Timeline for Case 2013-10493

Label Value Respondent:

Credential:

Planned Parenthood of the Great Northwest

MTSC.FS.00000038

Profession: Created:

Medical Test Site Categorized License

12/10/2013 03/05/2014

Closed:

Alleged Issues:

Breach of Confidentiality Failure to Maintain Records or Provide Medical, Financial, Other Required Information

Patient Rights

Case Nature:

Standard of Care/Services

Found Issues:

None

Resolutions: Evidence does not support a violation

Timeline Detail	Start	End	Days Used	
OPENED	12/06/2013	12/10/2013	4	
Intake	12/10/2013	12/10/2013	0	
Assessment .	12/10/2013	12/17/2013	7	
Investigation	12/17/2013	. 01/09/2014	23 ·	
Case Disposition	01/09/2014	03/05/2014	55	
CLOSED	03/05/2014		1	

Timetine Summary	Auth Days	Extend Days	Days Used	Days Remain
OPENED	0	0	4	-4
Intake	7	0	0	7
Assessment	14	0 .	7	7
Investigation	170	0	23	147
Case Disposition	140	0	55	85
CLOSED	0	0	1	-1
		Total	en	

	Parent of Salse Dispositi	ion Worksheet		
Respondent:	Profession:	Number: 2013	10492 Section:	
Presented by: N/A	Staff Attorney: Pre-Assigned or Reques	ted (circle one) ¹	Staff present a	ut B/C Disposition: <u>No</u>
involved. (It is recommended to a panel authorization for investigation for investigation).	ses, panel should refer sexual mis o make this referral only after inve	conduct cases to the estigation, however, a not refer.	Secretary whe	en there are no clinical issues
Authorized by Panel Chair: Print Name of Panel Chair:	Reviewing Commission (if applicable)			
A. REQUEST FOR L Summary Action: Suspension Statement of Charges: Statement of Allegation Notice of Correction: Notice of Determination Withdrawal of SOC:	☐ Practice Restrictions	,	ompliance: ompliance:	Release from STID Release from Order Referral to Collection Agend Authorization for Fast Track
Or	(12) Practice beyond (13) Misrepresent (14) Failure to sup (15) Public health draw (16) Unnecessary drugs (17) Criminal converse (18) Criminal abore Relevant State or Federal	petting ules ond scope ation or fraud pervise risk or inefficacious viction tion Law:	☐ (19) Tre ☐ (20) Bef ☐ (21) Re ☐ (22) Inte ☐ (23) Cu ☐ (24) Seg ☐ (25) Acce	eating by secret methods trayal of patient privilege bating erference w/ investigation rrent drug/alcohol misuse xual contact/patient abuse eptance of more than ominal gratuity
RCW 18.130 .170: B. /FILE CLOSED:	Mental Impairment	☐Physical Imp	airment	
☐ No Jurisdiction	No violation at the time the event occurred	Conduct was with of practice	in standard	☐ No violation determined
Evidence does not support a violation	Risk minimal, not likely to reoccur	Mistaken identity		Care rendered was within standard of care
☐ Insufficient evidence ☐ Application Investigation Only- No Action to Deny	Complainant withdrew	☐ No Whistleblower		Complaint unique closure
Further explanation (if any) C. OTHER, EXPLAIN	: N (Legal Review, Return to	o Investigation, e	etc.):	

¹ Program may request a specific staff attorney who has prior experience with the file or the Respondent. PLANNED PARENTHOOD 2013-10493FS PAGE 2

FORM 1-2-0/2/4 Flanne de Ministery Assessment Worksheet Respondent: of the Gual NW Case Number: 2013- 10493 Facility Type: M TX Board/Commission/Profession: Presented by: Tammy Kelley Staff present: ☐ Conference Call ☐ Board/Commission/CMT meeting Panel members: Tammy K Barb R John H ☐ Deb F ☐ Shannon W Marlee O ☐ Byron P Kirby P ☐ Tim T FILE CLOSED: ☐ BT- No violation at the □ BT- No Jurisdiction BT- Advertising that is a ■ BT- Communication and time the event occurred technical violation personality issues ■ BT- Aged or outdated ☐ BT- Risk minimal, not ■ BT- Lack of complaint ☐ BT- Complainant complaints likely to reoccur credibility withdrew BT- No complainant's or BT- Billing and fee ☐ BT- Practice on an BT - Insufficient client/patient's name and no disputes except as designated expired credential for a period information allegations of significant harm by disciplining authority of time accepted by the or potential harm disciplining authority BT- Profession-specific BT- Issues which have ☐ BT- If allegations are true. BT- Referral to another no violation of law occurred threshold. been otherwise resolved. program or agency. Explain:__ Explain resolution: ■ BT- Incident reported by facility a) Violating confidentiality Inappropriate delegation b) c) Failure to supervise Isolated incidents d) (detail corrective action: practitioner is already revoked; ongoing monitoring, etc.) В. Investigation of the complaint is authorized. Additional Instructions to investigator: Initiate investigation and obtain relevant records, including patient records. Authorized by Panel Chair/CMgr: Print Name of Panel Chair/CMgr: ___ Per Program Staff (initials) Reviewing Commission Member (if applicable) (if applicable) Date investigation authorized: Professions Facilities Recommended priority: (risk of immediate danger) # of days) \Box A # of days) (serious risk) □ B (moderate risk) # of days) # of days) \Box **D** (minor risk) # of days) (technical violations) \Box **E** SEXUAL MISCONDUCT CASES C. For Board and Commission cases, panel should refer sexual misconduct cases to the Secretary when the case does not involve clinical expertise or standard of care issues. (Note: any pre-investigation referral should still include a panel authorization for investigation.) Panel finds there are clinical issues, do not refer. \Box No clinical issues, refer case to Secretary

COMPLAINT INTAKE SUMMARY WORKSHEET

RESPONDENT INFORMATION

Name &	Planne	d Paren	thood of the Gr	eat NW C	entral	Case #	2013-1049	3(FS)MTSC
Address	Region				Allegation	Breach of	Confidentiality	
	Labora 2001 E	Planned Parenthood of the Great Northwest Laboratory Director 2001 E Madison St Seattle, WA 98122-2959					or Provide	Other Required n
	Ocallic	Seattle, VVA 90122-2939				License #	-	000000038
						Issued		
							06/30/201	5
Phone #						Status	Active	
Legal Action	Yes No Compliance Yes No					Cases	Open:	Closed:

COMPLAINANT INFORMATION

Name & Address	1 - Name - Whistleblower Regarding Health Care P	to the contract of the contrac	
		5 1.4	· ·
Phone #	1 - Name - Whistleblower Reg	E-Mail E-Mail	·

SUMMARY OF COMPLAINT

The complainant alleges that on 11/15/13 went to the clinic for STD testing including HIV/herpes blood test but after leaving realized that the blood test hadn't been done. On 11/21/13 the complainant received a call informing her that she tested positive for herpes but complainant informed the caller that it must be someone else diagnosis since her blood was never drawn. On 11/25/13 the complainant managed to talk to a manager, who informed her that she hadn't been informed about the incident.

S:\HSQA\CSO\ComplaintIntake\Facilities -\Case Summarys\2013\12 - December\Planned Parenthood of the Great NW Central Region\2013-10493(FS) MTSC.doc

Case Status	2013-10493 (PUBLIC: Internal) Assessment	Date Created Date Received	12/10/2013 12/06/2013	Audit Entry Items
Respondent ID Respondent Credential Address	Planned Parenthood of the Great Northwest MTSC.FS.00000038 Planned Parenthood of the Great NW Central Region Planned Parenthood of the Great NW Central Region Planned Parenthood of the Great NW Central Region Planned Parenthood of the Great Northwest Laboratory Director 2001 E Madison St Seattle, WA 98122-2959	How Received Receiving Board Receiving Profession Receiving Department Received By Alleged Issues Breach of Confidentiali Failure to Maintain Rec Other Required Inform Patient Rights Case Nature Standard of Care/Serv	cords or Provide Medical, Financial, ation	Notes Master Ca Participan Timeline I
Complainant ID Complainant	11n8949 1 - Name - Whistleblower R			<u></u>

Comments:

- Action ItemsResolution

- Participants
 Priority History
 HIPDB Reports
 TimeTracker

	[add] [add group] Assigned To	Activity	Track Time	Due	Effective	Completed	Order Signed	Created ▼
Present for	Case Management,		[add]		12/10/2013			12/10/2013
Assessment	Kelley, Tammy							
	Planned Parenthood of th	e Great No	rthwest, M	TSC.FS.	00000038			
Case Status:	Status Changed To:	Assessme	ent					
■ Intake	Case Intake, Brown,		[add]		12/10/2013	12/10/2013	•	12/10/2013
	Angel							
Target:	Planned Parenthood of th	e Great No	rthwest, M	TSC.FS.	00000038			
Warning:	Warning Type:	CASE PE	NDING					
	Warning Effective Date:	12/10/201	3					
	Suppress License Print:	NO		. ;				
	Warning:	2013-104	93					
Case Status:	Status Changed To:	Intake						
Action Info:	Complaint Source	Patient/Cl	lient/Reside	ent				
	Possible Imminent Danger?	No		'.	•			
	Single Complaint				ear yy S			
	Process Coordination	No						
	Needed?							
Comments:	The complainant alleges	that on 11/	15/13 went	to the cl	inic for STD tes	ting including HI\	//herpes blo	od test but after
	leaving realized that the t	plood test h	adn't been	done. O	n 11/21/13 the d	complainant rece	ived a call in	forming her that she
	tested positive for herpes	but compla	ainant infor	med the	caller that it mu	st be someone e	lse diagnosi:	s since her blood
	was never drawn. On 11/	25/13 the c	omplainant	t manage	ed to talk to a m	anager, who info	rmed her tha	it she hadn't been
	informed about the incide	nt.			,			

: {

Contact

Enforcemen

Cont. Edu

Audit

Credential View Screen

Planned Parenthood of the Great Northwest Address:

🗘 Public 🔎 Mail

Planned Parenthood of the Great NW Central Region Planned Parenthood of the Great Northwest

Laboratory Director 2001 E Madison St Seattle, WA 98122-2959 ID Warnings SSN/FEIN

CASE PENDING Federal ID

Secretary Of StateNumber 578040516 Contact Standing Contact Type

Public File .. Mailing List US Citizen ... 910686012

844360

50D0663561 In-Business **ORGANIZATION** YES

Documents Owners Owned By/k Exams Experience Notes Schools Librarian Application Other State

Online Inform

Comments:

Medical Test Site Categorized License [form letter]

Credential #

MTSC.FS.00000038 MTS-0038

Legacy License # Application Date

Effective Date 07/01/2013 **Expiration Date** 06/30/2015

First Issuance Date Last Date Of Contact

Next Examinations Date 02/28/2015

Credential Status Status Reason **Amount Due**

Date Last Activity Last Updated by Certificate Sent Date **ACTIVE (04/15/2013)** ACTIVE

\$0.00 4/15/2013 12:04:02 PM

Stewart, Kevin 04/15/2013

Audit : **Documents** Verification Workflow Key Mgmt Fees Notes **Print Docs** Comp. Audit Renewal Legacy Medical Testir

License Status

Comments: Forks closed 11/30/11, Silverdale closing 12/31/11, Oak Harbor closing 12/31/11, per email 12/12/11.

- User Defined License Data
- Workflow
- Legacy

User Definable License Data

Field

Value

Medical Test Site Type Community Clinic

Multiple Sites

Yes

Lab Director

Michael Romo MS MT

Lab Contact

Michael Romo

Lab Contact Email

michael.romo@ppgnw.org 206-328-6815

Lab Phone Number

Lab Fax Number

[update]

Field **Medical Test Site Region**

MTS Category

Region 2 Category A

Value

MTS Lab Testing Personnel 1

ARNP

MTS Lab Testing Personnel Quantity 1 1

MTS Lab Testing Personnel 2

On Job Training

MTS Lab Testing Personnel Quantity 2 9

Legacy Action -LQA Legacy Personnel-LQA Legacy Revenue - LQA



STATE OF WASHINGTON DEPARTMENT OF HEALTH

March 06, 2014

1 - Name - Whistleblower Regarding Health Care Prov...

Subject: Case No: 2013-10493

Dear 1 - Name - Whistleblower Regar...

Thank you for submitting your concern about Planned Parenthood of the Great Northwest.

Based on the information provided, we investigated your complaint. We issued a report of our findings to the facility. The complaint was unsubstantiated; the evidence does not support a violation.

You have the right to request any information contained in the file. You may submit a written request for a copy to the Department of Health, Public Disclosure & Records Center, PO Box 47865, Olympia, WA 98504-7865, by fax to (360) 586-2171, or by email pdrc@doh.wa.gov.

If you have questions, please contact us at (360) 236-2620 or email us at hsqacomplaintintake@doh.wa.gov.

Thank you for bringing this matter to our attention.

Sincerely,

Brandy L Boczar

Office of Customer Service

Complaint Intake Unit





WASHINGTON STATE DESARTMENT OF HEALTH OFFICE OF LABORATORY OLFALITY ASSURANCE 20425 72nd AVENUE SOUTH, SUITE 310 KENT, WA 98032

COMPLAINT INVESTIGATION REPORT

COMPLAINT # 13-20

Initial Contact Date	Priority Level: 3	ILRS# 2013-10493				
12/17/13						
Complainant's Name:	Laboratory: MTSC-0038					
1 - Name - Whistleblower Regar	CLIA -5	50D0663561				
	Accrediting Org -					
Address:	Name: Planned Parenthood of the Grea					
	Central Region					
1 - Name - Whistleblower Regarding He	Address: 2001 E Madison Street, Seattle, WA					
·	98122-2959					
Phone #	Director: Michael Ro	mo, MS, MT				
1 - Name - Whistleblower Re	Lab Contact:					
	Phone #					
Receiver's Name:	206-328-6815	Í				
Tammy Kelley/Susan Walker						

DESCRIPTION OF COMPLAINT

12/17/13- Tammy Kelley received a complaint and forwarded to Susan Walker.

We just received this case regarding Planned Parenthood, MTSC00000038. Can you please take a look at it and let me know your thoughts. Thanks!

The complainant alleges that on 11/15/13 went to the clinic for STD testing including HIV/herpes blood test but after leaving realized that the blood test hadn't been done. On 11/21/13 the complainant received a call informing her that she tested positive for herpes but complainant informed the caller that it must be someone else diagnosis since her blood was never drawn. On 11/25/13 the complainant managed to talk to a manager, who informed her that she hadn't been informed about the incident./lp

ACTION TAKEN

12/17/13 – Susan Walker requested more information such as complainant's name and which location did she have her testing performed. Complainant's information was entered into ILRS and the address of the clinic was 9641 28th Avenue SW in Seattle. Susan will contact the laboratory director and get additional information and will try to do a paper investigation../lp



Planned Parenthood of the Great WW Central Regio December 17, 2013 Page 2



12/31/13: I contacted Michael Romo today with the confidence of the clinic manager of gone until January 6th and he would garband to the Christopher Carlot and the clinic manager of the confidence of the conf

1/8/14: I got this email message from Michael Romo today. He is working on the complaint. He said that the complainant had gotten another HSV done by another lab and it came back negative. SW

I just met with LabCorp and they will run a report of all STD, HIV, and herpes ordered that day. Small clinic so should only be a couple. Then will have clinic check health records of those patients and all others if necessary that were seen that day to rule out if a printed label for the complainant wad placed on another patient's sample.

If patient is certain she did not have blood drawn (I have seen instances where patient did not remember) will find out if she was asked to come in for a redraw. LabCorp will do her test at no charge and GNW will also not charge any fees.

I know Kirsten is in meetings all day and Annelise may be as well. Still no reply to email so left voice messages.

1/9/14: The lab completed their complaint investigation and these are their findings.

We have completed our investigation of the complaint alleging no blood sample was taken at PPGNW's West Seattle Health Center but positive HSV results were reported to the patient.

The Health Center Manager, Annelise Ring, has interviewed the clinician who examined the patient and ordered STD screening tests including HSV. She also interviewed the phlebotomist who performed all blood draws on November 15, 2013 the day of the complainant's visit. All records in the electronic medical record as well as paper logs for tests ordered that day were also reviewed and compared with shipping and receipt documents at LabCorp.

On November 15 there were six samples collected and sent to LabCorp. Four were blood samples for STD screening including HSV testing. Four results matching each patient, including the complainant were received and reported to the centralized follow-up nurse who contacted and informed the patient of her results on November 25, 2013. HSV 1/2, IgM by EIA screening results are reported as a numerical ratio rather than clearly positive or negative. The reference intervals from LabCorp are:

- Negative: <0.91

- Equivocal: 0.91-1.09

Page 3

Positive: >1.09



The patients HSV 1 result was 2.73 and her HSV 2 result was 1.84. Documentation in the medical record shows she was encouraged to return for follow up testing in a few weeks. Here are the comments from Anna Alston, ARNP, Assistant Director of Clinician Services:

Hi- below is a response I sent to the West Seattle clinician today, who I assume was following up on the referenced patient complaint. It is a summary of the limitations of HSV testing, and low positive results. Our follow up RNs generally follow a standard script for STI notification, which includes: Causative agent, common symptoms, prevention of transmission, management of partners, and long term management options. This is also documented in the medical record. Please let me know if you need additional or clarifying information.

"As I sign off abnormal lab notification in WA and ID, I can confirm that the follow up RNs do include this information in their counseling points. My thoughts:

- There is quite a bit of evidence that ELISA results between 1.1 and 3.5 may be "falsely reactive".
 We know this can be caused by cross-reactivity with other herpes viruses, but there is also evidence that some individuals "live in a low range", particularly those who have been seropositive for many years.
- LabCorp reports 0.91-1.09 as equivocal, and >1.09 as positive. It is not incorrect to notify patients >1.09 that their <u>result</u> was positive, even if we are recommending additional follow up.
- ELISAs often convert faster than Western Blot, so having patients return in 3 months is reasonable if there is any risk of convalescence.
- There is also some evidence that starting daily suppression (a common request) early may delay conversion.
- I believe HMC uses 3.0 instead of 3.5 as assumption of positivity, but that may be outdated.
- The "About STI Testing" handout does include general information that "not every test is 100% accurate" and that there are limitations of testing in the incubation period. Routine HSV is also not recommended by the CDC or USPSTF, so discussing the limitations of testing with patients is definitely recommended."

Conclusion:

During the course of the exam the patient told the clinician she was "very hung over" from her birthday party the night before. Six days elapsed between the date of her visit and being contacted by the follow-up RN with the results. We conclude she failed to recall having her blood drawn a week earlier due most likely to her condition during her visit to the West Seattle Health Center. All documentation and staff interviews indicate she is mistaken about not having a blood sample taken that day.

PPGNW and I are certain all specimen collection, processing, handling procedures were followed per written protocols. We are convinced an appropriate blood sample was collected from this patient, tested, and results reported. The patient was drawn in the exam room immediately after her examination. The name and date of birth shown

Planned Parenthood of the Great NW Central Region December 17, 2013

Page 4.

on preprinted sample labels resulting from orders clinician input into the computer were verbally confirmed with patient before samples were obtained. Her specimens were labeled while in the room using those labels. There was a 10 minute interval between this patient and those before and after who also had blood drawn. That rules out any possibility of mislabeling as all sample labels are applied to blood sample tubes immediately after drawing before the patient leaves the room.

However, every patient complaint is an opportunity for improvement. The clinician leadership is aware of this incident and may issue additional guidance on how these results are to be reported to insure complete patient understanding. Secondly the additional test she had performed by another provider producing a negative result may be due to a different test method, e.g. DNA PCR which detects presence of HSV as opposed to the LabCorp EIA test performed on this patient which detects antibodies to HSV or their lab may use a higher threshold, such as a ratio score of 3.0 or higher indicating HSV positive.

After being made aware of this issue the health center manager did write off all charges for this test and LabCorp has agreed to provide an additional test at no charge should the patient elect follow-up testing as recommended.

If you or the patient requires additional information please contact me and I will forward to the appropriate staff at PPGNW as needed.

We have concluded that the complaint was unsubstantiated and this completes this investigation. SW

Notice

The identity of a whistleblower who complains in good faith to the Department of Health about the improper quality of care by a health care provider or in a health care facility <u>shall remain</u> <u>confidential</u>.

RCW 43.70.075

Department of Health staff need to:

- Place this notice in the file with the complaint.
- Keep this notice in the file with the complaint when the case is closed.

WAC 246-15-030

Notice



RECEIVED

DEC 0 6 2013 HSQA - CSO

Complaint Form

Today's Date: 12 3 13	
1. Your Infc 1 - Name - Whistleblower Regarding Health Care Provider or Healt Name:	
Address: 1 - Name - Whistleblower Regarding Health Care Provi	
City: 1 - Name - Whistleblower Regarding Healt	State: 1 - Name - W Zip 1 - Name - Whistleblower
Phone: Work () Home 1 - Name - Whistleblower Reg	garding Healt
2. Information about the Facility or Health Care Profession Type of facility or profession: Planned Parenthood	onal Cuhic
Name of facility or professional: Planned Parentho	and what frattle
Address: 96128 Ave SW	2001 - 14621 - 2000
City: <u>Seattle</u>	State: WA Zip: 98
3. Resident/Guest/Patient Information	
Full Name (if different than above)	
Date of Birth (of patient, if complaint involves a patient) Date of incident: 11 15 13	1 - Name - Whistleblower Regardin
4. Please describe your complaint in the space below. Include other patients, witnesses or staff members involved in the Customer Service Center at HSQAComplaintIntake@doh to:	incident. Email completed form to the
Washington State Department of Health Health Systems Quality Assurance Complaint Intake P.O. Box 47857 Olympia WA 98504-7857	

Please attach any supporting documentation and additional sheets if necessary.

Il visited this clinic on 11/15 and requested STD terting, including HIV/herpes blood tests. after leaving, I realized my blood hadn't been drawn.

On 11/21, I received a call from Planned Parenthood (1P) informing me I tested positive for hopes tope 1 + 2. Often the realized the nurse was referencing a blood test I realized the nurse was referencing a blood test I referred PP that it must have received another prison's diagnosis, as my blood hadn't been drawn.

d was net with resistence and it was implied that d was bying out of fear.

on 11/25 il managed to speak with the clinic manager, ammaliese, who informed me she hadnit been informed about this incident. Il acked that she been informed about this incident. Il acked that she bollow-up with any information she could share.

Il want to make sure Planned Parenthoud delivers the correct diagnoss to the correct patient!

•	-	For Dep	artment o	of Health use o	nly			
Reviewed for multiple authority applications:	Date			Name		 		
Routed to: Multi-authority coordinator:						 date		
Office						 date	,	
Office						 date		
Office		_				date	· 	

Case File_327489_pdf-r.pdf redacted on: 1/29/2018 13:51

Redaction Summary (15 redactions)

1 Privilege / Exemption reason used:

1 -- "Name - Whistleblower Regarding Health Care Provider or Health Care Facility - RCW 43.70.075(1), RCW 42.56.070(1)" (15 instances)

Redacted pages:

Page 4, Name - Whistleblower Regarding Health Care Provider or Health Care Facility - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances

Page 5, Name - Whistleblower Regarding Health Care Provider or Health Care Facility - RCW 43.70.075(1), RCW 42.56.070(1), 1 instance

Page 7, Name - Whistleblower Regarding Health Care Provider or Health Care Facility - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances

Page 8, Name - Whistleblower Regarding Health Care Provider or Health Care Facility - RCW 43.70.075(1), RCW 42.56.070(1), 3 instances

Page 13, Name - Whistleblower Regarding Health Care Provider or Health Care Facility - RCW 43.70.075(1), RCW 42.56.070(1), 7 instances