

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.

of Great NW

KL

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

CLIA Number: 50D0663561

Tax ID Number: 910686012

Classification:

A

Phone: (206) 328-6815

Fax: (206) ~~720-4657~~ 328-4984

Accreditation Agency (if accredited):

Site Address:

4500 9th Ave NE Ste 324
Seattle WA 98105-4778

Mailing Address:

Karen Gunderson
2001 E Madison St
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
Micro Contact: michael.romo@ppwnw.org
Lab Cytology Contact:
Lab Consultant:
Lab Administrative Contact:

ppgnw.org

Approved Specialties:

Immunohematology
ABO & Rh Typing

RCUB FEB19'09 DOH-100

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.

I 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

Waived Tests: Place a checkmark by the test kit/system if you perform any of the specific test methods listed below.
(waived test list as of 12/16/08)

Adenovirus

Rapid Pathogen Screening RPS Adeno Detector

Aerobic/Anaerobic Organisms-Vaginal

Genzyme Diagnostics OSOC BVBLUE Test
 Gryphus Diagnostics BVBlue

Alanine Aminotransferase (ALT)

Arkray SPOTCHEM EZ Chem Analyzer (ALT) (WB)
 Cholestech LDX (ALT) (whole blood)
 Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (WB)
(Lipid Panel Plus, Liver Panel Plus, CMP, BMP)

Albumin

Arkray SPOTCHEM EZ Chem Analyzer (WB)
 HemoCue Albumin 201 System (urinary albumin)
 Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB
(Liver Panel Plus Reagent Disc, Chem 13, CMP)

Alkaline Phosphatase (ALP)

Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (WB)
(Liver Panel Plus Reagent Disc, CMP, BMP)

Amylase

Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus)

Aspartate Aminotransferase (AST)

Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Cholestech LDX Aspartate Aminotransferase (AST)
 Piccolo Point of Care/Blood/xpress Chemistry Analyzer (WB)
(Lipid Panel/Plus, Liver Panel Plus, Chem 6/13, CMP)

B-Type Natriuretic Peptide (BNP)

Biosite Triage Meter/Meterpro (whole blood) BNP

Basic Metabolic Panel

Abbott 1-STAT CHEM8+ Cartridge (ionized calcium) WB
 Abaxis Piccolo Blood Chemistry/express (total calcium) WB

Bilirubin, Total

Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB
(Liver Panel Plus Reagent Disc. Chem 13, CMP)

Bladder tumor associated antigen

Bion Diagnostic Sciences BTA *stat* Test (for home use)
 Maritech BladderCheck Test (professional & prescription use)

BUN (Blood Urea Nitrogen)

Abbott i-STAT CHEM8+/6+ Cartridge
 Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP)

Calcium

Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Piccolo xpress & Blood Chem Analyzers WB (chem 13, CMP, BMP)

Calcium - Ionized

Abbott i-STAT CHEM8+ Cartridge

Carbon Dioxide (CO2)

Abbott i-STAT CHEM8+ Cartridge
 Piccolo xpress & Blood Analyzers (CMP,BMP,lytes)

Catalase, urine

Diatech Diagnostics Uriscreen (for OTC use)

Chloride

Abbott i-STAT CHEM8+/6+ Cartridge
 Piccolo xpress & Blood Analyzers (CMP,BMP,lytes)

Cholesterol

Accu-Check InstantPlus Cholesterol test system
 Accucheck Instant Plus Dual Testing System
 Advanced Care Cholesterol measuring system
 Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Biomedix Inc Q Steps Biometer G/C Dual Monitoring System
 ChemTrak AccuMeter Cholesterol test system
 Cholestech LDX Test System
 ENA C.T. Total Cholesterol or Total Cholesterol (PDU)
 Lifestream Technologies Cholesterol Monitors
 Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)
 Polymer Tech. Systems Bioscanner, Bioscanner Plus, Bioscanner 2000 PST, and MTS Bioscanner 1000
 Polymer Technology Cardiochek and Cardiochek PA
 Wako APOLOWAKO Analyzer (WB)

Comprehensive Metabolic Panel

Abaxis Piccolo Blood Chemistry/express WB

Creatinine

Abbott i-STAT CHEM8+/Crea Cartridge
 Arkray SPOTCHEM EZ Chemistry Analyzer (WB)
 Bayer Clinitek 50 Urine Chemistry Analyzer for Creatinine
 Bayer Diagnostics MICROALBUSTIX Reagent Strips
 Bayer MultiStix PRO 11, PRO 10LS, and PRO 7G
 Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP)
 Siemens Medical DCA Vantage Analyzer

Drugs of Abuse

Acon Laboratories Drug Home Tests
 Accu-Stat Diagnostics Drugs of Abuse Home Test
 Advantage Diagnostics
 Alatec Scientific Peace of Mind Multiple Drugs of Abuse
 Alfa Scientific Designs
 American Bio Medica Rapid TOX
 Applied Biotech
 Aventir Biotech LLC Home Check Multiple Drug Cup Test
 Biotechnostix Rapid Response Drug Screens
 Branam Medical Corp Fastect II/FasTox/QuickTox/ToxCup
 BTNX Know/Rapid Response Multi-Drug One Step Screen
 Drug Detection Devices Multi-Drug Multi-Line Screeners
 eScreen, Inc. mCheck Multi-Line Screen Test Device
 First Check Diagnostics Drug Screens
 Forefront Diag. Drug Screen
 Graman Medical Corporation
 Innovacon Integrated E-Z Split Key Cup II (professional use)
 Innovacon Multi-Clin Drug Screen Test Device
 Instant Technologies iTest, iCassette, iCup
 Jant Pharmacal Accutest MultiDrug ER11/SplitCup Drug Screen
 LifeSign Home Drug Tests
 Nobel Medical Split-Specimen Cup
 Phamatec At Home & QuickScreen
 Princeton Biomeditech Drug Tests
 Quest Diag. Integrated E-Z Split Key Cup II/Express Results
 Redwood Tech. Lab Reditest 6 & Reditest Home Drug Tests
 WayPoint Biomedical, Inc. Health Essist Multi-Drug Tests
 Wolfe Drug Testing RealityCheck Integrated Specimen Cup
 Worldwide Medical Corp. First Check Home Drug Tests

Electrolyte Panel

Abaxis Piccolo Blood Chemistry/express WB

Erythrocyte sedimentation rate (ESR)

Non-automated

Esterone-3-Glucuronide

Unipath Limited Clearplan Easy Fertility Monitor

Ethanol

OraSure Q.E.D. A-150 and A-350 Saliva Alcohol Tests

Follicle Stimulating Hormone (FSH)

- ___ Acon Lab FSH Menopause Predictor Test
- ___ Acon Lab FSH One Step Menopause Test Strip/Device
- ___ Applied Biotech Menopause Predictor/Instacheck FSH Test
- ___ Applied Biotech Menopause Predictor and RU25 Plus FSH
- ___ Biotechnostix Rapid Response FSH One Step Test Device
- ___ Genesis Fertell Female Fertility Test (FSH)
- ___ Genua Menopause Monitor Test, FSH (qualitative)
- ___ IND Diagnostic One Step FSH Menopausal Test (midstream)
- ___ IND Diagnostic One Step FSH (Strip/Cassette)
- ___ IND Diagnostic One Step Strip/Cassette Style FSH (prof use)
- ___ Phamatech Moments Menopause Check (FSH)
- ___ PanProbe Biotech EarlyDetect Menopause Test
- ___ QuantRx Biomedical QuantRx Female Fertility Test
- ___ RAC Medical Clarity FSH One Step Menopause (prof use)
- ___ Synova Healthcare Menocheck Menopause Indicator Test

Fructosamine

LXN (Duet and IN CHARGE Test Systems)

Gamma Glutamyl Transferase (GGT)

Piccolo Point of Care/Blood/xpress Chemistry Analyzer (Liver Panel Plus Reagent Disc, Chem 6, Chem 13)

Glucose

- ___ Arkray SPOTCHEM EZ Chem Analyzer (WB)
- ___ Abbott i-STAT CHEM8+/G/EC4+/6+ Cartridge
- ___ Biomedix, Inc Q Steps Biometer G/C Dual Monitoring System
- Blood glucose monitoring devices cleared by FDA - home use
- ___ Cygnus, Inc GlucoWatch Automatic Glucose Biographer
- ___ Diagnostic Test Grp, Clarity Blood Glucose Monitoring System
- ___ Hemocue B-Glucose Photometer & model 201 analyzer/201DM
- ___ LXN Duet and IN CHARGE Glucose Monitoring System
- ___ Cholestech LDX
- ___ Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Lipid Panel Reagent Disc, Chem 6/13, CMP, BMP)
- ___ Polymer Technology Systems CardioChek PA Analyzer
- ___ Roche Diagnostics AccuChek Instant Plus Dual Test System
- ___ Wako APOLOWAKO Analyzer (WB)

Glycosylated HGB Total yearly volume: _____

- ___ Axis-Shield Afinion AS10 Analyzer
- ___ Bayer DCA 2000/2000+/A1CNow+
- ___ Bio-Rad Micromat II
- ___ Bristol-Myers Squibb Choice DM
- ___ Cholestech GDX A1C (prescription home use)
- ___ Metrika A1c Now/DRX HbA1C/InView Multi Test
- ___ Provalis Diagnostics Glycosal/In2it In-office analyzer II/G5 I HbA1c/G5 II HbA1c
- ___ Siemens Medical DCA Vantage/2000/2000+ Analyzer
- ___ Wako APOLOWAKO Analyzer (WB)

HDL Cholesterol

- ___ Accutech CholesTrak HDL Cholesterol Home Test
- ___ Arkray SPOTCHEM EZ Chem Analyzer (WB)

___ Cholestech LDX

- ___ Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus),
- ___ Polymer Technology Systems BioScanner Plus and 2000
- ___ Polymer Technology Systems Cardiochek and Cardiochek PA

Helicobacter pylori

- ___ Abbott FlexPack HP, Signify, Cassette, and TestPack Plus (WB)
- ___ Acon *H. pylori* Rapid Test Device (whole blood)
- ___ Alfa Scientific Designs Instant View (whole blood)
- ___ Applied Biotech SureStep (whole blood)
- ___ Ballard (Delta West) CLOtest (gastric biopsy)
- ___ Beckman Coulter Flexsure (whole blood)
- ___ Becton Dickinson LINK 2 (whole blood)
- ___ BTNX Inc Rapid Response *H. pylori* Rapid Test Device(WB)
- ___ Cardinal Health SP Brand Rapid Test (whole blood)
- ___ ChemTrak AccuMeter (whole blood)
- ___ Clarity *H. pylori* Rapid Test Device (whole blood)
- ___ De Healthcare Products Truview *H. pylori* (whole blood)
- ___ Diagnostic Test Group Clarity *H. pylori* Rapid Test Device (WB)
- ___ Fisher Healthcare Sure-View *H. pylori* Test (WB)
- ___ Germaine Laboratories AimStep (whole blood)
- ___ GI Supply HP-FAST and HP One (gastric biopsy tissue)
- ___ Henry Schein OneStep+ / Rapid Test Device (whole blood)
- ___ Immunostics Detector *H. pylori* (WB)
- ___ Instant Technologies iScreen (whole blood)
- ___ Inverness BTNX Inc Rapid Response *H. pylori* Test (WB)
- ___ Inverness Medical Clearview *H. pylori* Test (WB)
- ___ Jant Pharmacal Corp. Accutest Rapid Test Device (whole blood)
- ___ LifeSign and LifeSign Status (whole blood)
- ___ McKesson Medi-Lab Performance *H. pylori* Test (WB)
- ___ Medical Instruments Corp Pronto Dry (gastric biopsy)
- ___ Meridian Bioscience ImmunoCard STAT! (whole blood)
- ___ Polymedco Polystat (whole blood)
- ___ PreMaxim RadiScreen Test Device (whole blood)
- ___ Princeton BioMeditech BioSign (whole blood)
- ___ Quidel QuickVue gII/One-Step/One-Step II (whole blood)
- ___ Remel RIM A.R.C. (whole blood)
- ___ Roche Diagnostics AccuStat *H. pylori* OneStep (WB)
- ___ Select Medical Products Brand Rapid Test *H. pylori* (WB)
- ___ Serim Pyloritek Test Kit and VP Test Kit (gastric biopsy)
- ___ SmithKline FlexSure HP (whole blood)
- ___ Trinity Uni-Gold (whole blood)
- ___ Wampole Laboratories Clearview *H. pylori* II (whole blood)

Hematocrit

- ___ Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- ___ Microhematocrit (spun)
- ___ Micro Diagnostics Spuncrit DRC-40 Infrared Analyzer
- ___ UltraCrit
- ___ Wampole STAT-CRIT for hematocrit

Hemoglobin

- ___ Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- ___ Biosafe laboraotry's Anemiapro Self Screener
- ___ Biotest Hemoglobin Measuring System
- ___ Copper Sulfate (non-automated)
- ___ EKF Diag. Hemo_Control Measurement & Microcuvettes
- HemoCue hemoglobin test systems (201, 201+, 301)
- ___ HemoCue Donor Hemoglobin Checker System
- ___ GDS Diagnostics HemoSite Meter for hemoglobin
- ___ GDS Technology STAT-Site M Hgb Test System
- ___ ITC HGB PRO Professional Hemoglobin Testing System

Starbio Hemoglobin Analyzer
 Stanbio HemoPoint H2 Hemoglobin Measurement System

HIV-1

Chembio HIV 1/2 STAT-PAK Assay (WB)
 Clearview COMPLETE HIV 1/2 fingerstick & venipuncture WB
 OraQuick Rapid HIV-1 Antibody Test (oral fluid, WB)
 OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)
 Trinity Biotech UniGold Recombigen HIV test (WB)

Influenza

Binax NOW Flu A and Flu B Tests and A&B Tests
 Quidel QuickVue Influenza Test (Influenza A/B)
 Quidel QuickVue Influenza A+B Test
 SA Scientific SAS Influenza A/Influenza B Tests
 ZymeTX Zstatflu (Influenza A/B)

Ketones (Blood)

Abbott Laboratories Precision Xtra/Xceed
 Polymer Technology Systems BioScanner 2000

Lactic Acid

KDK Corporation Lactate Pro System (for OTC use)

LDL Cholesterol

Polymer Tech. Systems Cardiocheck/Cardiocheck PA Analyzer

Lead

ESA Biosciences LeadCare II Blood Lead Testing System (WB)

Lithium

Akers Laboratory Inc InstaRead Lithium System (WB)
 ReliaLAB Inc. InstaRead Lithium System (WB)

Lyme Disease

Wampole PreVue *B. burgdorferi* Antibody

Lutenizing Hormone (also see ovulation tests)

Chembio Sure Check Ovulation Predictor
 Inverness Medical Early Ovulation Predictor Stix
 Unipath Limited Clearplan Easy Fertility Monitor

Microalbumin

Roche/Boehringer Mannheim Micral Chemstrip
 Bayer Clinitek 50 Urine Chemistry Analyzer
 Bayer Clinitek Status Urine Chemistry Analyzer
 Bayer Diagnostics MICROALBUSTIX Reagent Strips
 Diagnostic Chemicals ImmunoDip & Urinary Albumin Screen
 HemoCue Albumin 201 System
 Siemens Medical DCA Vantage Analyzer

Mononucleosis

Acon Mono rapid Test Strip/Device (whole blood)
 Applied Biotech One Step+, SureStep, Truview Mono Test
 BioStar Aceava Mono/Mono II Test (whole blood)
 Cardinal SP Brand Rapid Test (whole blood)
 Clarify MONO Mononucleosis Rapid Test (WB)
 Clearview Mono-Plus II / Mono Test Whole Blood (WB)
 Genzyme Contrast/OSOM/Rapid/Sure-Vue Signature MonoTest
 Henry Schein One Step+ Mono Test (whole blood)
 Immuno Detector Mono/BioSign Mono WB
 Instant Technologies iScreen (whole blood)
 Jant Accutest Valeu+/Infectious Mononucleosis Test (WB)
 LifeSign Status/UniStep Mono Test (whole blood)
 McKesson Medi-Lab Performance Infectious Mono Test
 Meridian ImmunoCard STAT Mono (whole blood)
 Polymedco, Inc. Poly stat Mono (whole blood)
 Poly Stat Mono Test (WB)
 PreMaxin RediScreen Mononucleosis (WB)
 Princeton BioMeditech BioSign Mono WB (whole blood)

Quidel CARDS O.S. and QuickVue+ Mono (whole blood)
 RAC Medical Clarity MONO Rapid Test Device (WB)
 Rapid Response Mono Rapid Test Device (whole blood)
 Remel RIM A.R.C. Mono Test
 Seradyn Color Q Mono (whole blood)
 Signify Mono Test / Mono Whole Blood / Mono Cassette (WB)
 Wampole Mono-Plus WB (whole blood)
 Wyntek Diagnostics OSOM and Signify Mono test (WB)

Nicotine (or its metabolites)

DynaGen NicCheck 1 Test Strips
 Mossman Associates NicCheck I Test Strips

Occult blood

Fecal Occult Blood
 Fecal Occult Blood Immunochemical/Immunological Tests
 Aerscher Hemaprompt FG Gastric Occult Blood
 Alfa Scientific Designs Instant-View FOB Self-Test Cassette
 Alfa Scientific Designs FOB Self-Test
 Beckman Coulter Primary Care Diagnostics Gastrocult/
 Hemocult Sensa Elite (gastric occult blood)
 Clarity Fecal Occult Blood Self Test
 Know Fecal Occult Blood Self Test
 Rapid Response Fecal Occult Blood Self Test
 Smithkline Gastrocult

Osteoporosis

Ostex International Osteomark NTX

Ovulation Tests

Visual color comparison tests for human luteinizing hormone
 Luna Fertility Indicator (saliva)
 O2 Unlimited Donna Ovulation Test (saliva)
 Stesans Maybe?Mom Mini Ovulation Microscope (saliva)
 TCI Ovulation Tester (saliva)

PH

All qual. color comparison pH - body fluids (not blood)
 Common Sense FemV/VI-Sense/VA-Sense/Norma Sense (vag pH)
 Duramed AmniScreen Home Dection Liner Kit
 Femtek Phem-Alert (vaginal pH)
 Litmus Concepts FemExam Test Card (vaginal pH & amines)
 Quickek QuickVue Advance pH and Amines Test

Platelet Aggregation

Accumetrics VerifyNow Aspirin Assay

Potassium

Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
 Piccolo xpress & Blood Analyzers (CMP, BMP, lytes)

Pregnancy Test (Urine)

Urine pregnancy test: visual color comparison
 Bayer Clinitek 50 Urine Chemistry Analyzer

Protine

AvoSure Pro and PT
 Hemosense INRATIO
 International Technidyne Corporation Protine Microcoagulation
 System and ProTime 3 Cuvette System
 Lifescan Harmony INR Monitoring System
 Lifescan Rubicom Prothrombin Time Monitoring System
 Roche Diag CoaguChek & CoaguChek S Systems, PT-S Strips,
 XS, XS PST

Protein, Total

Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus
 Reagent Disc, Chem 13, CMP)

RSV (Respiratory Syncytial Virus Direct Antigen)

- Binax NOW RSV Test
- Fisher Scientific Sure-Vue RSV Test
- Integrated Biotechnology Quick Lab RSV Test
- Meridian Bioscience Immunocard Stat! RSV Plus
- Quidel Quick Vue RSV Test
- Remel Xpect RSV
- SA Scientific SAS RSV Test/RSVAlert
- Wampole Laboratories Clearview RSV

Semen

- Embryotech Laboratories FertilMARQ for male infertility
- Fertil Male Fertility Test
- Fertility Solutions Semen Analysis (qualitative)
- SpermCheck Vasectomy

Sodium

- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP, BMP, lytes)

Strep Antigen Test

- Abbott Signify Strep A Test / Dipstick
- ACON Strep A Rapid, Strep A Twist Rapid, and ICON DS
- Applied Biotech SureStep Strep A (II)/Strep A Exact
- Beckman Coulter ICON Fx (formerly SmithKline)
- Beckman Coulter Primary Care Diag. DS, FX, and SC
- Becton Dickinson LINK 2/Chek Strep A Rapid test
- Binax NOW Strep A Test
- BioStar Aceava™ Strep A Test
- Biotechnostix Rapid Resp. Strep A Rapid Test Device/Strip
- Cardinal Health CP Brand Rapid Test Dipstick/Cassette
- Clearview Strep A Exact Dipstick
- DE Healthcare Products, TruView Strep A Test/Cassette
- Diagnostic Test Group Clarity Strep A Rapid Test Strips
- Fisher HealthCare Sure-Vue Strep A
- Genzyme Contrast Strep A and OSOM Ultra Strep A
- Germaine Laboratories Strep AIM Rapid Dipstick Test
- Germaine Laboratories Strep AIM Tower
- Henry Schein Inc, One Step+ Strep A Test , Strep A Dipstick
- Immunostics Immuno/Strep A Detector, Strep A Direct
- Instant Technologies Istrep Strep A Test
- Inverness Medical BioStar Aceava Strep A Test/Twist
- Inverness Medical Clearview Strep A Exact II Dipstick
- 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
- LifeSign LLC Status Strep A
- Mainline Confirms Strep A Dots test
- McKesson Strep A Medi-lab Performance Dipstick/Cassette/ Strep A Test - Twist

- Meridian Diag. ImmunoCard STAT Strep A
- MediLab Performance Strep A Twist Rapid Test
- Moore Medical Strep A Rapid Test - Dipstick/Cassette
- Performance Enhanced Products Strep A Cassette, Dipstick
- PerMaxin Rediscreen Strep A Rapid/Strep A Twist Cassette
- Polymedco Poly stat A (II), Strep A Liquid Test, Strep A Dipstick
- Princeton BioMediTech BioStrep A /Status First Strep A
- PSS World Medical Strep A Dipstick/Twist
- Quidel QuickVue In-Line and Dipstick and In-Line One-step
- RAC Medical Clarity Strep A Twist Rapid Test Device/Strip
- Remel RIM A.R.C. Strep A Test
- Sacks Medical Refuah Strep A Rapid Test
- SA Scientific SAS Strep A
- Select Medical Products Brand Rapid Test Strep A Dipstick
- Select Medical Products Brand Rapid Test Strep A Twist
- Signify Strep A Dipstick
- Stanbio Qustick Strep A, E-Z Well Strep A Rapid Test
- Wyntek Diag. OSOM Strep A and OSOM Ultra Strep A Test

Trichomonas

- Genzyme Osom Trichomonas Rapid Test

Triglycerides

- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Cholestech LDX
- 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

- Jant Pharmacal Corp Accutest TSH (WB)
- Little Nell Labs ThyroChek TSH (WB)
- Qualigen Inc FastCheck TSH (WB)
- ThyroTest Whole Blood TSH Test (WB)

Uric Acid

- Piccolo xpress & Blood Chem Analyzers (chem 13)WB

Urinalysis

- Urinalysis: Dipstick or tablet reagent (nonautomated)
- Acon Lab. Mission UTI Urinary Tract Infection Test Strips
- Bayer Clinitek 50/Status Urine Chemistry Analyzers
- Biosys Laboratories Optima/Optima II Urine Analyzer
- Consult diagnostics Urine Analyzer
- Henry Schein OneStepPlus Urine Analyzer
- Hypoguard Diascreen 50 Urine Chemistry Analyzer
- PSS Select Urine Analyzer
- Roche/BMC Mini UA and Chemstrip 101 Urine Analyzer
- Roche Diagnostics Urisys 1100 Urine Analyzer
- Teco Diagnostics URITEK TC-101 Urine Strip Reader
- ThermoBiostar PocketChem UA

Provider-Performed Microscopic Procedures (PPMP)

These tests can **only** be performed in your office by an MD, DO, DPM, ARNP, nurse midwife, PA, naturopath, or dentist. If these tests are performed by any other personnel in your office, fill out page 7 of this application.

Check all that apply

- Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- Fecal leukocyte examinations
- Fern tests
- Nasal Smears for granulocytes
- Pinworm examinations
- Post-coital direct, qualitative examinations of vaginal or cervical mucous
- Potassium hydroxide (KOH) preparations
- Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)
- 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.

<p>Microscopic Procedures <i>(If the following microscopic tests are ONLY done by the provider, DO NOT complete this section. See page 6 - PPMP)</i></p> <p><input type="checkbox"/> Wet Mounts <input type="checkbox"/> Fecal Leukocytes <input type="checkbox"/> KOH <input type="checkbox"/> Pinworm <input type="checkbox"/> Post Coital Vaginal Mucous Exam <input type="checkbox"/> Fern Tests <input type="checkbox"/> Qualitative Semen Analysis (post vas) <input type="checkbox"/> Quantitative Semen Analysis <input type="checkbox"/> Urine Sediment <input type="checkbox"/> Nasal Smear for Granulocytes</p> <p style="text-align: right;">Total Volume _____</p>	<p>Parasitology (continued) <input type="checkbox"/> Concentrate/Stain <input type="checkbox"/> Parasitic Antigens</p> <p>Virology <input type="checkbox"/> Herpes Antigen <input type="checkbox"/> Herpes Culture <input type="checkbox"/> Other Viral Cultures <input type="checkbox"/> Viral Antigen Detection <input type="checkbox"/> HPV <input type="checkbox"/> Influenza (<i>nonwaived kits</i>) <input type="checkbox"/> RSV (<i>nonwaived kits</i>) <input type="checkbox"/> Other (list)</p> <p style="text-align: right;">Total Volume _____</p>	
<p>Histocompatibility <input type="checkbox"/> Transplant <input type="checkbox"/> Nontransplant (list specific tests)</p> <p style="text-align: right;">Total Volume _____</p>	<p>Syphilis Serology <input type="checkbox"/> RPR <input type="checkbox"/> VDRL <input type="checkbox"/> MHA-TP (TP-PA) <input type="checkbox"/> FTA</p> <p style="text-align: right;">Total Volume _____</p>	
<p>Bacteriology <input type="checkbox"/> Affirm VP (TV, GV, YST) <input type="checkbox"/> Antibiotic Sensitivities <input type="checkbox"/> Bacterial Antigens <input type="checkbox"/> Clostridium difficile <input type="checkbox"/> Group A Strep (Rapid test - <i>nonwaived kits</i>) <input type="checkbox"/> Group B Strep <input type="checkbox"/> Blood Culture <input type="checkbox"/> Chlamydia <input type="checkbox"/> CSF Culture <input type="checkbox"/> Gram Stain <input type="checkbox"/> GC <input type="checkbox"/> Throat Culture <input type="checkbox"/> Urine Culture <input type="checkbox"/> Urine Colony Count <input type="checkbox"/> Other Culture/ID</p> <p style="text-align: right;">Total Volume _____</p>	<p>Gen. Immunology <input type="checkbox"/> Allergy Testing (count individual allergens tested) <input type="checkbox"/> Alpha-1 Antitrypsin <input type="checkbox"/> AFP/Tumor <input type="checkbox"/> AFP/Other <input type="checkbox"/> ANA <input type="checkbox"/> ASO <input type="checkbox"/> HIV <input type="checkbox"/> C3 <input type="checkbox"/> C4 <input type="checkbox"/> HBsAg <input type="checkbox"/> Anti-HBc <input type="checkbox"/> HBeAg <input type="checkbox"/> HCV <input type="checkbox"/> Anti-HCV <input type="checkbox"/> IgA <input type="checkbox"/> IgG <input type="checkbox"/> IgE <input type="checkbox"/> IgM <input type="checkbox"/> Infectious Mononucleosis (<i>nonwaived kits</i>) <input type="checkbox"/> Rheumatoid Factor <input type="checkbox"/> H. pylori (<i>nonwaived kits</i>) <input type="checkbox"/> Rubella Antibody <input type="checkbox"/> Protein Electrophoresis <input type="checkbox"/> Other (list)</p> <p style="text-align: right;">Total Volume _____</p>	
<p>Mycobacteriology <input type="checkbox"/> AFB Smear Only <input type="checkbox"/> AFB Smear/Culture <input type="checkbox"/> AFB Antibiotic Sensitivities <input type="checkbox"/> AFB Culture & ID</p> <p style="text-align: right;">Total Volume _____</p>		
<p>Mycology <input type="checkbox"/> DTM Only <input type="checkbox"/> Culture (Growth/No Growth) <input type="checkbox"/> Fungus <input type="checkbox"/> Yeast <input type="checkbox"/> Culture and ID <input type="checkbox"/> Fungus <input type="checkbox"/> Yeast</p> <p style="text-align: right;">Total Volume _____</p>	<p>Routine Chemistry <input type="checkbox"/> ALT/SGPT <input type="checkbox"/> Albumin <input type="checkbox"/> Alkaline Phosphatase <input type="checkbox"/> Amylase <input type="checkbox"/> AST/SGOT <input type="checkbox"/> Bilirubin, Total/Neonatal <input type="checkbox"/> pH (blood gas) <input type="checkbox"/> pO₂ (blood gas)</p> <p style="text-align: right;">Total Volume _____</p>	

NOTE: Each measured parameter must be counted as a separate test, added together, and included in the Routine Chemistry total volume above.

Routine Chemistry (continued)

- pCO₂ (blood gas)
- Calcium, Total
- Carbon Dioxide
- Chloride
- Cholesterol, Total
- HDL Cholesterol
- Creatine Kinase
- CK Isoenzymes
- Creatinine
- Glucose
- Glycohemoglobin (Hgb A_{1c} or equivalent)
- Iron, Total
- LDH
- LDH Isoenzymes
- Magnesium
- Potassium
- Sodium
- Total Protein
- Triglycerides
- Urea Nitrogen (BUN)
- Uric Acid
- CEA
- Cholinesterase: RBC methodology _____
- plasma/serum methodology _____
- CRP/HSCR
- Ferritin
- GGT
- Phosphorus
- Myoglobin
- Troponin
- BNP
- Other (list)

Total Volume

Urinalysis

- Strip by nonwaived instrument

Total Volume

Endocrinology

- Cortisol
- Free Thyroxine
- HCG (Serum Pregnancy or nonwaived urine HCG)
- T3 Uptake
- T3 (Triiodothyronine) Estradiol
- TSH FSH
- Thyroxine Luteinizing Hormone
- PSA Progesterone
- Other (list)

Total Volume

Toxicology

- Alcohol, Blood
- Blood Lead
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide/metabolites

Toxicology (continued)

- Quinidine
- Theophylline
- Tobramycin
- Valproic Acid
- Drugs of Abuse (urine)
- Other (list)

Total Volume

Hematology

Cell Identification/Manual Differential

<p>CBC (Complete Blood Count):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Automated WBC Differential <input type="checkbox"/> RBC <input type="checkbox"/> Hematocrit <input type="checkbox"/> Hemoglobin <input type="checkbox"/> WBC <input type="checkbox"/> Platelet Count 	<p>NOTE: Each measured parameter (automated differential, RBC, hematocrit (or MCV), hemoglobin, WBC, platelets) must be counted as a separate test, added together, and included in the Hematology total volume above.</p>
--	---

- Reticulocyte Count
- Hemoglobin Electrophoresis
- Flow Cytometry
- Other (list)

Total Volume

Coagulation

- Fibrinogen
- PTT
- Prothrombin Time
- Thrombin Time
- Factor Assays
- Activated Clotting Time
- D-dimer
- Other (list)

Total Volume

Immunoematology

- Antibody Detection (Screen)
- ABO Group
- D (Rh) Typing
- Antibody Identification
- Compatibility Test (Crossmatch)
- Other (list)

3230.7
per Michael Romo
= 3230
Total Volume

Pathology

- Histopathology
- Dermatopathology
- Oral Pathology
- Cytology
(add HPV testing under Virology)

Total Volume

Radiobioassay

- (list in vitro tests, i.e. blood volume by Cr 51, Schilling test, etc.)
- Do NOT include routine RIA tests**

Total Volume

Genetic Testing

- Biochemical Genetic Tests (list tests)
- Cytogenetic Tests (list tests)
- Molecular Genetic Tests (list tests)
(add HPV testing under Virology)
(add Chlamydia and/or GC testing under Bacteriology)

A



**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
Seattle WA 98105**

Additional Sites:

- ~~/~~Bremerton Clinic: 623 NE Riddell Road, Bremerton, WA 98310
- ~~/~~Issaquah 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

2/17/2009

NOTICE TO RENEW Return with Payment



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

Medical Test Site Categorized License
MTSC.FS.00000038
MTS Category Category A

CLIA #
50D0663561

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

+

910420030000 MTSCFS0000003800000000022009042000136400

⑈ 3 7 7 7 ⑈

Owner Federal Tax ID Number #: 910686012

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-804 \$1364.00

NOTICE TO RENEW Return with Payment



Due Date	Amount Due
June 1, 2009	\$ 200.00

[Handwritten signature]

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

Medical Test Site Provider Performed
MTSP.FS.00000682

CLIA #
50D0635226

Please Complete Reverse

Site address:
Family Planning of Clallam County
1106 E 1st St
Port Angeles, WA. 98362-4317

WA

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

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

*✓ KE
5/27/09*



110420030000 MTSPFS000006&2000000000022009040300020000

1150

Owner Federal Tax ID Number #: 910872258

Owner Name: Family Planning of Clallam County

Lab Director Name: *Jade Slowriver*
~~CHANDRA HUSTON~~

Lab Director Email: *jslowriver@familyplanningofcc.org*
~~sandy@familyplanningofcc.org~~

Lab Contact Name: GAIL MARSH RN

Lab Contact Email: gmarsh@familyplanningofcc.org

1150-4/30/2009 9:39:15 AM-861 \$200.00

all data current and correct

Multiple Sites

Credential View Screen update entity tree

Planned Parenthood of the Great Northwest Address: <input checked="" type="radio"/> Public <input type="radio"/> 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 Enforcement Cont. Edu Documents Owners Owned By/ Exams Experience Notes Schools Librarian Application Other State Online Info Reports
Comments:			

Medical Test Site Categorized License update form letter

Credential # MTSC.FS.00000038 Legacy License # MTS-0038 Application Date Effective Date 07/01/2015 Expiration Date 06/30/2017 First Issuance Date Last Date Of Contact Next Examinations Date 02/28/2017	Credential Status ACTIVE (05/14/2015) Status Reason ACTIVE Amount Due \$0.00 Date Last Activity 5/14/2015 1:44:57 PM Last Updated by Stewart, Kevin Certificate Sent Date 05/14/2015	Audit Document Verification Workflow Key Mgmt Fees Notes Print Docs Comp. Aud Renewal Legacy Medical Te License St Online Inf
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	Field	Value
Medical Test Site Type	Community Clinic	Medical Test Site Region	Region 2
Multiple Sites	Yes	MTS Category	Category A
Lab Director	Michael Romo MS MT	MTS Lab Testing Personnel 1	ARNP
Lab Contact	Michael Romo	MTS Lab Testing Personnel Quantity 1	1
Lab Contact Email	michael.romo@ppgnw.org	MTS Lab Testing Personnel 2	On Job Training
Lab Phone Number	206-328-6815	MTS Lab Testing Personnel Quantity 2	9
Lab Fax Number			

Legacy Action -LQA

Legacy Personnel-LQA
Legacy Revenue - LQA



RCVD APR 4 16 DOH-LOH

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 at all locations 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 honora.estes@doh.wa.gov, 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

Director e-mail address: michael.romo@ppgnhi.org

WA Professional License #: _____

Laboratory Contact Name: Michael Romo

Laboratory contact e-mail address: michael.romo@ppgnhi.org

Sign and date the last page

Facility Name: Planned Parenthood of the Great Northwest and the Hawaiian Islands

MTS #: 0038

CLIA #: 50D0663561

Waived & PPMP Tests performed in your facility

Waived Tests

Adenovirus

- AdenoPlus (human eye fluid)
- Rapid Pathogen Screening RPS Adeno Detector

Aerobic/Anaerobic Organisms-Vaginal

- Genzyme Diagnostics OSOC BVBLUE Test
- Gryphus Diagnostics BVBlue

Alanine Aminotransferase (ALT)

- Alere Cholestech LDX (ALT)(WB)
- Arkray SPOTCHEM EZ Chem Analyzer (ALT) (WB)
- Cholestech LDX (ALT) (whole blood)
- Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (WB) (Lipid Panel Plus, Liver Panel Plus, CMP, BMP)

Albumin

- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Genzyme Diagnostics OSOM ImmunDip Urinary Albumin Test
- HemoCue Albumin 201 System (urinary albumin)
- Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Liver Panel Plus Reagent Disc, Chem 13, CMP, Renal)

Alkaline Phosphatase (ALP)

- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (WB) (Liver Panel Plus Reagent Disc, CMP, BMP)

Amylase

- Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus)

Aspartate Aminotransferase (AST)

- Alere Cholestech LDX (AST) (WB)
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Cholestech LDX Aspartate Aminotransferase (AST)
- Piccolo Point of Care/Blood/xpress Chemistry Analyzer (WB) (Lipid Panel/Plus, Liver Panel Plus, Chem 6/13, CMP)

B-Type Natriuretic Peptide (BNP)

- Biosite Triage Meter/Meterpro (whole blood) BNP

Basic Metabolic Panel

- Abbott i-STAT CHEM8+ Cartridge (ionized calcium) WB
- Abaxis Piccolo Blood Chemistry/express (total calcium) WB

Bilirubin, Total

- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Liver Panel Plus Reagent Disc, Chem 13, CMP)

Bladder tumor associated antigen

- Alere NMP22 BladderChek
- Bion Diagnostic Sciences BTA stat Test (for home use)
- LifeSign Status BTA
- Maritech BladderCheck Test (professional & prescription use)

BUN (Blood Urea Nitrogen)

- Abbott i-STAT CHEM8+/6+ Cartridge
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP, Metlyte 8, Renal)

Calcium

- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo xpress & Blood Chem Analyzers WB (chem 13, CMP, BMP, Renal)

Calcium - Ionized

- Abbott i-STAT CHEM8+ Cartridge

Carbon Dioxide (CO2)

- Abbott i-STAT CHEM8+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP,BMP,lytes, Metlyte 8, Renal)

Catalase, urine

- Diatech Diagnostics Uriscreen (for OTC use)

Chloride

- Abbott i-STAT CHEM8+/6+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP,BMP,lytes,metlyte 8, Renal)

Cholesterol

- Abaxis Piccolo express Chem Analyzer (capillary-fingerstick)
- Accu-Check InstantPlus Cholesterol test system
- Accucheck Instant Plus Dual Testing System
- Advanced Care Cholesterol measuring system
- Alere Cholestech LDX Cholesterol(WB)
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Biomedix Inc Q Steps Biometer G/C Dual Monitoring System
- ChemTrak AccuMeter Cholesterol test system
- Cholestech LDX Test System
- ENA C.T. Total Cholesterol or Total Cholesterol (PDU)
- Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile & Glucose Measuring System
- Jant Pharmacal LipidPlus Lipid Profile and Glucose System
- Lifestream Technologies Cholesterol Monitors
- Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)
- Polymer Tech. Systems Bioscanner, Bioscanner Plus, Bioscanner 2000 PST, and MTS Bioscanner 1000
- Polymer Technology Cardiochek and Cardiochek PA
- Roche Diagnostics Accutrend Plus System (fingerstick WB)
- Wako APOLOWAKO Analyzer (WB)

Comprehensive Metabolic Panel

- Piccolo Blood Chem/express Analyzers WB

Creatine Kinase (CK)

- Piccolo Blood Chemistry/express Analyzers WB (Metlyte 8)

Creatinine

- Abbott i-STAT CHEM8+/Crea Cartridge
- Arkray SPOTCHEM EZ Chemistry Analyzer (WB)
- Bayer Clinitek 50 Urine Chemistry Analyzer for Creatinine
- Bayer Diagnostics MICROALBUSTIX Reagent Strips
- Bayer MultiStix PRO 11, PRO 10LS, and PRO 7G
- Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP, Metlyte 8, Renal)

Drugs of Abuse

- 1 Step Detect Assoc DTX Drug Test Cup Integrated E-Z Split Key Cup II
- Acon Laboratories Drug Home Tests
- Acon Mission U120 Urine Analyzer
- Accu-Stat Diagnostics Drugs of Abuse Home Test
- Advantage Diagnostics
- Advin Multi-Drug Screen Test
- AIT Lab Drug of Abuse Card/Cup
- Alatex Scientific Peace of Mind Multiple Drugs of Abuse

Waived Tests (continued)**Drugs of Abuse, continued**

Alere Toxicology Services iCassetts Dx/iCassette/iCUP Drug Screen/iScreen Dx/Tox Screen/iCup DX 14/DS Multi-Drugs Dip Test/iCupDX Pro Urine Drug Screening Device
 Alfa Scientific Designs - Multiple drug Screen test kits
 Amedica Biotech The Amedica Drug Test Cup/AmediCheck Instant Test Cup/Instant Test Cup
 Ameditech Inc ImmuTest Drug Screen Cup
 American Bio Medica Rapid TOX
 American Screening Corp Discover/OneScreen/Multi-Drug/Revel Multi-Drug Testing Cups/Cards
 APC Workforce Secure Check/ZeroChaos Multi-Drug Screen cup
 Applied Biotech
 Aventir Biotech LLC Home Check Multiple Drug Cup Test
 Biotech Screening Correction Cup
 Biotechnostix Rapid Response Drug Screens
 Branan Medical Corp Fastest II/FasTox/BUP/QuickTox/ToxCup (dipstick/dipcard)
 BTNX Know/Rapid Response Multi-Drug One Step. Screen/ Urine Test Cup
 BTNX Rapid Response X-Press Single Test (dip card or cup/strip or cassette)/Multi-Drug Urine Test Panel/Cup
 CR3 Keyless Split Sample Cup Morphine-Oxazepam
 Chemtron Biotech Chemtrue Single/Multi-Panel Drug Screen Cassette/Dip Cards
 CLIA-X Multiple/Instant/Drug Cup Test/Drug of Abuse Card
 CLIAwaived Inc. Rapid Drug Test Cup (OTC)/Test
 CLIAwaived Inc Single Drug Dipstick Test
 Clinical Research Intelligent Transport Cup (OTC)
 Confirm Biosciences Drugconfirm Instant/RELI ON Multi-Drug of Abuse
 Devon Medical CentralCheck Multiple Drug Cup Test
 Diag. Test Grp Clarity Multi/SimpleDrug of Abuse Urine Test/Cards
 Drug Detect. Devices Multi-Drug Multi-Line/Screeners AutoCup
 eScreen, Inc. mCheck Multi-Line Screen Test Device
 Express Diag DrugCheck Waive Drug Cards/Cup/Model 9308z/ TC
 First Check Diagnostics Drug Screens
 Forefront Diag. Drug Screen
 Graman Medical Corporation
 Greenbrier Intn'l East SCREEN Marijuana Test Strip
 IND Home Drug Tests (strip and cassette formats)
 IND Home Drug Test - Multi-Panel Strip and Cassette Formats
 Innovacon Integrated E-Z Split Key Cup II (professional use)
 Innovacon Multi-Clin Drug Screen Test Device
 Insight Medical Drug of Abuse Cassette/Cup (morphine, oxycodone) Multi-Drug of Abuse Urine Test
 Instant Tech, iTest/iCassette/iCup/iCupDx/Cassette Dx/iScreen
 Inverness Medical Innovations Signify ER Drug Screen
 Jant Pharmacal Accutest MultiDrug ER II/Multi-Drug of Abuse Urine Test/Multi X Drug Cup/SplitCup Drug Screen/Test Cup/Cassette,Cup/Buprenorphine/MDMA and OPI Drug Test Cup
 LifeSign Home Drug Tests
 Med Direct ProXam Drug Test Cards/Multiple Drug Screen Cups
 MedimpexQ Test Multi X Drug Cup Test/Buprenorphine
 Micro Distributing Multi-Drug/Stat Cup One Step Drug Test/Stat Dip One Step Multi-Drug Cup/Panel
 Millennium Lab Multi-Drug Pain Med Screen Cup/Multi-Drug of Abuse Urine Test

NexScreen Cup
 Nobel Medical NOBLE 1 Step Cup (OTC)/Split-Specimen Cup/ Insta-Screen cup
 On the Spot Drug Testing Multi-Drug of Abuse Urine Test
 Phamatec At Home & QuickScreen
 PharmTox Rapid Exam Drug Screen Test Cup
 Physicians' Test Multi-Drug of Abuse Urine Test
 Premier Integrity Solutions P/Tox Drug Screen Cup
 Princeton Biomeditech Drug Tests
 PTox Drug Screen Cup Cassette Dip Card format
 Quest Dx Integrated E-Z Split Key Cup II/Express Result/Drug HAWK
 QuickTest USA Multi-Drug of Abuse Urine Screen
 Redwood Tox Lab Reditest 6/Reditest Freedom Cup/Reditest Home Drug Tests
 RefuAH U120 Urine Analyzer
 Revolution Rx AccuSeal Pro Instant Test Cup/Buprenorphine/ MDMA/Opiates
 Screen Tox Multi-Drug of Abuse Urine Test
 SCI Int'l New Choice At Home Drug Test Marijuana strip format
 SD Biotech FurSure Buprenorphine Drug Cup (opiates)
 Syntrol Bioresearch Quikscreen Multiple Drug Cup/ Buprenorphine/MDMA/Opiate
 TeenSaver Diag. TeenSavers Home Drug Test
 Total Diagnostic Solutions Drug of Abuse Cassette/Cup (morphine, oxycodone)/Multi-Drug of Abuse Urine Test
 Twin Spirit Inc DrugSmart Cup
 uVera Diagnostics MultiDrug Test Cup CR2/CR3/Smartox U2/ U3
 UCP Home Drug/Multiple/U-Checker/Compact Drug Screening Test Cards/Cups/Home Drug Screening Cards&Cups
 UCP Biosciences UCP Compact Drug Test Cards/Multi_Drug Test Key Cups
 Ultimate Analysis Cup UA Cups/Cards
 US Diagnostics ProScreen/UScreen Drugs of Abuse Cup/Cards
 Wal-Mart ReliOn Home Drug Urine Cup Test
 WayPoint Biomedical, Inc. Health Essist Multi-Drug Tests
 Wolfe Drug Testing RealityCheck Integrated Specimen Cup
 Wondfo Multi Drug Urine Test Cup and Dipcard
 Wondfo Urine Test Cup and Dip Card
 Worldwide Medical Corp. First Check Home Drug Tests
 Wunder Test Home Drug Screen (Marijuana)

Electrolyte Panel

Abaxis Piccolo Blood Chemistry/express WB

Erythrocyte sedimentation rate (ESR)

Non-automated

Esterone-3-Glucuronide

Unipath Limited Clearplan Easy Fertility Monitor

Ethanol

Acon Laboratories Mission Saliva Alcohol Test Strip
 Alere Toxicology Services iScreen Saliva Alcohol Test Strip
 Alfa Scientific Designs Oral-View Saliva Alcohol Test Strip
 American Screening Corp. Revel Saliva Alcohol Test Strip
 Chematics Alco-Screen/Alco-Screen 02 Saliva Alcohol Test
 CLIAwaived rapid Saliva Alcohol Test
 Germaine Laboratories Aim Strip Alcohol Saliva
 Jant Pharmacal Corp Accustrip Saliva Alcohol Test Strip
 OraSure Q.E.D. A-150 and A-350 Saliva Alcohol Tests
 Teco Diagnostics Saliva Alcohol Test

Waived Tests (continued)**Follicle Stimulating Hormone (FSH)**

- ___ Acon Lab FSH Menopause Predictor Test
- ___ Acon Lab FSH One Step Menopause Test Strip/Device
- ___ Applied Biotech Menopause Predictor/Instacheck FSH Test
- ___ Applied Biotech Menopause Predictor and RU25 Plus FSH
- ___ Biotechnostix Rapid Response FSH One Step Test Device
- ___ BTNX Rapid Response FSH Menopausal Test
- ___ Genosis Fertell Female Fertility Test (FSH)
- ___ Genua Menopause Monitor Test, FSH (qualitative)
- ___ IND Diagnostic One Step FSH Menopausal Test (midstream)
- ___ IND Diagnostic One Step FSH (Strip/Cassette)
- ___ IND Diagnostic One Step Strip/Cassette Style FSH (prof use)
- ___ Phamatech Moments Menopause Check (FSH)
- ___ PanProbe Biotech EarlyDetect Menopause Test
- ___ QuantRx Biomedical QuantRx Female Fertility Test
- ___ RAC Medical Clarity FSH One Step Menopause (prof use)
- ___ Synova Healthcare Menocheck Menopause Indicator Test

Fructosamine

- ___ LXN (Duet and IN CHARGE Test Systems)

Gamma Glutamyl Transferase (GGT)

- ___ Piccolo Point of Care/Blood/xpress Chemistry Analyzer (Liver Panel Plus Reagent Disc, Chem 6, Chem 13)

Glucose

- ___ Alere Cholestech LDX (glucose)(WB)
- ___ Arkray SPOTCHEM EZ Chem Analyzer (WB)
- ___ Abbott i-STAT CHEM8+/G/EC4+/6+ Cartridge
- ___ Biomedix, Inc Q Steps Biometer G/C Dual Monitoring System
- ___ Blood glucose monitoring devices cleared by FDA - home use
- ___ Cygnus, Inc GlucoWatch Automatic Glucose Biographer
- ___ Diagnostic Test Grp, Clarity Blood Glucose Monitoring System
- ___ Hemocue B-Glucose Photometer & model 201 analyzer/201DM
- ___ Jant Pharmacal LipidPlus Lipid Profile and Glucose System
- ___ LXN Duet/IN CHARGE Glucose Monitoring System Cholestech LDX
- ___ Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Lipid Panel Reagent Disc, Chem 6/13, CMP, BMP, Metlyte 8, Renal)
- ___ Polymer Technology Systems CardioChek PA Analyzer
- ___ Roche Diagnostics AccuChek Instant Plus Dual Test System
- ___ Wako APOLOWAKO Analyzer (WB)

Glycosylated HGB

- ___ Axis-Shield Afinion AS10 Analyzer
- ___ Bayer A1C Now SelfCheck
- ___ Bayer A1C Now+ (professional use)
- ___ Bio-Rad Micromat II
- ___ Bristol-Myers Squibb Choice DM
- ___ Cholestech GDX A1C (prescription home use)
- ___ MEC Dynamics Avie A1c Test System
- ___ Metrika A1c Now/DRX HbA1C/InView Multi Test
- ___ Provalis Diagnostics Glycosal/In2it In-office analyzer II/G5 I
- ___ HbA1c/G5 II HbA1c
- ___ Siemens Medical DCA Vantage/2000/2000+ Analyzer
- ___ Wako APOLOWAKO Analyzer (WB)

HDL Cholesterol

- ___ Abaxis Piccolo express Chem Analyzer (capillary-fingerstick)
- ___ Accutech CholesTrak HDL Cholesterol Home Test
- ___ Alere Cholestech LDX (HDL cholesterol)(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/xpress Chemistry Analyzer WB (Lipid Panel/Plus)
- ___ Polymer Technology Systems BioScanner Plus and 2000
- ___ Polymer Technology Systems Cardiochek and Cardiochek PA

Helicobacter pylori

- ___ Abbott FlexPack HP, Signify, Cassette, and TestPack Plus (WB)
- ___ Acon *H. pylori* Rapid Test Device (whole blood)
- ___ Alfa Scientific Designs Instant View (whole blood)
- ___ Applied Biotech SureStep (whole blood)
- ___ ARJ Pylo-Plus Urease (gastric biopsy)
- ___ Ballard (Delta West) CLOtest (gastric biopsy)
- ___ Beckman Coulter Flexsure (whole blood)
- ___ Becton Dickinson LINK 2 (whole blood)
- ___ BTNX Inc Rapid Response *H. pylori* Rapid Test Device(WB)
- ___ Cardinal Health SP Brand Rapid Test (whole blood)
- ___ ChemTrak AccuMeter (whole blood)
- ___ Clarity *H. pylori* Rapid Test Device (whole blood)
- ___ CLIAwaived *H. pylori* Whole Blood Rapid Test
- ___ De Healthcare Products Truview *H. pylori* (whole blood)
- ___ Diagnostic Test Group Clarity *H. pylori* Rapid Test Device (WB)
- ___ EarlyDetect *H. pylori* Whole Blood Rapid Test
- ___ Fisher Healthcare Sure-Vue *H. pylori* Test (WB)
- ___ Germaine Laboratories AimStep (whole blood)
- ___ GI Supply HP-FAST and HP One (gastric biopsy tissue)
- ___ Henry Schein OneStep+ / Rapid Test Device (whole blood)
- ___ Immunostics Detector *H. pylori* (WB)
- ___ Instant Technologies iScreen (whole blood)
- ___ Inverness BTNX Inc Rapid Response *H. pylori* Test (WB)
- ___ Inverness Medical Clearview/SIGNIFY *H. pylori* Test (WB)
- ___ Jant Pharmacal Corp. Accutest Rapid Test Device (WB)/Rapid Urease Test
- ___ LifeSign and LifeSign Status (whole blood)
- ___ McKesson *H. pylori* Test (WB)
- ___ McKesson Medi-Lab Performance *H. pylori* Test (WB)
- ___ Medical Instruments Corp Pronto Dry (gastric biopsy)
- ___ Meridian Bioscience ImmunoCard STAT1 (whole blood)
- ___ Polymedco Polystat (whole blood)
- ___ PreMaxim RadiScreen Test Device (whole blood)
- ___ Princeton BioMeditech BioSign (whole blood)
- ___ Princeton BioMeditech BioSign *H. pylori* WB OSOM *H. pylori*
- ___ Pro-Advantage by NDC *H. pylori* Device (whole blood)
- ___ PSS Consult *H. pylori* Cassette (WB, fingerstick only)
- ___ Quidel QuickVue gII/One-Step/One-Step II (whole blood)
- ___ Remel RIM A.R.C. (whole blood)
- ___ Roche Diagnostics AccuStat *H. pylori* OneStep (WB)
- ___ Select Medical Products Brand Rapid Test *H. pylori* (WB)
- ___ Serim Pyloritek Test Kit and YP Test Kit (gastric biopsy)
- ___ SmithKline FlexSure HP (whole blood)
- ___ Stanbio RELY *H. pylori* (WB fingerstick only)
- ___ Trinity Uni-Gold (whole blood)
- ___ Wampole Laboratories Clearview *H. pylori* II (whole blood)

Waived Tests (continued)**Hematocrit**

- Abbott i-STAT CHEM8+3+/4+/6+ Cartridge
- AimStrip Hb Hemoglobin Testing System
- Microhematocrit (spun)
- Micro Diagnostics Spuncrit DRC-40 Infrared Analyzer
- UltraCrit
- Wampole STAT-CRIT for hematocrit

Hemoglobin

- Abbott i-STAT CHEM8+3+/4+/6+ Cartridge
- Alere HemoPoint H2 Hemoglobin Measuring System
- Avie Total Hb Test System (professional use)
- Biosafe Anemiapro Self Screener
- Biotest Hemoglobin Measuring System
- Clarity HbCheck Hemoglobin Testing System
- Copper Sulfate (non-automated)
- Diaspect Hemoglobin Measuring System
- EKF Diag. Hemo Control Measurement & Microcuvettes
- HemoCue hemoglobin test systems (201, 201+, 301)
- HemoCue Donor Hemoglobin Checker System
- GDS Diagnostics HemoSite Meter for hemoglobin
- GDS Technology STAT-Site M Hgb Test System
- ITC HGB PRO Professional Hemoglobin Testing System
- Mission Plus Hemoglobin (Hb) Testing System
- Stanbio Hemoglobin Analyzer
- Stanbio HemoPoint H2/H2 DM Hemoglobin Measurement Syst

Hepatitis C Virus Antibody

- OraQuick Rapid Aby Test/OraQuick HCV Visual Ref Panel

HIV-1

- bioLytical INSTI HIV-1 Antibody Test (fingerstick WB)
- Chembio HIV 1/2 STAT-PAK Assay (WB)
- Clearview COMPLETE HIV 1/2 fingerstick & venipuncture WB
- OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)
- OraQuick In-Home HIV Test (oral fluid)
- OraQuick Rapid HIV-1 Antibody Test (oral fluid, WB)
- Trinity Biotech UniGold Recombigen HIV test (WB)

Influenza

- Alere BinaxNOW Influenza A & B Card (nasal swab/waah/asp)
- Alere Influenza A & B Test (nasal swab only)
- BD Veritor Systems Rapid Det Flu A+B (nasal,nasopharyngeal)
- Binax NOW Flu A and Flu B Tests and A&B Tests
- BTNX Rapid Response Influenza A/B Test Cassette
- Clearview Exact II Influenza A&B (nasal swab only)
- EarlyDetect Pro Influenza A Test/Influenza B Test
- Henry Schein OneStep+Influenza A&B Test
- Quidel QuickVue Influenza Test (Influenza A/B)
- Quidel QuickVue Influenza A+B Test
- SA Scientific SAS Influenza A/Influenza B Tests
- Sofia Analyzer & Influenza A+B FIA (nasal, nasopharyngeal)
- ZymeTX Zstatflu (Influenza A/B)

Ketones (Blood)

- Abbott Laboratories Precision Xtra/Xceed/Freestle Precision Pro
- Nova Max Plus/Mini Glucose and B-Ketone Monitoring System
- Polymer Technology Systems BioScanner 2000

Lactic Acid

- KDK Corporation Lactate Pro System (for OTC use)

LDL Cholesterol

- Polymer Tech. Systems Cardiocheck/Cardiocheck PA Analyzer

Lead

- ESA Biosciences LeadCare II Blood Lead Testing System (WB)

Lithium

- Akers Laboratory Inc InstaRead Lithium System (WB)
- ReliaLAB Inc. InstaRead Lithium System (WB)

Lyme Disease

- Wampole PreVue *B. burgdorferi* Antibody

Lutenizing Hormone (also see ovulation tests)

- BTNX Inc Rapid Response LH Ovulation Test
- Chembio Sure Check Ovulation Predictor
- Inverness Medical Early Ovulation Predictor Stix
- Saless Enterprises New Choice Ovulation Predictor
- Unipath Limited Clearplan Easy Fertility Monitor

Matrix metalloproteinases-9 (MMP-9)

- Rapid Pathogen Screen Inc. InflammDry

Microalbumin

- Roche/Boehringer Mannheim Micral Chemstrip
- Bayer Clinitek 50 Urine Chemistry Analyzer
- Bayer Clinitek Status Urine Chemistry Analyzer
- Bayer Diagnostics MICROALBUSTIX Reagent Strips
- Diagnostic Chemicals ImmunoDip & Urinary Albumin Screen
- HemoCue Albumin 201 System

Mononucleosis

- Acceava Mono II (whole blood)
- Acon Mono rapid Test Strip/Device (whole blood)
- Applied Biotech One Step+, SureStep, Truview Mono Test
- BioStar Acceava Mono/Mono II Test (whole blood)
- Cardinal SP Brand Rapid Test (whole blood)
- Clarity MONO Mononucleosis Rapid Test (WB)
- Clearview Mono-Plus II / Mono Test Whole Blood (WB)
- Consult Diagnostics Mononucleosis Cassette (WB)
- De Healthcare Products Truview Mono Test (WB)
- Genzyme Contrast/OSOM/Rapid/Sure-Vue Signature MonoTest
- Henry Schein One Step+ Mono Test (whole blood)
- Immuno Detector Mono/BioSign Mono WB
- Instant Technologies iScreen (whole blood)
- Jant Accutest Valeu+/Infectious Mononucleosis Test (WB)
- LifeSign Status/UniStep Mono Test (whole blood)
- McKesson Medi-Lab Performance Infectious Mono Test
- Meridian ImmunoCard STAT Mono (whole blood)
- OneStep Pro+ Mono (WB)
- Polymedco, Inc. Poly stat Mono (whole blood)
- Poly Stat Mono Test (WB)
- PreMaxin RediScreen Mononucleosis (WB)
- Princeton BioMeditech BioSign Mono WB (whole blood)
- ProAdvantage by NDC Infectious Mono Test Device (WB)
- Quidel CARDS O.S. and QuickVue+ Mono (whole blood)
- RAC Medical Clarity MONO Rapid Test Device (WB)
- Rapid Response Mono Rapid Test Device (whole blood)
- Remel RIM A.R.C. Mono Test
- Seradyn Color Q Mono (whole blood)
- Signify Mono Test / Mono Whole Blood / Mono Cassette (WB)
- Wampole Mono-Plus WB (whole blood)
- Wyntek Diagnostics OSOM and Signify Mono test (WB)

Nicotine (or its metabolites)

- CLIAwaived Instant Nicotine Detection Test
- DynaGen NicCheck 1 Test Strips
- Mossman Associates NicCheck I Test Strips

Waived Tests (continued)**Occult blood**

- Fecal Occult Blood
- Fecal Occult Blood Immunochemical/Immunological Tests
- Aerscher Hemaprompt FG Gastric Occult Blood
- Alfa Scientific Designs Instant-View FOB Self-Test Cassette
- Alfa Scientific Designs FOB Self-Test
- Beckman Coulter Primary Care Diagnostics Gastrocclt/Hemocult Sensa Elite (gastric occult blood)
- Clarity Fecal Occult Blood Self Test
- Immunostics hema screen ER
- Know Fecal Occult Blood Self Test
- Rapid Response Fecal Occult Blood Self Test
- Siemens Hematest Reagent Tablets
- Smithkline Gastrocclt

Osmolarity

- TearLab Osmolarity System

Osteoporosis

- Ostex International Osteomark NTX

Ovulation Tests

- Visual color comparison tests for human luteinizing hormone
- BTNX Inc rapid Response LH Ovulation Test
- Luna Fertility Indicator (saliva)
- O2 Unlimited Donna Ovulation Test (saliva)
- Stesans Maybe?Mom Mini Ovulation Microscope (saliva)
- TCI Ovulation Tester (saliva)

pH

- All qual. color comparison pH - body fluids (not blood)
- Common Sense FemV/VI/VA/VS/Norma Sense (vag pH)
- Dale Med Products RightSpot/RightLevel (gastric pH)
- Duramed AmniScreen Home Dection Liner Kit
- Femtek Phem-Alert (vaginal pH)
- Lil' Drug Store Prod. Vagi-Screen Vaginal Health Test (vag pH)
- Litmus Concepts FemExam Test Card (vaginal pH & amines)
- Quicke QuickVue Advance pH and Amines Test
- RightBio Metrics Right Spot Infant pH Indicator/pH Indicator/Detector

Phosphorus

- Piccolo xpress/Blood Analyzers (Renal panel)

Platelet Aggregation

- Accumetrics VerifyNow Aspirin Assay

Potassium

- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- Piccolo xpress/Blood Analyzers (CMP, BMP, lytes, Metlyte 8, Renal)

Pregnancy Test (Urine)

- Urine pregnancy test: visual color comparison
- Siemens Clinitek 50/Status Urine Chemistry Analyzer

Protime

- Alere INRatio2 PT/INR Monitoring System (Professional/Home)
- AvoSure Pro and PT
- CoaguSense Prothrombin Time/Self-Test/Protime/INR
- Hemosense INRATIO
- International Technidyne Corporation Protime Microcoagulation System and ProTime 3 Cuvette System
- Lifescan Harmony INR Monitoring System
- Lifescan Rubicom Prothrombin Time Monitoring System
- Roche Diag CoaguChek & CoaguChek S Systems, PT-S Strips, XS, XS PST, XS Plus

Protein, Total

- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus Reagent Disc, Chem 13, CMP)

RSV (Respiratory Syncytial Virus Direct Antigen)

- BD Veritor System for Rapid Detection RSV (nasopharyngeal)
- Clere BinaxNOT RSV Card
- Binax NOW RSV Test
- Fisher Scientific Sure-Vue RSV Test
- Integrated Biotechnology Quick Lab RSV Test
- Meridian Bioscience Immunocard Stat! RSV Plus
- Quidel Quick Vue RSV Test
- Rapid Response RSV Test
- Remel Xpect RSV
- SA Scientific SAS RSV Test/RSVAlert
- Wampole Laboratories Clearview RSV

Semen

- Embryotech Laboratories FertilMARQ for male infertility
- Fertell Male Fertility Test
- Fertility Solutions Semen Analysis (qualitative)
- SpermCheck Fertility
- SpermCheck Vasectomy

Sodium

- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP, BMP, lytes, Metlyte 8, Renal)

Strep Antigen Test

- Abbott Signify Strep A Test / Dipstick
- Aceava Strep A Test/Twist Rapid Test
- ACON Strep A Rapid, Strep A Twist Rapid, and ICON DS
- Applied Biotech SureStep Strep A (II)/Strep A Exact
- Beckman Coulter ICON Fx (formerly SmithKline)
- Beckman Coulter Primary Care Diag. DS, FX, and SC
- BD LINK 2/Chek Strep A Rapid test /Veritor System
- Binax NOW/Clearview Advanced Strep A Test
- BioStar Aceava™ Strep A Test
- Biotechnostix Rapid Resp. Strep A Rapid Test Device/Strip
- BTNX Rapid Response Strep A Rapid Test Strips
- Cardinal Health CP Brand Rapid Test Dipstick/Cassette
- Clearview Strep A Exact Dipstick
- CLIA Waived Inc Rapid STREP A Test
- Consult Diagnostics STREP A RAPID Dipstick
- CTMI (Cole-Taylor Marketing Inc) Strep A Rapid Test Strip
- DE Healthcare Products, TruView Strep A Test/Cassette
- Diagnostic Test Group Clarity Strep A Rapid Test Strips
- Fisher HealthCare Sure-Vue Strep A
- Genzyme Contrast Strep A and OSOM Ultra Strep A
- Germaine Laboratories Strep AIM Rapid Dipstick Test
- Germaine Laboratories Strep AIM Tower
- Henry Sohein OneStep+/OneStep + Strep A Test/Strep A Dipstick
- IMI Signify Strep A Dipstick
- Immunostics Immuno/Strep A Detector, Strep A Direct
- Instant Technologies Istrep Strep A Test
- Inverness Medical BioStar Aceava Strep A Test/Twist
- Inverness Medical Clearview Strep A Exact II Dipstick
- Inverness Medical Signify Strep A Cassette
- 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
- PerMaxin Rediscreen Strep A Rapid/Strep A Twist Cassette
- Polymedco Poly stat A (II), Strep A Liquid Test, Strep A Dipstick
- Poly stat Strep A Flip Test
- Princeton BioMediTech BioStrep A /Status First Strep A
- ProAdvantage by NDC Strep A Test
- PSS Consult Diag Strep A Dipstick
- PSS World Medical Strep A Dipstick/Twist
- Quidel QuickVue In-Line and Dipstick and In-Line One-step
- RAC Medical Clarity Strep A Twist Rapid Test Device/Strip
- Remel RIM A.R.C. Strep A Test
- Sacks Medical Refuah Strep A Rapid Test
- SA Scientific SAS Strep A
- 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 Twist
- Signify Strep A Dipstick
- Stanbio Qustick Strep A, E-Z Well Strep A Rapid Test
- Wyntek Diag. OSOM Strep A and OSOM Ultra Strep A Test

Trichomonas

- Genzyme Osom Trichomonas Rapid Test
- Sekisui Diagnostics 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)

Uric Acid

- Piccolo xpress & Blood Chem Analyzers (chem 13)WB

Urinalysis

- Urinalysis: Dipstick or tablet reagent (nonautomated)
- Acon Lab Insight U120 Urine Analyzer
- Acon Lab. Mission UTI Urinary Tract Infection Test Strips
- 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 Uruclick 120 Urine Analyzer
- Germaine Laboratories AimStrip Urine Analyzer
- Henry Schein OneStepPlus/Urispec Plus Urine Analyzer
- Hypoguard Diascreen 50 Urine Chemistry Analyzer
- Immunostics Inc Detector Uristrip+ Analyzer
- Jant Pharmacal Corporation Accustrip URS Reader
- McKesson 120 Urine Analyzer
- Mediwatch urinewatch Urine Analyzer
- Moore Medical Urine Analyzer U120
- NDC Pro Advantage by NDC Urine Analyzer
- PSS Select Urine Analyzer
- RefuAH U120 Urine Analyzer
- Roche/BMC Mini UA and Chemstrip 101 Urine Analyzer
- Roche Diagnostics Urisys 1100 Urine Analyzer
- Siemens Clinitek 50/Status/Status+/Status Connect Analyzers
- Stanbio Uri-Trak 120 Urine Analyzer
- ThermoBiostar PocketChem UA

Provider-Performed Microscopic Procedures (PPMP)

These tests can **only** be performed in your office by an MD, DO, DPM, ARNP, nurse midwife, PA, naturopath, or dentist.

If these tests are performed by any other personnel in your office, fill out the Microscopic Procedures section on the next page of this application.

Check all that apply

- Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- Fecal leukocyte examinations
- Fern tests
- Nasal Smears for granulocytes
- Pinworm examinations
- Post-coital direct, qualitative examinations of vaginal or cervical mucous
- 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 Great North West and the Hawaiian Islands

MTS #: 0038

CLIA #: 50D0663561

Non-waived & Non-PPMP Tests performed in your facility (attach additional sheets if needed)

Microscopic Procedures Total Volume 5071

(If the following microscopic tests are ONLY done by the provider, DO NOT complete this section.)

- Wet Mounts
Fecal Leukocytes
KOH
Pinworm
Post Coital Vaginal Mucous Exam
Fern Tests
Qualitative Semen Analysis (post vas)
Quantitative Semen Analysis
Urine Sediment
Nasal Smear for Granulocytes

Total Volume

Histocompatibility

- Transplant
Nontransplant (list specific tests)

Total Volume

Bacteriology

- Affirm VP (TV, GY, YST)
Antibiotic Sensitivities
Bacterial Antigens
Clostridium difficile
Group A Strep (Rapid test - nonwaived kits)
Group B Strep
Blood Culture
Chlamydia
CSF Culture
Gram Stain
GC
Throat Culture
Urine Culture
Urine Colony Count
Other Culture/ID

Total Volume

Mycobacteriology

- AFB Smear Only
AFB Smear/Culture
AFB Antibiotic Sensitivities
AFB Culture & ID

Total Volume

Mycology

- DTM Only
Culture (Growth/No Growth)
Fungus Yeast
Culture and ID
Fungus Yeast

Total Volume

Parasitology

- Direct Smear
Concentrate/Stain
Parasitic Antigens

Total Volume

Virology

- Herpes Antigen
Herpes Culture
Other Viral Cultures

- Viral Antigen Detection
HPV
Influenza (nonwaived kits)
RSV (nonwaived kits)
Other (list)

Total Volume

Syphilis Serology

- RPR
VDRL
MHA-TP (TP-PA)
FTA

Total Volume

Gen. Immunology

- Allergy Testing (count individual allergens tested)
Alpha-1 Antitrypsin
AFP/Tumor
AFP/Other
ANA
ASO
ASO
HIV
C3
C4
HBsAg
Anti-HBc
HBeAg
HCV
Anti-HCV
IgA
IgG
IgE
IgM
Infectious Mononucleosis (nonwaived kits)
Rheumatoid Factor
H. pylori (nonwaived kits)
Rubella Antibody
Protein Electrophoresis
Other (list)

Total Volume

Routine Chemistry

- ALT/SGPT
Albumin
Alkaline Phosphatase
Amylase
AST/SGOT
Bilirubin, Total/Neonatal
pH (blood gas)
pO2 (blood gas)
pCO2 (blood gas)
Calcium, Total
Carbon Dioxide
Chloride
Cholesterol, Total
HDL Cholesterol
Creatine Kinase
CK Isoenzymes
Creatinine
Glucose
Glycohemoglobin (Hgb A1C or equivalent)
Iron, Total

NOTE: Each measured parameter must be counted as a separate test, added together, and included in the Routine Chemistry total volume above.

Non-Waived Tests (continued)

Routine Chemistry (continued)

- LDH
- LDH Isoenzymes
- Magnesium
- Potassium
- Sodium
- Total Protein
- Triglycerides
- Urea Nitrogen (BUN)
- Uric Acid
- CEA
- Cholinesterase; RBC methodology _____
plasma/serum methodology _____
- CRP/HSCRp
- Ferritin
- GGT
- Phosphorus
- Myoglobin
- Troponin
- BNP
- Other (list) _____

Total Volume _____

Urinalysis

- Strip by nonwaived instrument

Total Volume _____

Endocrinology

- Cortisol
- Free Thyroxine
- HCG (Serum Pregnancy or nonwaived urine HCG)
- T3 Uptake
- T3 (Triiodothyronine) _____ Estradiol _____
- TSH _____ FSH _____
- Thyroxine _____ Luteinizing Hormone _____
- PSA _____ Progesterone _____
- Other (list) _____

Total Volume _____

Toxicology

- Alcohol, Blood
- Blood Lead
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide/metabolites
- Quinidine
- Theophylline
- Tobramycin
- Valproic Acid
- Drugs of Abuse (urine)
- Other (list) _____

Total Volume _____

Hematology

- Cell Identification/Manual Differential

CBC (Complete Blood Count):

- Automated WBC Differential
- RBC
- Hematocrit
- Hemoglobin
- WBC
- Platelet Count

NOTE: Each measured parameter (automated differential; RBC, hematocrit (or MCV), hemoglobin, WBC, platelets) must be counted as a separate test, added together, and included in the Hematology total volume above

- Reticulocyte Count
- Hemoglobin Electrophoresis
- Flow Cytometry
- Other (list) _____

Total Volume _____

Coagulation

- Fibrinogen
- PTT
- Prothrombin Time
- Thrombin Time
- Factor Assays
- Activated Clotting Time
- D-dimer
- Other (list) _____

Total Volume _____

Immunoematology

- Antibody Detection (Screen) _____
- ABO Group _____
- D (Rh) Typing 5553
- Antibody Identification _____
- Compatibility Test (Crossmatch) _____
- Other (list) _____

Total Volume 5553

Pathology

- Histopathology _____
- Dermatopathology _____
- Oral Pathology _____
- Gyn Cytology _____
- Non-gyn Cytology _____

Total Volume _____

Radiobioassay

(list in vitro tests, i.e. blood volume by Cr 51, Schilling test, etc.) Do NOT include routine RIA tests

Total Volume _____

Genetic Testing

- Biochemical Genetic Tests (list tests)
- Cytogenetic Tests (list tests)
- Molecular Genetic Tests (list tests)
(add HPV testing under Virology)
(add Chlamydia and/or GC testing under Bacteriology)

Signature: I certify that I have received, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify that the information herein submitted is true to the best of my knowledge and belief.

Michael Romo

March 31, 2016

Signature of Owner/Authorized Representative of Medical Test Site

Date

Mail completed form by June 16, 2014 to: LQA, 20425 72nd Ave S Ste 310, Kent, WA 98032, or Fax to (253) 395-6365, or E-mail to: honora.estes@doh.wa.gov

MTS-0038

CLIA # 50D0663561 Exp: Jun 30, 2017

Planned Parenthood Seattle Health Center (primary)

Planned Parenthood White Center Health Center

Planned Parenthood 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

✓ 40056 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 Seattle clinic is shown below.	Planned Parenthood of the Great Northwest	Planned Parenthood of the Great NW Central Region	2001 St
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MTSC.FS.00000038	50D0663561	Remove Do not remove	Planned Parenthood of the Great Northwest	Seattle Clinic	2001 E Madison St	Seattle
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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 Parenthood 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 is shown below.	Planned Parenthood of the Great Northwest	Planned Parenthood of the Great NW Central Re
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 ZixCorp^(R).

This message was secured by ZixCorp^(R).



Washington State Department of
Health
 Medical Test Site (MTS) Credentialing
 P.O. Box 47877
 Olympia, WA 98504-7877
 360-236-4700

✓ MTS
 ✓ JC

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		
MTS Name Planned Parenthood of the Great NW and the Hawaiian Islands		
Effective date of change		
MTS License # MTS-0038	Clinical Laboratory Improvement Amendments (CLIA) # 50D0663561	
Type of Change to MTS Listed Above		
Address Change (current address) <input type="checkbox"/> Mailing <input type="checkbox"/> Physical <input type="checkbox"/> Both		
New Address		
City	State	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* Stacy C. Olea, MT(ASCP), FACHE	License # N/A	Email address stacy.olea@ppgnhi.org

* **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.
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).

Signature of Director:

I certify that the information included on this form is accurate:

Michael Romo MT (ASCP)

Signature of the Medical Test Site Director

September 8, 2016

Date (mm/dd/yyyy)

RECEIVED

SEP 21 2016

Department of Health
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,

A handwritten signature in cursive script that reads 'Carolyn S. Harvey'.

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 16 2016

DEPARTMENT OF HEALTH
Office of Investigation and Inspection



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



Washington State Department of
Health
 Medical Test Site (MTS) Credentialing
 P.O. Box 47877
 Olympia, WA 98504-7877
 360-236-4700

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

RCVD AUG 27 16 DOH-1391

RECEIVED

JUL 28 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.

Your Information		
MTS Name <i>Planned Parenthood of the Great NW and the Hawaiian Islands</i>		
Effective date of change <i>July 26, 2016</i>		
MTS License # <i>MTS-0038</i>	Clinical Laboratory Improvement Amendments (CLIA) # <i>50D0663561</i>	
Type of Change to MTS Listed Above		
Address Change (current address)		
New Address		
City	State	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*	License #	Email address
<i>Michael Romo</i>	<i>N/A</i>	<i>michael.romo@ppgwhi.org</i>

* 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.

- 8. Bachelor Degree in science, + 2 years laboratory training and/or experience and 2 years laboratory supervisory experience.

RECEIVED

JUL 28 2016

DOH/HSQA/OCS

- 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).

Signature of Director:

I certify that the information included on this form is accurate:



 Signature of the Medical Test Site Director

07/27/2016

 Date (mm/dd/yyyy)

RECEIVED

JUL 28 2016

DOH/HSQA/OCS

Qualifications of Personnel for High Complexity Testing

Director: (check only one)

- 1. Pathologist with state license.
- 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, ABCC, ABMLI).
- 5. PhD in science and before 2/24/2003, served or serving as director of a high complexity testing laboratory and have 2 years laboratory training and/or experience and 2 years directing or supervising high-complexity testing.
Which laboratory? _____ Dates _____
- 6. On 2/28/92, serving as a laboratory director and qualified or could have qualified as director under previous Medicare/CLIA independent laboratory personnel requirements.
- 7. On 2/28/92, was qualified under state law to direct laboratory.
- 8. For subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or American Osteopathic Board of Pathology or equivalent.

Complete the following information about the qualifications of your Clinical Consultant for Directors who are not qualified according to 1,2,3, or 7 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).
- 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

	Current		New Effective May 16 2013	Rh testing cont Lab Director on assigned Clii Michael Romo	Clinical Consultant Dr. Laurel Kuehl	Technical Consultant Michael Romo
WASHINGTON						
North	CLIA # 50D0633777	<u>MTS-0200</u>				
	Everett (primary)	Rh	Everett (primary)	Rh		
	Bellevue	Rh	Bellevue	Rh		
	Lynnwood	Rh	Lynnwood	Rh		
	Marysville	Rh	Marysville	Rh		
	Roosevelt		Roosevelt			
	Kenmore	Rh	Northgate	Rh		
		Will close May 2013				
Central	CLIA # 50D0663561	<u>MTS-0038</u>				
	Seattle (primary)	Rh	Seattle (primary)	Rh		
	W Seattle	Rh	W Seattle	Rh		
	Port Angeles	Rh	Port Angeles	Rh		
	Issaquah		Issaquah			
	Kent		Kent			
	First Hill	Rh	First Hill	Rh		
	Sequim		Sequim			
	Bremerton	Rh	Bremerton	Rh		
	Northgate	Rh				
	Silverdale					
	Oak Harbor					
	Forks					
		Closed				
		Closed				
		Closed				
South	CLIA # 50D0636085	<u>MTS-0085</u>				
	Federal Way (primary)	Rh	Federal Way (primary)	Rh		
	Centralia	Rh	Centralia	Rh		
	Olympia	Rh	Olympia	Rh		
	Puyallup	Rh	Puyallup	Rh		
	Shelton	Rh	Shelton	Rh		
	Tacoma	Rh	Tacoma	Rh		



RECEIVED

October 5, 2010

HEALTH PROFESSIONS
AND FACILITIES

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

ROUND OCT13*10 DGH-LDR

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**.

*closed
VIUS*

50D0663561

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

NTSP-0682

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 50D0663561 will 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. *STL 218*

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

Contact View Screen [update]		Family Planning of Clallam County
Address: <input checked="" type="radio"/> Public <input type="radio"/> Mail Family Planning of Clallam County PO Box 927 Port Angeles, WA 98362-0160	ID: 844983 Warnings SSN/FEIN Federal ID: 910872258 Secretary Of State Number: 600258997 Contact Standing: In-Business Contact Type: ORGANIZATION Criminal History: NO Public File: YES Mailing List	Audit Public Cases Cont. Edu Documents Owners Owned By/Key Mgmt Exams Experience Notes Schools Supervises SupervisedBy Legacy Librarian Application Other State License
Comments:		

Addresses | Credential List | Legacy

Contact Addresses [add]

Family Planning of Clallam County PO Box 927 Port Angeles, WA 98362-0160 County: Clallam Country: United States Joined on: 2/16/2008 Last updated by Leonard Kargacin	Phone Fax Cell Email	[update] MAIN ADDRESS Public Address Mail Address Form Letter
Family Planning of Clallam County 777 N 5th Ave Ste 109 Sequim, WA 98382-3080 County: Clallam Country: United States Last updated by Vicky Terry Comments: Open 2 days a week. Multiple site of MTSP.0682	Phone Fax Cell Email	[update] Branch Site Address Form Letter
Family Planning of Clallam County 231 Lupine Ave Forks, WA 98331-9269 County: Clallam Country: United States Last updated by Vicky Terry Comments: Open 2 days a week. Multiple site of MTSP.0682. Address change 9/4/09 per email.	Phone Fax Cell Email	[update] Branch Site Address Form Letter
Family Planning of Clallam County PO Box 927 Port Angeles, WA 98362-0160 County: Clallam Country: United States Joined on: 2/16/2008 Last updated by Leonard Kargacin	Phone (360)452-2954 Fax (360)457-7683 Cell Email	[update] Facility/Agency Site Address Form Letter Mail Address for: - MTSP.FS.00000682
Family Planning of Clallam County 426 E 8th St Port Angeles, WA 98362-6220 County: Clallam Country: United States Joined on: 2/16/2008 Last updated by Vicky Terry	Phone (360)452-2954 Fax (360)457-7683 Cell Email	[update] Facility/Agency Site Address Form Letter Public Address for: - MTSP.FS.00000682

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

*R 6-23-09
EUS
file*

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.

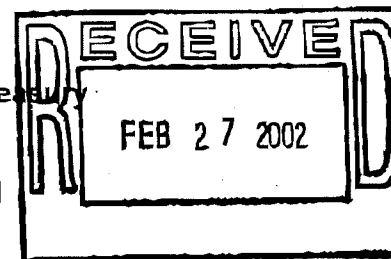
Sincerely,

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

Internal Revenue Service

Department of the Treasury

P. O. Box 2508
Cincinnati, OH 45201



Date: February 25, 2002

Person to Contact:
Richard Owens 31-00913
Customer Service Representative
Toll Free Telephone Number:
8:00 a.m. to 6:30 p.m. EST
877-829-5500
Fax Number:
513-263-3756
Federal Identification Number:
91-0872258

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

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.

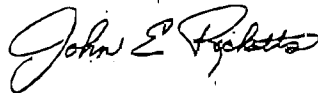
The law requires you to make your organization's annual return available for public inspection without charge for three years after the due date of the return. If your organization had a copy of its application for recognition of exemption on July 15, 1987, it is also required to make available for public 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) 3

To: Vicky Terry Fax #: 206-418-5505
Agency: WA st DOH office of Lab Q.A.

From: Helen Glad Toliver Fax # 360.457-7683

- Per Our Conversation
- Per Your Request
- For Necessary Action
- For Your Information
- Please Respond

Please see my e-mail sent today -

Comments:

*re: address change
of multiple site license
Thank you!*



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*

MUTSP.0000682

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

500068226

R
ILLS 9.14.09
files

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.

December 17, 2008

To: Vicky Terry, Office of Laboratory Quality Assurance
 From: Helen Glad Tolmer, Clinical Services Supervisor
 Date: December 17, 2008
 Re: Multiple site listing

*C 12-31-08
 HGS
 V. Terry*

Thank you, Vicky, for returning my 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 2 satellite clinics that utilize a microscope to perform wet mounts by our ARNPs at the following location:

FPC Sequim Clinic (located within the Dungeness Valley Health and Wellness Clinic). We function independently from the Dungeness 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

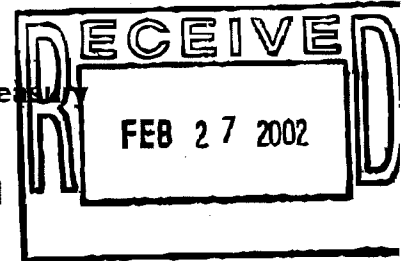
FPC Forks Clinic (located within the Forks Health Department, Clallam County Health & Human Services). We function independently from the Forks Health Department, providing family planning services one clinic day per week). The clinic is located at:

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.org if you need any further information.

Internal Revenue Service

Department of the Treasury

P. O. Box 2508
Cincinnati, OH 45201

Date: February 25, 2002

Person to Contact:

Richard Owens 31-00913
Customer Service Representative

Toll Free Telephone Number:

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

Fax Number:

513-263-3756

Federal Identification Number:

91-0872258

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

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, 2103, 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-E, 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.

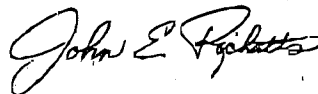
The law requires you to make your organization's annual return available for public inspection without charge for three years after the due date of the return. If your organization had a copy of its application for recognition of exemption on July 15, 1987, it is also required to make available for public 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: 12-17-08 Pages (including cover sheet) 84

To: Vicky Terry Fax #: 206-418-5505

Agency: Office of Laboratory Quality Assurance

From: Helen Glad Toliver Fax #: 360-457-7683

- Per Our Conversation
- Per Your Request
- For Necessary Action
- For Your Information
- Please Respond

Comments:

Planned Parenthood
of the Great Northwest

RECEIVED

CLIA LABORATORY PROGRAM
PO BOX 70948
CHARLOTTE, NC 28272-0948

changed
12-18-08

RECEIVED

DEC 05 2008

UHHS / LMS / 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

MTS-0038

C 12-18-08
ZURS
files

Failure to change address may delay your payment.

Thank you for helping make this a smooth transition.

RECEIVED
NOV 21 2008
UHHS / LMS / SAC
Region 10, Seattle, WA

NOV 15 2008 09H-10A

Redaction Summary (0 redactions)

0 Privilege / Exemption reason used:

Redacted pages: