STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34D0239689	A. BUILDING _____ B. WING _____	08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

(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 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. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on random review of 2013 and 2014 quality control logs 8/11/14, testing personnel failed to retain complete records for the Rh (Rhesus) D testing performed using the Eldon Cards. 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.	D5415	D5415: On Thursday, August 14, 2014, all Chapel Hill testing staff completed retraining on control testing and accurate documentation of 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 attestation statements. Controls for these tests were run and 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. Annual training of documentation of Eldon Cards RhD cards in use for staff will continue with emphasis on control testing and documentation. The Health Center Manager will regularly review the lab log for accurate and complete control testing and documentation.	
D5805 510M	493.1291(c) TEST REPORT The test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory	D5805	D5805: On Thursday, August 14, 2014, Chapel Hill staff received documentation refresher training. See attached attestation statements. (contd on page 2)	

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

Medical Director/Lab Director 8/8/2014

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
	34D0239689	A. BUILDING _____ B. WING _____	08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

(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
D6072	Continued From page 2 Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of procedures and review of 2013 and 2014 quality control logs 8/11/14, testing personnel failed to follow the laboratory's policy for performing Rh (Rhesus) D test quality control on the Eldon Cards. The laboratory's "Rh TESTING: USE OF ELDON CARDS" procedure states "QUALITY CONTROL:...Run controls and record results on appropriate QA document with each new shipment, with each lot number and each day that testing is performed." Random review of 2013 and 2014 laboratory logs where quality control testing results are documented revealed 2 days (5/29/14 and 7/31/14) when two different lot numbers of Eldon Cards were used to perform Rh (D) testing and only one set of quality control results were documented on the logs. a. On 5/29/14, the Lab Log Cover Sheet: EldonCard Rh test form listed Eldon Cards lot numbers 13431 and 13201 in use. The Rh Controls section of the log listed only 1 result for the positive control and 1 result for the negative control. There was also no documentation to indicate which one of the two lot numbers of Eldon Cards had quality control testing performed. b. On 7/31/14, the Lab Log Cover Sheet:	D6072	(Cont'd from page 2) The new EHR system is configured to include the testing site and/or lab address on each lab result. D6072:On Thursday, August 14, 2014, all Chapel Hill testing staff completed retraining on quality control testing and accurate documentation of these tests. See attached attestation statements. This training included a review of the lab manual policy and procedure and hands-on review of documentation errors. i. Testing personnel who were responsible for the quality control testing and documentation errors received individual one-on-one training on the requirement to document separate control testing on separate lots if they are used on the same testing day and how to document these tests. Because controls were run on subsequent testing days and each individual test card comes with its own control, we do not have reason to suspect that patients were impacted by these document (cont'd on page 4)	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34D0239689	A. BUILDING _____ B. WING _____	08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

(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 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. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on random review of 2013 and 2014 quality control logs 8/11/14, testing personnel failed to retain complete records for the Rh (Rhesus) D testing performed using the Eldon Cards. 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.	D5415		8/14/14
D5805 510M	493.1291(c) TEST REPORT The test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory	D5805		8/30/14

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 09/29/2014

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
	34D0239689	A. BUILDING _____ B. WING _____	08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

(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
D6072	Continued From page 2	D6072		

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on review of procedures and review of 2013 and 2014 quality control logs 8/11/14, testing personnel failed to follow the laboratory's policy for performing Rh (Rhesus) D test quality control on the Eldon Cards.

The laboratory's "Rh TESTING: USE OF ELDON CARDS" procedure states "QUALITY CONTROL:...Run controls and record results on appropriate QA document with each new shipment, with each lot number and each day that testing is performed."

Random review of 2013 and 2014 laboratory logs where quality control testing results are documented revealed 2 days (5/29/14 and 7/31/14) when two different lot numbers of Eldon Cards were used to perform Rh (D) testing and only one set of quality control results were documented on the logs.

a. On 5/29/14, the Lab Log Cover Sheet: EldonCard Rh test form listed Eldon Cards lot numbers 13431 and 13201 in use. The Rh Controls section of the log listed only 1 result for the positive control and 1 result for the negative control. There was also no documentation to indicate which one of the two lot numbers of Eldon Cards had quality control testing performed.

b. On 7/31/14, the Lab Log Cover Sheet:

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
34D0239689

(Y2) Multiple Construction
A. Building
B. Wing

(Y3) Date of Revisit
9/26/2014

Name of Facility
PLANNED PARENTHOOD OF CENTRAL NC

Street Address, City, State, Zip Code
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 Correction Completed	(Y4) Item	(Y5) Date Correction Completed	(Y4) Item	(Y5) Date Correction Completed
ID Prefix D5415 Reg. # 493.1252(c) LSC	09/13/2014	ID Prefix D6072 Reg. # 493.1425(b)(3) LSC	09/13/2014	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	Date:	Signature of Surveyor: Christine McDougherty	Date: 9/26/14
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on:
8/11/2014

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

PLANNED PARENTHOOD SOUTH ATLANTIC **CCN:** 34D0239689

Specialties / Subspecialties

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

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

Level of Reqt	Tag #	Requirement	Plan/Date of Correction	Status of Deficiency	Providers Not Meeting Requirements: State #	State %	Region #	Region %	Nation #	Nation %
STD	D5415	TEST SYSTEMS, EQUIPMENT, Specialties: 510	09/13/2014	Corrected	4	0.7	23	0.4	233	1.3
STD	D5805	TEST REPORT Specialties: 510	08/28/2014	Corrected	45	8.3	128	2.7	732	4.2
STD	D6072	TESTING PERSONNEL RESPONSIBILITIES	09/13/2014	Corrected	12	2.2	16	0.3	127	0.7

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

PLANNED PARENTHOOD SOUTH ATLANTIC CCN: 34D0239689

Deficiency Summary

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 Flag (Includes COPs)	0	0	1	1
Health Total	3	3	10	3

Status of COPs
Current Survey

	Deficiency not Corrected	Deficiency Corrected	Deficiency Corrected After Approval (L33)	Repeat COP Deficiency
COP	0	0	0	0

Complaint Survey Information

Survey Date	Status	Allegations	Allegation Status

No complaint surveys for this provider.

Enforcement Survey Information

Survey Date	Status

No enforcement surveys for this provider.

Survey Team Summary

Prior 3 Survey 09/2008	Prior 2 Survey 08/2010	Prior 1 Survey 10/2012	Current Survey 08/11/2014	670 Surveyor Team	Surveyor ID Number Prior 3 Survey 09/2008	Prior 2 Survey 08/2010	Prior 1 Survey 10/2012	Current Survey 08/11/2014
1	1	1	1	LABORATORIAN	12104	19613	19613	19613
1	1	1	1	Total Surveyors Onsite				

PLANNED PARENTHOOD SOUTH ATLANTIC CCN: 34D0239689

Proficiency Testing Scores

Routine Scores

Analyte	Current Program	2014 Event 1 Score	2014 Event 2 Score	2014 Event 3 Score	2015 Event 1 Score	2015 Event 2 Score	2015 Event 3 Score	2016 Event 1 Score	2016 Event 2 Score	2016 Event 3 Score
0860 ABO/RHO	3	100	100	100	100	100	100	100	100	
0875 D (RHO)	3	100	100	100	100	100	100	100	100	

Nonroutine

Analyte	Year	Cutoff Date	Score

No nonroutine scores found for this provider.

* = Unsatisfactory Scores

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
		X		N/E	STD		D5411-TEST SYSTEMS, EQUIPMENT, INSTRUMENTS,
			X C Specialties: 510	09/13/2014	STD		D5415-TEST SYSTEMS, EQUIPMENT, INSTRUMENTS,
	X	X		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	X C Specialties: 510	08/28/2014	STD		D5805-TEST REPORT
	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

PLANNED PARENTHOOD SOUTH ATLANTIC CCN: 34D0239689

Certificate History

PENDING Certificate - App Type: 1 COMPLIANCE

Certificate Type	Exempt	Eff Date	Exp Date	Term
1 COMPLIANCE	00	02/02/2017	02/01/2019	00

CURRENT Certificate - App Type: 1 COMPLIANCE

Certificate Type	Exempt	Eff Date	Exp Date	Term
1 COMPLIANCE	00	02/02/2015	02/01/2017	00

HISTORY Certificate

Certificate Type	Exempt	Eff Date	Exp Date	Term
1 COMPLIANCE	00	02/02/2013	02/01/2015	00
1 COMPLIANCE	00	02/02/2011	02/01/2013	00
1 COMPLIANCE	00	02/02/2009	02/01/2011	00
1 COMPLIANCE	00	02/02/2007	02/01/2009	00
1 COMPLIANCE	00	02/02/2005	02/01/2007	00
1 COMPLIANCE	00	02/02/2003	02/01/2005	00
1 COMPLIANCE	00	02/02/2001	02/01/2003	00
1 COMPLIANCE	00	02/02/1999	02/01/2001	00
9 REGISTRATION	00	11/14/1998	02/01/1999	00
4 PPM	00	03/14/1997	11/13/1998	00

Compliance Paid: Y Certificate Paid:

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34D0239689	A. BUILDING _____ B. WING _____	08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

(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
D5805	Continued From page 1 location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on random review of patient charts and staff interview 8/11/14, the laboratory's test report did not indicate the name and address of the laboratory location where the Rh (Rhesus) D testing was performed in 1 of 4 charts (chart #69702) reviewed. Review of 4 patient charts revealed Rh(D) testing results are recorded on the medication notes form in each chart. The medication notes form list the name and address of the laboratory and the name and address of two associated facilities across the top of the page. The medication notes form from the visit on 6/12/14 for patient #69702 did not indicate which of the three facilities performed the Rh(D) testing. During interview at approximately 2:00 p.m. the Vice President of Patient Services verified the testing personnel had not documented the facility where testing was performed for patient #69702. This deficiency was previously cited on 10/13/10 and 10/2/12.	D5805		
D6072	493.1425(b)(3) TESTING PERSONNEL RESPONSIBILITIES	D6072		8/14/14

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34D0239689	A. BUILDING _____ B. WING _____	08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

(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
D6072	Continued From page 3 EldonCard Rh test form listed Eldon Cards lot numbers 14111 and 13431 in use. The Rh Controls section of the log listed only 1 result for the positive control and 1 result for the negative control. There was also no documentation to indicate which one of the two lot numbers of Eldon Cards had quality control testing performed.	D6072	(Cont'd from page 3) we do not have reason to suspect that patients were impacted by these document. Annual training of quality control testing and documentation of Eldon Cards for staff will continue with emphasis on quality control testing and documentation. The Health Center Manager will regularly review the lab logs for accurate and complete control testing and documentation.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34D0239689	A. BUILDING _____ B. WING _____	08/11/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF CENTRAL NC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

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D5805	Continued From page 1 location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on random review of patient charts and staff interview 8/11/14, the laboratory's test report did not indicate the name and address of the laboratory location where the Rh (Rhesus) D testing was performed in 1 of 4 charts (chart #69702) reviewed. Review of 4 patient charts revealed Rh(D) testing results are recorded on the medication notes form in each chart. The medication notes form list the name and address of the laboratory and the name and address of two associated facilities across the top of the page. The medication notes form from the visit on 6/12/14 for patient #69702 did not indicate which of the three facilities performed the Rh(D) testing. During interview at approximately 2:00 p.m. the Vice President of Patient Services verified the testing personnel had not documented the facility where testing was performed for patient #69702. This deficiency was previously cited on 10/13/10 and 10/2/12.	D5805	(Cont'd from page 1) This training included retraining on documenting the following requirements: i. Tests results must be recorded on a form that includes the name and address of the testing site/lab. ii. Medication notes form documentation must include indication of which health center facility performed the tests/procedures. Patient health and safety was not impacted due to this lack of documentation because the remainder of the visit forms denotes the location of services. Annual training of required identifying information of test results for staff will continue with emphasis on complete and accurate documentation. The health center manager will audit a random sampling of charts by August 30, 2014 to ensure that this issue has been resolved. In addition, we are moving to Electronic Health Records in late October. (cont'd on page 3)	
D6072	493.1425(b)(3) TESTING PERSONNEL RESPONSIBILITIES	D6072		

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
34D0239689	A. Building B. Wing	9/15/2014

Name of Facility	Street Address, City, State, Zip Code
PLANNED PARENTHOOD OF CENTRAL 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 Correction Completed	(Y4) Item	(Y5) Date Correction Completed	(Y4) Item	(Y5) Date Correction Completed
ID Prefix **D5805** Reg. # **493.1291(c)** LSC	**08/28/2014**	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**	**Date:**	**Signature of Surveyor:** Christine M Daugherty	**Date:** 9/15/14
Reviewed By CMS RO	**Reviewed By**	**Date:**	**Signature of Surveyor:**	**Date:**

Followup to Survey Completed on: 8/11/2014

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34D0239689	A. BUILDING _____ B. WING _____	01/18/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD SOUTH ATLANTIC	1765 DOBBINS DRIVE CHAPEL HILL, NC 27515

(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
D 000	INITIAL COMMENTS The Planned Parenthood South Atlantic Chapel Hill laboratory was found in compliance with 42 CFR Part 493 Requirements for Laboratories as a result of an on-site survey performed on 1/18/17.	D 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | 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.

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
www.ncdhhs.gov/dhsr
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