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SERIAL: NLS-91-160 10CFR Part 26 Appendix A, 2.8(e)(4)

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FITNESS FOR DUTY - REPORT ON CHEMICAL TESTING LABORATORY PERFORMANCE TESTING

### Gentlemen:

10CFR Part 26, Appendix A requires licensees to report unsatisfactory performance testing results as part of the Fitness For Duty Program. Carolina Power & Light Company (CP&L) submitted a split sample specimen to a separate certified laboratory for confirmation of initial test results. The confirmatory laboratory test data provided conflicting results.

Accordingly, CP&L's investigative report concerning this instance is enclosed. As required by 10CFR Part 26, Appendix A, Section 2.8(e)(4), a record of the investigative findings and the corrective action taken by the laboratory, dated and signed by the individuals responsible for the day-to-day management and operation of the laboratory, is also enclosed.

For further information about this subject, please contact Mr. Fred Underwood, CP&L's Fitness For Duty Coordinator, at (919) 546-6180.

Yours very truly,

Manager

Nuclear Licensing Section

DBB/jbw (1163GLU)

Enclosures

cc: Mr. S. D. Ebneter

Ms. B. L. Mozafari

Mr. L. Garner (NRC-HBR) Mr. R. L. Prevatte (NRC-BSEP)

Mr. N. B. Le

Mr. J. E. Tedrow (NRC-SHNPP)

Mr. R. Lo

411 Fayetteville Street • P. O. Box 1551 • Raleigh, N. C. 27602

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May 29, 1991

# **MEMORANDUM**

TO:

Mr. Fred Underwood

FROM:

David E. Owen

**SUBJECT:** Administrative Error at Roche Biomedical Laboratories,

Research Triangle Park, NC

This is a report of our investigation into an administrative error committed by Roche Biomedical Laboratories during their processing of a split sample as part of the Fitness For Duty Program. Roche analyzes our split samples by GC/MS only, using their Limit of Detection (LOD) at the cut-off value.

On January 10, a split sample result was reported from Roche as negative. Upon our inquiry about the cut-off value used for the analysis, it was determined that the sample was positive -- above the Roche Biomedical Laboratories' Limit of Detection. The reason for the initial false negative report was Roche's reliance on their data reviewers to take exceptional actions for LOD analyses.

On February 5, Mr. Ted Shults reported to us the findings of his investigation into the causes, corrective actions, and preventive actions associated with the laboratory's administrative error. Mr. Shults' report (attached) recommended 1) our continued followup on all negative reports received from Roche, 2) Roche's discontinuance of relying on manual override of the reporting software, and 3) Roche's use of a specific test panel for LOD analyses.

On February 27, I requested Mr. John Irving, Co-Director of the Research Triangle Park Roche Biomedical Laboratories facility, to describe the actions that Roche would take in preventing future administrative errors in analysis reporting. A copy of this letter is attached.

On March 28, Dr. Paula Childs responded to our request. A copy of her letter is attached. Sile described their implementation of a revised data review and computer software system that allows for LOD samples to be entered qualitatively as "POSITIVE" or "NEGATIVE" for LOD samples.

This incident is considered closed, except for our continued review of any production split sample analysis reported as negative.

Program Director - Oceupational Health

# Attachments

c: Mr. Bob Barham Dr. D. Kim Broadwell Dr. Paula Childs Mrs. Betty Wilder, RN, COHN

# Roche Biomedical Laboratories



a subsidiary of Hoffmann-La Roche Inc.

Roche Biomedical Laboratories, Inc. P.O. Box 13973 Research Triangle Park, North Carolina 27709

Telephone: 919 361-7700

March 28, 1991

Mr. David Owen
Program Director - Occupational Health
Carolina Power and Light Company
411 Fayetteville Street
P. O. Box 1551
Raleigh, NC 27602

Dear Mr. Owen:

The details outlined in your letter to Mr. John Irving (February 27, 1991) have been reviewed, and I have prepared a report which describes the actions taken. The attached report includes the details of the investigation and follow-up which have taken place since the original report was issued for sample number 04186863.

I have also included information concerning the use of the NIDA profiles and NIDA chain of custody forms. If you need additional information, please call me at (800) 533-0567, x 7712.

Sincerely yours,

Paula S. Childs, Ph.D., D-ABFT

Co-Director, Toxicology

Tuela S. Childs

cc: Dr. Ken Broadwell

Ms. Betty Wilder, RN, COHN

### INVESTIGATION AND CORRECTIVE ACTION

### SAMPLE #04186863

### SUMMARY OF INVESTIGATION:

The specimen identified above was submitted to the Roche Biomedical Laboratory in Research Triangle Park, NC for analysis of cocaine at the Limit of Detection (LOD). The analysis was completed and a concentration of 71 ng/mL was determined for the specimen. When the result was entered into the computer system, the software compared the result to the threshold for positive ( $\geq 150$  ng/mL) and determined that the specimen was "NEGATIVE". The subsequent communications from Betty Wilder, RN led to an amended report which included the concentration of benzoylecgonine (cocaine metabolite).

### CORRECTIVE ACTIONS:

Roche Biomedical Laboratory has changed the computer software program to allow for specimen concentrations (when tested under LOD analysis conditions) to be reported as "POSITIVE" if the concentration exceeds the LOD concentration. The report has been set up to accept a qualitative (POSITIVE or NEGATIVE) result, and have no normal range or cutoff. This change in software became effective on March 11, 1991. An example of the report (the example is for Carboxy THC) is attached.

The Co-Directors of the Toxicology laboratory are Dr. Paula Childs and Mr. John Irving. They are recognized as Directors by the National Institute on Drug Abuse (NIDA). Dr. Myla Lai-Goldman is the physician who is the laboratory director under the state and federal regulations which require a licensed physician as the director of the site, although Dr. Lai-Goldman does not direct the toxicology program. Roche Biomedical Laboratory performs other medical tests which are covered under these state and federal regulations. Thus, Dr. Lai-Goldman must be listed on the reports for all specimens processed under the non-NIDA profiles. The name of Dr. Paula Childs appears on reports which are generated from specimens received under the NIDA quidelines.

Carolina Power and Light submits specimens to Roche Biomedical Laboratories with the non-NIDA chain of custody form, and orders test profiles which are listed as non-NIDA tests. Thus, the reports which are transmitted electronically include the name of Dr. Myla Lai-Goldman.

The NIDA chain of custody forms and NIDA test profiles are available for the use of Carolina Power and Light Company. However, the only tests which are routinely performed under this program are dictated by the NIDA program. The analytes include

Cannabinoids, Cocaine metabolite, Opiates (Codeine and Morphine), Phencyclidine, and Amphetamines (Amphetamine and Methamphetamine). Analyses for these substances are available at the NIDA thresholds (cutoffs) and also at the respective Limit of Detection for each analyte.

If Carolina Power and Light Company would like to initiate the use of these forms and tests, please advise the program director to contact Mr. Irving or Dr. Childs for additional information and implementation.

### CANNABINDID GC/MS RETEST

BD

THIS REPORT PROVIDES THE RESULTS OF A RETEST FOR THE ABOVE SPECIMEN PER YOUR REQUEST. PLEASE BE ADVISED THAT THE RESULTS HAVE BEEN DERIVED BASED ON THE RULES THAT GOVERN RETESTING OF A SAMPLE. THE STANDARD CUTOFF LEVELS MAY NOT HAVE BEEN USED TO DETERMINE THE RESULTS.

CARBOXY THC GC/MS CONF.

POSITIVE

BD

DIRECTOR: -

LAST PAGE OF REPORT (LAB SITES DEFINED ON BACK OF REPORT)

IF YOU HAVE ANY QUESTIONS CONTACT - BRANCH: 800-873-7251 LAB: 919-584-5171

February 27, 1991

Mr. John Irving, Co-Director Roche Biomedical Laboratories, Inc. 1912 Alexander Drive Research Triangle Park, NC 27709

Dear Mr. Irving:

In January of this year, your laboratory performed a drug urinalysis, to your limits of detection, on a split sample as part of CP&L's NRC Fitness For Duty drug testing program. The initial report for the sample was negative. Upon our request about the report, it was determined that an administrative error occurred in processing the test results and that the sample was positive for the specified metabolite.

We requested Mr. Theodore Shults to perform an investigation into your labroatory's processes and procedures to determine the cause of the reporting error and to recommend preventive actions needed to avoid this type of error in the future. Mr. Shults' February 5, 1991 report of this investigation is enclosed.

A disagreement between split sample analysis and the initial sample analysis is a serious flaw in any drug testing program. This compels us to require the following actions:

- 1. Roche shall respond to Mr. Shults' report of the investigation. This written response shall be provided to me no later than April 2, 1991.
- 2. The response shall describe those actions that Roche proposes to take in preventing future administrative errors similar to the ones that caused the incorrect report of sample number 04186863. The response shall include the date by which the proposed actions can be completed.

We will evaluate your response in consultation with our Medical Review Officer. This evaluation will most likely include:

- 1. an assessment of your proposed preventive actions,
- 2. the timeliness of your proposed completion schedule for these actions.

- 3. a requirement for your written confirmation that the preventive actions have been completed, and
- 4. a follow-up inspection.

We may report this incident to the NRC as a measure taken to assure acceptable laboratory performance in support of the FFD program.

I appreciate your efforts in providing accurate drug urinalyses and hope that we can mutually resolve the concerns described in the inquiry report.

Sincerely,

David E. Owen

Program Director - Occupational Health

### Enclosure

c: Mr. Dale Bates

Dr. Ken Broadwell

Mr. Oscar Hinton

Mr. Fred Underwood

Ms. Betty Wilder, RN, COHN

SHULTS AND ASSOCIATES

Consultants

15 RUNNING BROOK COURT
DURHAM, NORTH CAROLINA 27713

THEODORE F. SHULTS, M.S., J.D.
ATTORNEY AT LAW
TOXICOLOGIST

(919) 493-1952

P.O. Box 12873
RESEARCH TRIANGLE PARK
NORTH CAROLINA 27709
FAX: (919) 489-9588

M E M O R A N D U M

TO:

David Owen

Director Corporate Medical Department

Carolina Power & Light Co.

FROM:

Theodore F. Shults

DATE:

February 5, 1991

# INQUIRY AND INVESTIGATION OF INCORRECT LABORATORY REPORTING OF SAMPLE RESULTS 04186863

### I. INCIDENT:

# Background:

- 1. Carolina Power & Light (CP&L) uses two NIDA certified drug testing laboratories for the analysis of samples obtained under CP&L's fitness for duty program. CP&L procedures call for the collection of split samples. The split samples are urine specimens that have been produced from the same void and divided into two bottles, which are sealed and identified. One sample is submitted to CompuChem Laboratories for analysis in accordance with CP&L's technical specifications. The second laboratory is Roche Biomedical Laboratory-Research Triangle Park Facility (RBL).
- 2. CP&L has implemented special handling procedures in accordance with 10 CFR 26. Under CP&L's special handling procedures samples which have low creatinine values, designated as below 20 ng/dl, are retested for cocaine and THC at lower threshold values. Following these procedures a sample was identified by GC/MS analysis as positive for cocaine. The sample was reported by CompuChem to the administrator of CP&L's fitness for duty program, Ms. Betty Wilder as positive for benzoylecgonine at 60 ng/ml.

- 3. Following the medical review officer's interview with the individual donor of the sample, the split sample was submitted to RBL for analysis at their limits of detection.
- 4. On January 10, 1991 RBL generated a computer report of results for the split specimen. The report contained the patient name and identified as specimen 008-700-2102-0. The report indicated that a cocaine confirmation was performed and that the sample was NEG (negative).
- 5. Pursuant to the medical review officer's direction, Ms. Wilder contacted a laboratory customer service representative to confirm that the test was performed at the limits of detection. It was confirmed that this was performed.
- 6. Ms. Wilder then notified the representative of CP&L's plan to obtain further analysis of the split sample by another NIDA-certified laboratory.
- 7. In a follow up telephone call, Ms. Wilder asked the RBL representative to confirm the laboratory's detection limit for cocaine. The representative stated that the laboratory director would need to provide this information.
- 8. Mr. John Irving, co-director of RBL's forensic drug testing laboratory returned the call within one hour and stated that the sample had been reported as negative in error and that the actual results were positive at a concentration of 71 ng/ml. Ms. Wilder requested a revised written report. (Attachment B)
- 9. The revised report was generated on January 11, 1991. The report stated that the sample was NEG. A second line was added to indicate that the GC/MS Retest at LOD was Positive. The report also contained the following note:

"THIS REPORT PROVIDES THE RESULTS OF A RETEST FOR THE ABOVE SPECIMEN PER YOUR REQUEST. PLEASE BE ADVISED THAT THE RESULTS HAVE BEEN DERIVED BASED ON THE RULES THAT GOVERN RETESTING OF A SAMPLE UNDER THE NIDA GUIDELINES. THE STANDARD CUTOFF LEVELS MAY NOT HAVE BEEN USED TO DETERMINE THE RESULTS."

- 10. A third report was generated on January 12, 1991 (Attachment C). This report again reports the sample as NEG but states:
  - SPECIMEN LISTED AS NEGATIVE DUE TO CONCENTRATION LEVEL BEING BELOW 150 NG/ML DATA RE-ANALYZED ON LIMIT OF DETECTION CRITERIA.

The report also contains quantitative data reporting a Benzoylecgonine concentration equal to 71 Ng/Ml. This third report also contains the statement that the test was a retest.

11. This office, Shults & Associates, was contacted by Mr. David Owen of CP&L to investigate the facts and circumstances surrounding RBL's analysis and reporting of this sample.

# II. Investigation.

A preliminary telephone interview was held with John Irving, the laboratory co-director. This was followed up by a laboratory visit and in person interviews with Paula Childs PHD, the other co-director, and Diane Brown a certifying scientist.

Laboratory data, including the GC/MS data for the tested sample, chain of custody documentation, and lab reports were examined.

# III. Findings.

# A. Analysis Results for Sample.

The laboratory internal documents and data show that the sample in question was, in fact, analyzed by GC/MS. The GC/MS aliquot was injected onto the instrument twice. The first injection produced a positive chromatograph and was quantitated at 81 ng/ml.

This initial result was not accepted because the sample followed a positive with a large concentration. The laboratory procedure is to reinject such samples. The second sample injection was also positive and had a quantitative value of 71 ng/ml. This was the value that was entered onto the laboratory worksheet.

# B. Results Reporting.

### 1. First report 1/10/91 (Attachment A)

Drug test results are reported to CP&L electronically. The report is generated by the interaction of a data entry clerk and RBL's system software. In this system final certified results are entered manually. The system software compares the entered results against the client's threshold values. Samples with drug concentrations above these thresholds, or cutoffs,

are reported as positive with or without quantitation. Sample concentrations below these cutoffs are reported as negative.

The system software was not, however, programmed to accommodate CP&L's technical requirements. The laboratory procedure called for the data entry clerk to enter a special code to allow for the generation of a positive lab report when the client requested a limit of detection threshold.

The data entry clerk is prompted on the screen by the client information to enter the special code. When the data entry clerk enters the sample identification number, the screen provides information about the client including the special requests. The negative report generated (attachment A) was generated because the clerk entered PRC with the correct quantitative results. The PRC code was an error.

The PRC code indicates that there is no special technical-requirements for the client. The software defaults to the NIDA threshold values which in this case resulted in the generation of a negative report. The clerk should have reported entered simply P (for positive).

The laboratory has determined that this was a data entry error.

The 1/10/91 report, as well as all of the subsequent reports, states that:

"C.O.C. SPECIAL HANDLING PERFORMED"

This does not refer to special handling under 10 CFR 26. This "special handling" is simply to distinguish the laboratory test as being handled differently than a clinical drug test. It has appeared on both NIDA and non - NIDA tests.

The laboratory report also states:

"DIRECTOR: MYLA LAI-GOLDMAN DR"

This information is not correct. The NIDA laboratory directors at this facility are John Irving and Paula Childs.

# 2. Second report dated 1/11/91

The revised and corrected report contains conflicting and incorrect information due to the dependency on the software program. First it contains the abbreviation NEG. This apparently cannot be erased with override codes. The report also indicates that this is a re-test which is incorrect.

This repeated error is due in part to the system inflexibility using the existing drug test panel program and the laboratory's policy decision to include this information.

There appears to have been a lack of appreciation by the laboratory for the distinction between the circumstances where sample results can be reported as positive in the range between limits of detection and threshold limits under NIDA and the NRC regulations. Under NIDA guidelines the only time a sample can be reported out as a positive with a concentration below the NIDA cutoff is for a retest of a sample. This is not the case for samples being tested pursuant to special handling under 10 CFR 26.

### IV. Corrective Action.

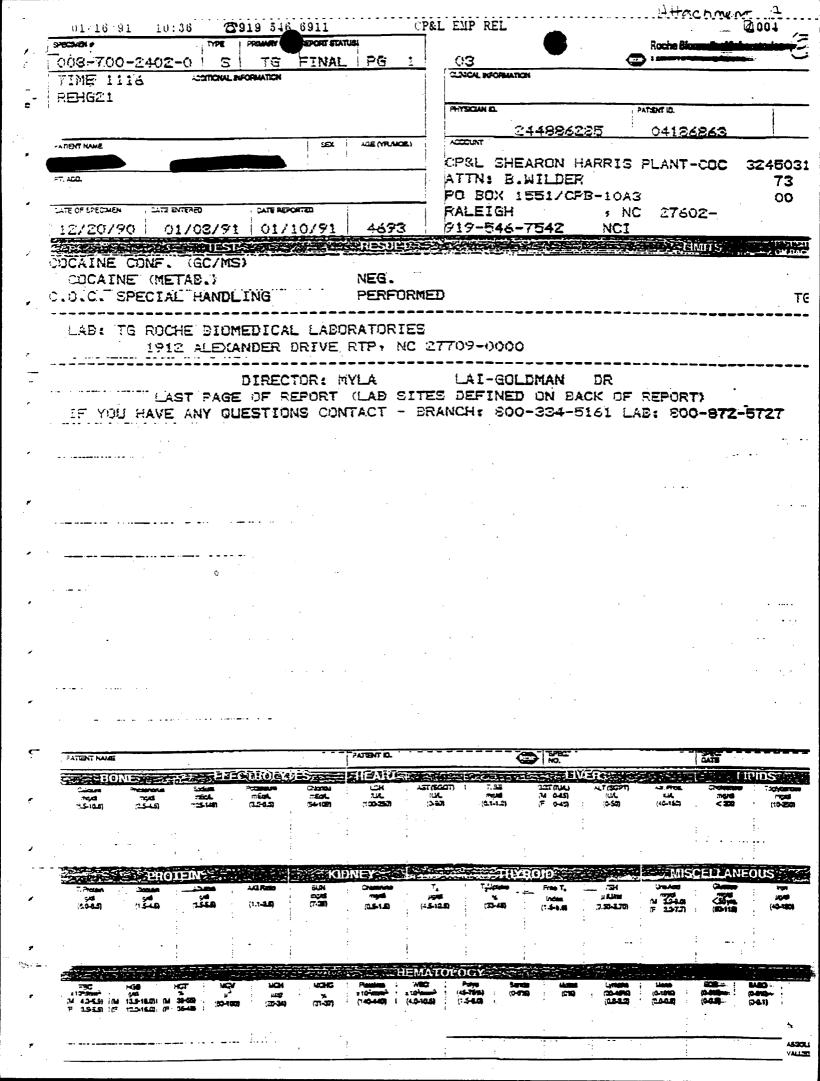
- A third report was generated for this sample with anadditional explanatory comment which indicated that the NEG comment appears because the concentration level is below 150 ng/ml. (Attachment C)
- 2. The data entry clerk was advised of the error by the certifying scientist and supervisor Diane Brown.

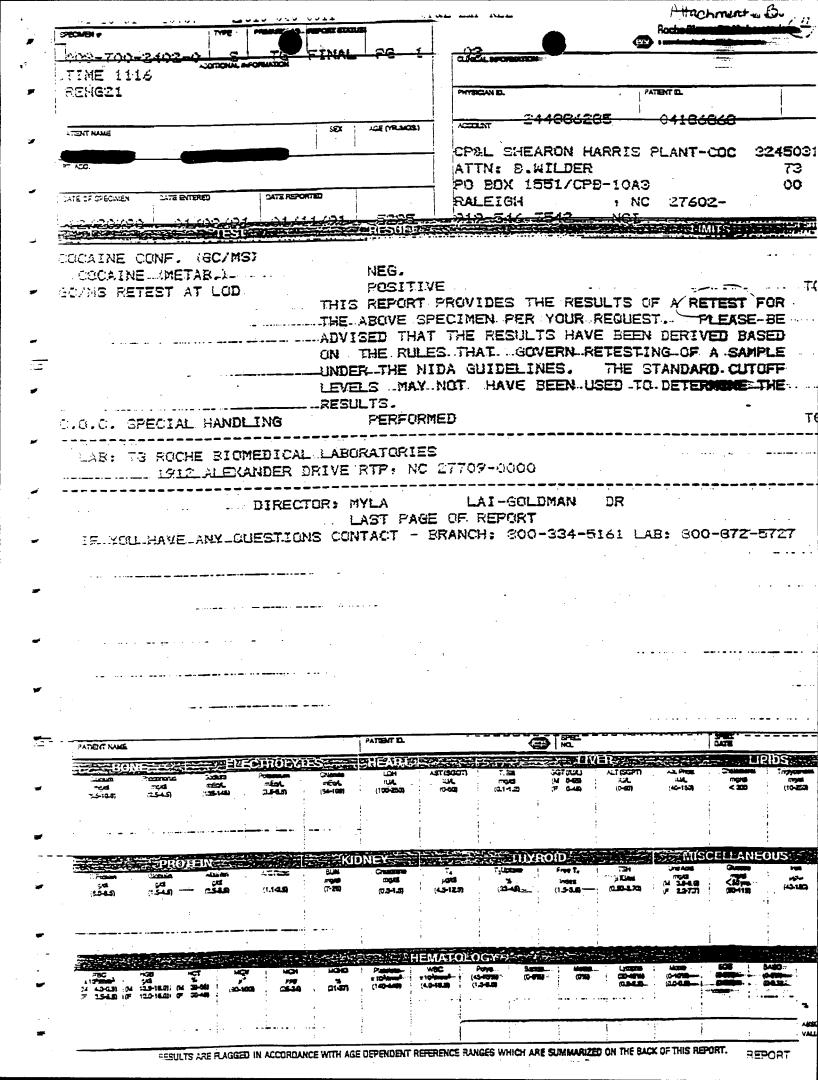
# V. Preventative Actions and Recommendations.

- 1. CP&L should continue to follow up on all negative reports from RBL in regards to special handling and retests where limits of detection are requested. This practice should be continued until additional safeguards are implemented by the laboratory.
- 2. RBL should discontinue relying on the manual override of the reporting software for special handling.
- 3. RBL should develop a specific test panel for NRC-special handling analysis, and NRC retests. The special field comments on the report should be appropriate for the situation.

### VI. Comments.

The reporting error was quickly identified through the vigilance and follow up actions of CP&L. The actual laboratory results obtained by RBL are consistent with that found in the original split sample sent to CompuChem. The quality of RBL's analysis and data is satisfactory.





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PATIENT NAME  BOND  CHART POORING	ALEXA	DIREC	TOR: M	PARENT D.	E DF F BRANCH	I-GOLI EPORT : 300	OMAN -334-5	DR 161 LAI	AL PRES.	CATE	PIDS
PATIENT NAME  BOND  CHART POORING	ALEXA	DIREC	TOR: M	PARENT D.	E DF F BRANCH	I-GOLI EPORT : 300	OMAN -334-5	DR 161 LAI	AL PRES.	CATE	PIDS
PATIENT NAME  BOND  CHART POORING	ALEXA	DIREC	TOR: M	PATENT D.	E DF F BRANCH	I-GOLI EPORT : 300	OMAN -334-5	DR 161 LAI	AL PRES.	CATE	PIOS
PROTESTANTE	ALEXA	DIREC	TOR: M	PARENT D.	E DF F BRANCH	I-GOLI EPORT : 300	OMAN -334-5	DR 161 LAI	AL PIECE CALLED	CATE CATE CATE CATE CATE CATE CATE CATE	PIDS TOPOROM (10-200)
PROTEST SCHOOL SERVING	ALEXA	DIREC	DRIVE	PATENT D.	E DF F BRANCH	I-GOLI EPORT : 300	OMAN -334-5	DR 161 LAI	MISC	CATE CATE CATE CATE CATE CATE CATE CATE	PIDS Troposo (16-24s)
PROTE  T. Froman 330000	ALEXA	DIREC	TOR: M NS CON	PATIENT D.  PATIEN	E DF F BRANCH	I-GOLI EPORT : 300	SA-5	DR. 161 LAI	MISC VIEAGO	CATE  CATE	PIDS: Tropicanos manas (10-200)  OUS- pyte
PROTEST SCHOOL SERVING	ALEXA	DIREC	TOR: M NS CON	PATIENT D.  PATIEN	E DF F BRANCH	I-GOLI EPORT : 300	SA-5	DR. 161 LAI	MISC VIEAGO	CATE  CATE	PIDS: Tropicanos manas (10-200)  OUS- pyte