North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

September 26, 2014 emailed

b(6) & b(7)(C) Director
Planned Parenthood of Central NC
1765 Dobbins Drive
Chapel Hill, NC 27515

CLIA # 34D0239689

RE: PLAN OF CORRECTION AND EVIDENCE OF CORRECTION ACCEPTABLE

Dear b(6) & b(7)(C)

By letter dated August 14, 2014, we notified you that based on the onsite survey completed on August 11, 2014 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 September 8, 2014, and have determined that your plan of correction and evidence of correction received on September 23, 2014 are 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 Division of Health Service Regulation 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 questions regarding this letter, please contact me at b(6) & b(7)(C)

Sincerely,

b(6) & b(7)(C)

b(6) & b(7)(C)
Division of Health Service Regulation

Acute, CLIA and Home Care Licensure and Certification Section

Phone b(6) & b(7)(C)
Mailing Address: CLIA Certification ■ 2713 Mail Service Center ■ Raleigh, North Carolina 27699-2713
Location: 1205 Umstead Drive (Lineberger Building) ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
An Equal Opportunity / Affirmative Action Employer

Planned Parenthood®
Care. No matter what.

PO Box 3258
Chapel Hill, NC 27515
t: 919.929.5402 · f: 919.933.5271
www.ppcentralnc.org

Planned Parenthood of Central North Carolina, Inc.

SEP 2 3 2014

September 19, 2014

b(6) & b(7)(C)
CLIA Certification
2713 Mail Service Center
Raleigh, NC 27699-2713

Re: Planned Parenthood of Central North Carolina, 34D0239689

Dear b(6) & b(7)(C)

Please find enclosed the documentation you requested to support our corrections made as proposed in our Plan of Corrections dated August 29, 2014 and received last week by your office. Date with no testing: 9/2/14.

If you have any questions or require any additional information, please feel free to contact me at b(6) & b(7)(C)

Sincerely,

b(6) & b(7)(C)

ako
Enclosure

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

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
34D0239689	PLANNED PARENTHOOD OF CENTRAL NC

Type of Survey (select all that apply)

[I][D][ ][ ][ ]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

[ ][ ][ ][ ][ ]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. (b)(6), (b)(7)C			0.25	0.00	0.00	0.00	0.00	0.75
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 0.25

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.25

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
34D0239689	PLANNED PARENTHOOD OF CENTRAL NC

Type of Survey (select all that apply)

[I][D][ ][ ][ ]

A Complaint Investigation
B Dumping Investigation
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F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

[ ][ ][ ][ ][ ]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. (b)(6), (b)(7)C			0.25	0.00	0.00	0.00	0.00	0.50
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4.								
5.								
6.								
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10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 0.25

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.25

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

September 15, 2014 Mailed

(b)(6), (b)(7)C

Planned Parenthood of Central North Carolina
1765 Dobbins Drive
Chapel Hill, North Carolina 27514

Dear (b)(6), (b)(7)C

Thank you for submitting the signed Plan of Correction (POC) alleging compliance with the deficiencies cited during the CLIA survey August 11, 2014, 2014. Your proposed Plan of Correction, received on September 8, 2014 has been reviewed and is acceptable. We are requesting that you submit additional documentation to verify that you have made the corrections proposed in your POC.

Please submit the following documentation to our office as soon as it is available or by September 30, 2014 at the latest:

D5415 / D6072 – a copy of the laboratory logs where Rh quality control results and lot numbers and expirations of reagents are documented for the following dates: 8/16/14, 8/21/14, 8/23/14, 8/28/14, 8/30/14, 9/2/14, 9/4/14, 9/6/14, 9/9/14, 9/11/14, 9/12/14, and 9/13/13 rec'd 9/23/14

Please fax the documentation to my attention at b(6) & b(7)(C) send as an attachment to e-mail or mail the documentation requested to my attention at CLIA Certification., 2713 Mail Service Center, Raleigh, North Carolina 27699-2713.

Your survey will be finalized after I have reviewed the documentation you submit to show the deficiencies have been corrected. If you have any questions about this request, please contact me by phone at (b)(6), (b)(7)C or by email at (b)(6), (b)(7)C dhhs.nc.gov.

Sincerely,

(b)(6), (b)(7)C

N.C. Department of Health and Human Services
Facility Survey Consultant II – Division of Health Service Regulation
Acute & Home Care Licensure and Certification

Planned Parenthood®
Care. No matter what.

PO Box 3258
Chapel Hill, NC 27515
p: 919.929.5402 · f: 919.933.5271
www.ppcentralnc.org

SEP 0 8 2014

Planned Parenthood of Central North Carolina, Inc.

September 4, 2014

(b)(6), (b)(7)C
CLIA Certification
2713 Mail Service Center
Raleigh, NC 27699-2713

Dear (b)(6), (b)(7)C

Please find enclosed the completed CMS-2567, Statement of Deficiencies and attached supporting documentation for Planned Parenthood of Central North Carolina located in Chapel Hill, North Carolina, 34D0239689.

If you have any questions or require any additional information, please feel free to contact me at b(6) & b(7)(C)

Sincerely,

(b)(6), (b)(7)C

ako
Enclosure

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

IMPORTANT NOTICE – ACTION NECESSARY

August 14, 2014

b(6) & b(7)(C)
Planned Parenthood of Central NC
1765 Dobbins Drive
Chapel Hill, NC 27515

Mailing Address: Attention: b(6) & b(7)(C)
PO Box 3258, Chapel Hill, NC 27515-3258

CLIA # 34D0239689

RE: STANDARD-LEVEL DEFICIENCIES

Dear b(6) & b(7)(C)

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 Division of Health Service Regulation conducted a Recertification survey of your laboratory that was completed on August 11, 2014. 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."

Acute, CLIA and Home Care Licensure and Certification Section

b(6) & b(7)(C)

Mailing Address: CLIA Certification ■ 2713 Mail Service Center ■ Raleigh, North Carolina 27699-2713
Location: 1205 Umstead Drive (Lineberger Building) ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
An Equal Opportunity / Affirmative Action Employer

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 CMS (Centers for Medicare & Medicaid Services) 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 Division of Health Service Regulation 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 questions regarding this letter, please contact me at b(6) & b(7)(C)

Sincerely,

b(6) & b(7)(C)

Division of Health Service Regulation

Enclosure: CMS-2567, Statement of Deficiencies

CLIA 116 - Update

CLIA # 34D0239689 | Name PLANNED PARENTHOOD SOUTH ATLANTIC | Most Current Survey 08/11/2014
116 Complete 03/12/1993 | Current 1 Compliance | Pending 1 Compliance | New | Survey Pending Date
Exp Date 02/01/2017 | Term 00 Active Provider Code | Last Upload Success - 02/19/2016 | Enforcement Status

Demographics | Multiple Sites | Accred Org Info | Specialties | Additional Info | PT Info | An asterisk (*) indicates the field is required

General Information

Reason for 116* | App Type Requested | State Agency Received Date * 03/12/1993

Name* PLANNED PARENTHOOD SOUTH ATLANTIC

Email Address b(6), (b)(7)C@ppsat.org

Fed Tax ID* (b)(4) | Phone* b(6) & b(7)(C) | Class Code * 00 Regular

Director Information

Last Name* (b)(6), (b)(7)C | First* (b)(6), (b)(7)C | M.I. b(6), (b)(7)C

Title 06 (b)(6), (b)(7)C | Other | Sal

Physical Address

Street * 1765 DOBBINS DRIVE

US* Zip* 27515 City* CHAPEL HILL State* NC County* 670 ORANGE

State Region* NCC NORTH CAROLI

International* Locality:* | Postal Code: | Country:*

Mailing Address

Street POST OFFICE BOX 3258

US Zip 27515 City CHAPEL HILL State NC

International Locality:* | Postal Code: | Country:*

Corporate Address

Street 100 SOUTH BOYLAN AVENUE

US Zip 27603 City RALEIGH State NC

International Locality:* | Postal Code: | Country:*

Form Mailing

Send bills to the* Mail address | Send certificate to the* Mail address

Type of Laboratory * 21 Physician Office | Other | Shared Lab No

Hours of Laboratory Testing

11Am-7pm

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	
FROM		12:00 pm	09:00 am	12:00 pm	10:00 am	08:00 am	08:00 am	24x7
TO		08:00 pm	05:00 pm	08:00 pm	04:00 pm	04:00 pm	04:00 pm	

Print | Notes | ATTACHMENTS(*) | Audit History | Certificate/Billing Inquiry | Status Change | Termination | Save | Cancel

(b)(6), (b)(7)C | Version 10.5 (PR1)

(b)(6), (b)(7)C ppsat.org 11:30 am

M 12/21/16 11AM

M 11AM 7pm T 9-5 W 11am-7p Thur 9-3pm Fri 8-4

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

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

ID: 8P8S

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

Facility ID: 000561

1. MEDICARE/MEDICAID PROVIDER NO. (L1) **34D0239689**
2. STATE VENDOR OR MEDICAID NO. (L2)

3. NAME AND ADDRESS OF FACILITY
(L3) **PLANNED PARENTHOOD SOUTH ATLANTIC**
(L4) **1765 DOBBINS DRIVE**
(L5) **CHAPEL HILL, NC** (L6) **27515**

4. TYPE OF ACTION: **2** (L8)
1. Initial 2. Recertification
3. Termination 4. CHOW
5. Validation 6. Complaint
7. On-Site Visit 9. Other
8. Full Survey After Complaint

5. EFFECTIVE DATE CHANGE OF OWNERSHIP (L9)

6. DATE OF SURVEY **01/18/2017** (L34)

8. ACCREDITATION STATUS: ___ (L10)
0 Unaccredited 1 TJC 2 AOA 3 Other

7. PROVIDER/SUPPLIER CATEGORY **22** (L7)
01 Hospital 05 HHA 09 ESRD 13 PTIP 22 CLIA
02 SNF/NF/Dual 06 PRTF 10 NF 14 CORF
03 SNF/NF/Distinct 07 X-Ray 11 ICF/IID 15 ASC
04 SNF 08 OPT/SP 12 RHC 16 HOSPICE

FISCAL YEAR ENDING DATE: (L35) **06/30**

11. LTC PERIOD OF CERTIFICATION
From (a):
To (b):

12. Total Facility Beds (L18)
13. Total Certified Beds (L17)

10. THE FACILITY IS CERTIFIED AS:
X A. In Compliance With Program Requirements
Compliance Based On:
___ 1. Acceptable POC
B. Not in Compliance with Program Requirements and/or Applied Waivers:

And/Or Approved Waivers Of The Following Requirements:
___ 2. Technical Personnel ___ 6. Scope of Services Limit
___ 3. 24 Hour RN ___ 7. Medical Director
___ 4. 7-Day RN (Rural SNF) ___ 8. Patient Room Size
___ 5. Life Safety Code ___ 9. Beds/Room
* Code: A* (L12)

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IID
(L37)	(L38)	(L39)	(L42)	(L43)

15. FACILITY MEETS 1861 (e) (1) or 1861 (j) (1): (L15)

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):
Onsite recertification survey with no deficiencies. CD 2/2/17

17. SURVEYOR SIGNATURE [redacted] Date: 02/02/2017 (L19)

18. STATE SURVEY AGENCY APPROVAL [redacted] Date: 2/6/2017 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY (L21)
___ 1. Facility is Eligible to Participate
___ 2. Facility is not Eligible

20. COMPLIANCE WITH CIVIL RIGHTS ACT:

21. 1. Statement of Financial Solvency (HCFA-2572)
2. Ownership/Control Interest Disclosure Stmt (HCFA-1513)
3. Both of the Above: ___

22. ORIGINAL DATE OF PARTICIPATION **09/01/1992** (L24)

23. LTC AGREEMENT BEGINNING DATE (L41)

24. LTC AGREEMENT ENDING DATE (L25)

25. LTC EXTENSION DATE: (L27)

27. ALTERNATIVE SANCTIONS
A. Suspension of Admissions: (L44)
B. Rescind Suspension Date: (L45)

26. TERMINATION ACTION: (L30)
VOLUNTARY **00**
01-Merger, Closure
02-Dissatisfaction W/ Reimbursement
03-Risk of Involuntary Termination
04-Other Reason for Withdrawal
INVOLUNTARY
05-Fail to Meet Health/Safety
06-Fail to Meet Agreement
OTHER
07-Provider Status Change
00-Active

28. TERMINATION DATE: (L28)

29. INTERMEDIARY/CARRIER NO. (L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

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

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
34D0239689	PLANNED PARENTHOOD SOUTH ATLANTIC

Type of Survey (select all that apply)

I								

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

A				

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (F)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. b(6) & b(7)(C)	01/18/2017	01/18/2017	0.50	0.00	5.00	0.00	1.50	0.75
2.								
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13.								
14.								

Total SA Supervisory Review Hours..... 0.25

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.25

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Form Approved

OMB. NO 0938-061

Survey Report Form (CLIA)

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, & 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 the Centers for Medicare & Medicaid Services, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction Project (OMB-0938-0616), Washington, D.C. 20503

Surveyor Instructions for CMS Form 1557

For Speciality/subspecialty(ies) added or deleted: Use the space provided to list corresponding information and effective dates.

For proficiency testing: Any comments pertinent to the survey or determination of compliance can be listed here.

Each surveyor must sign the certifying statement on page 2 for each type of survey conducted (see "survey status";"other") may include follow-up visit to verify a POC).

General Information

CLIA Identification Number: 34D0239689	Date of Survey: 01/18/2017	
Laboratory Name: PLANNED PARENTHOOD SOUTH ATLANTIC	Telephone No. (include area code): (919) 929 - 5402	
Laboratory Address (number, street): 1765 DOBBINS DRIVE	City/State: CHAPEL HILL, NC	Zip Code: 27515
Mailing Address (if different from above): POST OFFICE BOX 3258	City/State: CHAPEL HILL, NC	Zip Code: 27515

Name of Director (last, first, MI): b(6) & b(7)(C)

Survey Status: (check all that apply)

- ___ Initial Certification
- X Recertificaton
- ___ Validation
- ___ Complaint
- ___ State Exemption
- ___ Accreditation
- ___ Addition of (Sub)Specialty(ies)
- ___ Other

State / County Code: 670

State Region Code: NCC

State License Number (if applicable):

Medicare Provider Number(s):

Personnel: Show Number of People Qualified Under Each Applicable Regulatory Section.

Director, Moderate Complexity, 493.1405 (a) and

(b)(1) ___ (6) ___
(2) b(6)(4) (7) ___
(3) ___ ( ) ___
(4) ___ ( ) ___
(5) ___ ( ) ___

Clinical Consultant, Moderate Complexity, 493.1417

(a) b(6)(4)
(b) ___
( ) ___
( ) ___

Technical Consultant, Moderate Complexity, 493.1411 (a) and

(b)(1) ___ ( ) ___
(2) b(6)(4) ( ) ___
(3) ___
(4) ___

Director, High Complexity, 493.1443 (a) and

(b)(1) ___ (6) ___
(2) ___ ( ) ___
(3) ___
(4) ___
(5) ___

Clinical Consultant, High Complexity, 493.1455

(a) ___
(b) ___
( ) ___
( ) ___

Technical Supervisor, High Complexity, 493.1449 (a) and

(b) ___ (h) ___ (n) ___
(c) ___ (i) ___ (o) ___
(d) ___ (j) ___ (p) ___
(e) ___ (*) ___ (q) ___
(f) ___ (l) ___ ( ) ___
(g) ___ (m) ___ ( ) ___

General Supervisor, High Complexity, 493.1461 (a) and

(b)(1) ___ (d)(1) ___
(b)(2) ___ (d)(2) ___
(c)(1) ___ (d)(3) ___
(c)(2) ___ (e) ___
(c)(3) ___ ( ) ___
(c)(4) ___
(c)(5) ___

Cytotechnologist, 493.1483 (a) and

(b)(1) ___ (4) ___
(2) ___ (5) ___
(3) ___

Technical Supervisor - Cytology, 493.1449 (a) and

(k)(1) ___ ( ) ___
(2) ___ ( ) ___

General Supervisor - Cytology, 493.1469

(a) ___ ( ) ___
(b) ___ ( ) ___

SPECIALTIES/SUBSPECIALTIES			ACCREDITED PROGRAM	ANNUAL TEST VOLUMES	ADDED DATE	DELETED DATE	PROFICIENCY TESTING
010	☐	HISTOCOMPATIBILITY					
A	☐	TRANSPLANT					
B	☐	NONTRANSPLANT					
100	☐	MICROBIOLOGY		(b)(4)			
110	☐	BACTERIOLOGY					
115	☐	MYCOBACTERIOLOGY					
120	☒	MYCOLOGY			08/11/2014		
130	☒	PARASITOLOGY			08/11/2014		
140	☐	VIROLOGY					
200	☐	DIAGNOSTIC IMMUNOLOGY					
210	☐	SYPHILIS SEROLOGY					
220	☐	GENERAL IMMUNOLOGY					
300	☐	CHEMISTRY					
310	☐	ROUTINE CHEMISTRY					
320	☐	URINALYSIS					
330	☐	ENDOCRINOLOGY					
340	☐	TOXICOLOGY					
400	☐	HEMATOLOGY					
500	☐	IMMUNOHEMATOLOGY		(b)(4)			
510	☒	ABO GROUP & RH TYPE			02/02/1999		
520	☐	ANTIBODY DETECTION (TRANSFUSION)					
530	☐	ANTIBODY DETECTION (NONTRANSFUSION)					
540	☐	ANTIBODY IDENTIFICATION					
550	☐	COMPATIBILITY TESTING					
600	☐	PATHOLOGY					
610	☐	HISTOPATHOLOGY					
620	☐	ORAL PATHOLOGY					
630	☐	CYTOLOGY					
800	☐	RADIOBIOASSAY					
900	☐	CLINICAL CYTOGENETICS					

Are immunohematology tests performed for transfusion purposes? No

Are blood and/or blood products (including autologous) collected? No

For a partial survey (validation, addition of (sub)specialty, complaint, or follow-up) list the laboratory conditions(s) regulation numbers reviewed:

In acco[redacted]s found to be in compliance with program requirements.

Signatu[redacted] b(6) & b(7)(C) 2/2/17

Date

Signature

Date

Signature

Date

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

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☒ Survey
☐ Change in Certificate Type
☐ Closure/Other Changes (Specify) _____

Effective Date _____

CLIA IDENTIFICATION NUMBER: 34 0239689 D

(If an initial application leave blank, a number will be assigned)

FACILITY NAME: Planned Parenthood of Chapel Hill

FEDERAL TAX IDENTIFICATION NUMBER: (b)(4)

EMAIL ADDRESS: b(6) & b(7)(C)@ppsat.org

TELEPHONE NO. *(Include area code)*: b(6) & b(7)(C)

FAX NO. *(Include area code)*:

FACILITY ADDRESS — *Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*

NUMBER, STREET *(No P.O. Boxes)*: 1765 Dobbins Drive

CITY	STATE	ZIP CODE
Chapel Hill	NC	27514

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET

CITY	STATE	ZIP CODE

SEND CERTIFICATE TO THIS ADDRESS
☐ Physical
☒ Mailing
☐ Corporate

SEND FEE COUPON TO THIS ADDRESS
☐ Physical
☐ Mailing
☒ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*

NUMBER, STREET: 100 S. Boylan Ave.

CITY	STATE	ZIP CODE
Raleigh	NC	27603

NAME OF DIRECTOR *(Last, First, Middle Initial)*: (b)(6), (b)(7)C

CREDENTIALS: MD

FOR OFFICE USE ONLY

Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *((Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*
☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I – X)*
☒ Certificate of Compliance *(Complete Sections I – X)*
☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ AOA ☐ AABB ☐ A2LA
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 07 Comp. Outpatient Rehab Facility
- ☐ 08 End Stage Renal Disease Dialysis Facility
- ☐ 09 Federally Qualified Health Center
- ☐ 10 Health Fair
- ☐ 11 Health Main. Organization
- ☐ 12 Home Health Agency
- ☐ 13 Hospice
- ☐ 14 Hospital
- ☐ 15 Independent
- ☐ 16 Industrial
- ☐ 17 Insurance
- ☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- ☐ 19 Mobile Laboratory
- ☐ 20 Pharmacy
- ☒ 21 Physician Office
  Is this a shared lab?
  ☐ Yes ☐ No
- ☐ 22 Practitioner Other *(Specify)*
- ☐ 23 Prison
- ☐ 24 Public Health Laboratories
- ☐ 25 Rural Health Clinic
- ☐ 26 School/Student Health Service
- ☐ 27 Skilled Nursing Facility/ Nursing Facility
- ☐ 28 Tissue Bank/Repositories
- ☐ 29 Other *(Specify)*

IV. HOURS OF LABORATORY TESTING *(List times during which laboratory testing is performed in HH:MM format)* If testing 24/7 Check Here ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:		11	9	11	9	8	8
TO:		7	5	7	4	4	1

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☒ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?

   ☐ Yes ☐ No

   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

   ☐ Yes ☐ No

   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

   ☐ Yes ☐ No

   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

   If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.
e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the ESTIMATED TOTAL ANNUAL TEST volume for all waived tests performed (b)(4)

☐ Check if no waived tests are performed

VII. PPM TESTING

Identify the PPM testing (to be) performed. Be as specific as possible.
e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the ESTIMATED TOTAL ANNUAL TEST volume for all PPM tests performed (b)(4)

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Accreditation)*

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/ subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		(b)(4)
MICROBIOLOGY		(b)(4)	☒ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☒ Mycology 120			☐ Antibody Identification 540		
☒ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			**RADIOBIOASSAY 800**		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
☐ Toxicology 340			**TOTAL ESTIMATED ANNUAL TEST VOLUME**		(b)(4)

IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☒ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other Government
		_____ (Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY
34D1100458	Planned Parenthood South Atlantic
34D0718206	Planned Parenthood South Atlantic

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF DIRECTOR OF LABORATORY (Fine to ink)	DATE
(b)(6), (b)(7)C	1/26/17

NOTE: Completed ~~CLIA~~ applications must be sent to your local State Agency.

SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

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

Form Approved
OMB No. 0938-0151

LABORATORY PERSONNEL REPORT (CLIA)

(For moderate and high complexity testing)

1. LABORATORY NAME
PLANNED PARENTHOOD SOUTH ATLANTIC

2. CLIA IDENTIFICATION NUMBER
34D0239689

3. LABORATORY ADDRESS *(NUMBER AND STREET)*
1765 DOBBINS DRIVE

CITY
CHAPEL HILL

STATE
NC

ZIP CODE
27514

4. Instructions:
a. List below all technical personnel, by name, who are employed by the laboratory. Check (✓) the appropriate column for each position held. For TC and TS follow instructions on reverse.
b. Indicate whether shift worked is (1) day, (2) evening or (3) night.
c. Indicate highest level of testing for which personnel are qualified: Use (M) for moderate and (H) for high complexity.
d. Indicate whether position held is full (F) or part-time (P).

Positions:
D-Director
CC - Clinical Consultant
TC - Technical Consultant
TS - Technical Supervisor
GS - General Supervisor
TP - Testing Personnel
CT/GS - Cytology General Supervisor
CT - Cytotechnologist

5. TELEPHONE *(INCLUDE AREA CODE)*

FOR OFFICIAL USE ONLY
(NOT TO BE COMPLETED BY LABORATORY)
QUALIFIES ACCORDING TO SUBPART M

DATE OF SURVEY 1/18/17

EMPLOYEE NAMES LAST NAME	FIRST NAME	MI	a. POSITION HELD D	CC	TC	TS	GS	TP	CT/GS	CT	b. SHIFT 1 2 3	c. M OR H	d. F OR P	
(b)(6), (b)(7)C			✓	✓	✓									493.1405 b2 · 1417a; 1411b2
				✓				✓						493.1423b1
				✓				✓						493.1423b1
								✓						493.1423b4
								✓						493 1423b4
								✓						

D CC TC

☐ Check (✓) here if additional space is needed to list all technical personnel. Copy this page and attach continuation sheet(s) to the original form.

READ THE FOLLOWING CAREFULLY BEFORE SIGNING

Statement or Entities Generally: Whoever, in any manner within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY, TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M.

6. SIGNATURE OF LABORATORY DIRECTOR
(b)(6), (b)(7)C

7. DATE
1/26/17

IF CONTINUATION SHEET PAGE ___ OF ___

INSTRUCTIONS FORM CMS-209

This form will be completed by the laboratory. It will be used by the surveyor to review the qualifications of technical personnel in the laboratory.

Instructions for 4(a) TC/TS:
When listing those individuals holding technical consultant/technical supervisor (TC/TS) positions, use the following grid to indicate the specialty(ies)/subspecialty(ies) in which they presently function. Record the number corresponding to the specialty/subspecialty in the appropriate column (TC/TS). When an individual functions as a TC/TS in more than one specialty/subspecialty, use a line for each specialty/subspecialty.

GRID:

1. Bacteriology
2. Mycobacteriology
3. Mycology
4. Parasitology
5. Virology
6. Diagnostic Immunology
7. Chemistry
8. Hematology
9. Immunohematology
10. Clinical Cytogenetics
11. Histocompatibility
12. Radiobioassay
13. Histopathology
14. Oral Pathology
15. Cytology
16. Dermatopathology
17. Ophthalmic Pathology

EXAMPLE

EMPLOYEE NAMES			a. POSITION HELD								b. SHIFT 1 2 3	c. M OR H	d. F OR P
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT			
(b)(6), (b)(7)C					1						1	M	F
						4						H	
						6						H	

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Indicate the applicable regulatory citation under which the following individuals are qualified: Each laboratory director, technical consultant, technical supervisor, clinical consultant, general supervisor, cytology supervisor, and those testing personnel and cytotechnologist sampled during the survey process.