Validity Testing Information Part I

Laboratory Name: Diagnostic Services
Address: 12700 Westlinks Dr Ft Myers FL 33913

Responsible Person: Robin M. White (Printed Name)

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Signature, Responsible Person

04 OCT 00
Date

Robert M. White
Printed Name, Responsible Person

Validity Testing Information Part II

Conduct an audit of all DOT regulated specimens from the date your laboratory started validity testing. Summarize your findings in an Excel spread sheet in both hard copy and electronic format. Provide the following information in a separate column of the spreadsheet/audit for *each* DOT regulated specimen that was reported either adulterated or substituted:

- **Specimen ID number**
- **Laboratory Accession Number**
- **Date of receipt**
- **Date reported**
- **Reported result (i.e., adulterated or substituted)**
- **Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)**

Note: Retain a copy of this information to ensure that you would be able to retrieve additional data.

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Signature, Responsible Person

18 OCT 00

Date

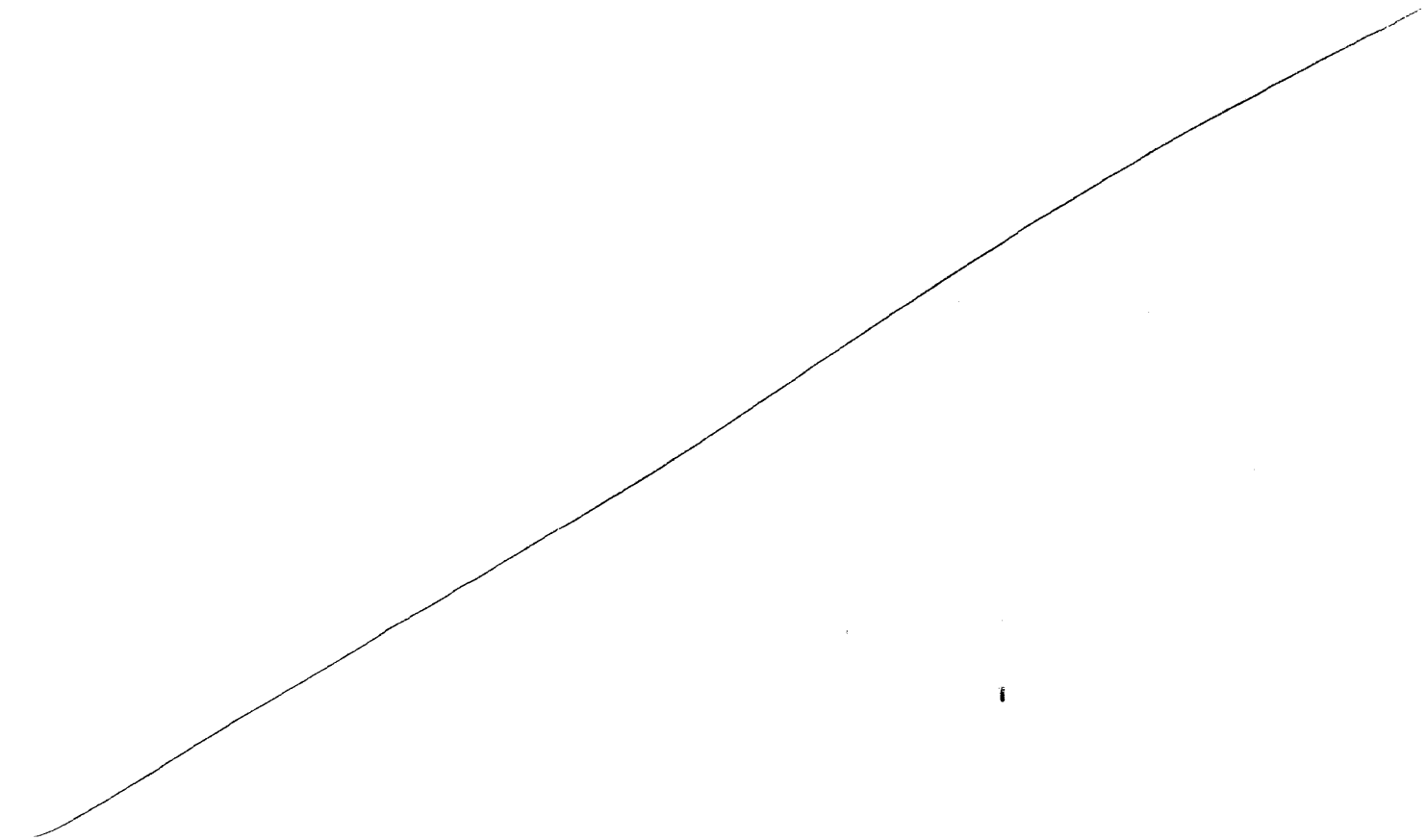
Robert M. White

Printed Name, Responsible Person

Diagnostic Services, INC
12700 Westlinks Drive
Fort Myers, FL 33913

Validity Testing Information Part II

Specimen ID	Accession Number	Date of Receipt	Date Reported	Reported Result	Quantitative Test Result: Creatinine (mg/dL)	Specific Gravity	Nitrite (mcg/mL)	pH



DSI LABORATORIES

A FAX FOR YOU

TO Frank Wallace

FROM: TOXI CLIENT SERVICE

FAX 515-541-7042

PAGES 2 *DATE* 10-18-00

DUE TO AN ERROR ON THE PART OF THE COLLECTOR WE ARE UNABLE TO RESULT THIS DRUG SCREEN WITHOUT A SIGNED STATEMENT FROM THE COLLECTOR. PLEASE SIGN IN ALL THE AREAS THAT ARE INDICATED WITH A X AND DATE WITH TODAYS DATE. FAX BACK A.S.A.P. THIS DRUG SCREEN WILL BE REJECTED AFTER 5 DAYS WITH OUT THE SIGNED STATEMENT

Our fax number is (941) 561-8255

Comments Correction on pg 2

DSI LABORATORIES
12700 WESTLINKS DRIVE
FORT MYERS FL 33931
PHONE (941) 561-8253
FAX (941 561-8255

Diagnostic Services, INC
12700 Westlinks Drive
Fort Myers, FL 33913

Validity Testing Information Part II

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 3, 2000

0171
Dr. Robert White
Diagnostic Services, Inc.
12700 Westlinks Drive
Ft. Myers, FL 33913

Dear Dr. White:

The enclosed critique was developed from the inspection report associated with the October 25-27, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to address the following issues raised:

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt171

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0171
Document No. Final

Laboratory: Diagnostic Services Inc.

Location: Fort Myers, FL

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 25 October 2000

A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests

Section K. Records Audit

Section L. Certification and Reporting

DSI LABORATORIES

received
SDC 12/4/00

01 December 2000

Ms. Susan Crumpton, NLCP Technical Analyst
Research Triangle Institute, NLCP
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709-2194

Dear Ms. Crumpton:

In response to your letter of November 3, 2000 (copy attached to this letter); I would offer the following responses:

Sincerely,

Robert M. White, Sr., Ph.D., D.A.B.C.C.(CC&TOX), C.H.R.M.
Scientific Director/Responsible Person

enc.

DSI Laboratories • 12700 Westlinks Dr. • Ft. Myers, FL 33913-8017 • Telephone: [941] 561-8200 • Fax: [941] 561-8210

RESEARCH TRIANGLE INSTITUTE

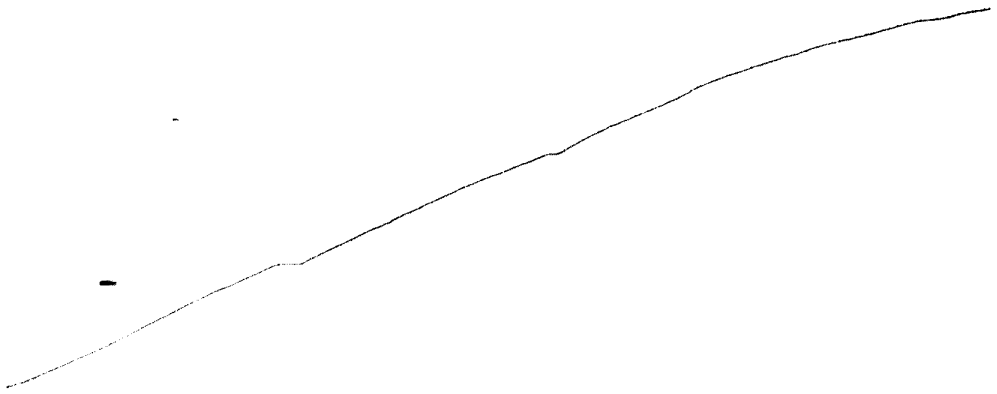
National Laboratory Certification Program

December 11, 2000

0171
Dr. Robert White
Diagnostic Services, Inc.
12700 Westlinks Drive
Ft. Myers, FL 33913

Dear Dr. White:

We have reviewed the material provided in your correspondence of December 1, 2000, submitted in response to issues raised during the October 25-27, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 3, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.



The laboratory must review its procedures and revise them as necessary to comply with these program requirements. The SOP and its implementation will be reviewed at the next inspection.

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection. Failure to comply may

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Telephone 919 541-6709 • Fax 919 541-7042

result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT171