Medical Test Site License Pre-Renewal Verification 2009

The following information for your facility is in our database. Please review, make changes if any, sign, and return this form to the Laboratory Quality Assurance office (address is on the back of this page) by February 20, 2009.

The signature of the owner or authorized representative is REQUIRED to process your MTSC license renewal.

Please sign where indicated on the reverse of this form.

Planned Parenthood of Western Washington Central MTSC.FS.00000038 Region

CLIA Number:

50D0663561

Tax ID Number:

910686012

Classification:

Phone:

(206) 328-6815

Fax:

(206) 720-4657 **328-4984**

Accreditation Agency (if accredited):

Site Address:

Mailing Address:

Karen Gunderson

4500 9th Ave NE Ste 324

2001 E Madison St

Seattle WA 98105-4778

Seattle WA 98122-2959

Multiple Site Addresses: (If applicable, please list the multiple sites for this credential on a separate piece of paper)

Personnel:

Owner:

Planned Parenthood of the Great Northwest

Lab Director:

MICHAEL ROMO MS MT(ASCP)

Lab Contact:

MICHAEL ROMO

michael.romo@ppww.org

Micro Contact:

Lab Cytology Contact:

Lab Consultant:

Lab Administrative Contact:

Approved Specialties:

Immunohematology ABO & Rh Typing

RCUD FFS19783 DOH-110

Please sign and return to the address below by February 20, 2009.

Laboratory Quality Assurance 1610 NE 150th Street Shoreline, WA 98155

PLEASE READ THE FOLLOWING CAREFULLY BEFORE SIGNING

As listed under RCW 70.42.160, any licensee who has knowingly, or with reason to know, made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department, may be assessed a monetary penalty of up to ten thousand dollars per violation, in addition to or in lieu of conditioning, suspending, or revoking a license.

l certify that the information included in this pre-renewal verification is accurate and complete.			
Signature of Owner/Authorized Representative of a Medical Test Site	 .	Date	

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Waived Tests (continued)	page 6
RSV (Respiratory Syncytial Virus Direct Antigen)	Meridian Diag. ImmunoCard STAT Strep A
Binax NOW RSV Test	MediLab Performance Strep A Twist Rapid Test
Fisher Scientific Sure-Vue RSV Test	Moore Medical Strep A Rapid Test - Dipstick/Cassette
Integrated Biotechnology Quick Lab RSV Test	Performance Enhanced Products Strep A Cassette, Dipstick
Meridian Bioscience Immunocard Stat! RSV Plus	PerMaxin Rediscreen Strep A Rapid/Strep A Twist Cassette
Quidel Quick Vue RSV Test	Polymedco Poly stat A (II), Strep A Liquid Test, Strep A Dipstick
Remel Xpect RSV	Princeton BioMediTech BioStrep A /Status First Strep A
SA Scientific SAS RSV Test/RSVAlert	PSS World Medical Strep A Dipstick/Twist
Wampole Laboratories Clearview RSV	Quidel QuickVue In-Line and Dipstick and In-Line One-step
Semen	RAC Medical Clarity Strep A Twist Rapid Test Device/Strip
Embryotech Laboratories FertilMARQ for male infertility	Remel RIM A.R.C. Strep A Test
Fertell Male Fertility Test	Sacks Medical Refuah Strep A Rapid Test
Fertility Solutions Semen Analysis (qualitative)	SA Scientific SAS Strep A
SpermCheck Vasectomy	Select Medical Products Brand Rapid Test Strep A Dipstick
Sodium	Select Medical Products Brand Rapid Test Strep A Twist
Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge	Signify Strep A Dipstick
Piccolo xpress & Blood Analyzers (CMP, BMP, lytes)	Stanbio Qustick Strep A, E-Z Well Strep A Rapid Test
	Wyntek Diag. OSOM Strep A and OSOM Ultra Strep A Test
Strep Antigen Test	Trichomonas
Abbott Signify Strep A Test / Dipstick	Genzyme Osom Trichomonas Rapid Test
ACON Strep A Rapid, Strep A Twist Rapid, and ICON DS	Triglycerides
Applied Biotech SureStep Strep A (II)/Strep A Exact	
Beckman Coulter ICON Fx (formerly SmithKline)	Arkray SPOTCHEM EZ Chem Analyzer (WB)
Beckman Coulter Primary Care Diag. DS, FX, and SC	Cholestech LDX
Becton Dickinson LINK 2/Chek Strep A Rapid test	Piccolo POC/xpressAnalyzer (Lipid Panel/Plus)
Binax NOW Strep A Test	Polymer Tech . Systems Bioscanner, Bioscanner Plus, & 2000
BioStar Acceava TM Strep A Test	Polymer Tech. Systems Cardiochek and Cardiochek PA
Biotechnostix Rapid Resp. Strep A Rapid Test Device/Strip	Wako APOLOWAKO Analyzer (WB)
Cardinal Health CP Brand Rapid Test Dipstick/Cassette	TSH
Clearview Strep A Exact Dipstick	Jant Pharmacal Corp Accutest TSH (WB)
DE Healthcare Products, TruView Strep A Test/Cassette	Little Nell Labs ThyroChek TSH (WB)
Diagnostic Test Group Clarity Strep A Rapid Test Strips	Qualigen Inc FastCheck TSH (WB)
Fisher HealthCare Sure-Vue Strep A	ThyroTest Whole Blood TSH Test (WB)
Genzyme Contrast Strep A and OSOM Ultra Strep A	Uric Acid
Germaine Laboratories Strep AIM Rapid Dipstick Test	Piccolo xpress & Blood Chem Analyzers (chem 13)WB
Germaine Laboratories Strep AIM Tower	Urinalysis
Henry Schein Inc, One Step+ Strep A Test, Strep A Dipstick	X Urinalysis: Dipstick or tablet reagent (nonautomated)
Immunostics Immuno/Strep A Detector, Strep A Direct	Acon Lab. Mission UTI Urinary Tract Infection Test Strips
Instant Technologies Istrep Strep A Test	Bayer Clinitek 50/Status Urine Chemistry Analyzers
Inverness Medical BioStar Acceava Strep A Test/Twist	Biosys Laboratories Optima/Optima II Urine Analyzer
Inverness Medical Clearview Strep A Exact II Dipstick	Consult diagnostics Urine Analyzer
Jant Pharm. AccuStrip Strep A (II), Accutest Integrated Strep A	Henry Schein OneStepPlus Urine Analyzer
Rapid Test, Clinipak Rapid Test Strip, Value+ Test,	Hypoguard Diascreen 50 Urine Chemistry Analyzer
Laboratory Supply Co PEP Strep A Cassette, Dipstick	PSS Select Urine Analyzer
LifeSign LLC Status Strep A	Roche/BMC Mini UA and Chemstrip 101 Urine Analyzer
Mainline Confirms Strep A Dots test	Roche Diagnotics Urisys 1100 Urine Analyzer
McKesson Strep A Medi-lab Performance Dipstick/Cassette/	Teco Diagnostics URITEK TC-101 Urine Strip Reader
Strep A Test - Twist	ThermoBiostar PocketChem UA
- F	
Provider-Performed Microscopic Procedures (PPMP)	
These tests can only be performed in your office by an MD, DC), DPM, ARNP, nurse midwife, PA, naturopath, or dentist.
If these tests are performed by any other personnel in your offic	ee, fill out page 7 of this application.
Check all that apply	
\(\frac{\text{\tint{\text{\tinit}}\\ \text{\tex{\tex	Post-coital direct, qualitative examinations of vaginal or
of bacteria, fungi, parasites, and human cellular elements	cervical mucous
_ Fecal leukocyte examinations	Y Potassium hydroxide (KOH) preparations
Fern tests	Qualitative semen analysis (limited to the presence/absence
Nasal Smears for granulocytes	of sperm and detection of motility)
Pinworm examinations	Y Urine sediment examinations

Place a checkmark by all the non-waived and non-PPMP tests that are performed at your medical test site. If the tests that you perform are not listed on the checklist, list them under the appropriate specialty/subspecialty. For volumes include the yearly estimate of the number of tests performed. Attach additional sheets if needed.

	Total Volume	Parasitology (continued)	
Microscopic Procedures		Concentrate/Stain	
(If the following microscopic tests are ONLY		Parasitic Antigens	
done by the provider, DO NOT complete this			Total Volume
section. See page 6 - PPMP)		Virology	
Wet Mounts		Herpes Antigen	
Fecal Leukocytes		Herpes Culture	
КОН		Other Viral Cultures	
Pinworm		Viral Antigen Detection	
Post Coital Vaginal Mucous Exam		HPV	
Fern Tests		Influenza (nonwaived kits)	
Qualitative Semen Analysis (post vas)		RSV (nonwaived kits)	
Quantitative Semen Analysis		Other (list)	
Urine Sediment			Total Volume
Nasal Smear for Granulocytes		Syphilis Serology	
	Total Volume	RPR	
Histocompatability			
Transplant		MHA-TP (TP-PA)	
Nontransplant		FTA	
(list specific tests)			Total Volume
· -	Total Volume	Gen. Immunology	
Bacteriology		Allergy Testing (count individual allerg	rens tested)
Affirm VP (TV, GV, YST)		Alpha-1 Antitrypsin	gens tested)
Antibiotic Sensitivities		AFP/Tumor	
Bacterial Antigens		AFP/Other	
Clostridium difficile		ANA	
Group A Strep (Rapid test - nonwaived	kits)	ASO	
Group B Strep	•	HIV	
Blood Culture		C3	
Chlamydia		C4	
CSF Culture		HBsAg	
Gram Stain		Anti-HBc	
GC		HBeAg	
Throat Culture		HCV	
Urine Culture		Anti-HCV	
Urine Colony Count		IgA	
Other Culture/ID		$\mathbf{I}_{\mathbf{G}}$	
	Total Volume	IgE	
Mycobacteriology		IgM	
AFB Smear Only		Infectious Mononucleosis (nonwaive	d kits)
AFB Smear/Culture		Rheumatoid Factor	
AFB Antibiotic Sensitivities		H. pylori (nonwaived kits)	
AFB Culture & ID		Rubella Antibody	
	Total Volume	Protein Electrophoresis	
Mycology		Other (list)	
DTM Only			Total Volume
Culture (Growth/No Growth)	ì	Routine Chemistry	
Fungus		ALT/SGPT	
Yeast		Albumin	
Culture and ID		Alkaline Phosphatase	NOTE: Each measured
Fungus	•	Amulaca	parameter must be
Yeast		AST/SGOT	counted as a separate
	Total Volume	min dom, rotal rotal	test, added together,
Parasitology		ph (blood gas)	and included in the Routine Chemistry total
Direct Smear		n() (blood cos)	volume above.

Non-Waived Tests (continu	page 8
Routine Chemistry (continued)	Toxicology (continued)
pCO, (blood gas)	Quinidine
Calcium, Total	Theophylline
Carbon Dioxide	Tobramycin
Chloride	Valproic Acid
Cholesterol, Total	Drugs of Abuse (urine)
HDL Cholesterol	Other (list)
Creatine Kinase	Total Volume
CK Isoenzymes	Hematology
Creatinine	Cell Identification/Manual Differential
Glucose	Cen Identification/ivianual Differential
Glycohemoglobin (Hgb A ₁ C or equivalent)	CBC (Complete Blood Count): NOTE: Each measured
Iron, Total	parameter (automated dif-
LDH	RBC Automated WBC Differential ferential, RBC, hematocrit (or MCV), hemoglobin,
LDH Isoenzymes	Hematocrit (or the v), Hemoglobin, WBC, platelets) must be
Magnesium	Hemoglobin counted as a separate
Potassium	test, added together, and
Sodium	Platelet Count included in the Hematol- ogy total volume above.
Total Protein	Flatelet Count ogy total volume above.
Triglycerides	Reticulocyte Count
Urea Nitrogen (BUN)	Hemoglobin Electrophoresis
Uric Acid	Flow Cytometry
CEA	Other (list)
Chalinesterase: RBC methodology	Total Volume
plasma/serum methodology	Coagulation
CRP/HSCRP	Fibrinogen
Ferritin	PTT
GGT	Prothrombin Time
Phosphorus	Thrombin Time
· ·	Factor Assays
Myoglobin	Activated Clotting Time
Troponin BNP	D-dimer
Other (list)	Other (list)
l ` ' '	olume Total Volume
·	Immunohematology
Urinalysis	Antibody Detection (Screen)
Strip by nonwaived instrument	A P.O. Crown
	ABO Group X D (Rh) Typing
Endocrinology	ABO Group ABO Group D (Rh) Typing Antibody Identification Compatibility Test (Crossmatch) Other (list) Total Volume
Cortisol	Compatibility Test (Crossmatch)
Free Thyroxine	Other (list)
HCG (Serum Pregnancy or nonwaived urine HCG)	Total Volume
T3 Uptake	Pothology Total Volume
T3 (Triiodothyronine) Estradiol	Pathology \\
TSH FSH	Histopathology Democratical and the leave
Thyroxine Luteinizing Horn	Dermatopathology
Progesterone Progesterone	Oral Pathology
Other (list)	Cytology
	olume (add HPV testing under Virology)
Toxicology	Total Volume
Alcohol, Blood	Radiobioassay
Blood Lead	(list in vitro tests, i.e. blood volume by
Carbamazepine	Cr 51, Schilling test, etc.)
Digoxin	Do NOT include routine RIA tests
Ethosuximide	Total Volume
Gentamicin	Genetic Testing
Lithium	Biochemical Genetic Tests (list tests)
Phenobarbital	Cytogenetic Tests (list tests)
Phenytoin	Molecular Genetic Tests (list tests)
Primidone	(add HPV testing under Virology)
Procainamide/metabolites	(add Chlamydia and/or GC testing under Bacteriology)



Medical Test Site License Washington Department of Health

License Number: MTS-0038 CLIA Number: 50D0663561

License Type: Category A

Expires: 6/30/2009

Primary Site:

University District Clinic 4500 9th Ave NE STE

4500 9th Ave NE STE Seattle WA 98105

Additional Sites:

Bremerton Clinic: 623 NE Riddell Road, Bremerton, WA 98310

Assaquah Clinic: 75 NW Dogwood Street, Suite B, Issaquah, WA 980273210

Kent Clinic: 10056 S.E. 240th, Ste. A, Kent, WA 98031

Oak Harbor Clinic: 3159 N. Goldie Road, P.O. Box 837 Oak Harbor, WA 98277

Seattle Clinic: 2001 East Madison Avenue, Seattle, WA 981

Silverdale Clinic: 10030 Silverdale Way, Suite 106, Silverdale, WA 98383

West Seattle Clinic: 9641 28th Avenue SW, Seattle, WA 98126

41 042003000 MTSC.FS.000008E000000 O2 200P0420 1,364.00

NOTICE TO RENEW Return with Payment

Washington State Department of Health

Please verify all information and record any change next to the incorrect information.

Medical Test Site Categorized License MTSC.FS.00000038

CLIA # 50D0663561

MTS Category Category A

Planned Parenthood of the Great Northwest Karen Gunderson 2001 E Madison St Seattle, WA 98122-2959 Due Date Amount Due

June 1, 2009 \$ 1,364.00

Please Complete Reverse

Site address:

Planned Parenthood of Great NW Central Region 4500 9th Ave NE Ste 324 Seattle, WA 98105-4778

Phone: (206)328-6815 Fax: (206)720-4657

0044EL0000FP0F00250000000BE000000T2XM 0000E00540LF

##∄የየየ#

Owner Name: Planned Parenthood of the Great Northwest

Lab Director Name: Michael Romo, MS, MT(ASCP)

Lab Director Email:

Lab Contact Name: Michael Romo

Lab Contact Email: michael.romo@ppgnw.org

3777-5/27/2009 9:56:49 AM-864

61364.00

51,042005000 E040P005 G2 2000000 G2 42TM 0000000 G2 200P0403 00200-00

NOTICE TO RENEW **Return with Payment**



Please verify all information and record any change next to the incorrect information.

Medical Test Site Provider Performed MTSP.FS.00000682

CLIA# 50D0635226

Family Planning of Clallam County PO Box 927 Port Angeles, WA 98362-0160

PAYABLE IN U.S. FUNDS

Due Dε

Amount Due

June 1, 2009

\$ 200.00

Please Complete Reverse

Site address:

Family Planning of Clallam County 1106 E 1st St

Port Angeles, WA 98362-4317

Phone: (360)452-2954 Fax: (360)457-7683



770450030000 WL262000008950000000550040300050000

III 1150 III

Owner Federal Tax ID Number #: 910872258

Owner Name: Family Planning of Clallam County

Jack Slownver

Lab Director Name: CHANDRA HUSTON

islowriver Chamily planning of co.org

Lab Director Email: sandy@familyplanningofcc.org

Lab Contact Name: GAIL MARSH RN

Lab Contact Email: gmarsh@familyplanningofcc.org

1150-4/30/2009 9:39:15 RM-861

\$200.00

regentiai	view	Screen	update	entity	tree	
						- 1

Planned Parenthood of the Great Northwest

Address:	
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Comments:

Public O Mail

change public address

Planned Parenthood of the Great NW Central Region

2001 E Madison St

Seattle, WA 98122-2959

ID 844360 Warnings SSN/FEIN

Federal ID 910686012 Secretary Of StateNumber 578040516

CLIA 50D0663561 Contact Standing In-Business

Contact Type **ORGANIZATION**

Public File YES

Mailing List US Citizen

Contact Audit Enforceme Cont. Edu Documents . Owners Owned By/ Exams Experience Notes Schools.

> Application Other State Online Info Reports

Librarian

Medical Test Site Categorized License

update

form letter

Credential #

MTSC.FS.00000038

Legacy License #

MTS-0038

Application Date

Effective Date Expiration Date 07/01/2015 06/30/2017

First Issuance Date Last Date Of Contact

Next Examinations Date 02/28/2017

Credential Status **ACTIVE** (05/14/2015) **ACTIVE**

Status Reason Amount Due

\$0.00

Date Last Activity

5/14/2015 1:44:57 PM

Last Updated by

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

Stewart, Kevin

Certificate Sent Date 05/14/2015

Audit Document Verification Workflow Key Mgmt

Fees Notes **Print Docs**

Comp. Aud Renewal Legacy

Medical T€ License St Online Info

- User Defined License Data
- · Workflow
- · Legacy

User Definable License Data Field Value update

Field

Value Region 2

Medical Test Site Type Community Clinic

Multiple Sites



MTS Category

Medical Test Site Region

Category A

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

Lab Director

Michael Romo MS MT

Lab Contact

Michael Romo

Lab Contact Email Lab Phone Number michael.romo@ppgnw.org

Lab Fax Number

206-328-6815

Legacy Action -LQA

Legacy Personnel-LQA Legacy Revenue - LQA MTS-CLIA Multiple Site Laboratories

Washington State Medical Test Site Multiple Site License Data Collection Current Personnel and Test Information

We are updating the MTS and CLIA databases and need the current personnel and test menu information for the multiple site labs under your jurisdiction. Please return the attached forms by **April 1, 2016.** It is essential that the information in our database and the CLIA database are accurate and current. The information in the CLIA database is accessed by government reimbursement agencies, which use the information to reimburse medical claims to providers.

- Complete the attached test menu form including all tests performed <u>at all locations</u> under your multiple site license. Attach additional pages if needed.
- Complete the personnel section.
- Attach a list of all current multiple sites, including the site names, physical addresses and phone numbers under your medical test site license.
- Sign the form and return it to our office by April 1, 2016.
- Return the form by e-mail to <u>honora.estes@doh.wa.gov</u>, by fax to 253-395-6365, or mail it to: Laboratory Quality Assurance
 20425 72nd Ave S Ste 310
 Kent, WA 98032
- If you have any questions, please call Honora Estes at (253) 395-6747.

Use the following guidelines for counting tests:

- Mark all tests, test kits and analyzers used at the sites under this multiple site license.
- Example: Site A performs Urinalysis and Site B performs Whole Blood Glucose. Mark both or list on the test menu below.

Current Personnel Information:

Laboratory Director Name:		Michael Romo	· · · · · · · · · · · · · · · · · · ·	
Di	rector e-mail address: _	michael.romo@ppgnhi.org	· ·	
WAF	rofessional License #:	·		
Labo	ratory Contact Name: _	Michael Romo		
Laboratory co	ontact e-mail address:	michael.romo@ppgnhi.org	1.	

Sign and date the last page

Facility Name: Panned Parenthood of the Great Northwest and the Hawaiia	rislands
MTS #: 0038	CLIA #: 50D0663561
Waived & PPMP Tests performed in your fac	en l'alla de l'anglair de la grapha de l'étable de le le le la
Walved Tests	
Adenovirus	Calcium - Ionized
AdenoPlus (human eye fluid)	Abbott i-STAT CHEM8+ Cartridge
Rapid Pathogen Screening RPS Adeno Detector	Carbon Dioxide (CO2)
Aerobic/Anaerobic Organisms-Vaginal	Abbott i-STAT CHEM8+ Cartridge
Genzyme Diagnostics OSOC BVBLUE Test Gryphus Diagnostics BVBlue	Piccolo xpress & Blood Analyzers (CMP,BMP,lytes, Metlyte 8, Renal) Catalase, urine
Alanine Aminotransferase (ALT)	Diatech Diagnostics Uriscreen (for OTC use)
Alere Cholestech LDX (ALT)(WB)	Chloride
Arkray SPOTCHEM EZ Chem Analyzer (ALT) (WB)	Abbott i-STAT CHEM8+/6+ Cartridge
Cholestech LDX (ALT) (whole blood) .	Piccolo xpress & Blood Analyzers (CMP,BMP,lytes,metlyte 8,
Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (WB)	Renal)
(Lipid Panel Plus, Liver Panel Plus, CMP, BMP)	Cholesterol
Albumin	Abaxis Piccolo express Chem Analyzer (capillary-fingerstick)
Arkray SPOTCHEM EZ Chem Analyzer (WB)	Accu-Check InstantPlus Cholesterol test system.
Genzyme Diagnostics OSOM ImmunDip Urinary Albumin Test	Accuchek Instant Plus Dual Testing System
HemoCue Albumin 201 System (urinary albumin) Picçolo Point of Care/Blood/xpress Chemistry Analyzer WB	Advanced Care Cholesterol measuring system
(Liver Panel Plus Reagent Disc, Chem 13, CMP, Renal)	Alere Cholestech LDX Cholesterol(WB) Arkray SPOTCHEM EZ Chem Analyzer (WB)
Alkaline Phosphatase (ALP)	Biomedix Inc Q Steps Biometer G/C Dual Monitoring System
Arkray SPOTCHEM EZ Chem Analyzer (WB)	ChemTrak AccuMeter Cholesterol test system
Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (WB)	Cholestech LDX Test System
(Liver Panel Plus Reagent Disc, CMP, BMP)	ENA C.T. Total Cholesterol or Total Cholesterol (PDU)
Amylase	Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile &
Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus)	Glucose Measuring System
Aspartate Aminotransferase (AST)	Jant Pharmacal LipidPlus Lipid Profile and Glucose System Lifestream Technologies Cholesterol Monitors
Alere Cholestech LDX (AST) (WB)	Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)
Arkray SPOTCHEM EZ Chem Analyzer (WB)Cholested LDX Aspartate Aminotransferase (AST)	Polymer Tech, Systems Bioscanner, Bioscanner Plus, Bioscanner
Piccolo Point of Care/Blood/xpress Chemistry Analyzer (WB)	2000 PST, and MTS Bioscanner 1000
(Lipid Panel/Plus, Liver Panel Plus, Chem 6/13, CMP)	Polymer Technology Cardiochek and Cardiochek PA
B-Type Natriuretic Peptide (BNP)	Roche Diagnostics Accutrend Plus System (fingerstick WB)
Biosite Triage Meter/Meterpro (whole blood) BNP	Wako APOLOWAKO Analyzer (WB)
Basic Metabolic Panel	Comprehensive Metabolic Panel
Abbott 1-STAT CHEM8+ Cartridge (ionized calcium) WB	Piccolo Blood Chem/express Analyzers WB Creatine Kinase (CK)
Abaxis Piccolo Blood Chemistry/express (total calcium) WB	Piccolo Blood Chemistry/express AnalyzersWB (Metlyte 8)
Bilirubin, Total	Creatinine
Arkray SPOTCHEM EZ Chem Analyzer (WB)	Abbott i-STAT CHEM8+/Crea Cartridge
Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Liver Panel Plus Reagent Disc, Chem 13, CMP)	Arkray SPOTCHEM EZ Chemistry Analyzer (WB)
Bladder tumor associated antigen	Bayer Clinitek 50 Urine Chemistry Analyzer for Creatinine
Alere NMP22 BladderChek	Bayer Diagnostics MICROALBUSTIX Reagent Strips
Bion Diagnostic Sciences BTA stat Test (for home use)	Bayer MultiStix PRO 11, PRO 10LS, and PRO 7G
LifeSign Status BTA	Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP,
Maritech BladderCheck Test (professional & prescription use)	Metlyte 8, Renal) Drugs of Abuse
BUN (Blood Urea Nitrogen)	•
Abbott i-STAT CHEM8+/6+ Cartridge	1 Step Detect Asoc DTX Drug Test Cup Integrated E-Z Split Key Cup I Acon Laboratories Drug Home Tests
Arkray SPOTCHEM EZ Chem Analyzer (WB)	Acon Mission U120 Urine Analyzer
Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP,	Accu-Stat Diagnostics Drugs of Abuse Home Test
Metlyte 8, Renal)	Advantage Diagnostics
Calcium Arkray SPOTCHEM EZ Chem Analyzer (WB)	Advin Multi-Drug Screen Test
Piccolo xpress & Blood Chem Analyzer (WB)	AIT Lab Drug of Abuse Card/Cup
Renal)	Alatex Scientific Peace of Mind Multiple Drugs of Abuse

Walved Tests (continued)	
Drugs of Abuse, continued	NexScreen Cup
Alere Toxicology Services iCassetts Dx/iCassette/iCUP Drug	Nobel Medical NOBLE 1 Step Cup (OTC)/Split-Specimen Cup
Screen/iScreen Dx/Tox Screen/iCup DX 14/DS Multi-Drugs Dip	Insta-Screen cup
Test/iCupDX Pro Urine Drug Screening Device	On the Spot Drug Testing Multi-Drug of Abuse Urine Test
Alfa Scientific Designs - Multiple drug Screen test kits	Phamatec At Home & QuickScreen
Amedica Biotech The Amedica Drug Test Cup/AmediCheck	PharmTox Rapid Exam Drug Screen Test Cup
Instant Test Cup/Instant Test Cup	Physicians' Test Multi-Drug of Abuse Urine Test
Ameditech Inc ImmuTest Drug Screen Cup	Premier Integrity Solutions P/Tox Drug Screen Cup
American Bio Medica Rapid TOX	Princeton Biomeditech Drug Tests
American Screening Corp Discover/OneScreen/Multi-Drug/	PTox Drug Screen Cup Cassette Dip Card format
Revel Multi-Drug Testing Cups/Cards	Quest Dx Integrated E-Z Split Key Cup II/Express Result/Drug
APC Workforce Secure Check/ZeroChaos Multi-Drug Screen cup	HAWK
_Applied Biotech	QuickTest USA Multi-Drug of Abuse Urine Screen
Ayentir Biotech LLC Home Check Multiple Drug Cup Test	Redwood Tox Lab Reditest 6/Reditest Freedom Cup/Reditest
Biotech Screening Correction Cup	Home Drug Tests
Biotechnostix Rapid Response Drug Screens	RefuAH U120 Urine Analyzer
Branan Medical Corp Fastect II/FasTox/BUP/QuickTox/ToxCup	Revolution Rx AccuSeal Pro Instant Test Cup/Buprenorphine/
	MDMA/Opiates
_BTNX Know/Rapid Response Multi-Drug One Step Screen/	Screen Tox Multi-Drug of Abuse Urine Test
Urine Test Cup	SCI Int'l New Choice At Home Drug Test Marijuana strip form
BTNX Rapid Response X-Press Single Test (dip card or cup/strip	SD Biotech FurSure Buprenorphine Drug Cup (opiates)
or cassette)/Multi-Drug Urine Test Panel/Cup	Syntrol Bioresearch Quikscreen Multiple Drug Cup/
CR3 Keyless Split Sample Cup Morphine-Oxazepam	Buprenorphine/MDMA/Opiate
Cho Reyless 3pth sample Cup Morphine-Oxazepam Chemtron Biotech Chemtrue Single/Multi-Panel Drug Screen	TeenSaver Diag, TeenSavers Home Drug Test
Cassette/Dip Cards	
	Total Diagnostic Solutions Drug of Abuse Cassette/Cup
CLIA-X Multiple/Instant/Drug Cup Test/Drug of Abuse Card	(morphine, oxycodone)/Multi-Drug of Abuse Urine Test
CLIAwaived Inc. Rapid Drug Test Cup (OTC)/Test	Twin Spirit Inc DrugSmart Cup
CLIAwaived Inc Single Drug Dipstick Test	uVera Diagnostics MultiDrug Test Cup CR2/CR3/Smartox U2/
Clinical Research Intelligent Transport Cup (OTC)	U3
Confirm Biosciences Drugconfirm Instant/RELI ON Multi-Drug	UCP Home Drug/Multiple/U-Checker/Compact Drug
of Abuse	Screening Test Cards/Cups/Home Drug Screening Cards⋓
Devon Medical CentralCheck Multiple Drug Cup Test	UCP Biosciences UCP Compact Drug Test Cards/Multi_Drug
Diag. Test Grp Clarity Multi/SimpleDrug of Abuse Urine Test/Cards	Test Key Cups
Drug Detect. Devices Multi-Drug Multi-Line/Screeners AutoCup	Ultimate Analysis Cup UA Cups/Cards
eScreen, Inc. mCheck Multi-Line Screen Test Device	US Diagnostics ProScreen/UScreen Drugs of Abuse Cup/Cards
Express Diag DrugCheck Waive Drug Cards/Cup/Model 9308z/	Wal-Mart ReliOn Home Drug Urine Cup Test
TC	WayPoint Biomedical, Inc. Health Essist Multi-Drug Tests
First Check Diagnostics Drug Screens	Wolfe Drug Testing RealityCheck Integrated Specimen Cup
Forefront Diag. Drug Screen	Wondfo Multi Drug Urine Test Cup and Dipcard
Graman Medical Corporation	Wondfo Urine Test Cup and Dip Card
Greenbrier Intn'l East SCREEN Marijuana Test Strip	Worldwide Medical Corp. First Check Home Drug Tests
_IND Home Drug Tests (strip and cassette formats)	Wunder Test Home Drug Screen (Marijuana)
IND Home Drug Test - Multi-Panel Strip and Cassette Formats	Electrolyte Panel
Innovacon Integrated E-Z Split Key Cup II (professional use)	Abaxis Piccolo Blood Chemistry/express WB
Innovacon Multi-Clin Drug Screen Test Device	Erythrocyte sedimentation rate (ESR)
Insight Medical Drug of Abuse Cassette/Cup (morphine,	Non-automated
oxycodone) Multi-Drug of Abuse Urine Test	Esterone-3-Glucuronide
Instant Tech, iTest/iCassette/iCup/iCupDx/Cassette Dx/iScreen	Unipath Limited Clearplan Easy Fertility Monitor
Inverness Medical Innovations Signify ER Drug Screen	Ethanol
Jant Pharmacal Accutest MultiDrug ER11/Multi-Drug of Abuse	·
Urine Test/Multi X Drug Cup/SplitCup Drug Screen/Test Cup/	Acon Laboratories Mission Saliva Alcohol Test Strip
Cassette, Cup/Buprenorphine/MDMA and OPI Drug Test Cup	Alere Toxicology Services iScreen Saliva Alcohol Test Strip
LifeSign Home Drug Tests	Alfa Scientific Designs Oral-View Saliva Alcohol Test Strip
Med Direct ProXam Drug Test Cards/Multiple Drug Screen Cups	American Screening Corp, Reveal Saliva Alcohol Test Strip
MedimpexQ Test Multi X Drug Cup Test/Buprenorphine	Chematics Alco-Screen/Alco-Screen 02 Saliva Alcohol Test
Micro Distributing Multi-Drug/Stat Cup One Step Drug Test/Stat	CLIAwaived rapid Saliva Alcohol Test
Dip One Step Multi-Drug Cup/Panel	Germaine Laboratories Aim Strip Alcohol Saliva
Millennium Lab Multi-Drug Pain Med Screen Cup/Multi-Drug of	Jant Pharmacal Corp Accustrip Saliva Alcohol Test Strip
Abuse Urine Test	OraSure Q.E.D. A-150 and A-350 Saliva Alcohol Tests
110 and Other Lout	Teco Diagnostics Saliva Alcohol Test

Walved Tests (continued)	
Follicle Stimulating Hormone (FSH)	Chalastach I DV
Acon Lab FSH Menopause Predictor Test	Cholestech LDX Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile &
Acon Lab FSH One Step Menopause Test Strip/Device	
Applied Biotech Menopause Predictor/Instacheck FSH Test	Glucose Measuring SystemJant Pharmacal LipidPlus Lipid Profile and Glucose System
Applied Biotech Menopause Predictor and RU25 Plus FSH	Piccolo POC/xpress Chemistry Analyzer WB (Lipid Pauel/Plus)
Biotechnostix Rapid Response FSH One Step Test Device	Polymer Technology Systems BioScanner Plus and 2000
BTNX Rapid Response FSH Menopausal Test	Polymer Technology Systems Cardiochek and Cardiochek PA
Genosis Fertell Female Fertility Test (FSH)	Helicobacter pylori
Genua Menopause Monitor Test, FSH (qualitative)	Abbott FlexPack HP, Signify, Cassette, and TestPack Plus (WB)
IND Diagnostic One Step FSH Menopausal Test (midstream)	Acon H. pylori Rapid Test Device (whole blood)
IND Diagnostic One Step FSH (Strip/Cassette)	Alfa Scientific Designs Instant View (whole blood)
IND Diagnostic One Step Strip/Cassette Style FSH (prof use)	Applied Biotech SureStep (whole blood)
Phamatech Moments Menopause Check (FSH)	ARJ Pylo-Plus Urease (gastric biopsy)
PanProbe Biotech EarlyDetect Menopause Test	Ballard (Delta West) CLOtest (gastric biopsy)
QuantRx Biomedical QuantRx Female Fertility Test	Beckman Coulter Flexsure (whole blood)
RAC Medical Clarity FSH One Step Menopause (prof use)	Becton Dickinson LINK 2 (whole blood)
Synova Healthcare Menocheck Menopause Indicator Test	BTNX Inc Rapid Response H. pylori Rapid Test Device(WB)
Fructosamine	Cardinal Health SP Brand Rapid Test (whole blood)
LXN (Duet and IN CHARGE Test Systems)	ChemTrak AccuMeter (whole blood)
Gamma Glutamyl Transferase (GGT)	Clarity H. pylori Rapid Test Device (whole blood)
Piccolo Point of Care/Blood/xpress Chemistry Analyzer (Liver	CLIAwaived H. pylori Whole Blood Rapid Test
Panel Plus Reagent Disc, Chem 6, Chem 13)	De Healthcare Products Truview H. pylori (whole blood)
Glucose	Diagnostic Test Group Clarity H. pylori Rapid Test Device (WB)
Alere Cholestech LDX (glucose)(WB)	EarlyDetect H. pylori Whole Blood Rapid Test
Arkray SPOTCHEM EZ Chem Analyzer (WB)	Fisher Healthcare Sure-Vue H. pylori Test (WB)
Abbott i-STAT CHEM8+/G/EC4+/6+ Cartridge	Germaine Laboratories AimStep (whole blood)
Biomedix, Inc Q Steps Biometer G/C Dual Monitoring System	GI Supply HP-FAST and HP One (gastric biopsy tissue)
Blood glucose monitoring devices cleared by FDA - home use	Henry Schein OneStep+/Rapid Test Device (whole blood)
Cygnus, Inc Gluco Watch Automatic Glucose Biographer Diagnostic Test Gran Clerity Blood Glycose Monitoring System	Immunostics Detector H. pylori (WB)
Diagnostic Test Grp, Clarity Blood Glucose Monitoring Systm Hemocue B-Glucose Photometer & model 201 analyzer/201DM	Instant Technologies iScreen (whole blood)Inverness BTNX Inc Rapid Response H. pylori Test (WB)
Jant Pharmacal LipidPlus Lipid Profile and Glucose System	Inverness Medical Clearview/SIGNIFY H, pylori Test (WB)
LXN Duet/IN CHARGE Glucose Monitoring System Cholestech LDX	Inversess Metalear Clear view of Orth 111, pylot 1 less (WB)
Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Lipid	Urease Test)
Panel Reagent Disc, Chem 6/13, CMP, BMP, Metlyte 8, Renal)	LifeSign and LifeSign Status (whole blood)
Polymer Technology Systems CardioChek PA Analyzer	McKesson H. pylori Test (WB)
Roche Diagnostics AccuChek Instant Plus Dual Test System	McKesson Medi-Lab Performance H. pylori Test (WB)
Wako APOLOWAKO Analyzer (WB)	Medical Instruments Corp Pronto Dry (gastric blopsy)
Glycosylated HGB	Meridian Bioscience ImmunoCard STAT! (whole blood)
Axis-Shield Afinion AS10 Analyzer	Polymedco Polystat (whole blood)
Bayer A1C Now SelfCheck	PreMaxim RadiScreen Test Device (whole blood)
Bayer A1C Now+ (professional use)	Princeton BioMeditech BioSign (whole blood)
Bio-Rad Micromat II	Princeton BioMeditech BioSign H. pylori WB OSOM H. pylori
Bristol-Myers Squibb Choice DM.	Pro-Advantage by NDC H. pylori Device (whole blood)
Cholestech GDX A1C (prescription home use)	PSS Consult H. pylori Cassette (WB, fingerstick only)
MEC Dynamics Avie A1c Test System	Quidel QuickVue gII/One-Step/One-Step II (whole blood)
Metrika A1c Now/DRX HbA1C/InView Multi Test	Remel RIM A.R.C. (whole blood)
Provalis Diagnostics Glycosal/In2it In-office analyzer II/G5 I	Roche Diagnostics AccuStat H. pylori OneStep (WB)
HbA1c/G5 II HbA1c Siemens Medical DCA Vantage/2000/2000+ Analyzer	Select Medical Products Brand Rapid Test H. pylori (WB)
Wako APOLOWAKO Analyzer (WB)	Serim Pyloritek Test Kit and VP Test Kit (gastric biopsy)
HDL: Cholesterol	SmithKline FlexSure HP (whole blood) Stanbio RELY H.pylori (WB fingertstick only)
Abaxis Piccolo express Chem Analyzer (capillary-fingerstick)	Trinity Uni-Gold (whole blood)
Accutech Choles Trak HDL Cholesterol Home Test	Wampole Laboratories Clearview <i>H. pylori</i> II (whole blood)
Accurect Choles trak HDL Cholesterol Home Test Alere Cholestech LDX (HDL cholesterol)(WB)	
Arkray SPOTCHEM EZ Chem Analyzer (WB)	
•	

łematocrit	11
Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge	Lead
AimStrip Hb Hemoglobin Testing System	ESA Biosciences LeadCare II Blood Lead Testing System (WB
_Amount no Aemoglobil Testing System Microhematocrit (spun)	Lithium
_Micro Diagnostics Spuncrit DRC-40 Infrared Analyzer	Akers Laboratory Inc InstaRead Lithium System (WB)
UltraCrit	ReliaLAB Inc. InstaRead Lithium System (WB)
Wampole STAT-CRIT for hematocrit	Lyme Disease
emoglobin	Wampole PreVue B. burgdorferi Antibody
	Lutenizing Hormone (also see ovulation tests)
_Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge	BTNX Inc Rapid Response LH Ovulation Test
Alere HemoPoint H2 Hemoglobin Measuring System	Chembio Sure Check Ovulation Predictor
_Avie Total Hb Test System (professional use)	Inverness Medical Early Ovulation Predictor Stix
_Biosafe Anemiapro Self Screener	Saless Enterprises New Choice Ovulation Predictor
Blotest Hemoglobin Measuring System	Unipath Limited Clearplan Easy Fertility Monitor
_Clarity HbCheck Hemoglobin Testing System	Matrix metalloproteinases-9 (MMP-9)
_Copper Sulfate (non-automated)	Rapid Pathogen Screen Inc. InflammaDry
Diaspect Hemoglobin Measuring System	Microalbumin
EKF Diag, Hemo_Control Measurement & Microcuvettes	Roche/Boehringer Mannheim Micral Chemstrip
HemoCue hemoglobin test systems (201, 201+, 301)	Bayer Clinitek 50 Urine Chemistry Analyzer
HemoCue Donor Hemoglobin Checker System	Bayer Clinitek Status Urine Chemistry Analyzer
_GDS Diagnostics HemoSite Meter for hemoglobin	Bayer Diagnostics MICROALBUSTIX Reagent Strips
GDS Technology STAT-Site M Hgb Test System	Diagnostic Chemicals ImmunoDip & Urinary Albumin Screen
_ITC HGB PRO Professional Hemoglobin Testing System	HemoCue Albumin 201 System
Mission Plus Hemoglobin (Hb) Testing System	Mononucleosis
Stanbio Hemoglobin Analyzer	Acceava Mono II (whole blood)
Stanbio HemoPoint H2/H2 DM Hemoglobin Measurement Syst	Acon Mono rapid Test Strip/Device (whole blood)
epatitis C Virus Antibody	Applied Biotech One Step+, SureStep, Truview Mono Test
_OraQuick Rapid Aby Test/OraQuick HCV Visual Ref Panel	BioStar Acceava Mono/Mono II Test (whole blood)
IV-1	Cardinal SP Brand Rapid Test (whole blood)
_bioLytical INSTI HIV-1 Antibody Test (fingerstick WB)	Clarity MONO Mononucleosis Rapid Test (WB)
_Chembio HIV 1/2 STAT-PAK Assay (WB)	Clearview Mono-Plus II / Mono Test Whole Blood (WB)
Clearview COMPLETE HIV 1/2 fingerstick & venipuncture WB	Consult Diagnostics Mononucleosis Cassette (WB)
OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)	De Healthcare Products Truview Mono Test (WB)
_OraQuick In-Home HIV Test (oral fluid)	Genzyme Contrast/OSOM/Rapid/Sure-Vue Signature Mono To
_OraQuick Rapid HIV-1 Antibody Test (oral fluid, WB)	Henry Schein One Step+ Mono Test (whole blood)
_Trinity Blotech UniGold Recombigen HIV test (WB)	Immuno Detector Mono/BioSign Mono WB
nfluenza	Instant Technologies iScreen (whole blood)
Alere BinaxNOW Influenza A & B Card (nasal swab/waah/asp)	Jant Accutest Valeu+/Infectious Mononucleosis Test (WB)
Alere Influenza A & B Test (nasal swab only)	LifeSign Status/UniStep Mono Test (whole blood)
BD Veritor Systems Rapid Det Flu A+B (nasal,nasopharyngeal)	McKesson Medi-Lab Performance Infectious Mono Test
Binax NOW Flu A and Flu B Tests and A&B Tests	Meridian ImmunoCard STAT Mono (whole blood)
BTNX Rapid Response Influenza A/B Test Cassette	OneStep Pro+ Mono (WB)
Clearview Exact II Influenze A&B (nasal swab only)	Polymedco, Inc. Poly stat Mono (whole blood)
EarlyDetect Pro Influenza A Test/Influenza B Test	Poly Stat Mono Test (WB)
Henry Schein OneStep+Influenza A&B Test	PreMaxin RediScreen Mononucleosis (WB)
Quidel QuickVue Influenza Test (Influenza A/B)	Princeton BioMeditech BioSign Mono WB (whole blood)
Quidel QuickVue Influenza A+B Test	ProAdvantage by NDC Infectious Mono Test Device (WB)
SA Scientific SAS Influenza A/Influenza B Tests	Quidel CARDS O.S. and QuickVue+ Mono (whole blood)
Sofia Analyzer & Influenze A+B FIA (nasal, nasopharyngeal)	RAC Medical Clarity MONO Rapid Test Device (WB)
ZymeTX Zstatflu (Influenza A/B)	Rapid Response Mono Rapid Test Device (whole blood)
(etones (Blood)	Remel RIM A.R.C. Mono Test
Abbott Laboratories Precision Xtra/Xceed/Freestle Precision Pro	Seradyn Color Q Mono (whole blood)
Nova Max Plus/Mini Gludose and B-Ketone Monitoring System	
Polymer Technology Systems BioScanner 2000	Signify Mono Test / Mono Whole Blood / Mono Cassette (W
totyliner feelinology systems bloscaliner 2000 actic Acid	Wampole Mono-Plus WB (whole blood)
·	Wyntek Diagnostics OSOM and Signify Mono test (WB)
KDK Corporation Lactate Pro System (for OTC use)	Nicotine (or its metabolites)
_DL Cholesterol	CLIAwaived Instant Nicotine Detection Test
Polymer Tech. Systems Cardiocheck/Cardiocheck PA Analyzer	DynaGen NicCheck 1 Test Strips
Polymer Tech. Systems Cardiocheck Cardiocheck PA Analyzei	DynaGen NicCheck I Test Strips Mossman Associates NicCheck I Test Strips

Occult blood	Protein, Total
Fecal Occult Blood	Arkray SPOTCHEM EZ Chem Analyzer (WB)
Fecal Occult Blood Immunochemical/Immunological Tests	Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus
Aerscher Hemaprompt FG Gastric Occult Blood	Reagent Disc, Chem 13, CMP)
Alfa Scientific Designs Instant-View FOB Self-Test Cassette	RSV (Respiratory Syncytial Virus Direct Antigen)
Alfa Scientific Designs FOB Self-Test	BD Veritor System for Rapid Detection RSV (nasopharyngeal)
Beckman Coulter Primary Care Diagnostics Gastroccult/	Clere BinaxNOT RSV Card
Hemoccult Sensa Elite (gastric occult blood)	Binax NOW RSV Test
Clarity Fecal Occult Blood Self Test	Fisher Scientific Sure-Vue RSV Test
Immunostics hema screen ER	Integrated Biotechnology Quick Lab RSV Test
Know Fecal Occult Blood Self TestRapid Response Fecal Occult Blood Self Test	Meridian Bioscience Immunocard Stat! RSV Plus
Kapid Response Fecal Occur Blood Sen TestSiemens Hematest Reagent Tablets	Quidel Quick Vue RSV Test
Smithkline Gastroccult	Rapid Response RSV Test
omitted astrocount Desmolarity	Remel Xpect RSV
•	SA Scientific SAS RSV Test/RSVAlert
TearLab Osmolarity System Osteoporosis	Wampole Laboratories Clearview RSV
Ostex International Osteomark NTX	Semen
Oslet international Osleonialk NTA Dvulation Tests	Embryotech Laboratories FertilMARQ for male infertility
Visual color comparison tests for human luteinizing hormone	Fortility Solvations Someon Analysis (availtative)
BTNX Inc rapid Response LH Ovulation Test	Fertility Solutions Semen Analysis (qualitative) SpermCheck Fertility
Luna Fertility Indicator (saliva)	SpermCheck Vasectomy
O2 Unlimited Donna Ovulation Test (saliva)	Sodium
Stesans Maybe?Mom Mini Ovulation Microscope (saliva)	Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
TCI Ovulation Tester (saliva)	Piccolo xpress & Blood Analyzers (CMP, BMP, lytes, Metlyte 8
PH	Renal)
All qual. color comparison pH - body fluids (not blood)	Strep Antigen Test
Common Sense FemV/VI/VA/VS/Norma Sense (vag pH)	Abbott Signify Strep A Test / Dipstick
Dale Med Products RightSpot/RightLevel (gastric pH)	Acceava Strep A Test/Twist Rapid Test
Duramed AmniScreen Home Dection Liner Kit	ACON Strep A Rapid, Strep A Twist Rapid, and ICON DS
Femtek Phem-Alert (vaginal pH)	Applied Biotech SureStep Strep A (II)/Strep A Exact
Lil' Drug Store Prod. Vagi-Screen Vaginal Health Test (vag pH)	Beckman Coulter ICON Fx (formerly SmithKline)
Litmus Concepts FemExam Test Card (vaginal pH & amines)	Beckman Coulter Primary Care Diag. DS, FX, and SC
Quicek QuickVue Advance pH and Amines Test	BD LINK 2/Chek Strep A Rapid test / Veritor System
RightBio Metrics Right Spot Infant pH Indicator/pH Indicator/	Binax NOW/Clearview Advanced Strep A Test
Detector	BioStar Acceava TM Strep A Test
Phosphorus	Biotechnostix Rapid Resp. Strep A Rapid Test Device/Strip
Piccolo xpress/Blood Analyzers (Renal panel)	BTNX Rapid Response Strep A Rapid Test Strips
Platelet Aggregation	Cardinal Health CP Brand Rapid Test Dipstick/Cassette
Accumetrics VerifyNow Aspirin Assay	Clearview Strep A Exact Dipstick
Potassium	CLIA Waived Inc Rapid STREP A Test
Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge	Consult Diagnostics STREP A RAPID Dipstick CTMI (Cole-Taylor Marketing Inc) Strep A Rapid Test Strip
Piccolo xpress/Blood Analyzers (CMP, BMP, lytes, Metlyte 8, Renal)	DE Healthcare Products, TruView Strep A Test/Cassette
Pregnancy Test (Urine)	Diagnostic Test Group Clarity Strep A Rapid Test Strips
Vine pregnancy test: visual color comparison	Fisher HealthCare Sure-Vue Strep A
Siemens Clinitek 50/Status Urine Chemistry Analyzer Protime	Genzyme Contrast Strep A and OSOM Ultra Strep A
Alere INRatio2 PT/INR Monitoring System (Professional/Home)	Germaine Laboratories Strep AIM Rapid Dipstick Test
AvoSure Pro and PT	Germaine Laboratories Strep AIM Tower
	Henry Schein OneStep+/OneStep + Strep A Test/Strep A Dipst
Hemosense INRATIO	IMI Signify Strep A Dipstick
International Technidyne Corporation Protime Microcoagulation	Immunostics Immuno/Strep A Detector, Strep A Direct
System and ProTime 3 Cuvette System	Instant Technologies Istrep Strep A Test
Lifescan Harmony INR Monitoring System	Inverness Medical BioStar Acceava Strep A Test/Twist
Lifescan Rubicom Prothrombin Time Monitoring System	Inverness Medical Clearview Strep A Exact II Dipstick
Roche Diag CoaguChek & CoaguChek S Sytems, PT-S Strips,	Inverness Medical Signify Strep A Cassette
XS, XS PST, XS Plus .	Jant Pharm. AccuStrip Strep A (II), Accutest Integrated Strep A
	Rapid Test, Clinipak Rapid Test Strip, Value+ Test,
	Laboratory Supply Co PEP Strep A Cassette, Dipstick

Waived Tests (continued)	
Strep Antigen Test, continued LifeSign LLC Status Strep A Mainline Confirms Strep A Dots test McKesson Strep A Medi-lab Performance Dipstick/Cassette/ Strep A Test - Twist/Dipstick Meridian Diag. ImmunoCard STAT Strep A MediLab Performance Strep A Twist Rapid Test Moore Medical Strep A Rapid Test - Dipstick/Cassette OneStep Pro+ Mono (WB) Performance Enhanced Products Strep A Cassette, Dipstick Perlmaxin Rediscreen Strep A Rapid/Strep A Twist Cassette Polymedco Poly stat A (II), Strep A Liquid Test, Strep A Dipstick Polystat Strep A Flip Test Princeton BioMediTech BioStrep A /Status First Strep A ProAdvantage by NDC Strep A Test PSS Consult Diag Strep A Dipstick/Twist PSS World Medical Strep A Dipstick/Twist Quidel Quick/Vue In-Line and Dipstick and In-Line One-step RAC Medical Clarity Strep A Test Sacks Medical Refuah Strep A Rapid Test Sacks Medical Refush Strep A Rapid Test Sacks Medical Refush Strep A Test (direct - throat swab) Sekisui Diagnostics OSOM Strep A Test (direct - throat swab) Sekisui Diagnostics OSOM Ultra Strep A Test Select Medical Products Brand Rapid Test Strep A Dipstick Select Medical Products Brand Rapid Test Strep A Test Select Medical Products Brand Rapid Test Strep A Test Select Medical Products Brand Rapid Test Strep A Test Select Medical Products Brand Rapid Test Strep A Test Select Medical OsoM Strep A, B-Z Well Strep A Rapid Test Wyntek Diag. OSOM Strep A and OSOM Ultra Strep A Test Trichomonas Genzyme Osom Trichomonas Rapid Test Trichomonas Genzyme Osom Trichomonas Rapid Test Triglycerides Abaxis Piccolo express Chem Analyzer (capillary-fingerstick) Alere Cholestech LDX (triglyceride)(WB) Arkray SPOTCHEM EZ Chem Analyzer (WB) Cholestech LDX Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile & Glucose Measuring System Jant Pharmacal LipidPlus Lipid Profile and Glucose System	Piccolo POC/xpressAnalyzer (Lipid Panel/Plus) Polymer Tech . Systems Bioscanner, Bioscanner Plus, & 2000 Polymer Tech . Systems Cardiochek and Cardiochek PA Wako APOLOWAKO Analyzer (WB) TSH Aventir Biotech LLC FORSURE TSH (WB) BTNX Inc Rapid Response TSH test cassette (WB) CLIA Waived Inc Thyroid Test Rapid TSH Cassette (WB) Jant Pharmacal Corp Accutest TSH (WB) Little Nell Labs ThyroChek TSH (WB) Pharmaceutical Marketing Thyroteset Whole Blood TSH Qualigen Inc FastCheck TSH (WB) ThyroTest Whole Blood TSH Test (WB) Urlc Acid Piccolo xpress & Blood Chem Analyzers (chem 13)WB Urinalysis XUrinalysis: Dipstick or tablet reagent (nonautomated) Acon Lab Insight U120 Urine Analyzer Acon Mission U120/Foresight U120 Urine Analyzer Biosys Laboratories Optima/Optima II Urine Analyzer Cole-Taylor Marketing Inc CTI-120 Urine Strip Analyzer Consult diagnostics Urine Analyzer Diagnostic Group Clarity Urucheck 120 Urine Analyzer Germaine Laboratories AimStrip Urine Analyzer Henry Schein OneStepPlus/Urispec Plus Urine Analyzer Henry Schein OneStepPlus/Urispec Plus Urine Analyzer Immunostics Inc Detector Uristrip+ Analyzer Jant Pharmacal Corporation Accustrip URS Reader McKesson 120 Urine Analyzer Mediwatch urinewatch Urine Analyzer Mediwatch urinewatch Urine Analyzer Mediwatch urinewatch Urine Analyzer RefuAH U120 Urine Analyzer RefuAH U120 Urine Analyzer Reche/BMC Mini UA and Chemstrip 101 Urine Analyzer Roche/BMC Mini UA and Chemstrip 101 Urine Analyzer Siemens Clinitek 50/Status/Status+/Status Connect Analyzers Stanbio Uri-Trak 120 Urine Analyzer ThermoBiostar PocketChem UA
this application.	
Check all that apply	
	Post-coital direct, qualitative examinations of vaginal or cervical mucous X Potassium hydroxide (KOH) preparations Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility) Urine sediment examinations
·	

Facility Name: Planned Parenthood of the Green MTS #: 0038	at North West and the H	awaiian Islands CLIA #: 50D0663561	
Non-waived & Non-PPMP Tests	performed in	your facility (attach additional she	ets if needed)
	Total Volume	Viral Antigen Detection	
Microscopic Procedures	5071	HPV Influenza (nonvaived kits)	
(If the following microscopic tests are ONLY		RSV (nornvaived kits)	
done by the provider, DO NOT complete this section	วท.)	Other (list)	
		,	
XKOH		• •	Total Volume
Pinworm		Syphilis Serology	
Post Coital Vaginal Mucous Exam		RPR	·
Fern Tests		VDRL	•
X Qualitative Semen Analysis (post vas)		MHA-TP (TP-PA)	•
Quantitative Semen Analysis X Urine Sediment	•	FTA	•
Nasal Smear for Granulocytes	•	•	Total Volume
Masai Silicat for Chandiocytes	Total Volume	Gen. Immunology	<u>.</u>
Wiotocompetability.	TOTAL VOIDING	Allergy Testing (count individual allergens tested))
Histocompatability	•	Alpha-1 Antitrypsin	
Transplant Nontransplant (list specific tests)		AFP/Tumor	
Nontanapiant (tast specific tests)	Total Volume	AFP/Other	
Pactoriology	TOTAL VOIGILIE	ANA ASO	
BacteriologyAffirm VP (TV, GV, YST)		— HIV	
Antibiotic Sensitivities		C3	
Bacterial Antigens		C4	
Clostridium difficile	•	HBsAg	
Group A Strep (Rapid test - nonwaived kits)		Anti-HBc	·
Group B Strep		HBeAg	
Blood Culture		HCV	
Chlamydia	4	Anti-HCV IgA	
CSF Culture Gram Stain	•	IgG	
GC Gram Stain	•	IgE	
Throat Culture		IgM	
Urine Culture		Infectious Mononucleosis (nonwaived kits)	
Urine Colony Count	,	Rheumatoid Factor	
Other Culture/ID	•	H. pylori (nonvaived kits)	
	Total Volume	Rubella Antibody	
Mycobacteriology	•	Protein Electrophoresis Other (list)	
AFB Smear Only		Other (list)	Total Volume
AFB Smear/Culture		Pouting Chamistry	rotal volume
AFB Antibiotic Sensitivities.	•	Routine Chemistry ALT/SGPT	
AFB Culture & ID	7 (1)/ 1	Albumin	
1	Total Volume	Alkaline Phosphatase	
Mycology		Amylase	
DTM Only		AST/SGOT	•
Culture (Growth/No Growth) Fungus Yeast	•	Bilirubin, Total/Neonatal	
Culture and ID			E: Each measured
Fungus Yeast			neter must be ed as a separate
	Total Volume		added together,
Parasitology		Carbon Dioxide and in	ncluded in the
Direct Smear		— Chlorido Routi	ne Chemistry total
Concentrate/Stain		Cholesterol, Total	ne above,
Parasitic Antigens		HDL Cholesterol	
	Total Volume	Creatine Kinase	
Virology		CK Isoenzymes	
Herpes Antigen		Creatinine Glucose	
Herpes Culture	•	Glucose Glycohemoglobin (Hgb A ₁ C or equivalent)	•
Other Viral Cultures		Gryconemogloom (rigo A ₁ C or equivalent)	

Non-Waived Tests (continued)	网络科技学 和自己的工程等的工程等的基本基础的现在分词。
Routine Chemistry (continued)	Total Volume
LDH	Hematology
LDH Isoenzymes	Cell Identification/Manual Differential
Magnesium	
Potassium	CBC (Complete Blood Count): NOTE: Each measured
Sodium	Automated WBC Differential parameter (automated differential ferential; RBC, hemalociti
Total Protein Triglycerides	RBC (or MCV), hemoglobin,
Urea Nitrogen (BUN)	Hematocrit WBC, platelets) must be
Uric Acid	Hemoglobin counted as a separate
CEA	WBC lest, added together, and included in the Hematol-
Cholinesterase: RBC methodology	Platelet Count ogy total volume above
plasma/serum methodology	Reticulocyte Count
CRP/HSCRP	Hemoglobin Electrophoresis
Ferritin	Flow Cytometry
GGT	Other (list)
Phosphorus Myoglobin	Total Volume
Troponin	Coagulation
BNP	Fibrinogen
Other (list)	PTT
Total Volume	Prothrombin Time
Urinalysis	Thrombin Time Factor Assays
Strip by nonwaived instrument	Activated Clotting Time
Total Volume	D-dimer
Endocrinology	Other (list)
Cortisol	Total Volume
Free Thyroxine	Immunohematology 5553
HCG (Serum Pregnancy or nonvaived urine HCG)	Antibody Detection (Screen)
T3 Uptake	ABO Group
T3 (Triiodothyronine)Estradiol	XD (Rh) Typing5553_
TSHFSH	Antibody Identification
Thyroxine Luteinizing Hormone	Compatibility Test (Crossmatch)
PSA Progesterone Other (list)	Other (list)
Total Volume	Total Volume
·	Pathology
Toxicology Alcohol, Blood	Histopathology
Blood Lead	Dermatopathology
Carbamazepine	Oral Pathology Gyn Cytology
Digoxin	Non-gyn Cytology
Ethosuximide	Total Volume
Gentamicin	Radiobioassay
Lithium	(list in vitro tests, i.e. blood volume by
Phenobarbital	Cr 51, Schilling test, etc.)Do NOT include routine RIA tests
Phenytoin Primidena	,
Primidone Procainamide/metabolites	Total Volume
Quinidine Processing Processing Control of the Cont	
Theophylline	Genetic Testing Biochemical Genetic Tests (list tests)
Tobramycin	Cytogenetic Tests (list tests)
Valproic Acid	Cytogenetic Tests (list tests) Molecular Genetic Tests (list tests)
Drugs of Abuse (urine)	(add HPV testing under Virology)
Other (list)	(add Chlamydia and/or GC testing under Bacteriology)
category. I also certify that the information herein submitted is	d agree to comply with state law and rule regulating this licensing
Michael Romo	March 31, 2016
Signature of Owner/Authorized Representative of Medical Tes	st Site Date
Mail completed form by June 16, 2014 to: LQA, 20423 72nd Fax to (253) 395-6365, or E-mail to: honora.estes@doh.w	

MTS-0038

CLIA # 5000663561 Exp: Jun 30, 2017

Planned Parenthood Seattle Health Center (primary)

Planned Parenthood White Center Health Center

Planned Parenhood Port Angeles Health Center

Planned Parenthood Kent Health Center
Planned Parenthood First Hill Health Center
Planned Parenthood Sequim Health Center
Planned Parenthood Bremerton Health Center

2001 East Madison Ave, Seattle WA 98122

9942 8th Avenue, SW, Seattle WA 98106

426 East 8th St, Port Angeles WA 98362

20056 SE 240th Ste A, Kent WA 98301

1229 Madison St, Ste 1040, Seattle WA 98104

675 N. 5th Avenue, Ste 2B, Sequim WA 98382

723 NE Riddell Road, Bremerton WA 98310

(206) 328-7700 (206) 935-0152 .(360) 452-6501 (253) 854-2343 (206) 624-0291 (360) 797-1692 (360) 373-6827

Estes, Honora L (DOH)

From:

Romo, Michael < Michael.Romo@ppgnhi.org>

Sent:

Thursday, April 07, 2016 10:59 AM

To:

Estes, Honora L (DOH)

Subject:

RE: Multi Site Data Collection MTS 038

This message was sent securely using ZixCorp.

OK that makes sense. Just looks like a duplication.

Thanks Honora

Sent from my Verizon Wireless 4G LTE smartphone

----- Original message -----

From: "Estes, Honora L (DOH)" < honora.estes@doh.wa.gov>

Date: 4/7/2016 10:52 AM (GMT-08:00)

To: "Romo, Michael" < Michael.Romo@ppgnhi.org> Subject: RE: Multi Site Data Collection MTS 038

Hi Michael,

We go by address, so the 2001 W Madison (Seattle Clinic) is accounted for in our system under the primary site, so it is not being removed as much as it is included under the primary site. If we have them both in there it would be an unnecessary duplicate address. So it does not say "Seattle Clinic" only because the primary site is the name that appears on your license, which is just the way our database works.

MTSC.FS.00000038 50D0663561	1 Not a clinic. The	Planned Parenthood of the Great	Planned Parenthood of the Great NW	2001
	Seattle clinic is shown below.	Northwest	Central Region	St

MTSC.FS.00000038	50D0663561	Remove Do not remove	Planned Parenthood of the Great Northwest	Seattle Clinic	2001 E Madison St	Seattle

Explaining this in email form is a bit confusing so please call me if this isn't making sense.

Thank you,

Honora

From: Romo, Michael [mailto:Michael.Romo@ppgnhi.org]

Sent: Thursday, April 07, 2016 10:18 AM

To: Estes, Honora L (DOH)

Subject: Multi Site Data Collection MTS 038

This message was sent securely using ZixCorp.

Hi Honora

Here is what I sent for 038 which is correct and I added some corrections to your chart below. I don't now why records don't match. I did submit updated notifications of clinic closures and mergers. Hope this clears it up but let me know if you need more information.

Thanks Honora!

MTS-0038

CLIA # 50D0663561 Exp: Jun 30, 2017

Planned Parenthood Seattle Health Center (primary)	2001 East Madison Ave, Seattle WA 98122	(206) 328-7700
Planned Parenthood White Center Health Center	9942 8th Avenue, SW, Seattle WA 98106	(206) 935-0152
Planned Parenhood Port Angeles Health Center	426 East 8th St, Port Angeles WA 98362	(360) 452-6501
Planned Parenthood Kent Health Center	10056 SE 240th Ste A, Kent WA 98301	(253) 854-2343
Planned Parenthood First Hill Health Center	1229 Madison St, Ste 1040, Seattle WA 98104	(206) 624-0291
Planned Parenthood Sequim Health Center	675 N. 5th Avenue, Ste 2B, Sequim WA 98382	(360) 797-1692
Planned Parenthood Bremerton Health Center	723 NE Riddell Road, Bremerton WA 98310	(360) 373-6827

From: "Estes, Honora L (DOH)" < honora.estes@doh.wa.gov>

Date: April 7, 2016 at 9:33:22 AM PDT

To: "Romo, Michael" < Michael.Romo@ppgnhi.org > Subject: RE: Multi Site Data Collection MTS 038

Hi Michael,

I wanted to verify with you that the locations for MTS-0038 are accurate, they differed more than I would expect from what we have in our records.

The ones that say "remove" are the clinics that would be taken off this license based on the paperwork I received. Please let me know if this is accurate.

MTSC.FS.00000038	50D0663561	1 Not a clinic. The Seattle clinic	Planned Parenthood of the Great Northwest	Planned Parenthood of the Great NW Central Re
		is shown below.		
MTSC.FS.00000038	50D0663561	2 Correct	Planned Parenthood of the Great Northwest	Kent Clinic
MTSC.FS.00000038	50D0663561	3 Correct	Planned Parenthood of the Great Northwest	White Center Health Center
MTSC.FS.00000038	50D0663561	4 Correct	Planned Parenthood of the Great Northwest	Port Angeles Heath Center
MTSC.FS.00000038	50D0663561	5 Correct	Planned Parenthood of the Great Northwest	First Hill Health Center
MTSC.FS.00000038	50D0663561	6 Correct	Planned Parenthood of the Great Northwest	Sequim Health Center
MTSC.FS.00000038	50D0663561	7 Correct	Planned Parenthood of the Great Northwest	Bremerton Health Center
MTSC.FS.00000038	50D0663561	Remove Do not remove	Planned Parenthood of the Great Northwest	Seattle Clinic
MTSC.FS.00000038	50D0663561	Remove Duplication of # 7	Planned Parenthood of the Great Northwest	Bremerton Clinic
MTSC.FS.00000038	50D0663561	Remove Closed	Planned Parenthood of the Great Northwest	Issaquah Clinic
MTSC.FS.00000038	50D0663561	Remove Relocated to White Center #3	Planned Parenthood of the Great Northwest	West Seattle Clinic
MTSC.FS.00000038	50D0663561	Remove OK to remove. No longer	Planned Parenthood of the Great Northwest	Family Planning of Clallam County

		exists. Planned Parenthood took over #4 and #6 in Clallam County		
MTSC.FS.00000038	50D0663561	Remove. OK to remove. This center is under MTS 0200.	Planned Parenthood of the Great Northwest	Northgate Clinic

Thank you,

Honora L. Estes, MS, MLS(ASCP)CM

Advisory Laboratorian

Department of Health – Office of Investigations and Inspections

(w) 253-395-6747

(f) 253-395-6365

20425 72nd Ave S Ste 310

Kent, WA 98032

From: Romo, Michael [mailto:Michael.Romo@ppgnhi.org]

Sent: Thursday, March 31, 2016 3:50 PM

To: Estes, Honora L (DOH)

Subject: Multi Site Data Collection MTS 038

Michael Romo MS, MT(ASCP)

PPGNW Lab Director & Technical Consultant

(253) 365-8329

Mailing Address:

1412 Heron Court

Dupont, WA 98327

From: mwrwa66@gmail.com <mwrwa66@gmail.com>

Sent: Thursday, March 31, 2016 3:39 PM

To: Romo, Michael

Subject: Multi Site Data Collection MTS 038

This message was secured by <u>ZixCorp</u> ^(R) .
This message was secured by ZixCorn (R)





Credential Status Change Form

Use this form for address, phone number, fax number, email, or facility name or contact changes to individual credentials. Send the completed change form to the address listed above.

Complete pages two and three only if you are changing the director of a categorized or accredited license.

Your Information			* Annual Control of the Control of t	
MTS Name Planned Parenthood of	of the Great NW an	d the Hawaiian I	slands	
Effective date of change				
MTS License # MTS-0038	Clinica	·	nprovement Amendn DD0663561	nents (CLIA) #
Type of Change to MTS Listed Abo	ove			
Address Change (current address)	Mailing P	hysical 🗌 Botl	า	
New Address			· .	
City	te	Zip Code		
New phone (enter 10 digit #)	New fax (enter 10 digit #)			
Facility Name change (new name of	MTS)			
Name of new laboratory contact	Email address			
Name of new microbiology contact	Email address			
Name of new cytology contact		Email address		
Name of new laboratory director* L Stacy C. Olea, MT(ASCP), FACHE		Email address stacy.olea@ppgnhi.o	rg	

Do not complete pages two and three unless you are changing the director of a categorized or accredited license.

Qualifications of Personnel for Moderate Complexity Testing	
Director: (check only one)	
	1. Pathologist with state license.
	2. MD, DO, DPM, with state license and 1 year directing or supervising non-waived testing.
	Which laboratory?Dates
	3. MD, DO, DPM, with state license and 20 CMEs in laboratory practice.
	Which program? Dates
	4. MD, DO, DPM, with state license and laboratory training during residency equivalent to 20 CMEs.
	Which program? Dates
	5. PhD in science and board certification (ABB, ABMM, ABCC, ABMLI).
	6. PhD in science and 1 year directing or supervising non-waived testing.
	Which laboratory?Dates
	7. Master Degree in science, + 1 year laboratory training and/or experience and 1 year laboratory supervisory experience.
X	8. Bachelor Degree in science, + 2 years laboratory training and/or experience and 2 years laboratory supervisory experience.
	9. On 2/28/92, serving as laboratory director and qualified or could have qualified as director under previous Medicare/CLIA independent laboratory personnel requirements.
	10. On 2/28/92, was qualified under state law to direct a laboratory.
Complete the following information about the qualifications of your Clinical Consultant for Directors who are not qualified according to 1 through 4 above. Clinical Consultant: (check only one)	
	Pathologist with state license.
	MD, DO, DPM with state license.
	PhD in science and board certification (ABB, ABMM, ABCC, ABMLI).
Sig	nature of Director:
I certify that the information included on this form is accurate:	
	Michael Romo MT (ASCP)
Sign	ature of the Medical Test Site Director September 8, 2016 Date (mm/dd/yyyy)

SEP 2 1 2016

DE LITTERENT OF MENT

Office of Investigation and Inspection



Planned Parenthood of the Great Northwest and the Hawaiian Islands

September 14, 2016

Department of Health Health Systems Quality Assurance PO Box 47874 Olympia, Washington 98504-7874

Change of Laboratory Director and Technical Consultant Notification

Re: CLIA Certificate 50D0636085 MTS 0085, 1105 S 348th St. Ste B103, Federal Way, WA 98003-7027

CLIA Certificate 50D0663561 MTS 0038, 2001 E Madison St, Seattle, WA 98122-2959

CLIA Certificate 50D0633777 MTS 0200, 1509 32 St, Everett, WA 98201-4302

Effective September 19th, 2016, Stacy C. Olea, MT (ASCP), FACHE will assume the duties of Laboratory Director and Technical Consultant for Planned Parenthood of the Great Northwest and the Hawaiian Islands (formally Planned Parenthood of the Great Northwest) for the multisite CLIA certificates shown above.

We need to know what addition information and documentation is required for her approval to assume these duties.

Sincerely,

Carolyn S. Harvey

Vice President of Human Resources

Planned Parenthood of the Great Northwest and the Hawaiian Islands

Carolyn.Harvey@PPGNHI.org

206-328-7746

Bush, Veronica L (DOH)

From:

Bush, Veronica L (DOH)

Sent:

Thursday, July 28, 2016 6:34 AM

To:

Walker, Susan (DOH)

Subject:

RE: Credentials Change Forms

I will.

Veronica L. Bush Advisory Laboratorian Laboratory Quality Assurance 20425 72nd Ave S, Ste 310 Kent, WA 98032

Phone: (253)395-6782 Fax: (253)395-6365

Email: veronica.bush@doh.wa.gov

~Public Health-Always working for a safer and healthier Washington

From: Walker, Susan (DOH)

Sent: Thursday, July 28, 2016 5:39 AM

To: Bush, Veronica L (DOH)

Subject: Fwd: Credentials Change Forms

Should probably make sure these get done soon.

Sent from my iPhone

Begin forwarded message:

From: "Romo, Michael" < Michael.Romo@ppgnhi.org < mailto: Michael.Romo@ppgnhi.org >>

Date: July 27, 2016 at 5:29:41 PM MDT

To: Susan Walker < susan.walker@doh.wa.gov < mailto:susan.walker@doh.wa.gov >>

Subject: Credentials Change Forms

This message was sent securely using ZixCorp.http://www.zixcorp.com/get-started/

Susan these are in expedited mail and will be delivered by around noon tomorrow. I was informed of the issue with my replacement just this morning. I agreed to cover for a few months until a new Lab director can be hired. Then back to happy retirement!

Thanks for your help and understanding

Regards,

RECEIVED
MAY 1 6 2016





Planned Parenthood of the Great Northwest and the Hawaiian Islands

May 10, 2016

Department of Health Health Systems Quality Assurance PO Box 47874 Olympia, Washington 98504-7874

Change of Laboratory Director and Technical Consultant Notification

Re: CLIA Certificate 50D0636085 MTS 0085, 1105 S 348th St. Ste B103, Federal Way, WA 98003-7027

CLIA Certificate 50D0663561 MTS 0038, 2001 E Madison St, Seattle, WA 98122-2959

CLIA Certificate 50D0633777 MTS 0200, 1509 32 St, Everett, WA 98201-4302

Effective July 1, 2016 Debra L. Callahan, M.D. will assume the duties of Laboratory Director and Technical Consultant for Planned Parenthood of the Great Northwest and the Hawaiian Islands (formally Planned Parenthood of the Great Northwest) for the multisite CLIA certificates shown above.

Dr. Callahan is a pathologist and is board certified by the American Board of Pathology in Clinical Pathology and Blood Bank/Transfusion Medicine. We need to know what addition information and documentation is required for her approval to assume these duties.

Sincerely,

Carolyn S. Harvey

Vice President of Human Resources

Planned Parenthood of the Great Northwest and the Hawaiian Islands

Carolyn.Harvey@PPGNHI.org

206-328-7746





Planned Parenthood of the Great NW Central Region 2001 E Madison St Seattle, WA 98122-2959 MTSC.FS.00000038

RECEIVED JUL 2 8 2016

DOH/HSGA/OCS

Credential Status Change Form

Use this form for address, phone number, fax number, email, or facility name or contact changes to individual credentials. Send the completed change form to the address listed above.

Complete pages two and three only if you are changing the director of a categorized or accredited license.

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the Great	NW my	the HAWIID Islands	
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Thy 26, 2016 TS License # Clinical Laboratory Improvement Amendments (CLIA) #			
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^{*} **Do not** complete pages two and three unless you are changing the director of a categorized or accredited license.

Qualif	fications of Personnel for Moderate Comp	lexity Testing
Director:	r: (check only one)	
□ 1 Dot	athologist with state license	
	athologist with state license.	
2. ML	ID, DO, DPM, with state license and 1 year directing or supervising r	non-waived testing.
Wh	Vhich laboratory?D	ates
☐ 3. MD	ID, DO, DPM, with state license and 20 CMEs in laboratory practice.	
Wh	/hich program? D	ates
4. MD	ID, DO, DPM, with state license and laboratory training during reside	ncy equivalent to 20 CMEs.
Wh	/hich program? D	ates
5. Phl	hD in science and board certification (ABB, ABMM, ABCC, ABMLI).	
6. Phí	hD in science and 1 year directing or supervising non-waived testing	
Wh	/hich laboratory?D	ates
sup	laster Degree in science, + 1 year laboratory training and/or experier upervisory experience.	
8. Bad labo	achelor Degree in science, + 2 years laboratory training and/or expe boratory supervisory experience.	rience and 2 years ^{RECEIVED} JUL 2 8 2016
	n 2/28/92, serving as laboratory director and qualified or could have nder previous Medicare/CLIA independent laboratory personnel requ	qualified as director
	On 2/28/92, was qualified under state law to direct a laboratory.	
Directors v	e the following information about the qualifications of your Clinical Cos who are not qualified according to 1 through 4 above. Consultant: (check only one)	onsultant for
□ Dotho	cologist with state license	
	nologist with state license.	
	DO, DPM with state license.	
ו אחטו	in science and board certification (ABB, ABMM, ABCC, ABMLI).	
Signatu	ture of Director:	
I certify that	hat the information included on this form is accurate:	
		,
1/1/	e of the Medical Test Site Director Date (mm/dd/y	12016
Sīgnature c	e of the Medical Test Site Director Date (mm/dd/y	ууу)

Qualifications of Personnel for High C	omplexity Testing RECEIVED
Director: (check only one)	
1. Pathologist with state license.	Doug
2. MD, DO, DPM, with state license and 1 year laboratory	training in medical residency.
Which program?	Dates
3. MD, DO, DPM, with state license and 2 years directing	or supervising high complexity testing.
Which laboratory?	Dates
4. PhD in science and board certification (ABB, ABMM, AB	BCC, ABMLI).
5. PhD in science and before 2/24/2003, served or serving a laboratory and have 2 years laboratory training and/or e supervising high-complexity testing.	
Which laboratory?	Dates
6. On 2/28/92, serving as a laboratory director and qualified under previous Medicare/CLIA independent laboratory process.	ed or could have qualified as director
7. On 2/28/92, was qualified under state law to direct labor	ratory.
8. For subspecialty of oral pathology, be certified by the Ar American Board of Pathology, or American Osteopathic	
Complete the following information about the qualifications of y Directors who are not qualified according to 1,2,3, or 7 above. Clinical Consultant: (check only one)	your Clinical Consultant for
Pathologist with state license.	
MD, DO, DPM with state license.	
☐ PhD in science and board certification (ABB, ABMM, ABC	C, ABMLI).
DDS certified in oral pathology (ABOP, ABP, AOBP).	
Signature of Director:	
I certify that the information included on this form is accurate:	
Signature of the Medical Test Site Director	Date (mm/dd/yyyy)

2013 MULTI-SITE LICENSES

WASHINGTO	Current			New Effective May 16 2013	Rh testing cont Lab Director on assigned Cli Michael Romo	Clinical Consultant Dr. Laurel Kuehl	Technical Consultant Michael Romo
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North	CLIA # 50D0633777	MTS-0200	en.	Frank (asimana)	n L		-
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South	√Federal Way (primary) ~	<u> </u>		Federal Way (primary)	Rh		
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	₹ácoma ∕	Rh		·Tacoma	Rh		



RECEIVED

October 5, 2010

Office of Laboratory Quality Assurance Washington State Department of Health P.O. Box 47852 Olympia, WA 98504-7852 Sent by email and USPS HEALTH PACFESSIONS AND FACILITIES

ROUD DOTISTED DON-LOR

Dear Office of Laboratory Quality Assurance:

Several changes are in process at Planned Parenthood of the Great Northwest (PPGNW). This is notification of the changes affecting our site licenses for MTS-0038.

As of October 1, 2010 Family Planning of Clallam County (FPCC) is merged with PPGNW. Their site number 50D0635226 should be discontinued effective November 8, 2010

Effective November 8, 2010 the locations under the FPCC site number should be moved to the PPGNW site number 50D0663561

- As of November 15, 2010 the University District Health Center, primary site for 50D0663561will be closed and we wish to move that primary site license for MTS-0038 to the Madison Street Clinic, 2001 East Madison, Seattle WA 98122-2959.

- Effective December 1, 2010 we will open our new health center located at 2111 N. Meridian, Seattle, 98133. This new location will operate under site license 50D0663561.

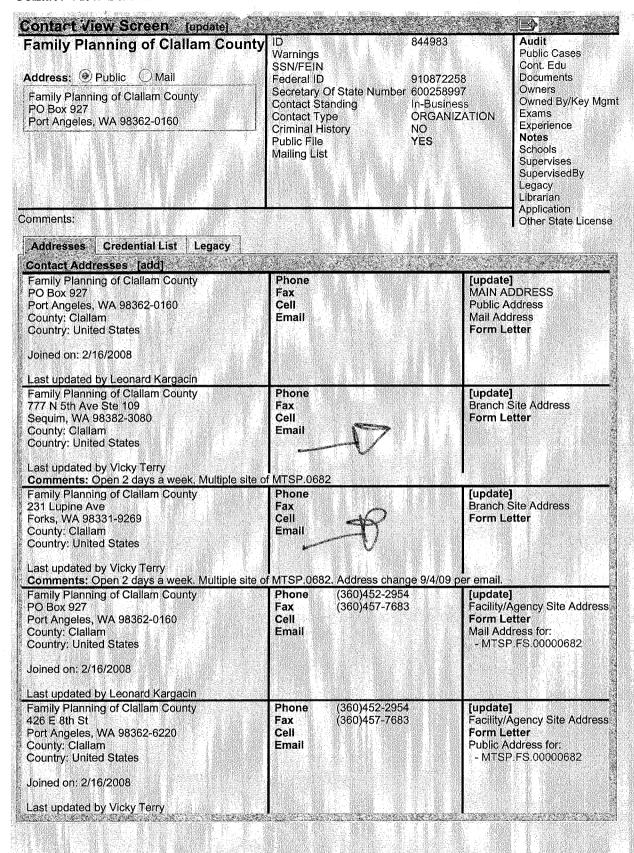
If you have any questions about these changes please contact me at the address below or by telephone at (206) 328-6815.

Sincerely,

Michael Romo MT(ASCP)

Chief Operating Officer and Laboratory Director Planned Parenthood of the Great Northwest

Cc: Karen Gunderson Jack Slowriver



Terry, Vicky (DOH)

To:

Helen Glad Toliver

Subject: RE: Address change & multiple site license

HI Helen.

Thank you for all the information. I have updated your address and will request a new license to be mailed out. Also, I do show that your facility is already listed as a multiple site license for the 2 addresses you gave me. It looks like we updated this back in December 2008.

Cordially ~ Vicky

From: Helen Glad Toliver [mailto:hglad@familyplanningofcc.org]

Sent: Friday, June 19, 2009 3:58 PM

To: Terry, Vicky (DOH)

Subject: Address change & multiple site license

Hello, Vicky. Thank you for your time today by phone. As I mentioned, we will be moving our main Port Angeles clinic to a new location, effective July 1, 2009. In addition, I am sending along our two satellite clinic locations, and will fax our 501-C3 determination letter to you today, as I believe we now need a multiple site license. Our CLIA # is 50D0635226, and our credential # is MTSP.FS.00000682

Our new Port Angeles clinic address, effective 7/1/09, is: 426 East 8th Street, Port Angeles, WA 98362

Our Sequim clinic is located at 777 North 5th Ave., Suite 109, Sequim, WA 98382 (within the Dungeness Wellness Clinic – we share their space but operate separately).

Our Forks clinic is located at 140 C Street, Forks, WA 98331 (within the Forks/Clallam County Health & Human Services clinic – we share their space but operate separately).

Please contact me if you need any additional information. Thank you so much for your assistance.

Sincerely,

Helen Glad Toliver, RN Clinical Services Supervisor Family Planning of Clallam County (360)-452-2954 ext. 23

Internal Revenue Service

Date: February 25, 2002

Family Planning of Clallam County 1106 E 1st Street Port Angeles, WA 98362-4317 Department of the TreP. O. Box 2508
Cincinnati, OH 45201

FEB 2 7 2002

Person to Contact:

Richard Owens 31-00913
Customer Service Representative

Toll Free Telephone Number:

8:00 a.m. to 8:30 p.m. EST 877-829-5500

Fax Number: 513-263-3756

Federal Identification Number: 91-0872258

Dear Sir or Madam:

This letter is in response to your request for a copy of your organization's determination letter. This letter will take the place of the copy you requested.

Our records indicate that a determination letter issued in July 1979, granted your organization exemption from federal income tax under section 501(c)(3) of the Internal Revenue Code. That letter is still in effect,

Based on information subsequently submitted, we classified your organization as one that is not a private foundation within the meaning of section 509(a) of the Code because it is an organization described in sections 509(a)(1) and 170(b)(1)(A)(vi).

This classification was based on the assumption that your organization's operations would continue as stated in the application. If your organization's sources of support, or its character, method of operations, or purposes have changed, please let us know so we can consider the effect of the change on the exempt status and foundation status of your organization.

Your organization is required to file Form 990, Return of Organization Exempt from Income Tax, only if its gross receipts each year are normally more than \$25,000. If a return is required, it must be filed by the 15th day of the fifth month after the end of the organization's annual accounting period. The law imposes a penalty of \$20 a day, up to a maximum of \$10,000, when a return is filed late, unless there is reasonable cause for the delay.

All exempt organizations (unless specifically excluded) are liable for taxes under the Federal Insurance Contributions Act (social security taxes) on remuneration of \$100 or more paid to each employee during a calendar year. Your organization is not liable for the tax imposed under the Federal Unemployment Tax Act (FUTA).

Organizations that are not private foundations are not subject to the excise taxes under Chapter 42 of the Code. However, these organizations are not automatically exempt from other federal excise taxes.

Donors may deduct contributions to your organization as provided in section 170 of the Code. Bequests, legacies, devises, transfers, or gifts to your organization or for its use are deductible for federal estate and gift tax purposes if they meet the applicable provisions of sections 2055, 2106, and 2522 of the Code.

-2-

Family Planning of Clallam County 91-0872258

Your organization is not required to file federal income tax returns unless it is subject to the tax on unrelated business income under section 511 of the Code. If your organization is subject to this tax, it must file an income tax return on the Form 990-T, Exempt Organization Business Income Tax Return. In this letter, we are not determining whether any of your organization's present or proposed activities are unrelated trade or business as defined in section 513 of the Code.

The law requires you to make your organization's annual return available for public inspection without charge for three years after the due date of the return. If your organization had a copy of its application for recognition of exemption on July 15, 1987, it is also required to make available for public inspection a copy of the exemption application, any supporting documents and the exemption letter to any individual who requests such documents in person or in writing. You can charge only a reasonable fee for reproduction and actual postage costs for the copied materials. The law does not require you to provide copies of public inspection documents that are widely available, such as by posting them on the Internet (World Wide Web). You may be liable for a penalty of \$20 a day for each day you do not make these documents available for public inspection (up to a maximum of \$10,000 in the case of an annual return).

Because this letter could help resolve any questions about your organization's exempt status and foundation status, you should keep it with the organization's permanent records.

If you have any questions, please call us at the telephone number shown in the heading of this letter.

This letter affirms your organization's exempt status.

Sincerely,

John E. Ricketts, Director, TE/GE Customer Account Services



FAMILY PLANNING OF CLALLAM COUNTY

1106 East First Street P.O. Box 927 Port Angeles, WA 98362-0160 Telephone 360.452.2954 Fax 360.457,7683

Confidential Fax Cover Sheet

IMPORTANT: This facsimile, including any attachment, contains information that may be confidential or privileged, and is intended solely for the entity or individual to whom it is addressed. If you are not the intended recipient, please notify us immediately by telephone and destroy all information received. You are hereby notified that any disclosure, copying, or distribution of this message is strictly prohibited. Thank you.

Date 6-19-09	Pages (including cover sheet)
To: Vicky Terry Agency: WA St Doff	Fax#: 206-418-5505
From: Helen Glad Tolive	Fax# 360.457-7683
Per Our Conversation Per Your Request For Necessary Action For Your Information Please Respond	Phase see my c-Mail sent today- : address change
Comments:	1Hiple side license
	kyou!

Terry, Vicky (DOH)

To:

Helen Glad Toliver

Cc:

Jack Slowriver; Gail Marsh

Subject: RE: An update for our Forks Clinic

Hi Helen,

Thank you notifying our office of the address change for your Forks facility. I have updated your records. Cordially ~ Vicky

Vicky Terry ~ Administrative Assistant III Washington State, Department of Health Office of Laboratory Quality Assurance 1610 NE 150th Street Shoreline WA 98155-9701

Phone: 206-418-5600 Fax: 206-418-5505

www.doh.wa.gov/lqa.htm

From: Helen Glad Toliver [mailto:hglad@familyplanningofcc.org]

Sent: Friday, September 04, 2009 6:25 PM

To: Terry, Vicky (DOH) **Cc:** Jack Slowriver; Gail Marsh

Subject: An update for our Forks Clinic

Hello, Vicky. We currently have a medical test site license for 3 clinics here in Clallam County, in Port Angeles, Sequim, and Forks. We have previously provided you with documentation confirming our organization's status as a 501 (c)(3).

Effective this week, our Forks clinic has moved to a new location.

Our old address was 140 C Street, Forks, WA, and operated one day per week.

Our new address is 231 Lupine Avenue, (mailing address PO Box 1681), Forks, WA 98331. Our clinic will be operating two days per week. Thanks so much for your assistance in updating our medical test site license to reflect our new clinic location.

Helen Glad Toliver, RN
Clinical Services Supervisor
Family Planning of Clallam County
426 East 8th Street
Port Angeles, WA 98362
P (360) 452-2954 ext. 23 Fax (360) 457-7683
hglad@familyplanningofcc.org

DISCLAIMER: The information in this email is intended for the use of the individual or entity named above. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of the contents of this information is prohibited. If you have received this electronic transmission in error, please notify the sender immediately by a "reply to sender only" message and destroy all electronic and hard copies of the communication, including attachments. Although we make reasonable efforts to protect the confidentiality of e-mail, communications regarding highly confidential medical matters should be reserved for other forms of communication, such as telephone or personal visits. In addition, you should not use e-mail for emergencies or other time-sensitive matters. Should you have any questions about our policies regarding e-mail communications please contact FPCC's Executive Director at 426 East 8th Street, Port Angeles, WA 98362.

NUTSP.0000680.

5000135726

December 17, 2008

To:

Vicky Terry, Office of Laboratory Quality Assurance

From:

Helen Glad Toliner, Clinical Services Supervisor

Date:

December 17, 2008

Re:

Multiple site listing

Thank you, Vicky, for returning the call yesterday. As we discussed, I am sending a copy of a document confirming our organization's status as a 501 (c)(3). In addition to our Port Angeles clinic operating five days per week, we have added a satellite clinics that utilize a microscope to perform wet mounts by our ARNPs at the following location:

<u>FPCC Sequim Clinic</u> (located within the Dungeness Valley Health and Wellness Clinic). We function independently from the Dungeniuss Valley Health and Wellness Clinic, providing family planning services on two clinic days). The clinic is located at:

777 North 5th Ave., Suite 109, Sequim, WA 98382

<u>FPCC Forks Clinic</u> (located within the Forks Health Department, Clallam County Health & Human Services). We function independently from the Forks Health Department, providing family planning services one clinic day per week. The clinic is located at:

140 C Street, Forks, WA 98331

Thank you for your assistance in changing our medical test site license to a multiple site license. Please contact me at (360) 452-2954 ext. 23, or by email at hglad@familyplanningofcc.prg if you need any further Information.

Internal Revenue Service

Date: February 25, 2002

Family Planning of Clallam County
1106 E 1st Street
Port Angeles, WA 98362-4317

Department of the Treatment of the Treat

Person to Contact:

Richard Ower s 31-00913 Customer Service Representative

Toll Free Telephone Number:

8:00 a.m. to 6:30 p.m. EST 877-829-5500

Fax Number: 513-263-3750

Federal Identification Number:

91-0872258

Dear Sir or Madam:

This letter is in response to your request for a copy of your organization's determination letter. This letter will take the place of the copy you requested.

Our records indicate that a determination letter issued in July 1979, granted your organization exemption from federal income tax under section 501(c)(3) of the Internal Revenue Code. That letter is still in effect.

Based on information subsequently submitted, we classified your organization as one that is not a private foundation within the meaning of \parallel ection 509(a) of the Code because it is an organization described in sections 509(a)(1) and 170(b)(1)(\parallel)(vi).

This classification was based on the assumption that your organization's operations would continue as stated in the application. If your organization's sources of support, or its character, method of operations, or purposes have changed, please but us know so we can consider the effect of the change on the exempt status and foundation status of your organization.

Your organization is required to file Form 990, Return of Organization Exempt from Income Tax, only if its gross receipts each year are normally more than \$25,000. If a return is required, it must be filed by the 15th day of the fifth month after the end of the organization's annual accounting period. The law imposes a penalty of \$20 a day, up to a maximum of \$10,000, when a return is filed late, unless there is reasonable cause for the delay.

All exempt organizations (unless specifically excluded) are liable for taxes under the Federal Insurance Contributions Act (social security sixes) on remuneration of \$100 or more paid to each employee during a calendar year. Your organization is not liable for the tax imposed under the Federal Unemployment Tax Act (FUTA).

Organizations that are not private foundations are not subject to the excise taxes under Chapter 42 of the Code. However, these organizations are not automatically exempt from other federal excise taxes.

Donors may deduct contributions to your organization as provided in section 170 of the Code. Bequests, legacies, devises, transfers, or gifts to your organization or for its use are deductible for federal estate and gift tax purposes if they meet the hipplicable provisions of sections 2055, 2103, and 2522 of the Code.

-2-

Family Planning of Ciallam County 91-0872258

Your organization is not required to file federal income tax returns unless it is subject to the tax on unrelated business income under section 51% of the Code. If your organization is subject to this tax, it must file an income tax return on the Form 99% Exempt Organization Business Income Tax Return. In this letter, we are not determining whether any off your organization's present or proposed activities are unrelated trade or business as defined in section 51% of the Code.

The law requires you to make your organization's annual return available for public inspection without charge for three years after the due date of the return. If your organization had a copy of its application for recognition of exemption on July 15, 1987, it is also required to make available for public inspection a copy of the exemption application, any supporting documents and the exemption letter to any individual who requests such documents in person or in writing. You can charge only a reasonable fee for reproduction and actual postage costs for the copied materials. The law does not require you to provide copies of public inspection documents that are widely available, such as by posting them on the Internet (World Wide Web). You may be liable for a penalty of \$20 a day for each day you do not make these documents available for public inspection (up to a maximum of \$10,000 in the case of an annual return).

Because this letter could help resulve any questions about your organization's exempt status and foundation status, you should keep it with the organization's permanent records.

If you have any questions, please call us at the telephone number shown in the heading of this letter.

This letter affirms your organization's exempt status.

Sincerely,

John E. Ricketts, Director, TE/GE Customer Account Services



FAMIL | PLANNING OF CLALLAM COUNTY

1106 East First Street P.O. Box 927 Port Angeles, WA 98362-0160 Telephone 360.452.2954 Fax 360.457.7683

Confidential Fax Cover Sheet

IMPORTANT: This facsimile, including any attachment, contains information that may be confidential or privileged, and is intended solely for the entity or individual to whom it is addressed. If you are not the intended recipient, please notify us immediately by telephone and destroy all information received. You are hereby notified that any disclosure, copying, or distribution of this message is strictly prohibited. Thank you.

Date: 12-17-08	Pages (including cover sheet)
To: Vicky Terry Agency: Office of Labo	Fax#: 206-418-5505 ratory Quality Assurance
	Fax#: 360-457-7683
Per Our Conversation Per Your Request For Necessary Action For Your Information Please Respond	
0.5	

Comments:





CLIA LABORATORY PROGRAM PO BOX 70948 CHARLOTTE,NC 28272-0948 changed 12-18-08

DEC 05 2008

unhs/CMS/SAC Region 10, Seattle, WA

Dear, CLIA LABORATORY PROGRAM:

Planned Parenthood of Western Washington, Planned Parenthood of Idaho and Planned Parenthood Alaska have merged operations as Planned Parenthood of the Great Northwest effective November 1, 2008.

Please send all invoices and correspondence to:

Planned Parenthood of the Great Northwest 2001 E Madison Street Seattle, WA 98122 206-328-7734 Federal Tax ID # 91-0686012 mailing

MUZ-0038

Failure to change address may delay your payment.

Thank you for helping make this a smooth transition.

245 D



Redaction Summary (0 redactions)
0 Privilege / Exemption reason used:
Redacted pages:

Application File FS_00000038_pdf-r.pdf redacted on: 1/29/2018 13:46