Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
01D0698418	A. Building B. Wing	5/22/2009

Name of Facility	Street Address, City, State, Zip Code
PLANNED PARENTHOOD OF ALABAMA INC	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date Correction Completed	(Y4) Item	(Y5) Date Correction Completed	(Y4) Item	(Y5) Date Correction Completed
ID Prefix D2000 Reg. # 493.801 LSC	05/22/2009	ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	

Reviewed By State Agency	Reviewed By Brenda Stanley	Date: 5/26/09	Signature of Surveyor: Mark	Date: 5/22/09
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on:	Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility?	YES	NO
5/7/2009			

Department of Health and Human Services
Centers for Medicare & Medicaid Service

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
01D0698418	A. Building B. Wing	2/28/2012

Name of Facility	Street Address, City, State, Zip Code
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix D2015 Reg. # 493.801(b)(5)(6) LSC	Correction Completed 02/28/2012	ID Prefix D5805 Reg. # 493.1291(c) LSC	Correction Completed 02/28/2012	ID Prefix D6014 Reg. # 493.1407(e)(3)(iii) LSC	Correction Completed 02/28/2012
ID Prefix D6029 Reg. # 493.1407(e)(11) LSC	Correction Completed 02/28/2012	ID Prefix D6046 Reg. # 493.1413(b)(8) LSC	Correction Completed 02/28/2012	ID Prefix D6047 Reg. # 493.1413(b(8)(i) LSC	Correction Completed 02/28/2012
ID Prefix D6070 Reg. # 493.1425(b)(1) LSC	Correction Completed 02/28/2012	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By State Agency ✓ BF	Reviewed By Brenda Furlow	Date: 2/28/202	Signature of Surveyor: Brenda Furlow	Date: 2/28/2012
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on:	Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility?
6/23/2011	YES NO

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

Public reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
01D0698418	A. Building B. Wing	8/5/2011

Name of Facility	Street Address, City, State, Zip Code
PLANNED PARENTHOOD SOUTHEAST INC	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date Correction Completed	(Y4) Item	(Y5) Date Correction Completed	(Y4) Item	(Y5) Date Correction Completed
ID Prefix D6000 Reg. # 493.1403 LSC	08/05/2011	ID Prefix D6033 Reg. # 493.1409 LSC	08/05/2011	ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	
ID Prefix Reg. # LSC		ID Prefix Reg. # LSC		ID Prefix Reg. # LSC	

Reviewed By State Agency	Reviewed By [signature]	Date: 8-12-11	Signature of Surveyor: [signature]	Date: 8-8-11
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on:		Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility?	YES	NO
6/23/2011				

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

August 22, 2011

Barbara Buchanan, MT (ASCP)
Planned Parenthood Southeast
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Ms. Buchanan:

Re: First Revisit

We conducted an off-site review on August 5, 2011, regarding a condition-level deficiency cited on your recertification survey on June 23, 2011. We have received documented verification that substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) has been achieved and maintained for the condition-level deficiencies D6000 (Laboratory Director - Moderate Complexity) and D6033 (Technical Consultant - Moderate Complexity), cited on your recertification survey.

However, there are seven deficiencies that remain out at standard level cited on that survey. We will be contacting your laboratory at a later date to provide supporting documentation to those deficiencies that will substantiate the corrective actions your laboratory has implemented as a result of your survey on June 23, 2011.

If you have any questions concerning this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Jaye R. Allen
for

CLIA Laboratory Unit
Division of Health Care Facilities

STATE OF ALABAMA DEPARTMENT OF

PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

IMPORTANT NOTICE - ACTION NECESSARY

June 27, 2011

Barbara Buchanan, MT ASCP
Planned Parenthood Southeast Inc
1211 27th Place South
Birmingham, AL 35205-1806

Re: CLIA #01D0698418

Dear Ms. Buchanan:

RE: CONDITION-LEVEL DEFICIENCIES

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, conducted a routine recertification survey of your laboratory that was completed on June 23, 2011. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following CLIA Conditions were not met:

D6000 - 42 C.F.R. 493.1403 Condition: Laboratory director - moderate complexity

D6033 - 42 C.F.R. 493.1409 Condition: Technical consultant - moderate complexity

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet CLIA Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur; and

4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the CLIA Laboratory Unit will recommend to the Atlanta Regional Office

of the Centers for Medicare & Medicaid Services (CMS) that **sanctions** be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to $3,000 per day of noncompliance per 42 C.F.R. 493.1834, Directed Plan of Correction per 42 C.F.R. 493.1832, State Onsite Monitoring per 42 C.F.R. 493.1836) and principal sanctions (suspension, limitation, and/or revocation of your laboratory's CLIA certificate and cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature. the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the State agency at any time to address complaints or other noncompliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Jeff Meank, BS, MT (ASCP)
CLIA Laboratory Unit
Division of Health Care Facilities

Enclosure: CMS-2567 Statement of Deficiencies

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

June 9, 2009

Barbara Buchanan, MT (ASCP)
Planned Parenthood of Alabama Inc
1211 27th Place South
Birmingham, AL 35205-1806

CLIA ID #01D0698418

Dear Ms. Buchanan:

Re: Revisit survey

By letter dated May 11, 2009, we notified you that based on the onsite survey completed on May 7, 2009, your facility was not in compliance with Condition-level CLIA requirements. In our letter we requested that you submit an acceptable allegation of compliance and acceptable evidence of correction. We received your response on May 21, 2009, and have determined that your allegation of compliance and evidence of correction are acceptable.

Based on the documentation submitted with your allegation of compliance, we conducted an off-site revisit survey on May 22, 2009, regarding deficiencies cited on your on-site recertification survey on May 7, 2009. The documentation verified that substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) has been achieved and maintained, effective May 22, 2009.

If you have any questions concerning this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Faye R. Allen
for

Brenda Furlow, Director
CLIA Laboratory Unit
Division of Health Care Facilities

BF/fra

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

IMPORTANT NOTICE - ACTION NECESSARY

May 11, 2009

Barbara Buchanan, MT (ASCP)
Planned Parenthood of Alabama, Inc.
1211 27th Place South
Birmingham, AL 35205-1806

Re: CLIA #01D0698418

Dear Ms. Buchanan:

RE: CONDITION-LEVEL DEFICIENCIES

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, conducted a routine recertification survey of your laboratory that was completed on May 7, 2009. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following CLIA Condition was not met:

D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of samples

Enclosed is Form CMS-2567, Statement of Deficiencies, listing all deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet CLIA Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur; and

4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the CLIA Laboratory Unit will recommend to the Atlanta Regional Office

of the Centers for Medicare & Medicaid Services (CMS) that **sanctions** be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to $3,000 per day of noncompliance per 42 C.F.R. 493.1834, Directed Plan of Correction per 42 C.F.R. 493.1832, State Onsite Monitoring per 42 C.F.R. 493.1836) and principal sanctions (suspension, limitation, and/or revocation of your laboratory's CLIA certificate and cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature. the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the State agency at any time to address complaints or other noncompliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at (334) 206-5120.

Sincerely,

Brenda Furlow

Brenda Furlow, Director
CLIA Laboratory Unit
Division of Health Care Facilities

BF/fra
Enclosure: CMS-2567 Statement of Deficiencies

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	01D0698418	A. BUILDING _____ B. WING _____	05/07/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF ALABAMA INC	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2000	493.801 ENROLLMENT AND TESTING OF SAMPLES Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. This CONDITION is not met as evidenced by: Based on a review of AAB proficiency testing records and on an interview with the Director, it was revealed that the Laboratory failed to enroll in proficiency testing for Urine Human Chorionic Gonadotrophin (non-waived slide test). The finding are: 1. A review of AAB proficiency testing records revealed that the laboratory was not currently enrolled in proficiency testing for Urine HCG (non-waived). 2. This finding was confirmed by the Director. Surveyor: Jeff Meank, BS, MT(ASCP) Licensure and Certification Surveyor	D2000	Please see attached Plan of correction and receipt of purchase.	5-12-09

Received
MAY 2009
Bureau of Health Provider Standards

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Barbara Buchanan - CEO	Lab Director	5.19.09

...y deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that ... safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days ...owing the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 ays following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued ...ogram participation.

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

Public reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
01D0698418	A. Building B. Wing	4/30/2010

Name of Facility	Street Address, City, State, Zip Code
PLANNED PARENTHOOD OF ALABAMA INC	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix D2016 Reg. # 493.803(a)(b)(c) LSC	Correction Completed 04/30/2010	ID Prefix D2107 Reg. # 493.843(f) LSC	Correction Completed 04/30/2010	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By	Reviewed By	Date:	Signature of Surveyor:	Date:
State Agency ✓ BF	Brenda Furlow	4/30/2010	[signature]	4-30-10
CMS RO				

Followup to Survey Completed on:	Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility?	YES	NO
5/7/2009			

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

May 4, 2010

Barbara Buchanan, MT (ASCP)
Planned Parenthood of Alabama Inc
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Ms. Buchanan:

RE: ALLEGATION OF COMPLIANCE CREDIBLE AND EVIDENCE OF CORRECTION

By letter dated April 13, 2010, the Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, notified you that your laboratory was not in compliance with the Conditions of successful participation in proficiency testing (PT) based on unsatisfactory performance in PT for Urine (HCG) Pregnancy for the testing events 2009-3 and 2010-1. In the letter, we requested that you submit a credible allegation of compliance and acceptable evidence of correction. We received your response on April 27, 2010, and have determined that your allegation of compliance is credible and evidence of correction is acceptable.

We caution your laboratory to remain in compliance with all CLIA requirements for proficiency testing. If it is discovered that your allegation of compliance was not implemented or that compliance was not maintained, the CLIA Laboratory Unit will refer the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be taken against your laboratory's CLIA certificate.

Any future proficiency testing failure that results in a subsequent occurrence of unsuccessful participation in proficiency testing will be basis for such referral to the CMS Regional Office to initiate sanction actions against your laboratory's CLIA certificate. These sanctions may include alternative sanctions of a Directed Plan of Correction, Civil Money Penalty, and suspension of the laboratory's approval to receive Medicare payments as well as principal sanctions of suspension, limitation, or revocation of your laboratory's CLIA certificate and cancellation of the laboratory's approval to receive Medicare payments.

If you have any questions regarding this letter, please contact me at (334) 206-5120.

Sincerely,

Stacy R. Allen
for

Brenda Furlow, Director
CLIA Laboratory Unit
Division of Health Care Facilities

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

April 13, 2010

Barbara Buchanan, MT (ASCP)
Planned Parenthood of Alabama Inc
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Ms. Buchanan:

RE: CONDITIONS OUT - UNSUCCESSFUL PARTICIPATION IN PROFICIENCY TESTING

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, conducted survey of your laboratory that was completed on April 2, 2010. As a result of the survey, it was determined that there was unsatisfactory performance in proficiency testing (PT) for the events listed below:

AAB	2009-3	Urine (HCG) Pregnancy	60%
AAB	2010-1	Urine (HCG) Pregnancy	40%

The CLIA regulations at 493.2 defines unsuccessful PT performance as failure to attain the minimum satisfactory score for an analyte, test, subspecialty or specialty for two consecutive or two out of three consecutive testing events. Based on the PT failures listed above, your facility is not in compliance with the Conditions of successful participation in PT.

D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement of documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required.

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and;

4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

CLIA regulations at 42 C.F.R. 493.1838 allow a laboratory at the first occurrence of unsuccessful PT performance to undertake training of its personnel, or obtain necessary technical assistance, or both, if appropriate to the circumstances. If your laboratory determines that training/technical assistance is the appropriate corrective action, evidence must be submitted to document that the training and/or technical assistance have been undertaken and were effective in correcting the problems that caused the unsuccessful PT performance. In particular, the evidence must include documentation that your laboratory has taken action to correct actual or potential patient outcome during the period of PT failure. See the requirements for acceptable evidence of correction above.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of

compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the CLIA Laboratory Unit will recommend to the Atlanta Regional Office of the Centers for Medicare & Medicaid Services (CMS) that **sanctions** be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to $3,000 per day of noncompliance or per violation per 42 C.F.R. 493.1834, Directed Plan of Correction per 42 C.F.R. 493.1832, State Onsite Monitoring per 42 C.F.R. 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the CLIA Laboratory Unit at any time to address complaints or other noncompliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have any questions regarding this letter, please contact me at (334) 206-5120.

Sincerely,

Brenda Furlow

Brenda Furlow, Director
CLIA Laboratory Unit
Division of Health Care Facilities

BF/fra
Enclosure: CMS-2567, Statement of Deficiencies

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	01D0698418	A. BUILDING _____ B. WING _____	R 04/02/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF ALABAMA INC	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2016	493.803(a)(b)(c) SUCCESSFUL PARTICIPATION Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a desk review of AAB proficiency testing evaluations, it was revealed that the laboratory failed to successfully participate in	D2016		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Barbara Bachanan | TITLE: Lab Director | (X6) DATE: 4-23-2010

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	01D0698418	A. BUILDING _____ B. WING _____	R 04/02/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF ALABAMA INC	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2016	Continued From page 1 proficiency testing for URINE (HCG) PREGNANCY. The findings are: 1. On Q3, 2009, the laboratory scored 60% for urine (hcg) pregnancy. 2. On Q1, 2010, the laboratory scored 40% for urine (hcg) pregnancy. 3. This is an initial unsuccessful participation in proficiency testing for URINE (HCG) PREGNANCY.	D2016	Please see attached plan of correction 4.23.2010	3-11-10
D2107	493.843(f) ENDOCRINOLOGY Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: refer to D2016. Surveyor: Jeff Meank, BS, MT(ASCP) Licensure and Certification Surveyor	D2107	Please see attached Plan of Correction 4.23.2010	3-11-10

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

Public reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
01D0698418	A. Building B. Wing	9/19/2013

Name of Facility	Street Address, City, State, Zip Code
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix D2006 Reg. # 493.801(b) LSC	Correction Completed 09/19/2013	ID Prefix D5415 Reg. # 493.1252(c) LSC	Correction Completed 09/19/2013	ID Prefix D5417 Reg. # 493.1252(d) LSC	Correction Completed 09/19/2013
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By State Agency ✓ BF	Reviewed By Brenda Fulson	Date: 9/19/2013	Signature of Surveyor: Brenda Fulson	Date: 9/19/2013
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on: 4/11/2013

Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

September 20, 2013

Hedwige Saint Louis MD
Planned Parenthood Southeast
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Dr. Saint Louis:

Re: Revisit survey

We conducted an off-site revisit survey on September 19, 2013, regarding deficiencies cited on your on-site recertification survey on April 11, 2013. We have received documented verification that substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) has been achieved.

If you have any questions concerning this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Brenda Fuller

CLIA Laboratory Unit
Division of Health Care Facilities

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

May 7, 2013

Hedwige Saint Louis, MD
Planned Parenthood Southeast
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Dr. Saint Louis:

RE: PLAN OF CORRECTION AND EVIDENCE OF CORRECTION ACCEPTABLE

By letter dated April 15, 2013, we notified you that based on the onsite survey completed on April 11, 2013, your facility was not in compliance with standard-level CLIA requirements. In our letter we requested that you submit an acceptable plan of correction and acceptable evidence of correction. We received your response on April 30, 2013, and have determined that your plan of correction is acceptable.

We encourage your laboratory to maintain compliance with all CLIA requirements. It is the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

If it is discovered that your plan of correction was not implemented or that compliance was not maintained, the Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, will refer the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be taken against your laboratory's CLIA certificate.

If you have any questions regarding this letter, please contact the Laboratory Unit at (334) 206-5120.

Sincerely,

Tracy L. Allen
for

CLIA Laboratory Unit
Division of Health Care Facilities

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

IMPORTANT NOTICE - ACTION NECESSARY

April 15, 2013

Hedwige Saint Louis, MD
Planned Parenthood Southeast
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Dr. Saint Louis:

Re: STANDARD-LEVEL DEFICIENCIES

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, conducted a routine recertification survey of your laboratory that was completed on April 11, 2013. Enclosed is form CMS-2567, Statement of Deficiencies, listing the deficiencies found during the survey. The deficiency statement references the CLIA regulations at 42 C.F.R. 493.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a Plan of Correction that is acceptable to the Centers for Medicare & Medicaid Services (CMS) in content and time frames. Further regulations at 42 C.F.R. 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, we will recommend to CMS imposition of principal sanctions, i.e., suspension, limitation, and/or revocation of your laboratory's CLIA certificate and concurrent cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. For your information, acceptable evidence of correction must include:

1. Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3. What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur; and

4. How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the CLIA Laboratory Unit at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have any questions regarding this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Jeff Meank, BS, MT (ASCP)
CLIA Laboratory Unit Director
Division of Health Care Facilities

Enclosure: CMS-2567, Statement of Deficiencies

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/12/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	01D0698418	A. BUILDING _____ B. WING _____	04/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2006	493.801(b) TESTING OF PROFICIENCY SAMPLES The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of API proficiency testing records and on interviews with administrative staff and testing personnel, it was revealed that proficiency testing samples were not tested in the same manner as patient samples for four of six testing events reviewed. The findings are: 1. A review of API records, including attestation statements, revealed that samples were tested by two individuals for events #3, 2011, #1, 2012 and #1, 2013. Three individuals tested samples for event #2, 2012. Patient samples are not tested in this manner. 2. Interviews with administrative staff and testing personnel on 4/11/2013 confirmed that multiple individuals routinely test proficiency testing samples.	D2006	Existing proficiency testing policy specifies that one person shall perform proficiency tests each quarter. New Center Manager was oriented to policy on 4-11-13. Center Manager will reorient all testing personnel to this policy prior to second quarter 2013 proficiency test. Lab Director and Center Manager together will supervise and document performance of second quarter 2013 proficiency test to ensure compliance with protocol. --- Lab Director and Center Manager will by May 1, 2013 appoint a specific lab tech to be accountable for clearly printing labels for Rh controls that identify positive or negative, temperature storage requirement of 2-8° C and dates of preparation and expiration. (Expire 30 days from preparation.)	4-11-13 6-30-13 6-30-13 5-1-13
D5415 510M	493.1252(c) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates.	D5415		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

MD | Laboratory Director | 4-24-13

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/12/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	01D0698418	A. BUILDING _____ B. WING _____	04/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5415	Continued From page 1 (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and on an interview with testing personnel #1 and the center manager, it was revealed that Rh controls were not legibly labeled with all required information. The findings are: 1. Rh controls currently in use were observed in the refrigerator. Information on the tubes was illegible. 2. When questioned, testing personnel #1 stated that the controls identity (positive or negative control), storage requirements and preparation and expiration dates were not routinely included on control tubes.	D5415	Continued from page 1 Director of Quality Management will by May 3, 2013 produce a label template that specifies information to be included, ie. Storage temp, expiration, etc.	5-3-13
D5417 510M	493.1252(d) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of Rh control documentation and on interviews with administrative staff, it was revealed that on one day in August, 2012, expired Rh controls were used. The findings are: 1. Rh controls used by the laboratory have expiration dates of thirty days from the date specimens were collected.	D5417	Lab log currently requires entry of expiration date of lab controls on a daily basis. Lab Director and Center Manager will by May 1, 2013 appoint a specific lab tech to be accountable for verifying daily that lab test controls have not exceeded their expiration date. Lab Director will at monthly inspections monitor compliance with expiration dates.	5-1-13

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/12/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	01D0698418	A. BUILDING _____ B. WING _____	04/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5417	Continued From page 2 2. On 8/31/2012, controls which expired on 8/30/2012 were used. Patient Rh typing was performed on 8/31/2012. 3. Interviews with testing personnel and administrative staff confirmed this finding. Surveyor: Jeff Meank, BS, MT(ASCP) Licensure and Certification Supervisor	D5417		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

POST-CERTIFICATION REVISIT REPORT

PROVIDER / SUPPLIER / CLIA / IDENTIFICATION NUMBER	MULTIPLE CONSTRUCTION	DATE OF REVISIT
01D0698418 Y1	A. Building B. Wing Y2	3/9/2016 Y3

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction, that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

ITEM Y4	DATE Y5	ITEM Y4	DATE Y5	ITEM Y4	DATE Y5
ID Prefix D2015 Reg. # 493.801(b)(5)(6) LSC	Correction Completed 03/09/2016	ID Prefix D6014 Reg. # 493.1407(e)(3)(iii) LSC	Correction Completed 03/09/2016	ID Prefix D6020 Reg. # 493.1407(e)(5) LSC	Correction Completed 03/09/2016
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

REVIEWED BY STATE AGENCY ☐	REVIEWED BY (INITIALS)	DATE	SIGNATURE OF SURVEYOR [signature]	DATE 3/9/16
REVIEWED BY CMS RO ☐	REVIEWED BY (INITIALS)	DATE	TITLE	DATE
FOLLOWUP TO SURVEY COMPLETED ON 4/9/2015	☐ CHECK FOR ANY UNCORRECTED DEFICIENCIES. WAS A SUMMARY OF UNCORRECTED DEFICIENCIES (CMS-2567) SENT TO THE FACILITY? ☐ YES ☐ NO			

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Thomas M. Miller, M.D.
Acting State Health Officer

March 10, 2016

Hedwige Saint Louis, MD
Planned Parenthood Southeast
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Dr. Saint Louis:

Re: Revisit survey

We conducted an off-site revisit survey on March 9, 2016, regarding deficiencies cited on your on-site recertification survey on April 9, 2015. We have received documented verification that substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) has been achieved.

If you have any questions concerning this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Faye R. Allen
for

CLIA Laboratory Unit
Division of Health Care Facilities

STATE OF ALABAMA DEPA

PUBLIC HE

Donald E. Williamson, I
State Health Officer

Accept
POC

May 18, 2015

Hedwige Saint Louis, MD
Planned Parenthood Southeast
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Dr. Louis:

RE: PLAN OF CORRECTION AND EVIDENCE OF CORRECTION ACCEPTABLE

By letter dated April 13, 2015, we notified you that based on the onsite survey completed on April 9, 2015, your facility was not in compliance with standard-level CLIA requirements. In our letter we requested that you submit an acceptable plan of correction and acceptable evidence of correction. We received your response on May 15, 2015, and have determined that your plan of correction is acceptable.

We encourage your laboratory to maintain compliance with all CLIA requirements. It is the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

If it is discovered that your plan of correction was not implemented or that compliance was not maintained, the Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, will refer the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be taken against your laboratory's CLIA certificate.

If you have any questions regarding this letter, please contact the Laboratory Unit at (334) 206-5120.

Sincerely,

Jay R. Allen
for
Jeff Meank, BS, MT (ASCP)
CLIA Laboratory Unit Director
Division of Health Care Facilities

STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH
Donald E. Williamson, MD
State Health Officer

IMPORTANT NOTICE - ACTION NECESSARY

April 13, 2015

Hedwige Saint Louis, MD
Planned Parenthood Southeast
1211 27th Place South
Birmingham, AL 35205-1806

CLIA #01D0698418

Dear Dr. Louis:

Re: STANDARD-LEVEL DEFICIENCIES

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Alabama Department of Public Health, Division of Health Care Facilities, CLIA Laboratory Unit, conducted a routine recertification survey of your laboratory that was completed on April 9, 2015. Enclosed is form CMS-2567, Statement of Deficiencies, listing the deficiencies found during the survey. The deficiency statement references the CLIA regulations at 42 C.F.R. 493.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a Plan of Correction that is acceptable to the Centers for Medicare & Medicaid Services (CMS) in content and time frames. Further regulations at 42 C.F.R. 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, we will recommend to CMS imposition of principal sanctions, i.e., suspension, limitation, and/or revocation of your laboratory's CLIA certificate and concurrent cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. For your information, acceptable evidence of correction must include:

1. Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3. What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur; and

4. How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the CLIA Laboratory Unit at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have any questions regarding this letter, please contact the CLIA Laboratory Unit at (334) 206-5120.

Sincerely,

Jeff Meank, BS, MT (ASCP)
CLIA Laboratory Unit Director
Division of Health Care Facilities

Enclosure: CMS-2567, Statement of Deficiencies

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CUA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	0100698418	A. BUILDING _____ B. WING	04/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPR DEFICIENCY)	(X5) COMPLETION DATE
D2015	493.801(b)(5)(6) TESTING OF PROFICIENCY TESTING SAMPLES (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of 2013 API proficiency testing records and interviews with the administrator and testing personnel #1, it was determined signed attestation statements were not retained for two events in 2013. The findings are: 1. A review of 2013 API records revealed both the director and testing personnel failed to sign the attestation statement for event #2, and the director failed to sign the statement for event #3. 2. Interviews with the administrator and testing personnel #1 at approximately 10:30 AM on 4/9/2015 confirmed these findings.	D2015	The VP of Operations will conduct an audit of 2014 API testing events that will be reviewed by the affiliate CEO. Any failure to comply with the required process or signatures will result in disciplinary action All future API Testing events will be reviewed by the VP of Operations for compliance with process and documentation. Any failure to comply will required action or signatures will result in disciplinary action. Implementation: Future reviews within 14 days of testing events. API Testing events will be added to the PPSE Risk & Quality Management calendar to be tracked for completion and also results reviewed by enterprise wide committee to ensure quality standards are maintained. Implementation: Reviewed at the Risk and Quality Management meeting immediately following testing (committee meetings bi-monthly) All laboratory staff and Director will review required timeline, scope and documentation that must accompany all API Testing events. This training will be done by the Director of Risk and Quality Management and will be documented.	6/12/15 06/30/15 06/30/15 06/30/15
D6014	493.1407(e)(3)(iii) LABORATORY DIRECTOR RESPONSIBILITIES The laboratory director is responsible for the			

LABORATORY DIRECTOR S OR PROVIDER/SUPPLIER REPRESENTATIVE S SIGNATURE	TITLE	(X6) DATE
	Affiliate Medical Director/Laboratory Director	05/13/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	01D0698418	A. BUILDING _____ B. WING	04/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6014	Continued From page 1 overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, a review of procedures and interviews with the administrator and testing personnel #1, it was determined the director failed to ensure testing personnel were adequately trained prior to patient testing. The findings are: 1. At approximately 10:30 AM, testing personnel #1 was observed performing Rh typing using the Eldoncard RhD method. 2. A review of the procedure revealed testing personnel #1 did not follow manufacturers' instructions to include patient information on the Eldoncard and did not collect the specimen and apply the sample on the card as per manufacturer's instructions. 3. After a review of the procedure with the administrator and testing personnel #1 at approximately 11:00 AM on 4/9/2015, these findings were confirmed. Testing must be performed exactly as stated by the manufacturer.	D6014	Training on proper use of the Eldoncard will be conducted and documented by the affiliate's Lead Nurse and verified by the Laboratory Director for all Birmingham Laboratory staff, Clinic Administrator and Director of Compliance Risk & & Quality Management. The Clinic Administrator will conduct weekly audits and observation for 3 months and then monthly audits and observation to ensure proper use of the Eldoncard. Any failure to comply with required process or documentation will result in disciplinary action. Implementation: Complete of 3 months of audits by Administrator: The Director of Compliance Risk & Quality Management will conduct quarterly audits and observation for one year to ensure proper use of the Eldoncard. Any failure to comply with required process or documentation will result in disciplinary action. The impact to the patients was minimal And would have not affected patient care. While the manufacturer's direction were not followed properly, the appropriate sample and sample amount was placed in the right location on the Eldon card. That notwithstanding all laboratory personnel involved in Rh testing will be re-educated and trained by the Lead Nurse on the manufacturer's instruction to maintain the quality and standard set by the manufacturer of the Eldon card.	06/12/15 06/19/15 09/18/15 06/19/15
D6020	493.1407(e)(5) LABORATORY DIRECTOR RESPONSIBILITIES			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	0100698418	A. BUILDING _____ B. WING	04/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	1211 27TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6020	Continued From page 2 The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of 2014 and 2015 RhD blood typing quality control records and interviews with the administrator and testing personnel #1, it was determined the director failed to ensure the established quality control program was maintained to assure the quality of laboratory services provided. The findings are: 1. RhD typing quality control is required each day of client testing. On 10/16/2014, quality control was not performed and/or documented. Four clients had RhD testing performed on 10/16/2014. 2. Personnel failed to document RhD control lot numbers accurately. On 12/12/2014, lot numbers BRN917857 and BRN917858, both with an expiration date of 12/13/2014 were documented on the daily quality control log. On 12/22/2014, the same lot numbers, with a 1/2/2015 expiration date, were documented as used. Lot numbers can not have two expiration dates. 3. Interviews with the administrator and testing personnel at approximately 11:30 AM on 4/9/2015 confirmed these findings.	D6020	Training on proper use and documentation of lot numbers of The RhD typing quality control will be conducted and documented by the Laboratory Director for all Birmingham laboratory staff, Clinic Administrator and Director of Compliance Risk & Quality Management.	06/12/15
			The Clinic Administrator will conduct weekly audits for 3 months and then monthly audits to ensure proper use of the RhD typing quality control. Any failure to comply with required process or documentation will result in disciplinary action.	
			Implementation:	06/19/15
			Completion of 3 months of audits by Administrator	09/18/15
			The Director of Compliance Risk & Quality Management will conduct quarterly audits for one year to ensure proper use of the RhD typing quality control. Any failure to comply with required process or documentation will result in disciplinary action.	06/19/16
			The four patients who received RhD testing on 10/16/14 will be contacted by the Lab Director/Medical Director. The importance of knowing RhD	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CUA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	0100698418	A. BUILDING _____ B. WING	04/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTHEAST	121127TH PLACE SOUTH BIRMINGHAM, AL 35205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(XS) COMPLETION DATE
	Continued From page 3	06020		

Surveyor:
Jeff Meank, BS, MT(ASCP)
Licensure and Certification Supervisor

status will be explained and the patients will be an opportunity to return to the the clinic for a free RhD test. 05/29/15

A full RhD control review from October 1 2014 through May 8, 2015 will be completed by the Lab Director. If it is found that additional patients did not receive RhD testing, they will be contacted, as well, and given an opportunity to return for free testing. Disciplinary action will be taken if audits Reveal a persistent lack of compliance. 06/12/15