

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 12, 1998

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 reports of the two inspectors who conducted the seventh maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

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,

A handwritten signature in cursive script that reads 'Susan Crumpton'.

Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M7



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: Application Form
 Inspection Report #M7 Date: 29 October 1998
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the two independent National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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. Records Audit

Section H. Personnel

Section I. Reagents

Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry

May 26, 1999

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 reports of the inspectors who conducted the eighth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

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 Inspection Analyst

Enclosure

cc: Project Files/M8



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: Application Form
 Inspection Report #M8
 Other _____

Date: 29 April 1999

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 3, 1999

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 reports of the inspectors who conducted the ninth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

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,

A handwritten signature in cursive script, appearing to read 'Susan Crumpton', written over a horizontal line.

Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M9



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: Diagnostic Services, Inc.

Location: Ft. Myers, FL

Document Reviewed: Application Form
 Inspection Report #M9
 Other _____

Date: 28 October 1999

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

June 5, 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 reports of the inspectors who conducted the tenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in the attached critique.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M10



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: Application Form
 Inspection Report #M10 Date: 27 April 2000
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 2, 2001

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 reports of the inspectors who conducted the eleventh maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

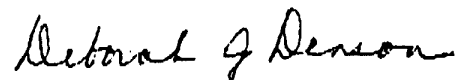


Dr. White
January 02, 2001
Page 2 of 2

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M11

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: Application Form
 Inspection Report # M11
 Other _____

Date: 26 October 2000

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

[Redacted content]

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

[Redacted content]

Section G. Quality Control

[Redacted content]

Section H. Initial Tests

Section I. Confirmatory Tests

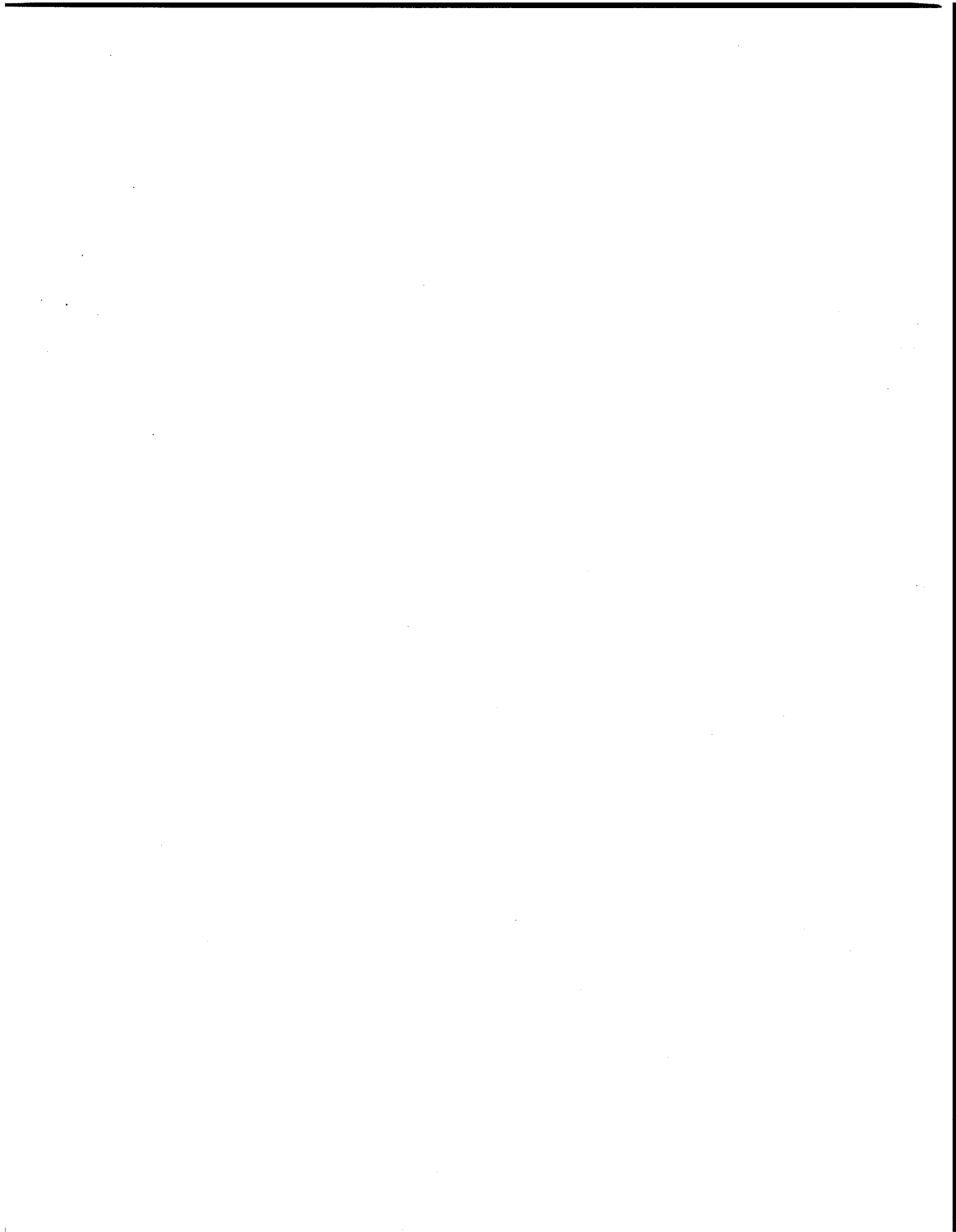
Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 13, 1998

0205
Mr. Dwain C. Fuller
Laboratory Corporation of America
888 Willow Street
Reno, NV 89502

Dear Mr. Fuller:

The enclosed critique was developed from the inspection reports of the two inspectors who conducted the fourteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. However, the laboratory must correct/clarify the following issues raised:

[A large, faint, diagonal line is drawn across the page, likely a scanning artifact or a placeholder for a signature.]



Mr. Fuller
Page 2 of 2
10/13/98

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

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 Inspection Analyst

Enclosure

cc: Project Files/M14

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0205
Document No. Final

Laboratory: Laboratory Corporation of America

Location: Reno, NV

Document Reviewed: Application Form
 Inspection Report #M14 Date: 17 September 1998
 Other _____

Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the two independent National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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. Records Audit

Section H. Personnel

Section I. Reagents

Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry

