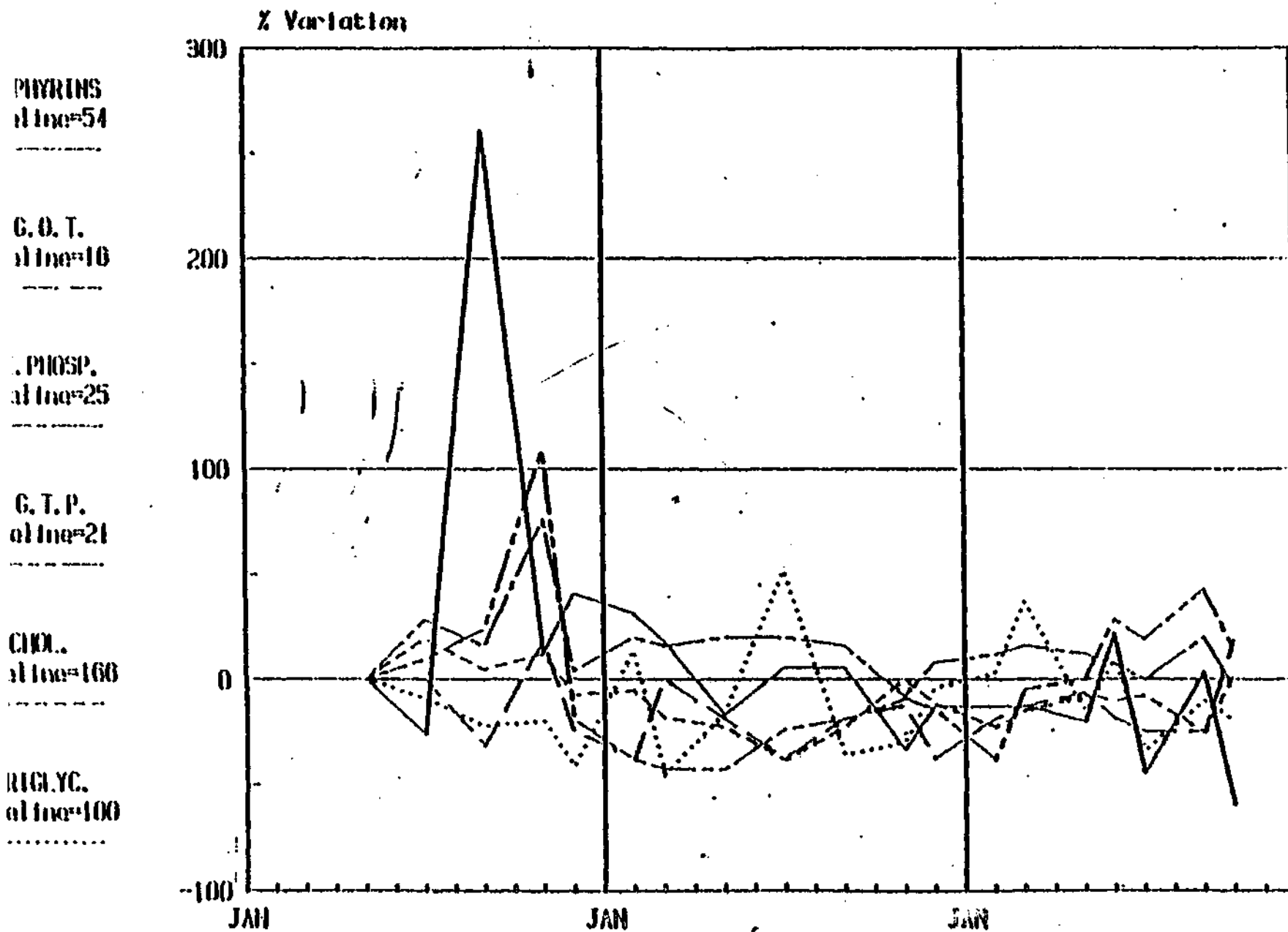


Fig. 53 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #16: E. P., 30 yrs.

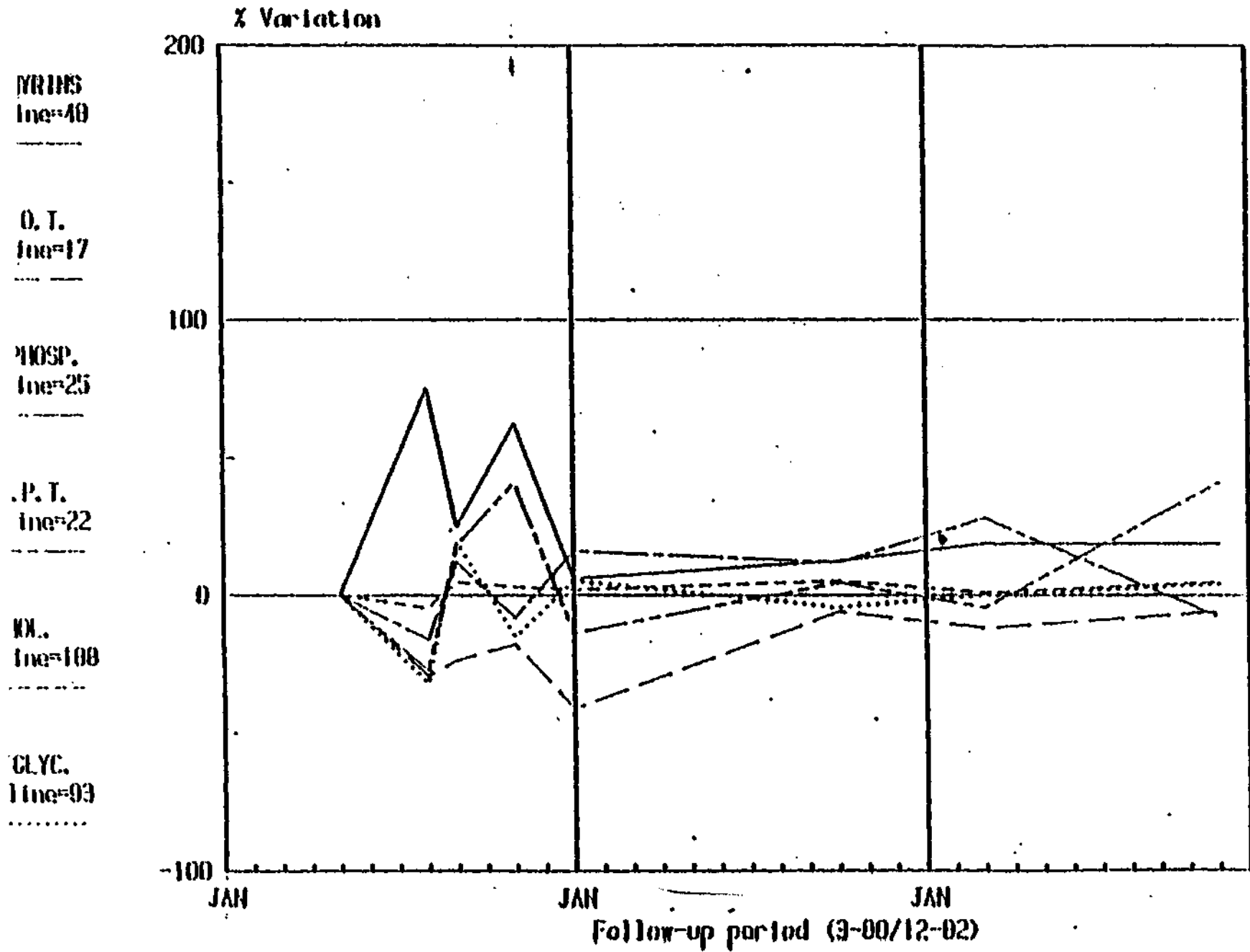


Fig. 54 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #17: G. R., 35 yrs.

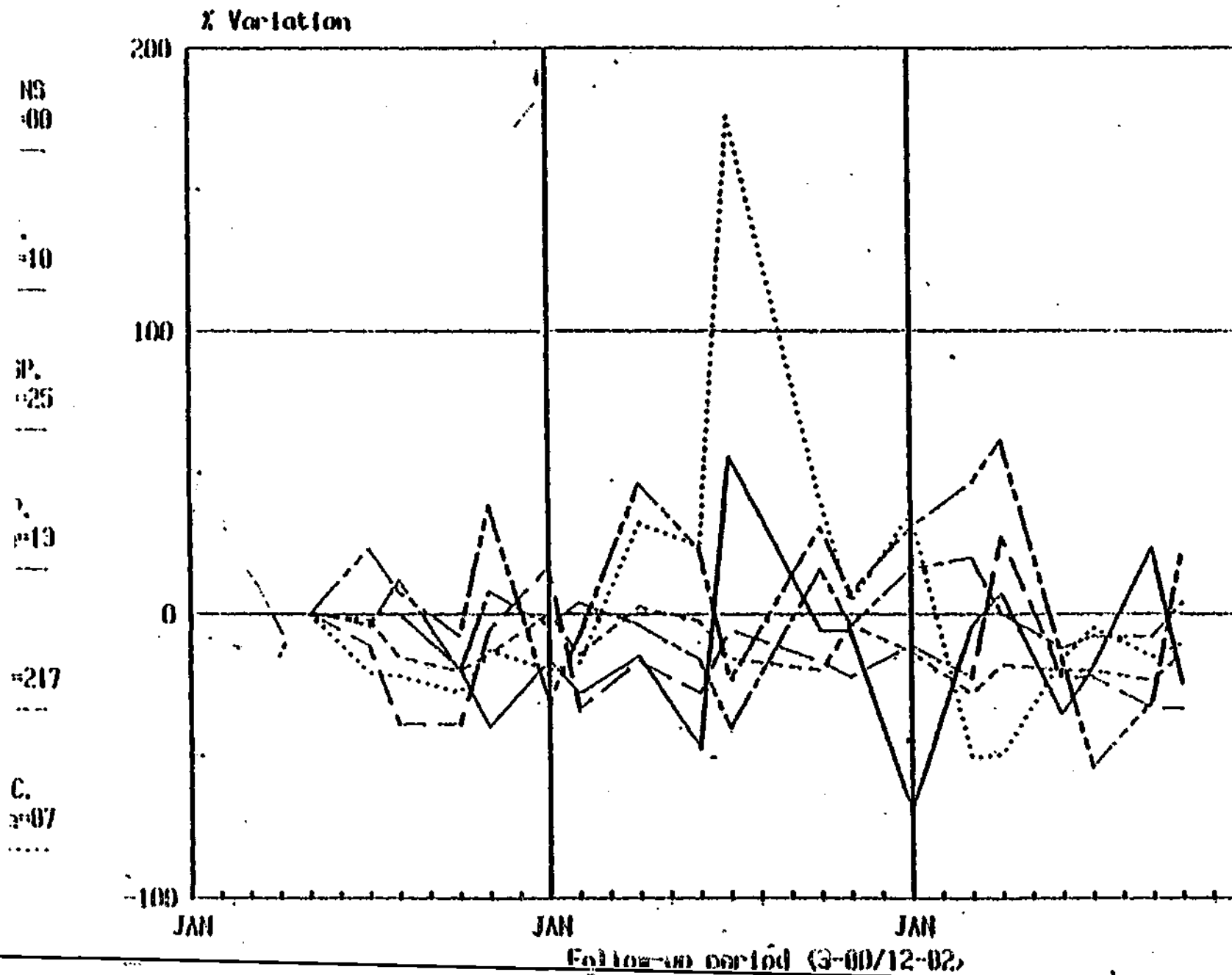


Fig. 55. TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #18: A. C., 34 yrs.

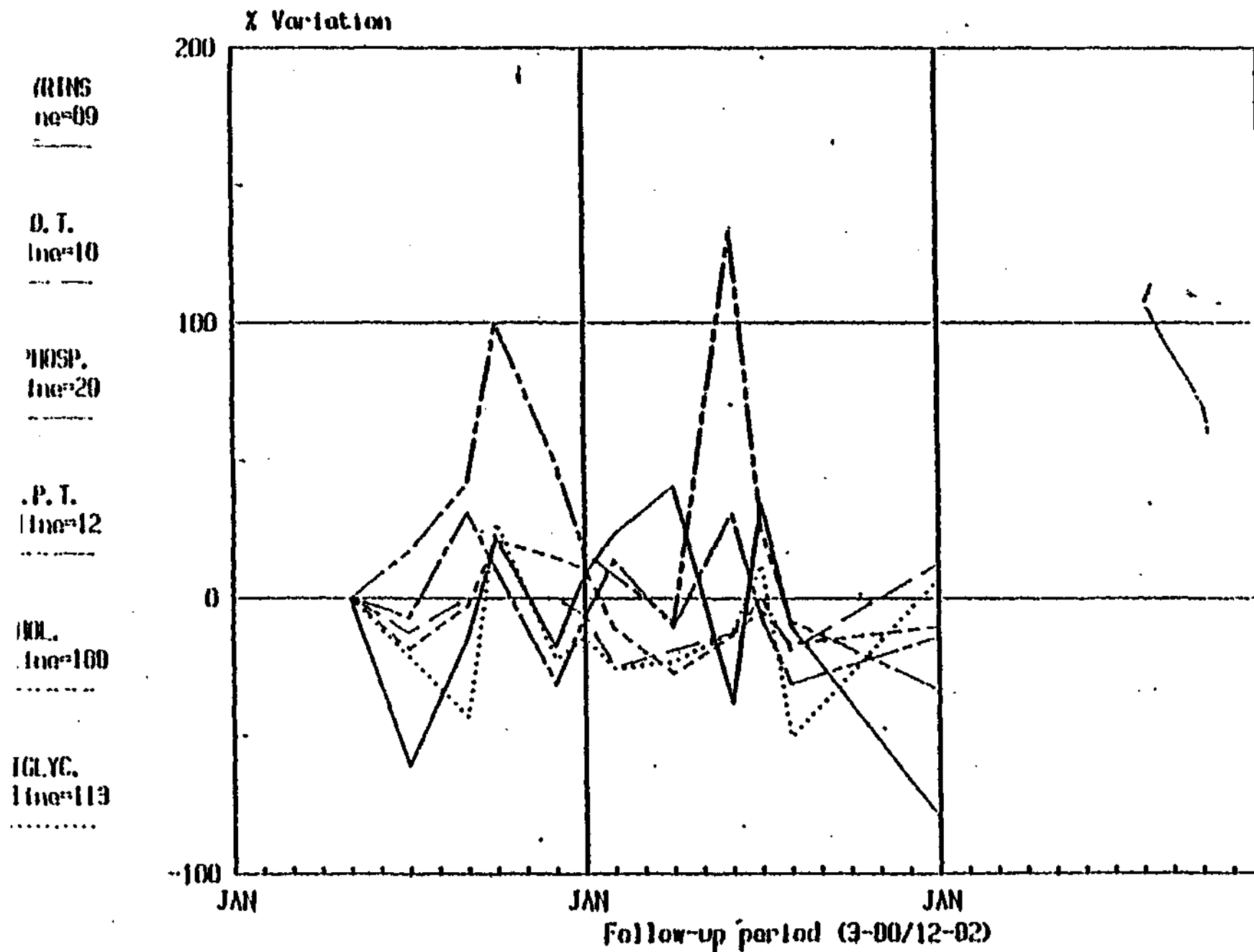


Fig. 56 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #19: S. C., 23 yrs.

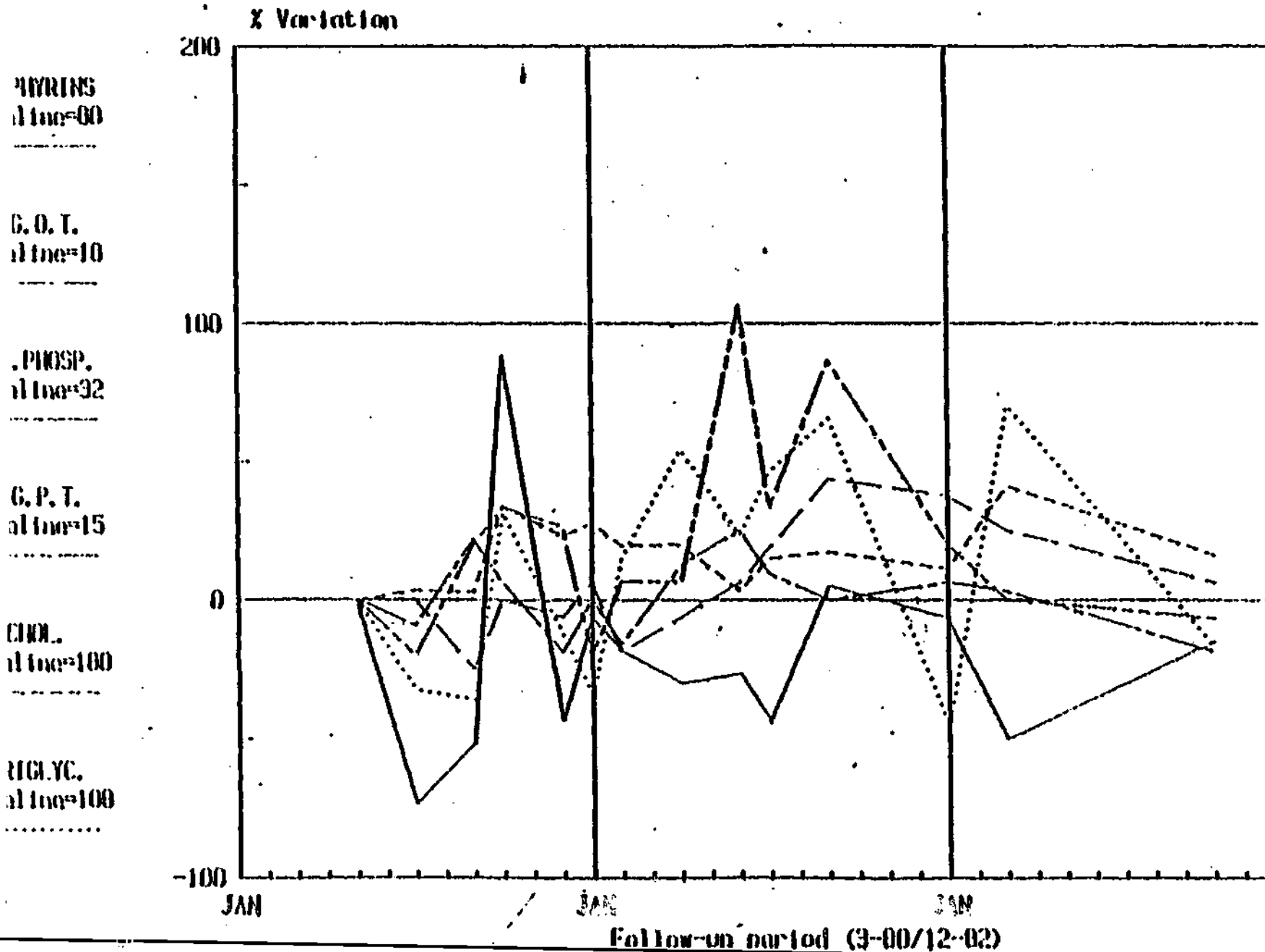


Fig. 57 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #20: W. R., 43 yrs.

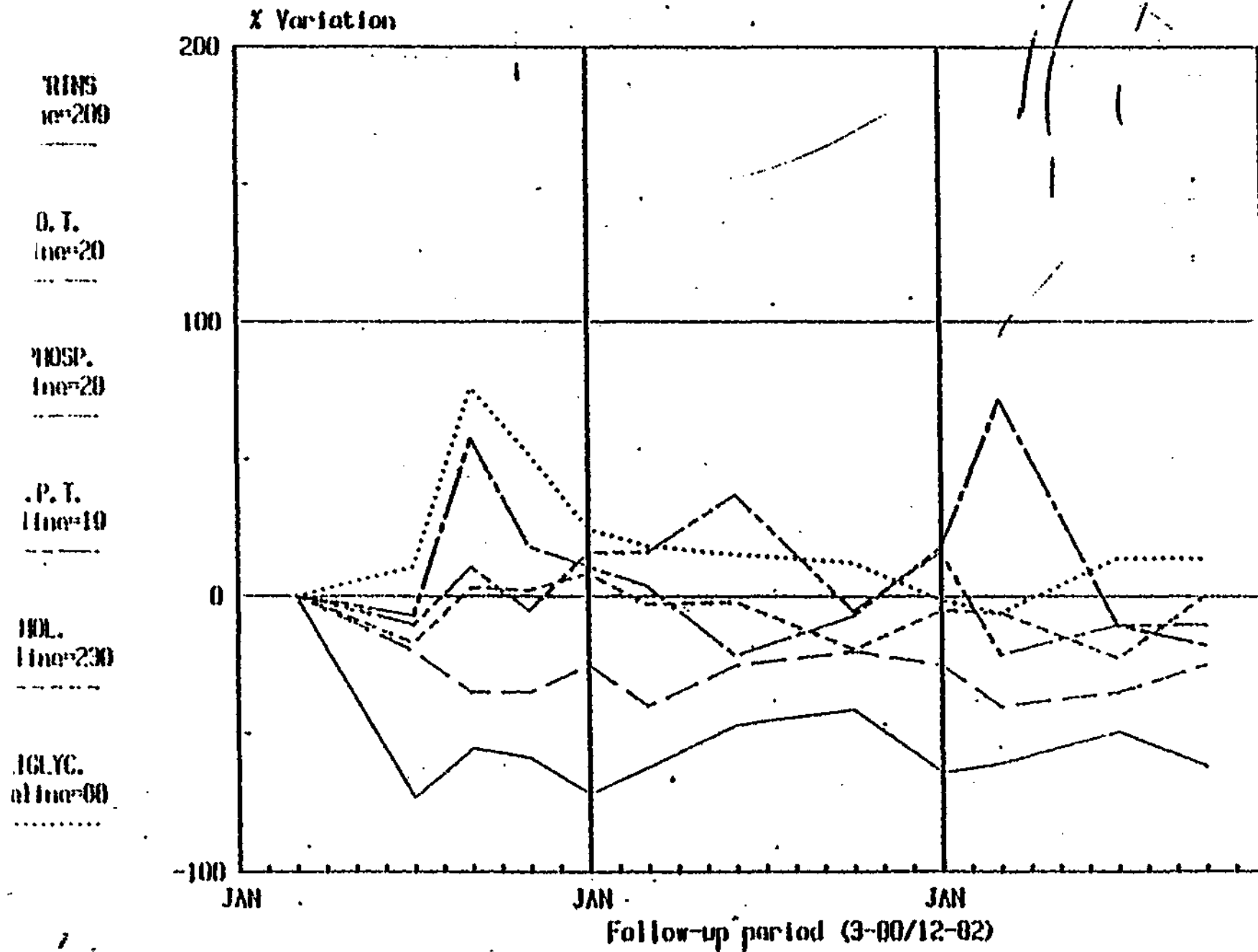


Fig. 58. TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #21; G. I., 45 yrs.

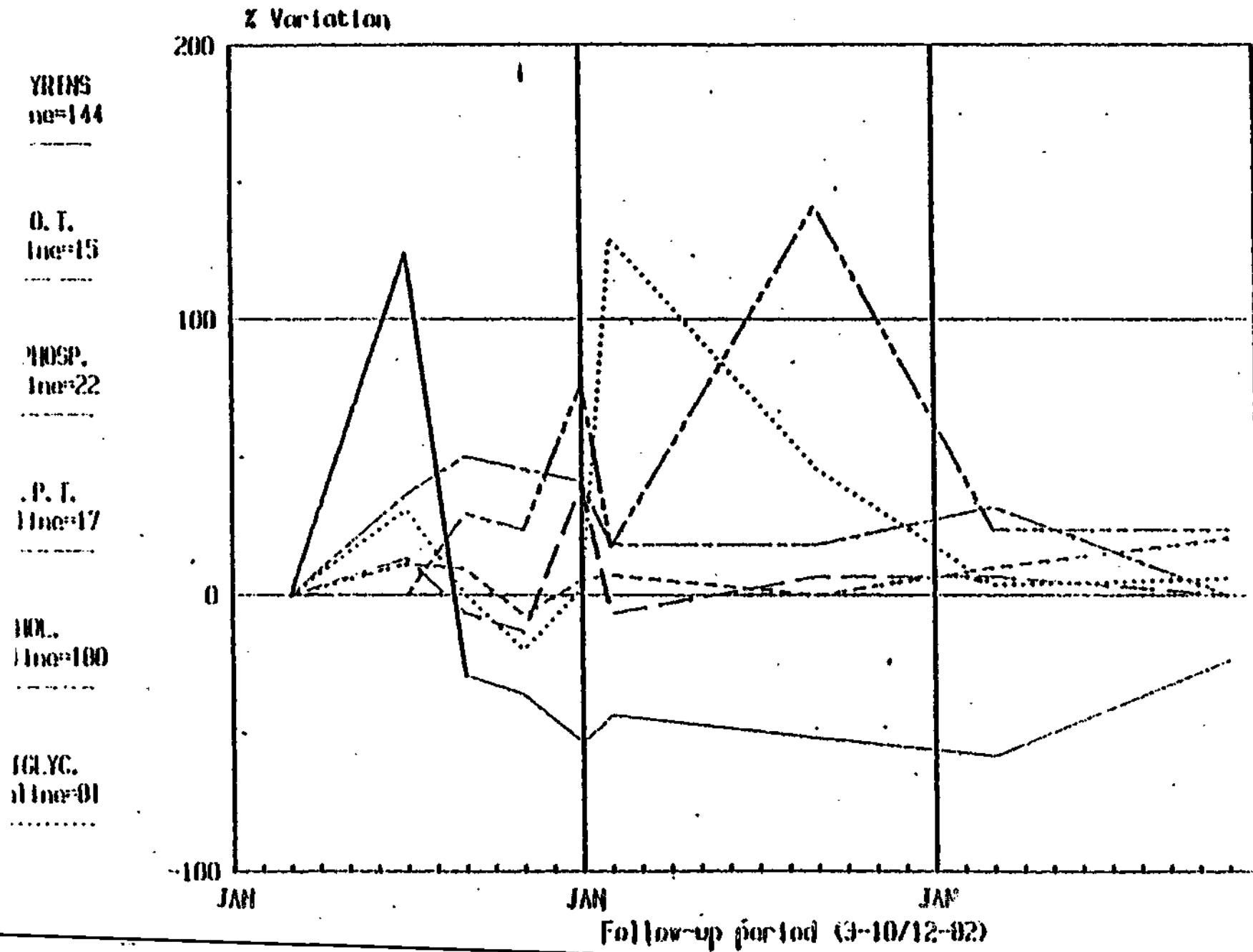


Fig. 59 TIME TRENDS OF U PARAMETERS IN
CLEAN-UP WORKER #22; E. B., 35 yrs.

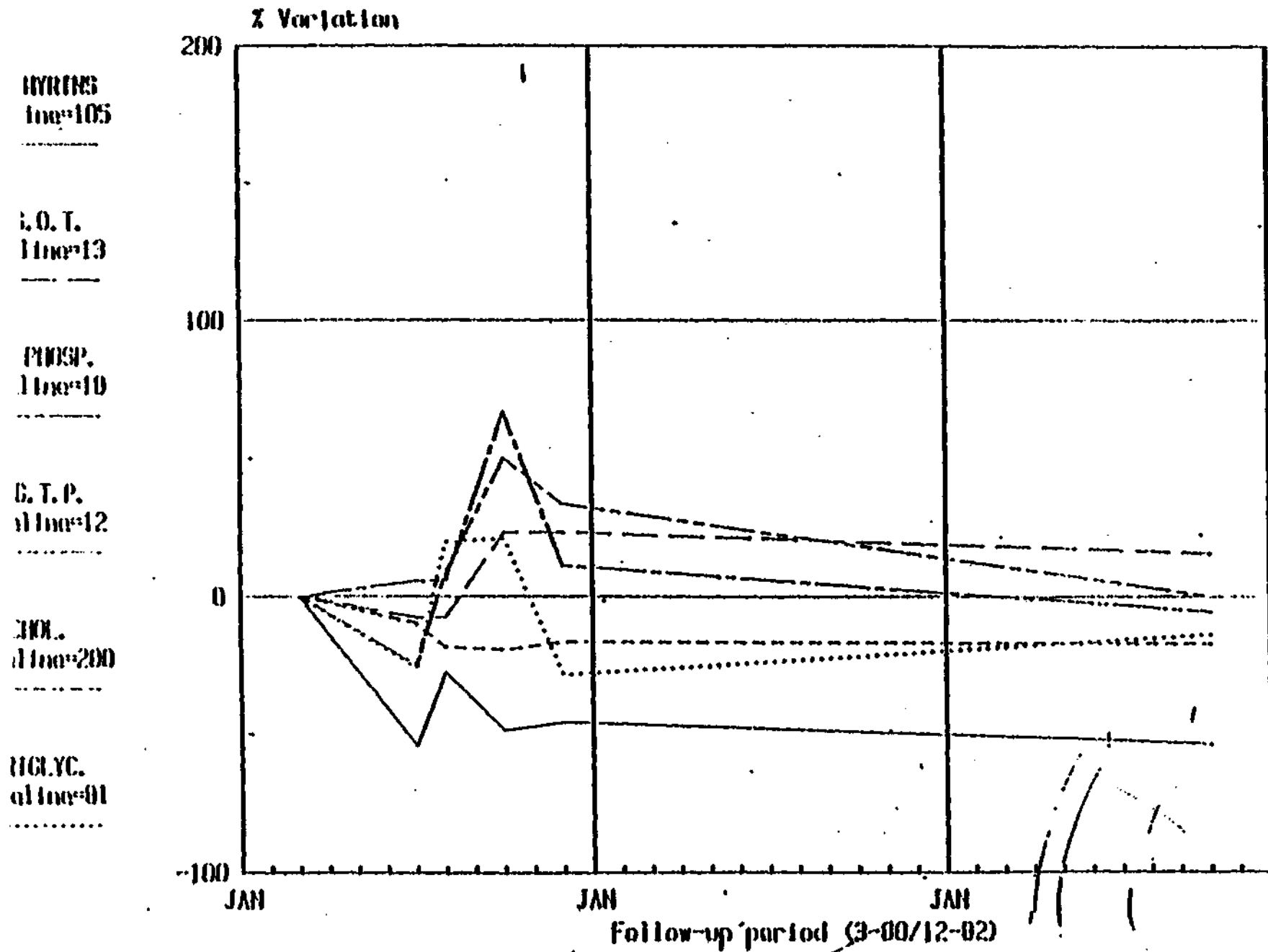


Fig. 60 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #23; F. C., 46 yrs.

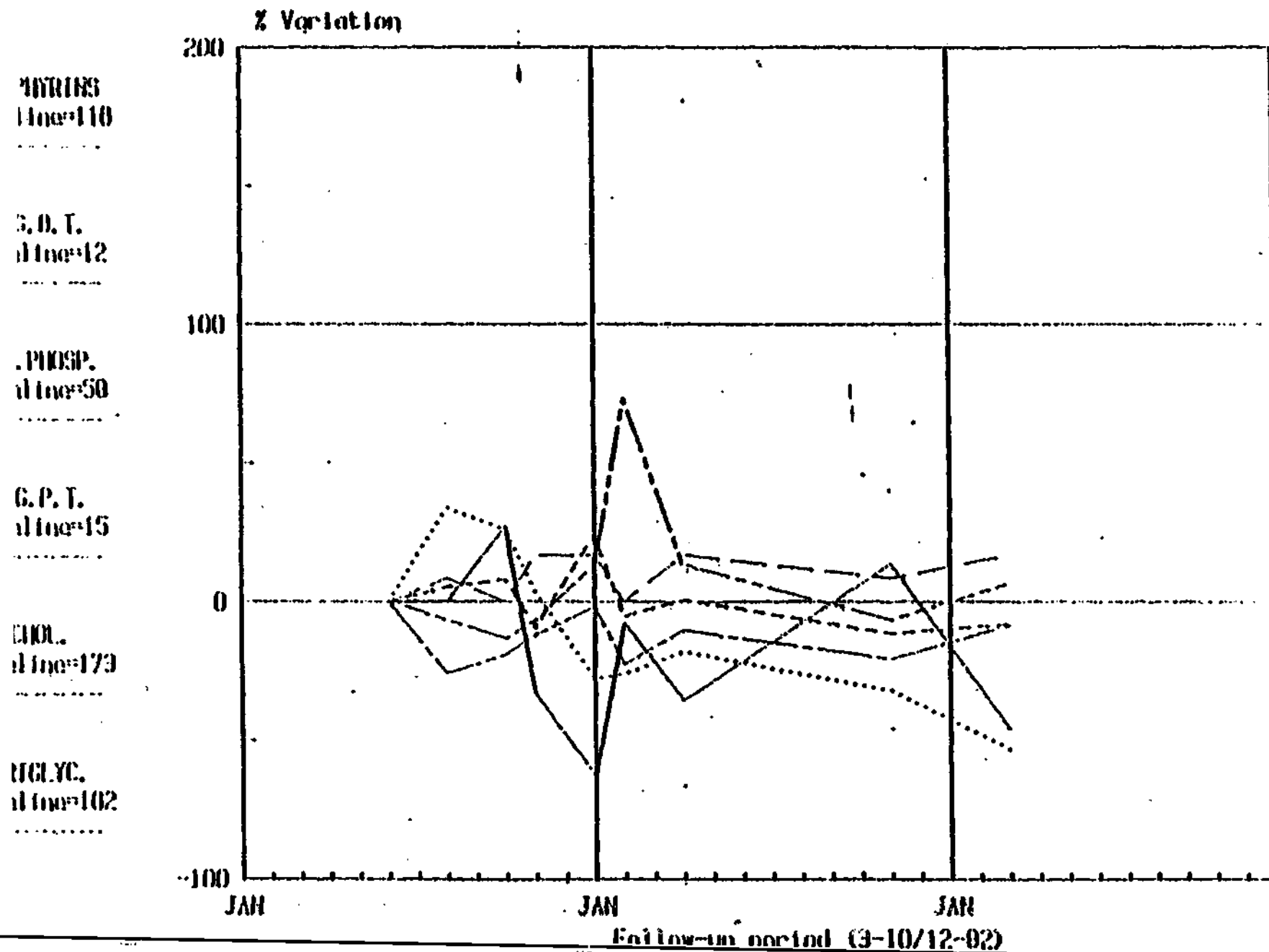


Fig. 61 TIME TRENDS
 CLEAN-UP WORKER #24; M. V., 34 yrs.

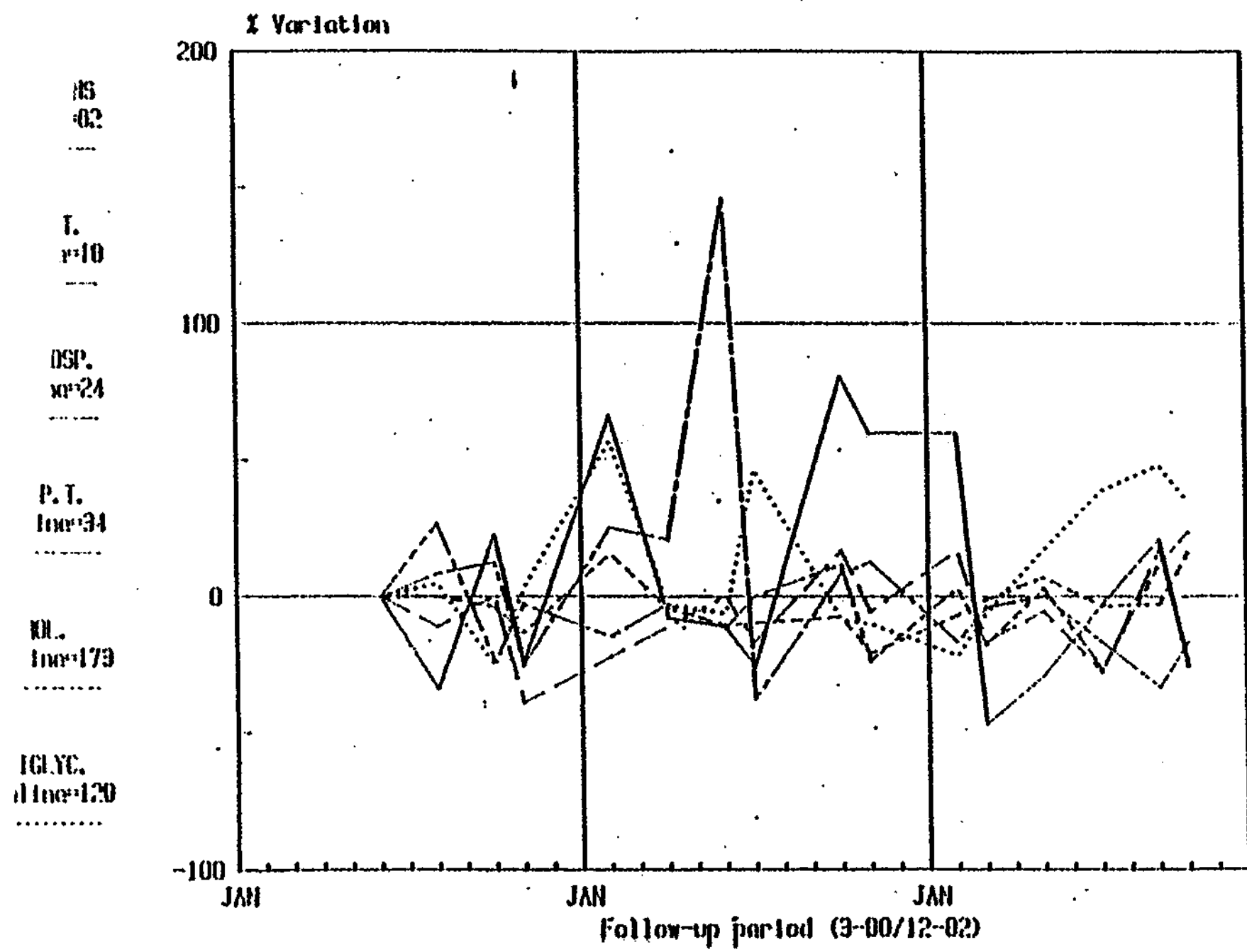


Fig. 62 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #25; A.S., 51 yrs

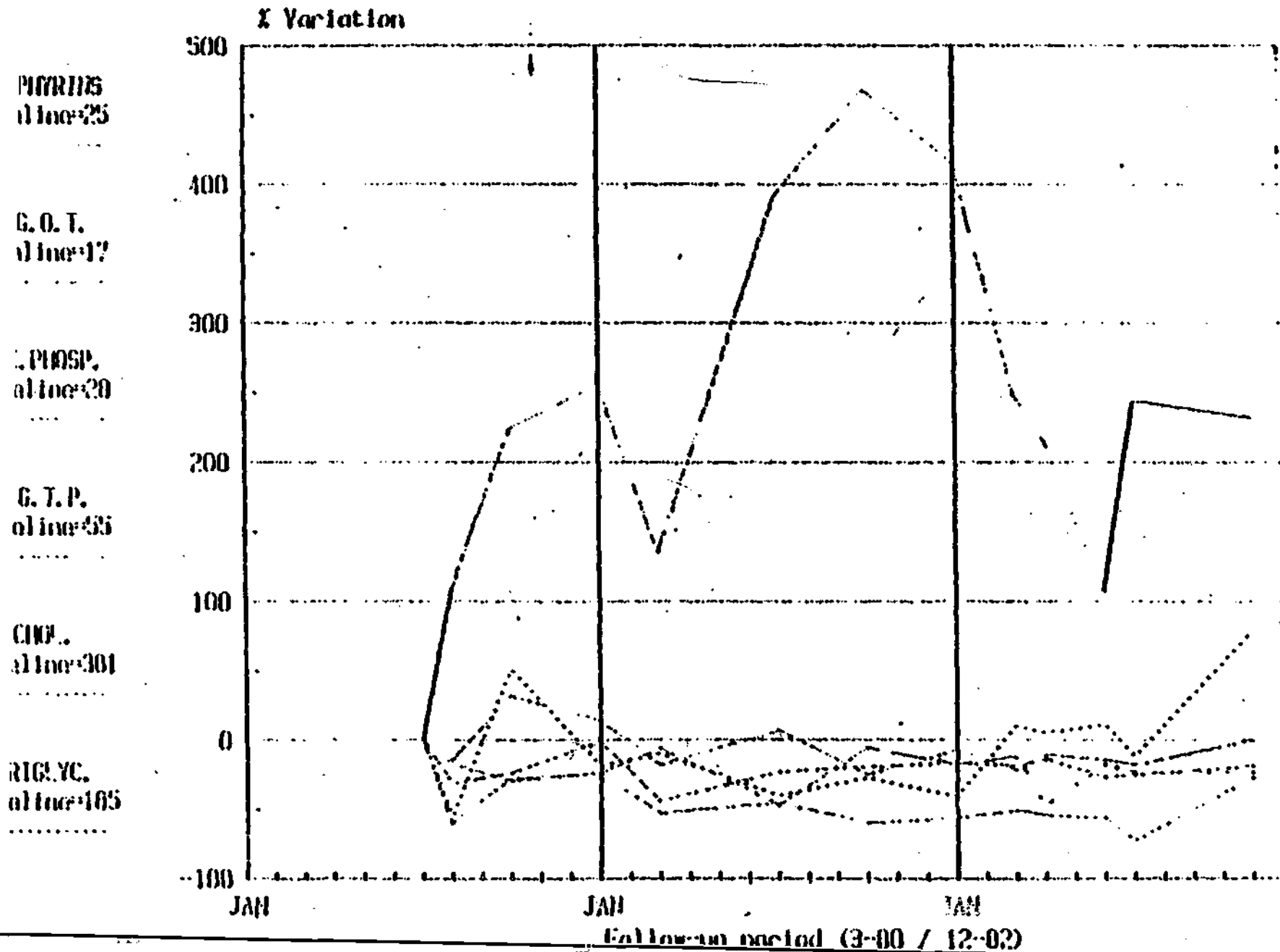


Fig. 63 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #26; A.G., 24 yrs

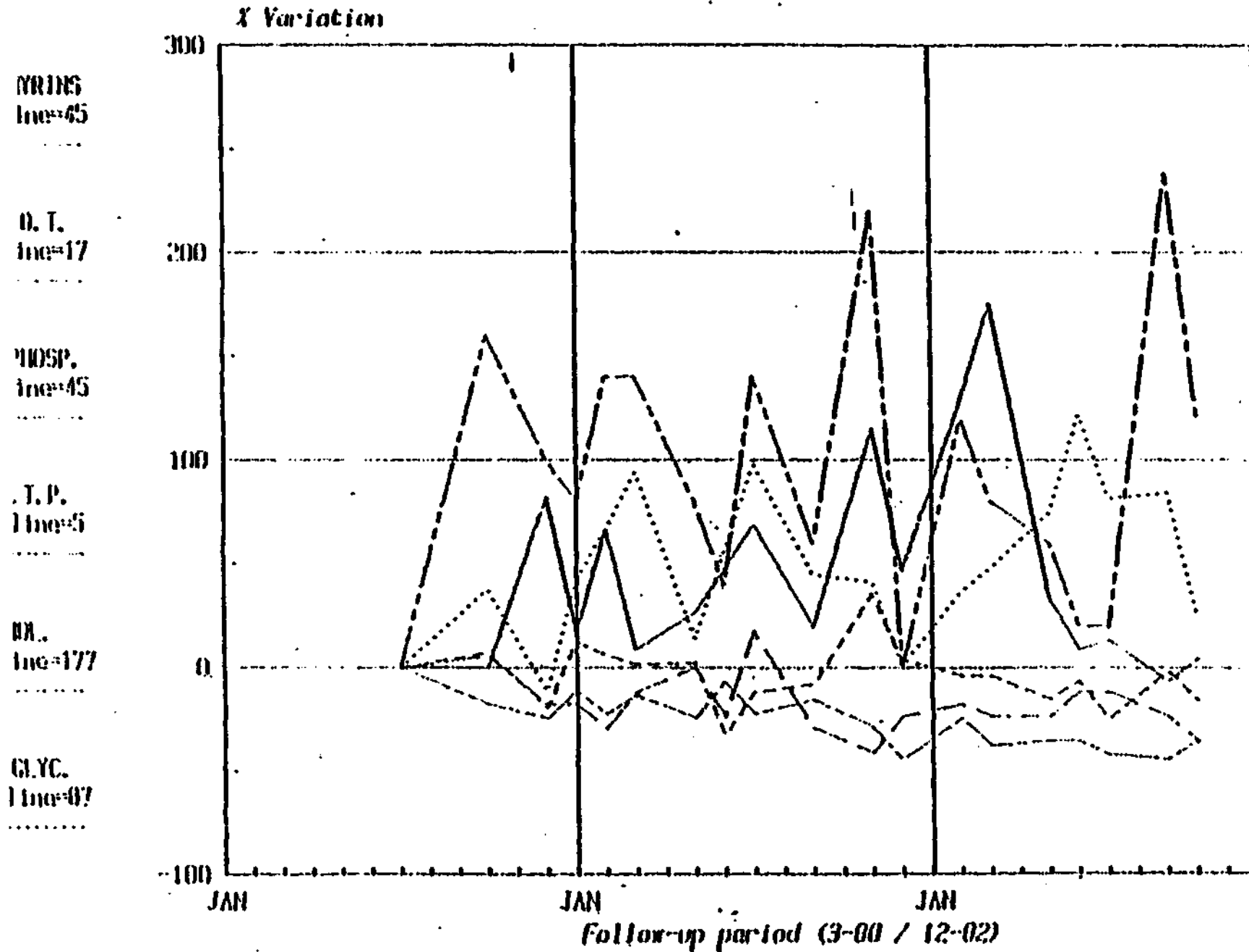


Fig. 64 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #27; H.S., 30 yrs

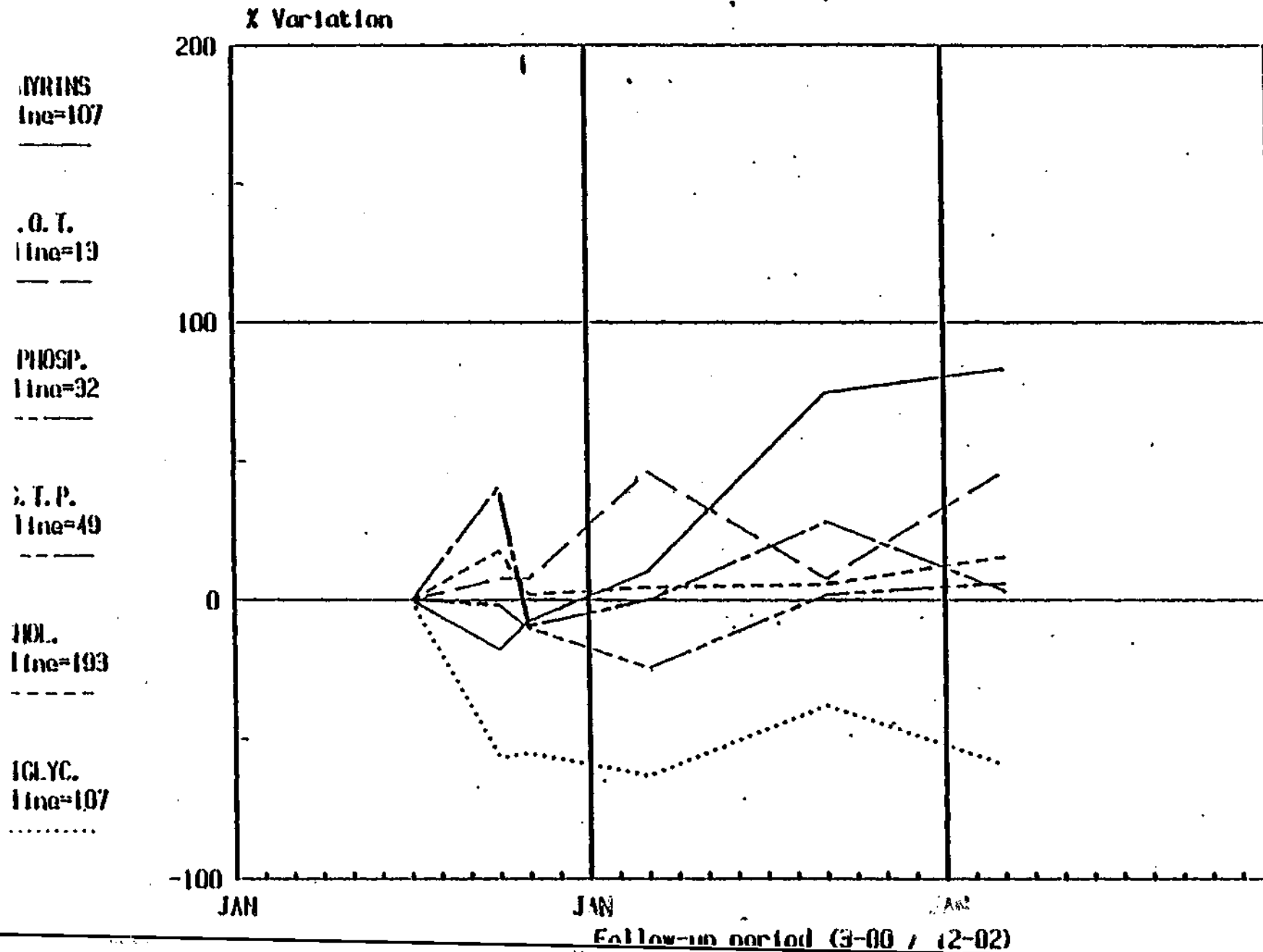


Fig. 65 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #28: J.S., 36 yrs

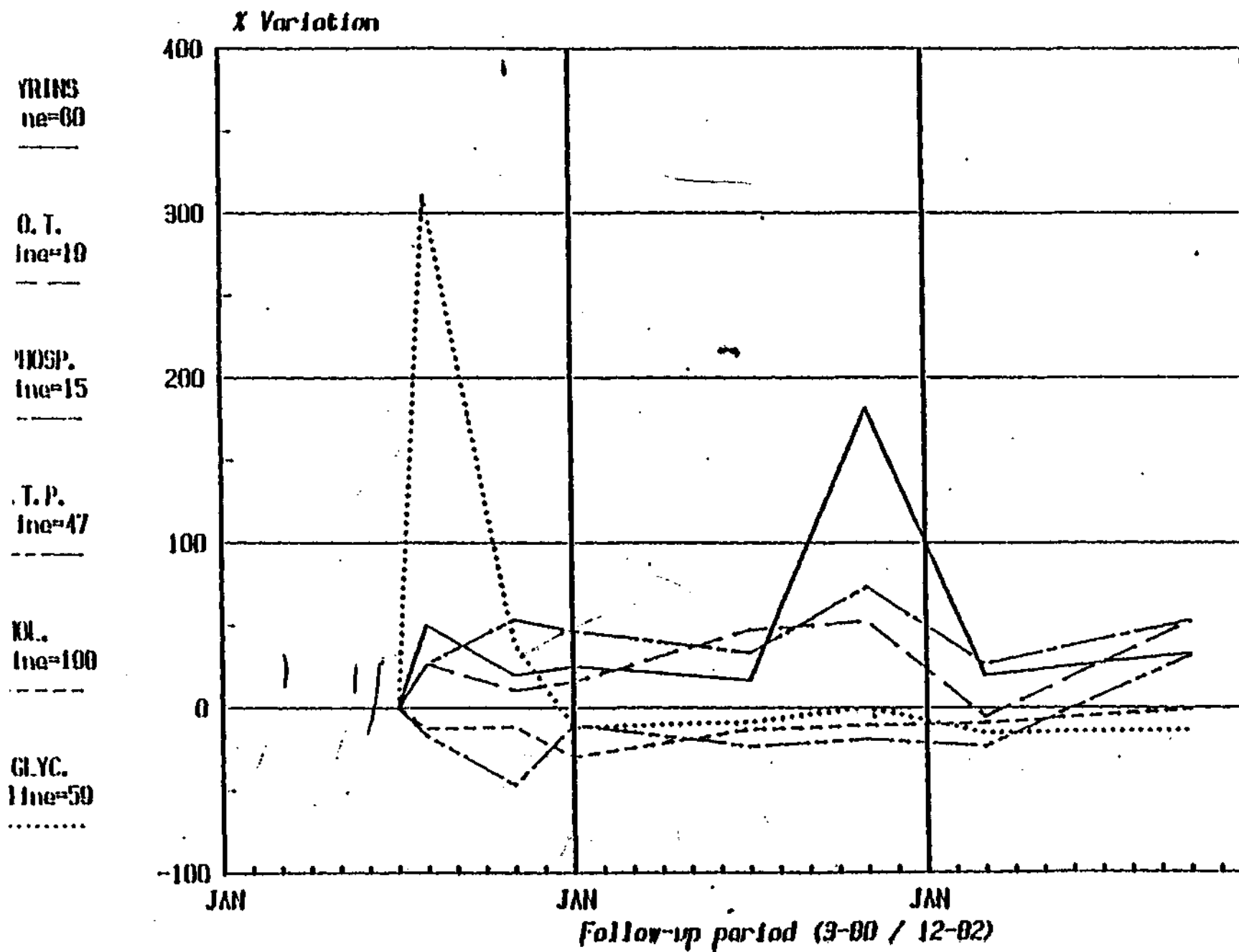


Fig. 66 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #29: G.F., 43 yrs

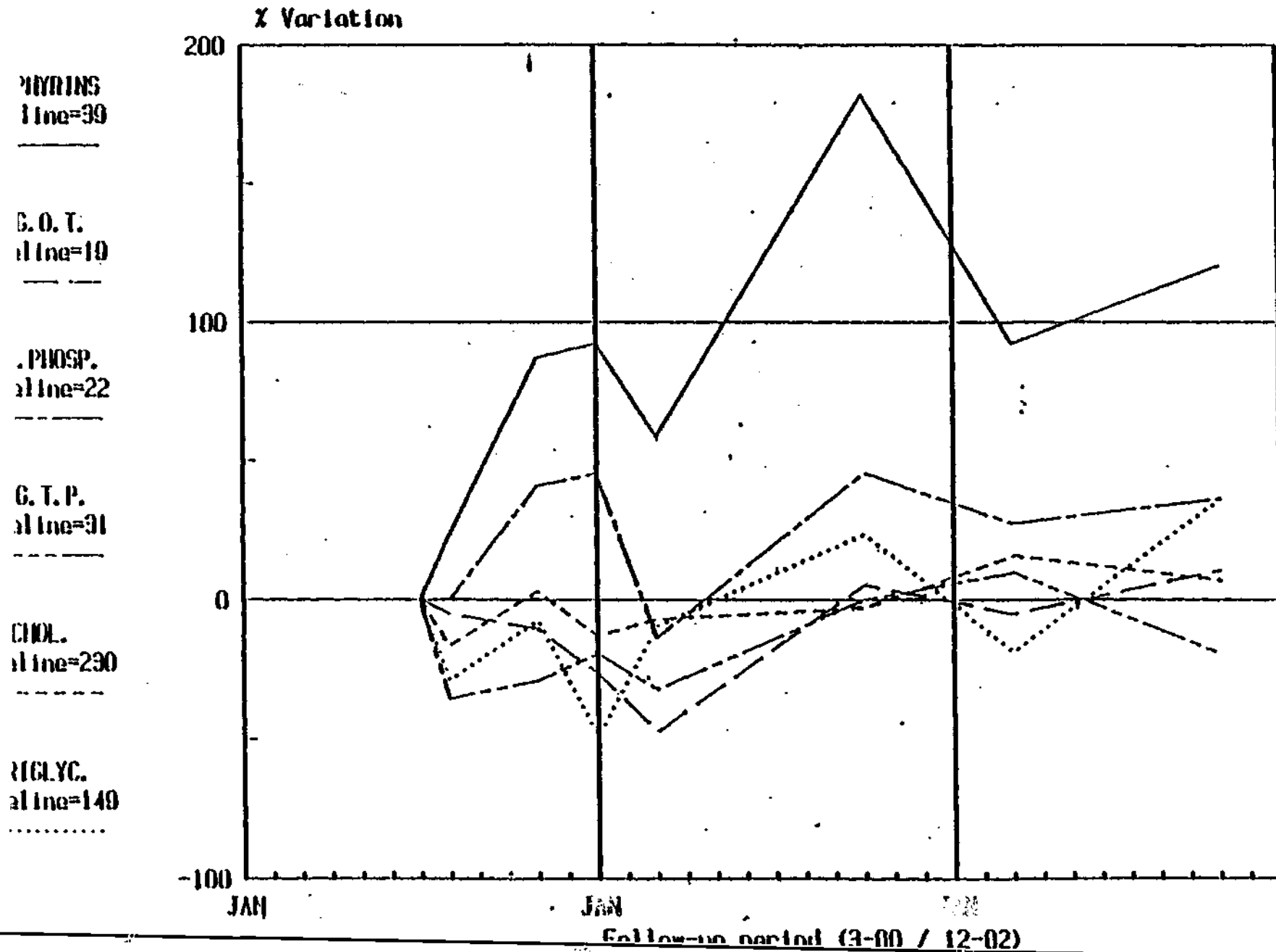


Fig. 67 TIME TRENDS OF 6 PARAMETERS IN
CLEAN-UP WORKER #30: R.R., 23 yrs

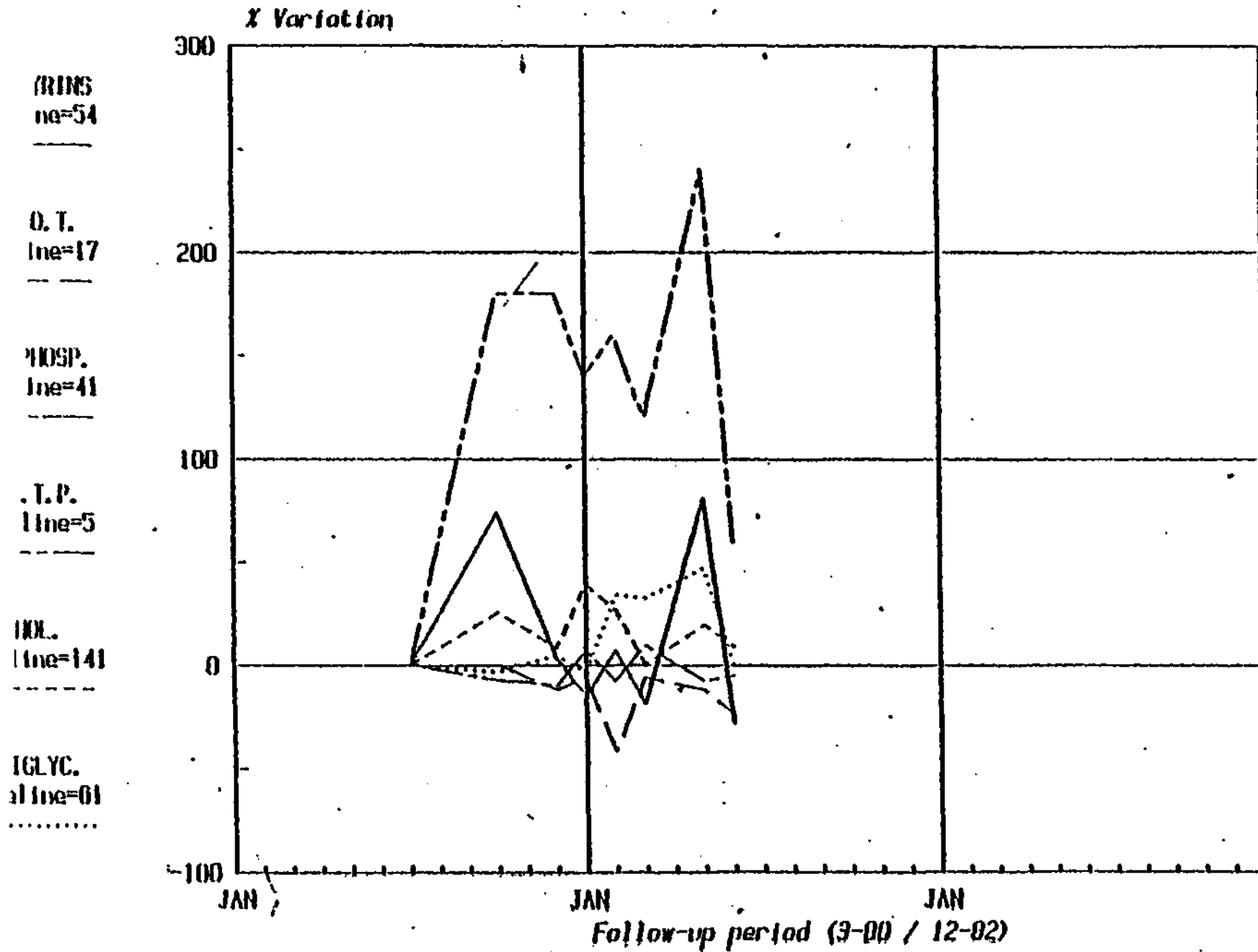


Fig. 68 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #31: N.F., 37 yrs

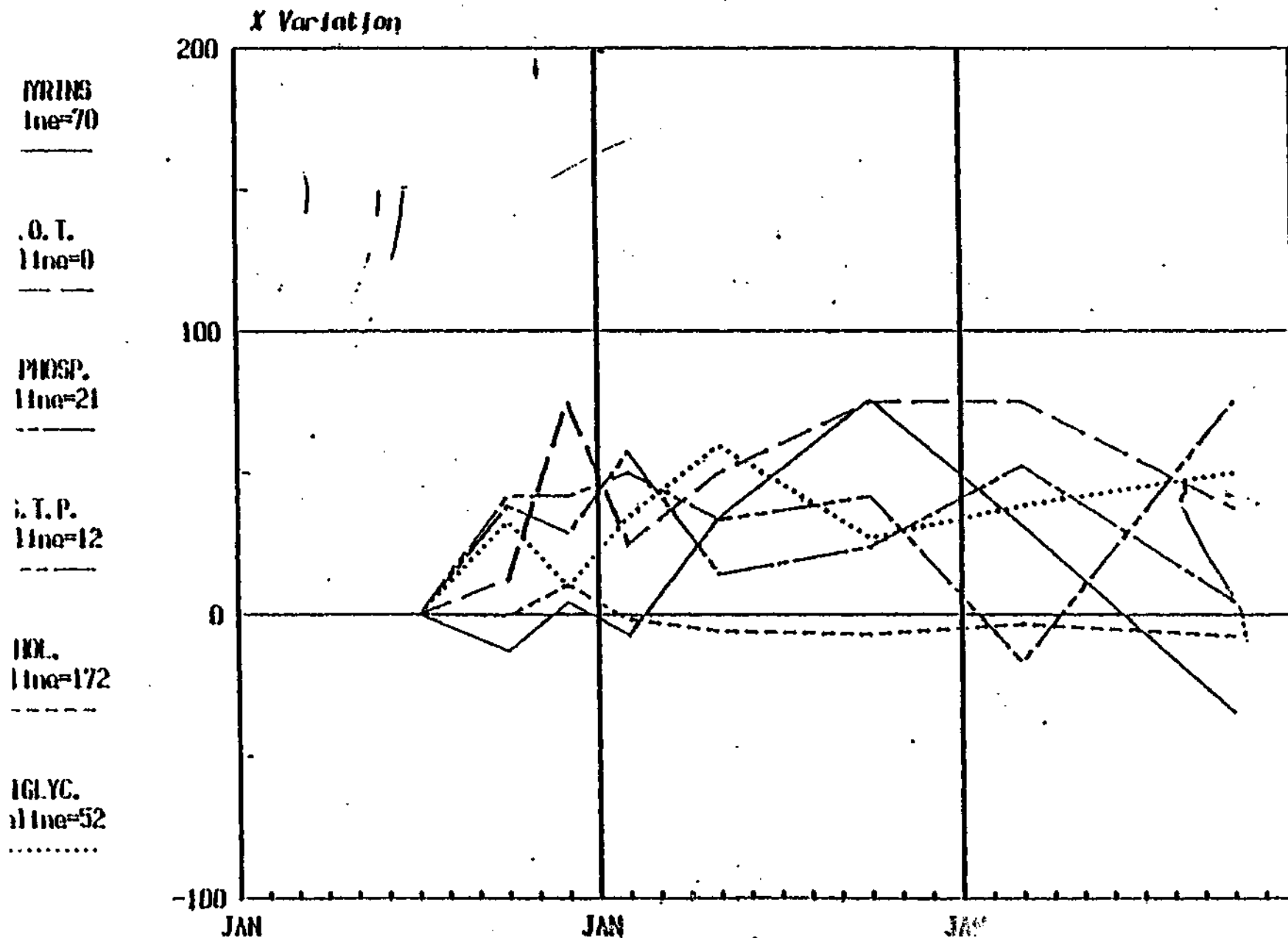


Fig. 69 TIME TRENDS OF U [unclear]
 CLEAN-UP WORKER #32; F.D., 27 yrs

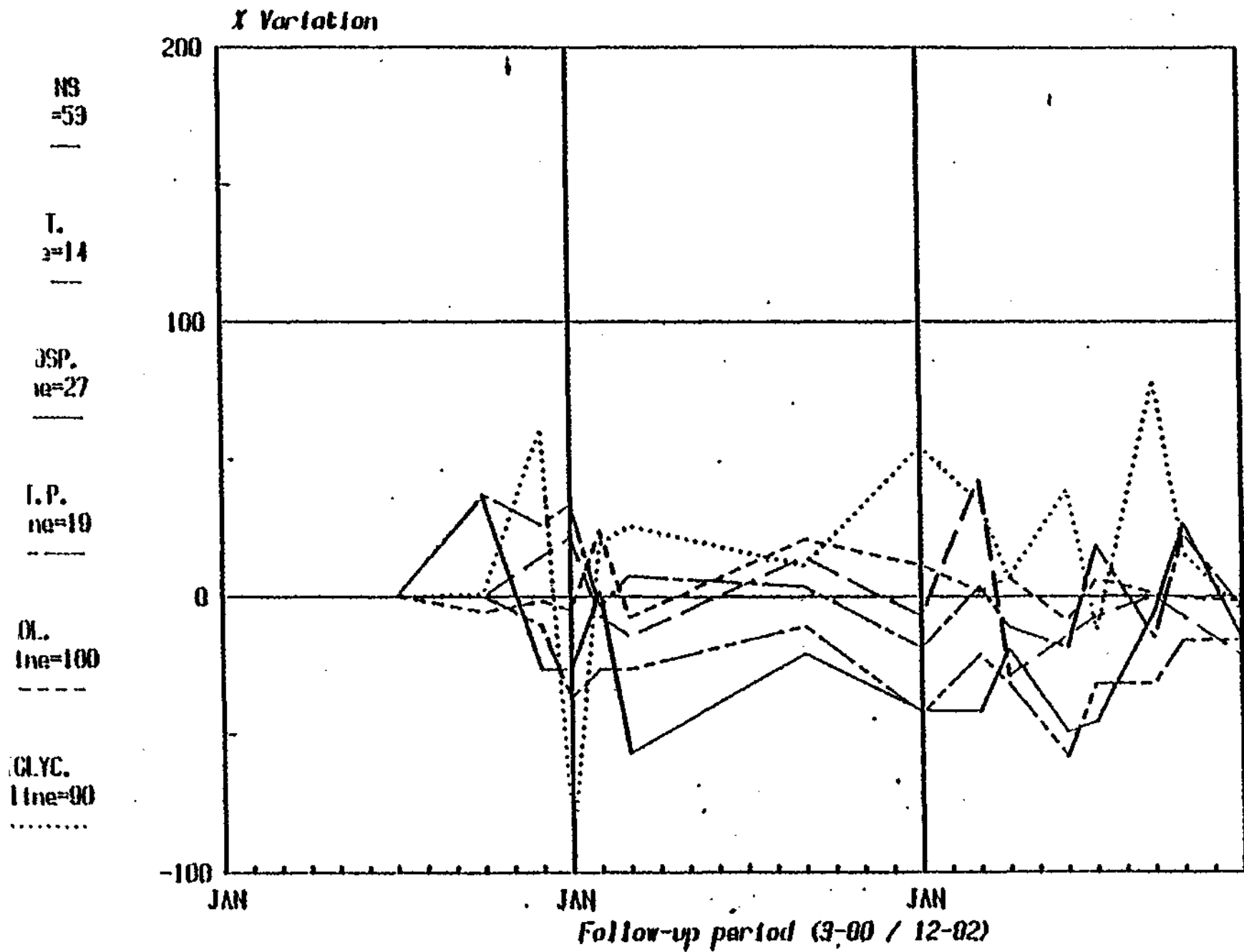


Fig. 70 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #33; R. S., 43 yrs

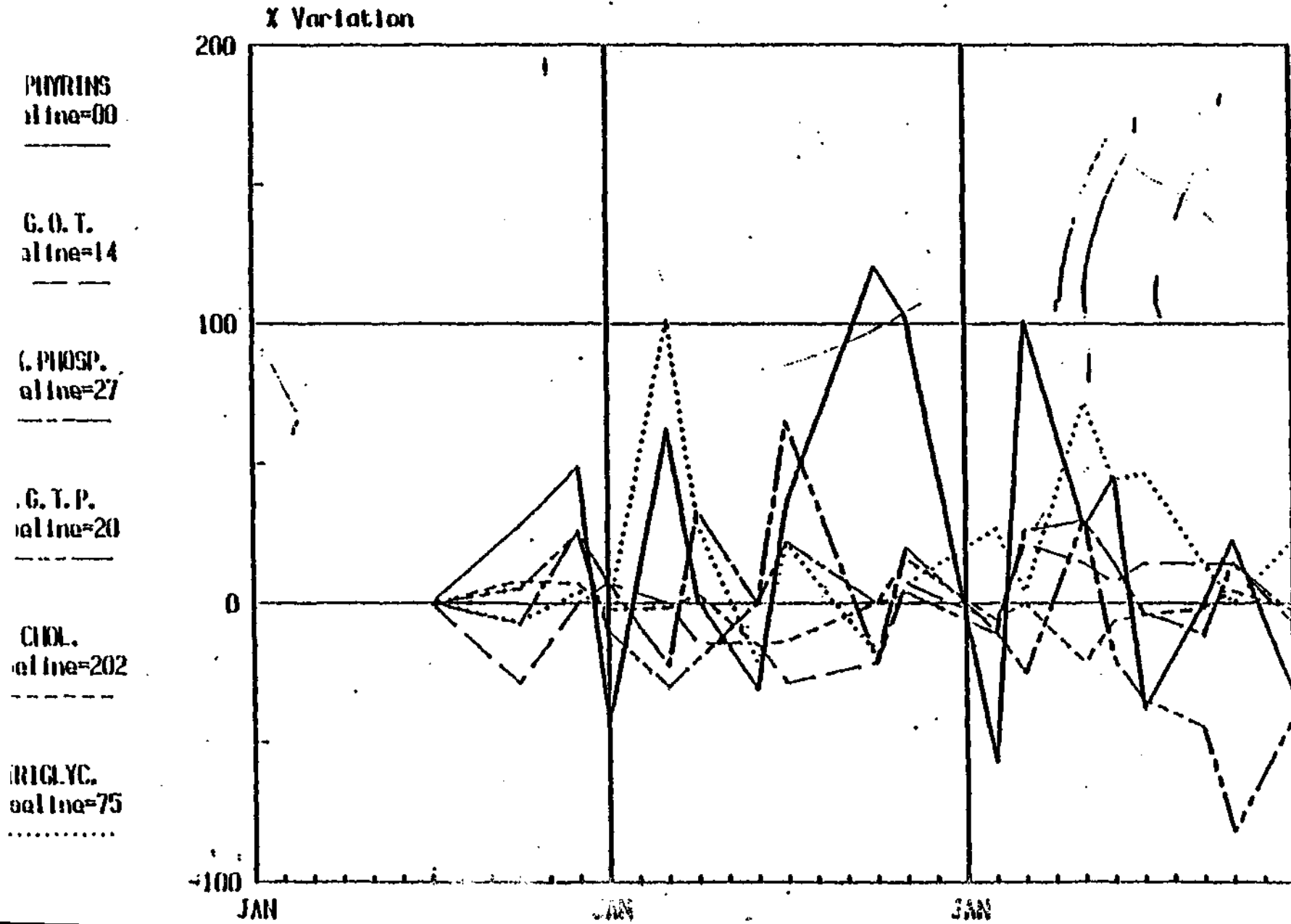


Fig. 71 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #34: A. Z., 31 yrs

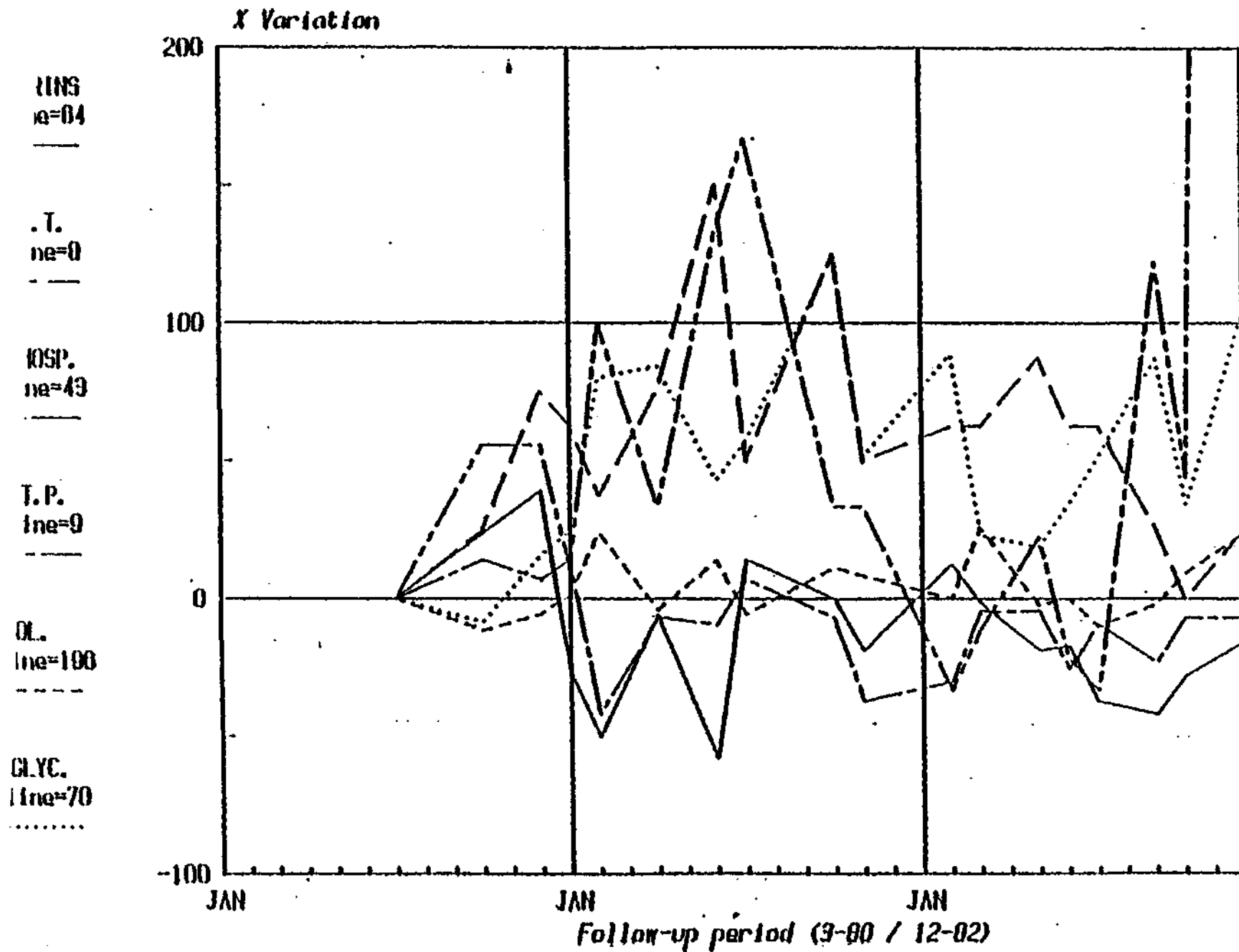


Fig. 72 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #35: T.C., 33 yrs

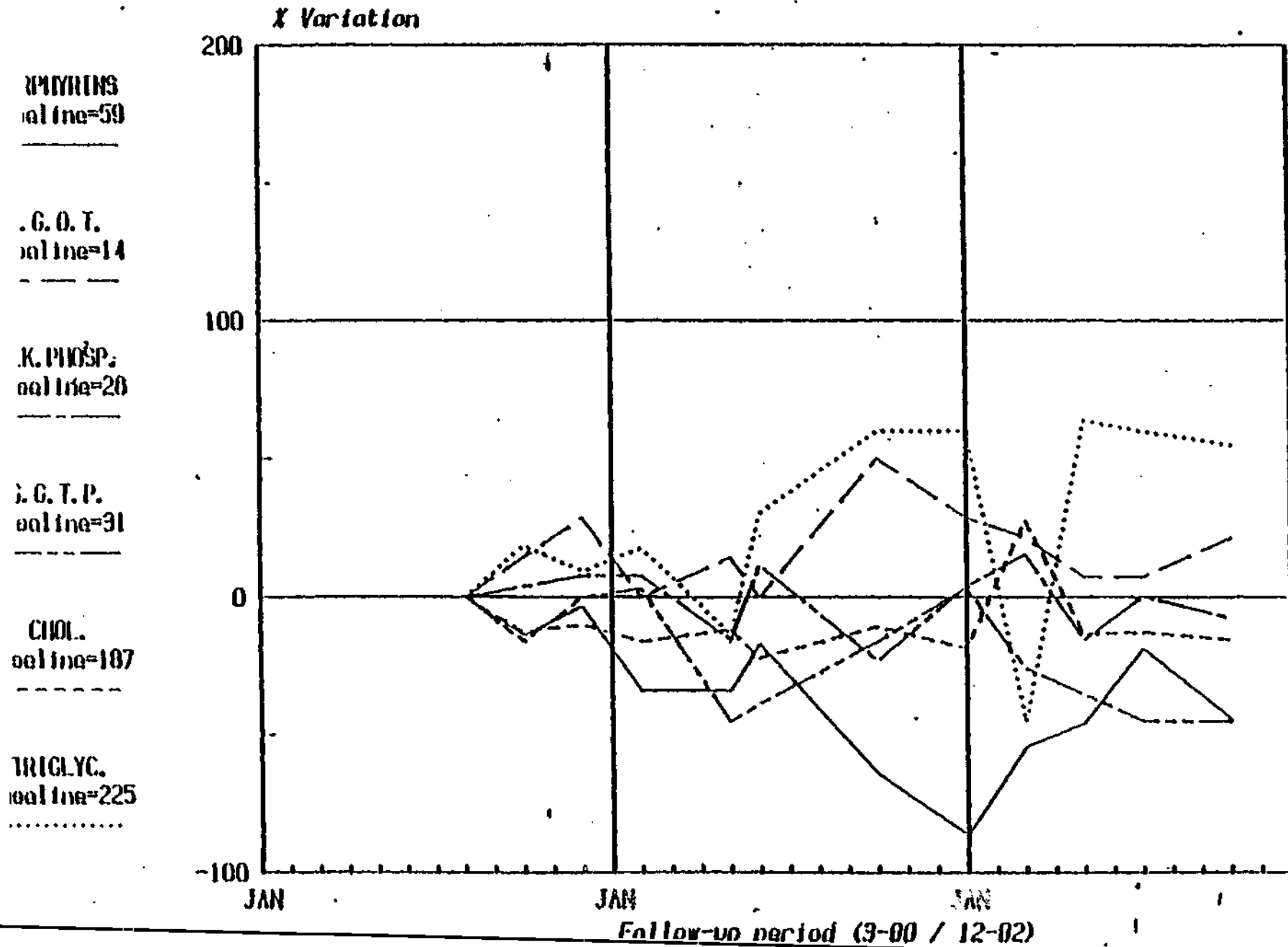
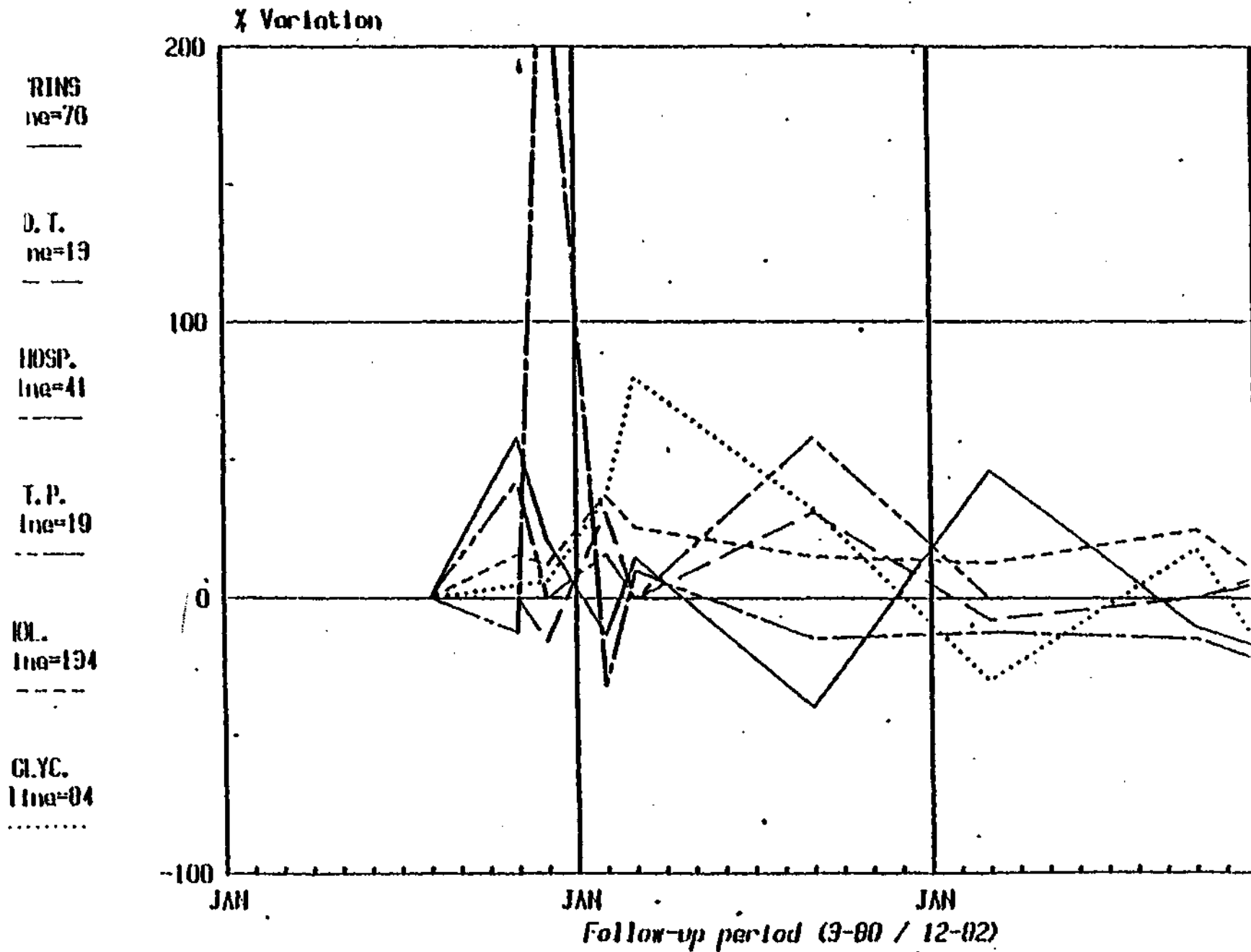


Fig. 73 TIME TRENDS OF 6 PARAMETERS IN
 CLEAN-UP WORKER #36: A. S., 23 yrs



APPENDIX A

FACSIMILE OF INTERVIEW QUESTIONARY

Study on the surveillance of the clean-up workers in the TCDD
decontamination, Seveso, Italy.

Date of the interview _____
Starting time _____
Interviewer's number _____
Interview number _____

A - Personal Data

A1 - "What is your full name?"

A2 - "When were you born?" (Specify day, month and year)

A3 - "Where were you born?" (Specify Town and Province)

A4 - "What is your address?" (Specify street, number, Town, province and
postal code)

A5- "Do you have a telephone?"

Yes /___/

No /___/

I don't know /___/

No answers /___/

If YES, go to A6
else, go to A7

A6- "What is your telephone number?"

I don't know /___/

A7 - "What is your present civil status?"

- Single /_/_/
- Married /_/_/
- Separated /_/_/
- Divorced /_/_/
- Widow/er /_/_/
- Other (specify)
..... /_/_/
- No answers /_/_/

A8 - "What is the highest educational record you have got?"

- University degree /_/_/
- High School /_/_/
- Secondary School /_/_/
- Primary School /_/_/
- Other (specify)..... /_/_/
- No records /_/_/
- I don't know /_/_/
- No answers /_/_/

A9 - "Did you do the military service?"

- YES /_/_/
- NO /_/_/
- I DON'T KNOW /_/_/
- NO ANSWERS /_/_/
- OTHER (Specify) /_/_/

If NO, go to A10
else, go to A12

A10 - "Why did you not do the military service?"

- Health reasons /_/_/
- Family reasons /_/_/
- Other (Specify) /_/_/

A11 - "In the last month, have you been smoking cigarettes?"

YES / /

NO / /

I CANNOT REMEMBER / /

NO ANSWERS / /

OTHER / /

If YES, go to A12

else, go to A17

A12 - "How many a day?" / / /

A13 - "At what age did you start smoking?"

..... / /

I cannot remember / /

No answers / /

A14 - "How long have you been smoking?"

YEARS / / /

I CANNOT REMEMBER ... / /

A15 - "Over the last five years, the number of cigarettes you
smoke a day has:

INCREASED / /

DECREASED / /

THE SAME / /

I DON'T KNOW / /

OTHER (Specify)

.....

..... / /

In case of increase or
decrease, go to A16, el
se, co to A17.

A16 - "Why?" (Specify)

Go to A21

A17 - "Have you ever smoked in the past?"

If yes, go to 18
else, go to A21

A18 - "How old were you when you smoked the first cigarette?"

AGE/ /
I CANNOT REMEMBER / /

A18bis - "Have you smoked more than 5 packets of cigarettes in your life?"

If yes, go to A19
else, go to B1

YES / /
NO / /

A19 - "For how many years have you been smoking?" / /

A20 - "How many cigarettes a day were you smoking in that period?"

NUMBER OF CIGARETTES / /
I CANNOT REMEMBER / /

ALCOHOL

B1 - "Have you ever drunk alcoholic drinks like wine, liquors, beer?"

YES / /
NO / /
I DON'T KNOW / /
OTHER (Specify)..... / /
..... / /
NO ANSWERS / /

If YES, go to B2
else, go to C1

B2 - "At what age did you start drinking alcoholic beverages?"

- YEARS /
- I DON'T KNOW /
- NO ANSWERS /
- OTHER (Specify) /
- /

B3 - "At present, are you drinking alcoholic beverages?"

- YES /
- NO /
- I DON'T KNOW /
- NO ANSWERS /

-If YES, go to B6
else, go to B4

B4 - "At what age did you give up drinking alcoholic beverages?"

- YEARS /
- I DON'T KNOW /
- NO ANSWERS /

B5 - "Why did you give up drinking alcoholic beverages?"

- /
- /
- I DON'T KNOW /
- NO ANSWERS /

Note for the interviewer:
read DRINKS if yes at B2, else read DRINKED

B6 - "Could you specify what kind of alcoholic beverages you usual DRINK/DRANK?"

- WINE /
- BEER /
- OTHER (Specify) /

REGULARLY DURING MEALS /
 REGULARLY DURING AND
 BETWEEN MEALS /
 REGULARLY BETWEEN MEALS /
 I DON'T KNOW /
 NO ANSWERS /

38 - "On these occasions, how much do you drink?"

WINE /
 1-2 glasses a day /
 Two glasses to half a liter a day /
 Half a liter to one liter a day /
 More than one liter a day /
 I don't know /
 No answers /

BEER /
 1-2 glasses a day /
 Two glasses to half a liter a day /
 Half a liter to one liter a day /
 More than one liter a day /
 I don't know /
 No answers /

39 - "Have you been drinking these drinks in the last week?:
Whisky, Brandy, Bitters, etc.?"

YES /
 NO /
 I DON'T KNOW /
 NO ANSWERS /

If YES, go to B10
 else go to C1

B10 - "What kind of hard liquors have you ~~drinks~~?"

ALCOHOLIC APERITIFS /
 BITTERS-DIGESTIVES /
 FAU-DE-VIE /
 COGNAC /
 WHISKY /
 COFFEE WITH LIQUEUR /
 OTHER /
 /

B11 - "You usually drink these drinks:

- OCCASIONALLY /_/_/
- REGULARLY BEFORE OR AFTER MEALS /_/_/
- REGULARLY BETWEEN MEALS /_/_/
- REGULARLY BOTH ON AND BETWEEN MEALS /_/_/

B12 - "On these occasions, how much do you drink?"

- ONE TO TWO LIQUEUR GLASSES A DAY..... /_/_/
- THREE TO FOUR LIQUEUR GLASSES A DAY..... /_/_/
- MORE THAN FOUR LIQUEUR GLASSES A DAY..... /_/_/

C1 - "In the last two months from today, have you been taking medicine pills, suppositories, syrups, etc.

- YES /_/_/
- NO /_/_/
- I DON'T KNOW /_/_/
- NO ANSWERS /_/_/

 If YES, go to C2
 else, go to D1

C2 - "Would you please tell the names of the medicines you have taken:

- 1) _____
- 2) _____
- 3) _____
- 4) _____

 For each medicine at C2,
 go to the questions C3, C4, C5

C3 - "Have you been taking 1), 2), 3), 4) for more than one week?"

| | | | | |
|--------------------|----------|---------|---------|----------|
| YES | 1) /_/_/ | 2 /_/_/ | 3 /_/_/ | 4) /_/_/ |
| NO | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| I DON'T KNOW | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| NO ANSWERS | /_/_/ | /_/_/ | /_/_/ | /_/_/ |

C4 - "What troubles caused you to take 1), 2), 3), 4)?"

Note: Specify the type of trouble for each medicine

- 1)
 2)
 3)
 4)

C5 - "Did the physician prescribe the medicine 1), 2), 3), 4)?"

| | 1) /_/_/ | 2) /_/_/ | 3) /_/_/ | 4) /_/_/ |
|----------------|----------|----------|----------|----------|
| YES | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| NO | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| I DON'T KNOW . | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| NO ANSWERS ... | /_/_/ | /_/_/ | /_/_/ | /_/_/ |

C6 - "For how long have you been taking the medicine 1), 2), 3), 4)?"

| | YEARS | MONTHS |
|----|-------|--------|
| 1) | /_/_/ | /_/_/ |
| 2) | /_/_/ | /_/_/ |
| 3) | /_/_/ | /_/_/ |
| 4) | /_/_/ | /_/_/ |

D1 - MEDICAL HISTORY

"Have you ever suffered from any of the following troubles or diseases?"

| | YES | NO | I DON'T REM. | I DON'T KNOW | YEAR OF ST. |
|---|-------|-------|--------------|--------------|-------------|
| Acne | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| Boils | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| Viral hepatitis | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| Chronic hepatitis | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| Hepatic cirrhosis | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| Epilepsy | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| Gall-bladder and/or biliary ducts stones | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |
| Diabetes | /_/_/ | /_/_/ | /_/_/ | /_/_/ | /_/_/ |

For each YES at D1, ask for D2 and fill in the above column, else go to D3

D2 - "When did it start (read the disease)?"

D3 - "Have you ever been hospitalized?"

YES //
NO //
I DON'T KNOW //
NO ANSWERS //

If YES go to D4, else go to D9

D4 - "How many times have you been hospitalized?"

Number of times //

D5 - For each time, write the disease, the year, the Hospi-
tal name and the town where it is.

"For what disease have you been hospitalized the (1st,
2nd, 3rd) time?"

D6 - "When did it happen?" (year)

D7 - "What is the name of the Hospital?"

D8 - "Where is the Hospital?" (town)

| Disease | Number of Hospitalizations | Year of Hospitalization | Hospital Name | Town |
|-------------------------------|----------------------------|-------------------------|---------------|------|
|/...../...../...../..... | | | | |
|/...../...../...../..... | | | | |
|/...../...../...../..... | | | | |
|/...../...../...../..... | | | | |
|/...../...../...../..... | | | | |

D9 - "Please, tell us the name and the address of your physician"

.....

D10 - "Have your physician ever told you that your liver is in bad conditions?"

YES //
NO //
I DON'T KNOW //
I DON'T REMEMBER //

D11 - "In the last two years, have you ever lost more than 5 kilos without being on a special diet?"

- YES / /
- NO / /
- I DON'T KNOW / /
- I DON'T REMEMBER / /

If YES go to D12, else go to D13

D13 - "Why did you lose weight?"

.....

D13 - "In the last two years have you ever been under treatment again. anaemia?"

- YES / /
- NO / /
- I DON'T KNOW / /
- I DON'T REMEMBER / /
- NO ANSWERS / /

If YES specify the treatment

D14 - "Have you ever suffered from skin troubles because of exposure sunbeams?"

- YES / /
- NO / /
- I DON'T KNOW / /
- NO ANSWERS / /

If YES go to D15 else go to E1

D15 - "Please describe these troubles"

.....

D16 - "Do these troubles reappear after each exposure to sunbeams?"

- YES / /
- NO / /
- I DON'T KNOW / /

ENDING TIME OF THE QUESTIONNAIRE /_/_/_/_/

E1 - "Is the interviewed hard of hearing?"

YES /_/_/
NO /_/_/
I DON'T KNOW /_/_/

E2 - "Can the interviewed speak and understand Italian correctly?"

YES /_/_/
NO /_/_/
I DON'T KNOW /_/_/

E3 - "In which day of the week was the interview made?"

Monday /_/_/
Tuesday /_/_/
Wednesday /_/_/
Thursday /_/_/
Friday /_/_/

APPENDIX B

CASE SHEET USED FOR MEDICAL EXAMINATION

DESIO HOSPITAL

OCCUPATIONAL HEALTH SERVICE

Chief Physician: Prof. I.Ghezzi

CLINICO-EPIDEMIOLOGICAL SURVEY

MDL - 1 ICMESA
MDL - 2 CLEAN-UP WORK

Desio Hospital

Surname and name

Place of birth

date

Registered residence

tel.

Usual address

Marital status

married unmarried widower separated divorced

Occupation

Exposed

control

Treating physician

Examining physician

FAMILY HISTORY

Father

Mother

Siblings

Wife

PHYSIOLOGICAL HISTORY

| | | | |
|-------------|------------|-------------|-------------|
| Birth | at term | premature | |
| Delivery | normal | dystocic | twin |
| Development | normal | precocious | late |
| Schooling | compulsory | high school | university. |

Military service:

| | |
|-----|------------------|
| yes | force |
| no | health reasons : |
| | yes |
| | no |

| | | |
|-----------|-----|---------------|
| Marriage: | no | |
| | yes | at ... years |
| | | no. children |
| | | no. abortions |

Present occupation

Previous "

(for risks see questionnaire)

smoking (see questionnaire)
drinking (see questionnaire)
drugs (see questionnaire)

} only
additions,
if any

Diet

poor

normal

plentiful

Digestion: normal yes

no why

Bowel movements: normal

constipated

loose

Urine output: normal yes

no why

Sex Life:

reported normal

reported abnormal

since which year

why

PAST HISTORY: (supplemented by questionnaire)

Diseases:

Hospital admissions

Accidents

Allergies

PRESENT HISTORY: (past year)

Visual apparatus

disturbances

diseases

Auditory apparatus

disturbances

diseases

Respiratory system

disturbances

diseases

Heart

disturbances

diseases

Digestive tract

disturbances

diseases

Urinary system
disturbances
diseases

Limbs
disturbances
diseases

Musculoskeletal system
disturbances
diseases

Skin
disturbances
diseases

Nervous system
disturbances
diseases

PHYSICAL EXAMINATION

| Height | Weight | kg | Usual weight |
|---------------|--------|-------------|--------------|
| Constitution: | | | |
| longilineal | normal | brevilineal | athletic |
| thin | medium | fat | obese |

BP max min Heart rate

Skin: normal
 abnormal
 specialist examination

Subcutaneous tissue. Abnormal findings
no
yes which

Lymph nodes. Abnormal findings
no
yes specify

Musculature. Abnormal findings
no
yes specify

Skeletal system. Abnormal findings
no
yes specify

Head: mobility ache yes
no

eyes abnormal findings no
yes
ears: abnormal findings no
nose: yes

mouth: oropharynx abnormal findings no
yes
teeth abnormal findings no
yes

Neck: abnormal findings no
yes

Respiratory System: abnormal findings no
yes

if yes: chest deformity
F.V.T. (Fremitus - vocal - tactile)
percussion
auscultation

Mammary Glands: abnormal findings no
yes

Heart: abnormal findings no yes
if yes:

Abdomen: abnormal findings no
yes

Liver: normal findings yes no

in any case:

- upper limit on the right midclavicular line:
intercostal space or rib
- lower limit (cm from the costal arch on right
midclavicular line):
 - . at end of normal inspiration
palpation
percussion
 - . in max forced inspiration
palpation
percussion
- margin and surface
- consistency
- tenderness

Spleen: normal findings yes no

Other Findings Abdominal Organs

Genitourinary System

Kidneys: abnormal findings no yes

Bladder: abnormal findings no yes

External genitalia: abnormal findings no yes

Limbs: abnormal findings no yes

upper

lower

varices no yes

peripheral pulses (radial, posterior tibial, dorsal artery
of foot)

abnormal findings

no yes

if yes:

Nervous System And Psyche

abnormal findings no yes

Remarks: