SEP 0 8 2014

PRINTED: 08/14/2014 FORM APPROVED OMB NO. 0938-0391

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MUL A. BUILD		li i	(X3) DATE SURVEY COMPLETED	
34D0239689						08/11/2014	
	PROVIDER OR SUPPLIER D PARENTHOOD OF	CENTRAL NC					
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC (DENTIFYING INFORMATION)	ID PREFII TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
D5415 510M	Reagents, solutions materials, calibration supplies, as approprincipal indicate the following (1) Identity and whe concentration. (2) Storage requirer (3) Preparation and (4) Other pertinent use. This STANDARD is Based on random quality control logs failed to retain com	s, culture media, control in materials, and other riate, must be labeled to ig: in significant, titer, strength or ments.	D54	115	D5415: On Thursday, August 14, 2014, all Chapel Hill testing staff completed retraining on control testing and accurate documentation Eldon Card Rh D cards in use. This training included a review of the lab manual policy and procedure and hands-on review of documentation errors. Please see attached attestatio statements. Controls for these tests were run an each individual test card comes with its own control so we do not have reason to suspect that patients were impacted by these documentation errors.	n d	
D5805 510M	Random review of 2013 and 2014 laboratory logs where quality control testing results are documented revealed testing personnel failed to document the expiration date of the Eldon Cards in use on 6/27/13, 9/14/13, 12/6/13, 2/14/14, 3/6/14, and 6/21/14. Random review of 2013 and 2014 laboratory logs where quality control testing results are documented revealed testing personnel failed to document the lot number of the Eldon Cards in use on 10/31/13, 3/6/14, and 6/21/14.				Annual training of documentation of Eldon Cards RhD cards in use for staff will continue with emphasis or control testing and documentation. The Health Center Manager will regularly review the lab log for accurate and complete control testing and documentation. D5805: On Thursday, August 14, 2014, Chapel Hill staff received documentation refresher training. Sattached attestation statements. (coron page 2)	ng ee	
		ER/SUPPLIER REPRESENTATIVE'S SIGN			TITLE	(X6) DAYE	

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.

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				TIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		34D0239689	B. WING		08	08/11/2014	
}	PROVIDER OR SUPPLIER ED PARENTHOOD OF	CENTRAL NC		STREET ADDRESS, CITY, STATE, ZIP COD 1765 DOBBINS DRIVE CHAPEL HILL, NC 27515			
(X4) ID PREFIX TAG	(EACH DEFICIENC)	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		OULD BE	(X5) COMPLETION DATE	
D6072	testing must adhere control policies, doc activities, instrumer and maintenance p This STANDARD is Based on review of 2013 and 2014 qual testing personnel far policy for performing control on the Eldon The laboratory's "R CARDS" procedures CONTROLRun of appropriate QA doc shipment, with each testing is performed. Random review of where quality control control on the Eldon Cards were used to only one set of qual documented on the Eldon Card Rh testing indicate which one Eldon Cards had quality control control. There was indicate which one Eldon Cards had quaperformed.	forming moderate complexity to the laboratory's quality cument all quality control at and procedural calibrations erformed. Is not met as evidenced by: f procedures and review of ality control logs 8/11/14, ailed to follow the laboratory's g Rh (Rhesus) D test quality in Cards. In TESTING: USE OF ELDON estates "QUALITY controls and record results on sument with each new in lot number and each day that id." 2013 and 2014 laboratory logs of testing results are ed 2 days (5/29/14 and different lot numbers of Eldon perform Rh (D) testing and lity control results were	D60	(Cont'd from page 2) The new EHR system is control to include the testing site and address on each lab result acompleted retraining on que control testing and accurate documentation of these testines training included a result the lab manual policy and procedure and hands-on responsible for the quality testing and documentation received individual one-on training on the requirement document separate control on separate lots if they are the same testing day and document these tests. Because controls were rusubsequent testing days a individual test card comes own control, we do not have reason to suspect that paywere impacted by these of (cont'd on page 4)	ind/or lab inst 14, g staff lality le sts. See nents. view of eview of eview of errors l-one of testing e used or how to n on and each s with its ve tients		

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		' '	TIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED		
		34D0239689	B. WING		08	3/11/2014	
	PROVIDER OR SUPPLIER D PARENTHOOD OF	CENTRAL NC		STREET ADDRESS, CITY, STATE, ZIP O 1765 DOBBINS DRIVE CHAPEL HILL, NC 27515			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG	PROVIDER'S PLAN OF COI X (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
	INSTRUMENTS, F	SYSTEMS, EQUIPMENT, REAGENT	D54	15		8/14/14	
]	Reagents, solution materials, calibratic supplies, as approjindicate the following (1) Identity and who concentration. (2) Storage require (3) Preparation and (4) Other pertinent use. This STANDARD Based on random quality control logs failed to retain com (Rhesus) D testing Cards. Random review of where quality control documented reveal document the expiring use on 6/27/13, 3/6/14, and 6/21/14. Random review of where quality control documented reveal document the lot in use on 10/31/13, 3/493.1291(c) TEST	en significant, titer, strength or ements. If expiration dates, information required for proper is not met as evidenced by: review of 2013 and 2014 8/11/14, testing personnel uplete records for the Rhaperformed using the Eldon 2013 and 2014 laboratory logs rol testing results are led testing personnel failed to ration date of the Eldon Cards 9/14/13, 12/6/13, 2/14/14, 4. 2013 and 2014 laboratory logs rol testing results are reled testing personnel failed to umber of the Eldon Cards in /6/14, and 6/21/14. REPORT	D58	305		8/30/14	
	(1) For positive pa patient's name and unique patient ider (2) The name and	st indicate the following: tient identification, either the d identification number, or a ntifier and identification number. address of the laboratory					
LABORATOR	Y DIRECTOR'S OR PROVI	DER/SUPPLIER REPRESENTATIVE'S SIG	NATURE	TITLE		(X6) DATE	

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.

09/29/2014

PRINTED: 09/26/2014 FORM APPROVED OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` '	TIPLE CONSTRUCTION NG		(X3) DATE SURVEY COMPLETED		
		34D0239689	B. WING		08/11/2014			
	PROVIDER OR SUPPLIE		STREET ADDRESS, CITY, STATE, ZIP CODE 1765 DOBBINS DRIVE CHAPEL HILL, NC 27515					
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO THI DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE		
D6072	testing must adher control policies, of activities, instrum and maintenance. This STANDARD Based on review 2013 and 2014 questing personnel policy for perform control on the Electric Control on the Electric Control in the	erforming moderate complexity are to the laboratory's quality locument all quality control ent and procedural calibrations a performed. is not met as evidenced by: of procedures and review of quality control logs 8/11/14, failed to follow the laboratory's sing Rh (Rhesus) D test quality don Cards. 'Rh TESTING: USE OF ELDON are states "QUALITY" of controls and record results on ocument with each new each lot number and each day that	D60	72				
	Cards were used only one set of question documented on the control of the control of the positive control. There was indicate which or Eldon Cards had performed.	to perform Rh (D) testing and uality control results were						

Form Approved OMB NO. 0938-0390

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 / (Y2) Multiple Construction (Y3) Date of Revisit dentification Number A. Building 9/26/2014
34D0239689 B. Wing

Name of Facility Street Address, City, State, Zip Code

PLANNED PARENTHOOD OF CENTRAL NC

requirement on the survey report form).

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

Y4) Item	(Y	5) Date	(Y4) Item		(Y5) Date	(Y4)	<u>Item</u>	(75)	Date
ID Prefix Reg. #	D5415 493.1252(c)	Correction Completed 09/13/2014	ID Prefix Reg. #	D6072 493.1425(b)(3)	Correction Completed 09/13/2014		ID Prefix		Correction Completed
LSC			LSC				LSC		
		Correction			Correction				Correction
		Completed			Complete				Completed
ID Prefix		·	ID Prefix		22		ID Prefix		
Reg. #			Reg.#				Reg. #		
LSC			LSC			-	LSC		
		Correction			Correction	; !			Correction
		Completed			Complete				Completed
ID Prefix			ID Prefix			;	ID Prefix		
Reg. #			Reg. #				Reg. #		
LSC	and the second of the second o	· 	LSC				LSC	· · · · - <u></u>	
		Correction	;		Correction	,			Correction
		Completed			Complete	,			Completed
ID Prefix	·		ID Prefix			:	ID Prefix		
Reg. #	ŧ		Reg. #				Reg. #		
LSC			LSC	;			LSC		<u></u>
		Correction	:		Correctio	n ¦			Correction
		Completed			Complete	ed l			Completed
ID Prefix	(_	ID Prefix	*		ì	ID Prefix		
Reg. #		m- ··	Reg. t						
) 		LSC	· · <u></u> ·			LSC		·
							••••	· •	
Reviewed State Age	,	red By	Date:	Signatur	e of Surveyor:	77.Q	oughe do	Date	9/26/14
Reviewed		ved By	Date:	Signatu	e of Surveyor:		7-1-1	Date	:
CMS RO		-	;		-			: : :	•
Followup	to Survey Completed	l on:		Check for a	ny Uncorrected D	eficier	ncles. Was a Summa 2567) Sent to the Fac	78*4.	
	8/11/2014) !	Uncorrec	ted Deliciencies	CIAI 2-7	Sor Joen to the Fac	HITY! YES	NO



North Carolina

Run Date: 12/12/2016 Job # 52854398

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PLANNED PARENTHOOD SOUTH ATLANTIC

CCN: 34D0239689

Specialties / Subspecialties

Specialty / Subspecialty HISTOCOMPATIBILITY Transplant Nontransplant	Accrediting Organization	Eff Date	Test Volume	Specialty / Subspecialty HEMATOLOGY Hematology	Accrediting Organization	Eff Date	Test Volume
MICROBIOLOGY Bacteriology Mycobacteriology X Mycology X Parasitology Virology DIAGNOSTIC IMMUNOLOGY Syphilis Serology General Immunology		08/11/2014 08/11/2014	350	IMMUNOHEMATOLOGY X ABO Group & Rh Group Antibody Detection (transfusion) Antibody Detection (nontransfusion) Antibody Identification Compatibility Testing PATHOLOGY Histopathology Oral Pathology		02/02/1999	2,692
CHEMISTRY Routine Urinalysis Endocrinology Toxicology	. 2 0.42			_ Cytology RADIOBIOASSAY _ Radiobioassay CLINICAL CYTOGENETICS _ Clinical Cytogenetics			

Survey Total Annual Test Volume: 3,042

Director Affiliation with Other Laboratories

Name of Lab	Address	CLIA Number
PLANNED PARENTHOOD SOUTH	105 NEWSOM STREET SUITE 101 DURHAM, NC 27704	34D0718206
PLANNED PARENTHOOD SOUTH	4551 YADKIN ROAD FAYETTEVILLE NC 28303	34D1100458



North Carolina

Run Date: 12/12/2016 Job # 52854398

Last Update: 12/09/2016

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PLANNED PARENTHOOD SOUTH ATLANTIC

CCN: 34D0239689

Current Program Requirements

Compliance Status: Provider meets requirements

Survey from: 08/11/2014

Date Provider Signed POC: 08/29/2014
Type of Action: RECERTIFICATION
Revisit Dates: 09/15/2014 09/26/2014

				Pro	viders l	lot Meeti	ng Req	uirements	s
Tag		Plan/Date	Status of	St	State		gion	Nation	
#	Requirement	of Correction	Deficiency	#	%	#	%	#	%
D5415	TEST SYSTEMS, EQUIPMENT,	09/13/2014	Corrected	4	0.7	23	0.4	233	1.3
D5805	Specialties: 510 TEST REPORT	08/28/2014	Corrected	45	8.3	128	2.7	732	4.2
D6072	Specialties: 510 TESTING PERSONNEL RESPONSIBILITIES		Corrected	12	2.2	16	0.3	127	0.7
	D5415 D5805	# Requirement D5415 TEST SYSTEMS, EQUIPMENT, Specialties: 510 D5805 TEST REPORT Specialties: 510 D6072 TESTING PERSONNEL RESPONSIBILITIES	# Requirement of Correction D5415 TEST SYSTEMS, EQUIPMENT, 09/13/2014	# Requirement of Correction Deficiency D5415 TEST SYSTEMS, EQUIPMENT, 09/13/2014 Corrected Specialties: 510 D5805 TEST REPORT 08/28/2014 Corrected Specialties: 510	Tag Plan/Date of Correction Status of Deficiency Status of Deficiency <td>Tag # Requirement Plan/Date of Correction of Correction Status of Deficiency Status of Deficiency Status of Deficiency Status of Deficiency Corrected % D5415 TEST SYSTEMS, EQUIPMENT, Specialties: 510 09/13/2014 Corrected 4 0.7 D5805 TEST REPORT Specialties: 510 08/28/2014 Corrected 45 8.3</td> <td>Tag # Requirement Plan/Date of Correction of Correction Operation Status of Deficiency Status of William Regular of Correction of Correction Operation D5415 TEST SYSTEMS, EQUIPMENT, Specialties: 510 09/13/2014 Corrected 4 0.7 23 D5805 TEST REPORT Specialties: 510 08/28/2014 Corrected 45 8.3 128</td> <td>Tag # Requirement Plan/Date of Correction of Correction of Correction Deficiency State with the property Region with the property D5415 TEST SYSTEMS, EQUIPMENT, Specialties: 510 09/13/2014 Corrected 4 0.7 23 0.4 D5805 TEST REPORT Specialties: 510 08/28/2014 Corrected 45 8.3 128 2.7</td> <td># Requirement of Correction Deficiency # % # % # D5415 TEST SYSTEMS, EQUIPMENT, 09/13/2014 Corrected 4 0.7 23 0.4 233 Specialties: 510 D5805 TEST REPORT 08/28/2014 Corrected 45 8.3 128 2.7 732 Specialties: 510</td>	Tag # Requirement Plan/Date of Correction of Correction Status of Deficiency Status of Deficiency Status of Deficiency Status of Deficiency Corrected % D5415 TEST SYSTEMS, EQUIPMENT, Specialties: 510 09/13/2014 Corrected 4 0.7 D5805 TEST REPORT Specialties: 510 08/28/2014 Corrected 45 8.3	Tag # Requirement Plan/Date of Correction of Correction Operation Status of Deficiency Status of William Regular of Correction of Correction Operation D5415 TEST SYSTEMS, EQUIPMENT, Specialties: 510 09/13/2014 Corrected 4 0.7 23 D5805 TEST REPORT Specialties: 510 08/28/2014 Corrected 45 8.3 128	Tag # Requirement Plan/Date of Correction of Correction of Correction Deficiency State with the property Region with the property D5415 TEST SYSTEMS, EQUIPMENT, Specialties: 510 09/13/2014 Corrected 4 0.7 23 0.4 D5805 TEST REPORT Specialties: 510 08/28/2014 Corrected 45 8.3 128 2.7	# Requirement of Correction Deficiency # % # % # D5415 TEST SYSTEMS, EQUIPMENT, 09/13/2014 Corrected 4 0.7 23 0.4 233 Specialties: 510 D5805 TEST REPORT 08/28/2014 Corrected 45 8.3 128 2.7 732 Specialties: 510

^{* =} Regional Office Flag (Includes COPs) STD = Standard COP = Condition



North Carolina

Run Date: 12/12/2016 Job # 52854398

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ANNIED	PARENTHOOD	COLITH	ATLANTIC .

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PLANNED PARE	NTHOOD SOU	TH ATLANTIC		CCN: 34	ID0239689				
				Deficie	ency Summar	y			
Type of Deficiency			Current Survey	Prior 1 Survey	Prior 2 Survey	Prior 3 Survey			
Condition			0	0	1	1			
Standard			3	3	9	2			
Regional Office F	lag (Includes C	OPs)	0	0	1	1			
Health Total	•	·	3	3	10	3			
				Stat	tus of COPs				
				Cur	rent Survey				
Deficiency n			not	Deficier	-	Deficiency Corrected			Repeat COP
Corrected		ed	Corrected		After Approval (L33)			Deficiency	
COP	COP 0			0			0		0
				Complaint	Survey Inforn	nation			
Survey Date	Status	Ail	legations			Alle	gation Status		
-				No complaint	surveys for this p	rovider.			
				Enforcemen	t Survey Infor	mation			
				Lillorcomen	t out voy milot				
Survey Date	Status			Ne anfaraomon	t surveys for this	nrovidar			
					<u>-</u>	•			
				Survey	Team Summa	ıry		15 M	
			_ ,			Duian 3		r ID Number Prior 1	Current
Prior 3	Prior 2	Prior 1	Current			Prior 3	Prior 2		
Survey	Survey	Survey	Survey			Survey	Survey	Survey	Survey
09/2008	08/2010	10/2012	08/11/2014	670 Surveyor	Team	09/2008	08/2010	10/2012	08/11/2014
1	1	1	1	LABORATORI	AN	12104	19613	19613	19613

Total Surveyors Onsite



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PLANNED PARENTHOOD SOUTH ATLANTIC

CCN: 34D0239689

Proficiency Testing Scores

North Carolina

			2014			2015		,	— 2016 —	
Routine Scores Analyte	Current Program	Event 1 Score	Event 2 Score	Event 3 Score	Event 1 Score	Event 2 Score	Event 3 Score	Event 1 Score	Event 2 Score	Event 3 Score
0860 ABO/RHO 0875 D (RHO)	3 3	100 100								
Nonroutine Analyte	Year		utoff ate	Sc	ore					
-		No nonro	utine score	s found for th	nis provider.					

^{* =} Unsatisfactory Scores



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North Carolina

PLANNED PARENTHOOD SOUTH ATLANTIC

CCN: 34D0239689

Program Requirements

Revisit Date(s) for Current Survey: 09/15/2014 09/26/2014

Prior 3 Survey 09/2008	Prior 2 Survey 08/2010	Prior 1 Survey 10/2012	Current Survey 08/11/2014	Plan/Date of Correction	Type	Requirement
	X			N/E	STD	D2007-TESTING OF PROFICIENCY TESTING SAMPLES
	X			N/E	STD	D3031-RETENTION REQUIREMENTS
X	X			N/E	STD	D5403-PROCEDURE MANUAL
		Х		N/E	STD	D5411-TEST SYSTEMS, EQUIPMENT, INSTRUMENTS,
			хс	09/13/2014	STD	D5415-TEST SYSTEMS, EQUIPMENT, INSTRUMENTS,
			Specialties: 510			
	X	Х		N/E	STD	D5417-TEST SYSTEMS, EQUIPMENT, INSTRUMENTS,
	X			N/E	STD	D5431-MAINTENANCE AND FUNCTION CHECKS
	X			N/E	STD	D5783-CORRECTIVE ACTIONS
	X	X	ХС	08/28/2014	STD	D5805-TEST REPORT
			Specialties: 510			
	X			N/E	STD	D6012-LABORATORY DIRECTOR RESPONSIBILITIES
X	X			N/E	COP	* D6063-LABORATORY TESTING PERSONNEL
X	X			N/E	STD	D6065-TESTING PERSONNEL QUALIFICATIONS
			x c	09/13/2014	STD	D6072-TESTING PERSONNEL RESPONSIBILITIES

^{^ =} Past Non-compliance C = Date of Correction N = No Date Given P = Plan of Correction R = Refused to Correct W = Waived F = FSES X = Deficient

^{* =} Regional Office Flag (Includes COPs)

STD = Standard

COP = Condition



Compliance Paid: Y

CASPER Report 0096D CLIA Application and Survey Summary

Run Date: 12/12/2016

Job # 52854398

Last Update: 12/09/2016

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North Carolina

PLANNED PARENTHOOD SOUTH ATLANTIC

CCN: 34D0239689

Certificate History

		PENDING Certificate - App T	VDE: 1 COMPLIANCE	
Certificate Type	Exempt	Eff Date	Exp Date	Term
COMPLIANCE	00	02/02/2017	02/01/2019	00
		CURRENT Certificate - App T	ype: 1 COMPLIANCE	
Certificate Type	Exempt	Eff Date	Exp Date	Term
COMPLIANCE	00	02/02/2015	02/01/2017	00
		HISTORY Cert	tificate	
Certificate Type	Exempt	Eff Date	Exp Date	Term
COMPLIANCE	00	02/02/2013	02/01/2015	00
COMPLIANCE	0 0	02/02/2011	02/01/2013	00
COMPLIANCE	00	02/02/2009	02/01/2011	00
COMPLIANCE	00	02/02/2007	02/01/2009	00
COMPLIANCE	00	02/02/2005	02/01/2007	00
COMPLIANCE	00	02/02/2003	02/01/2005	00
COMPLIANCE	00	02/02/2001	02/01/2003	00
COMPLIANCE	00	02/02/1999	02/01/2001	00
• • • • • • • •	00	11/14/1998	02/01/1999	00
PPM	00	03/14/1997	11/13/1998	00
COMPLIANCE REGISTRATION	00 00	02/02/1999 11/14/1998	02/01/2001 02/01/1999	

Certificate Paid:



North Carolina

Run Date: 12/12/2016 Job # 52854398

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PLANNED PARENTHOOD SOUTH ATLANTIC

1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

Phone Number: (919)929-5402 Fax Number: (919)933-5170 Federal Jurisdiction Lab: N Lab Status: ACTIVE PROVIDER CCN: 34D0239689

Type of Application: COMPLIANCE
Type Ownership: PRIVATE

Type Laboratory: Physician Office

New Appl Type: N/E

State's Region Code: NCC

County Code: 670

Certificate Eff: 02/02/2015 Certificate Exp: 02/01/2017

Accreditation: N/E

N/E = No data was entered

Director Name: MATTHEW ZERDEN M.D. **Mailing Address:** POST OFFICE BOX 3258

CHAPEL HILL, NC 27515

Hours of Operation

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:	-	1200	0900	1200	1000	0800	0800
To:		0800	0500	0800	0400	0400	0400

Multiple Sites

One Certificate for Multiple Sites? Y

Number of Sites: 2

Temporary Testing Sites? N

Non-profit or Government Lab with Limited Public Health Testing with Single Certificate for Multiple Sites? Y Hospital with Multiple Labs at a Single Location with Single Certificate? N

Total Waived Tests Performed: 4,270 Total PPM Tests Performed: 270

PRINTED: 09/26/2014 FORM APPROVED OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		1		NSTRUCTION	(X3) DATE SURVEY COMPLETED		
		34D0239689	B. WING			08/	11/2014
	ROVIDER OR SUPPLIER D PARENTHOOD OF	CENTRAL NC		1765 D	T ADDRESS, CITY, STATE, ZIP CODE OBBINS DRIVE EL HILL, NC 27515		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG	×	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPE DEFICIENCY)	BE	(X5) COMPLETION DATE
D5805	(3) The test report (4) The test perform (5) Specimen source (6) The test result a measurement or in (7) Any information disposition of specilaboratory's criteria. This STANDARD is Based on random staff interview 8/11 did not indicate the laboratory location testing was perform #69702) reviewed. Review of 4 patient results are recorde form in each chart, the name and address across the top of the form from the visit did not indicate who performed the Rh(1). During interview at Vice President of Fitesting personnel his where testing was This deficiency was and 10/2/12.	test was performed. date. ned. ce, when appropriate. and, if applicable, the units of terpretation, or both. regarding the condition and mens that do not meet the for acceptability. s not met as evidenced by: review of patient charts and /14, the laboratory's test report name and address of the where the Rh (Rhesus) D ned in 1 of 4 charts (chart c charts revealed Rh(D) testing d on the medication notes The medication notes form list ress of the laboratory and the of two associated facilities are page. The medication notes on 6/12/14 for patient #69702 ich of the three facilities D) testing. approximately 2:00 p.m. the relation to documented the facility performed for patient #69702. s previously cited on 10/13/10 STING PERSONNEL	D58				8/14/14

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		34D0239689	B. WING		i	08/	11/2014
	PROVIDER OR SUPPLIER D PARENTHOOD OF	CENTRAL NC		STREET ADDRESS, CITY, STATE, ZII 1765 DOBBINS DRIVE CHAPEL HILL, NC 27515	PCODE		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FUL! SC IDENTIFYING INFORMATION)	PREFI TAG		ON SHOULD HE APPROPE	BE	(X5) COMPLETION DATE
D6072	numbers 14111 and Controls section of the positive control control. There was indicate which one	form listed Eldon Cards lot is 13431 in use. The Rh the log listed only 1 result for and 1 result for the negative also no documentation to of the two lot numbers of wality control testing	Dec	(Cont'd from page 3) we do not have reason that patients were impa these document. Annual training of quali testing and documenta Cards for staff will cont emphasis on quality co and documentation. The Health Center Mar regularly review the lat accurate and complete testing and documenta	ity control ition of Etinue with introl test mager with the logs for	ol Eldon h sting	

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				IPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		34D0239689	B. WING _		08/11/2014	
-	PROVIDER OR SUPPLIER D PARENTHOOD OF	CENTRAL NC		STREET ADDRESS, CITY, STATE, ZIP CODE 1765 DOBBINS DRIVE CHAPEL HILL, NC 27515		
(X4) ID PREF;X TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPRIES DEFICIENCY)	DBE COMPLETION	
	(3) The test report of (4) The test perform (5) Specimen source (6) The test result a measurement or interpretation of the test result at the manual staff interview 8/11/did not indicate the laboratory location of testing was perform #69702) reviewed. Review of 4 patient results are recorder form in each chart, the name and address across the top of the form from the visit of did not indicate while performed the Rh(During interview at Vice President of Plesting personnel havere testing was and 10/2/12.	test was performed. date. hed. hed. he, when appropriate. hind, if applicable, the units of terpretation, or both. regarding the condition and mens that do not meet the for acceptability. In not met as evidenced by: review of patient charts and he laboratory's test report name and address of the where the Rh (Rhesus) D hed in 1 of 4 charts (chart charts revealed Rh(D) testing d on the medication notes The medication notes The medication notes form list less of the laboratory and the of two associated facilities le page. The medication notes on 6/12/14 for patient #69702 ch of the three facilities lead not documented the facility performed for patient #69702. It previously cited on 10/13/10 STING PERSONNEL	D580	documenting the following requirements: i. Tests results must be record on a form that includes the nand address of the testing sit ii. Medication notes form documentation must include indication of which health certacility performed the tests/procedures. Patient health and safety was impacted due to this lack of documentation because the remainder of the visit forms denotes the location of service Annual training of required identifying information of test results for staff will continue emphasis on complete and accurate documentation. The health center manager audit a random sampling of by August 30, 2014 to ensure this issue has been resolved addition, we are moving to the staff that the seconds in the staff that the staff th	rded ame te/lab. nter s not ces. t with will charts re that d. In	
	KESPUNSIBILITE	5				

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

Form Approved OMB NO. 0938-0390

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 34D0239689	(Y2) Multiple Construction A. Building B. Wing		(Y3) Date of Revisit 9/15/2014
Name of Facility		Street Address, City, State, Zip Code	
PLANNED PARENTHOOD OF CE	NTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515	

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	D5805		Correction Completed 08/28/2014	ID Prefix		Correction Completed	:	ID Prefix		Correction Completed
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LSC		<u></u>		100						
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State Age			•		Christo	100 F	f/χ	uwkud	$\chi = -3$	1/5/14
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Followup	to Survey Co	mpleted o	on:		Check for any Unco	rrected Def	icienc	cies. Was a Sum	imary of	
	8/11	/2014			Uncorrected Defi	ciencies (C	MS-25	567) Sent to the i	Facility? YES	NO
										^

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:					CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		34D0239689	B. WING	i		01	/18/2017
	PROVIDER OR SUPPLIER D PARENTHOOD SO			176	EET ADDRESS, CITY, STATE, ZIP CODE 5 DOBBINS DRIVE APEL HILL, NC 27515	, · · · · · · · · · · · · · · · · · · ·	
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D 000 INITIAL COMMENTS			D	000			:
	Hill laboratory was CFR Part 493 Re	renthood South Atlantic Chapel is found in compliance with 42 quirements for Laboratories as site survey performed on					
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LABORATO	DIRECTORIS OF PRO	VIDENSUPPLIER REPRESENTATIVE'S SI	CNATURE	: : : :	TITLE		(XG) DATE

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 DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR

MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

February 2, 2017

Matthew Zerden, M.D., Director Planned Parenthood South Atlantic 1765 Dobbins Drive Chapel Hill, NC 27515

CLIA # 34D0239689

RE: CERTIFICATION OF COMPLIANCE

Dear Dr. Zerden:

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 Recertification survey of your laboratory on January 18, 2017. The results of the survey showed that all CLIA Condition-level requirements were met during the time of the onsite survey. We are recommending to CMS that your laboratory be recertified in the CLIA program.

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 instance of non-compliance that may have occurred in the laboratory. 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.

If you have questions regarding this letter, please contact me at Christine. Dougherty@dhhs.nc.gov.

Sincerely,

Christine M Dougherty

Christine M. Dougherty, BS, MTASCP Facility Survey Consultant II NC Division Of Health Service Regulation

Enclosure: CMS-2567, Statement of Deficiencies



Acute and Home Care Licensure and Certification Section