



Washington State Department of

Health

Revenue Section

P.O. Box 1099

Olympia, WA 98507-1099

253.395.6746

<http://www.doh.wa.gov/LQA.htm>

Certificate of Waiver Medical Test Site (MTS) Application Packet

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Important Information:

The Washington Medical Test Site (MTS) licensure program is exempt from the Clinical Laboratory Improvement Amendments of 1988 (CLIA). You do not need to apply to the Centers for Medicare & Medicaid Services (CMS) for a CLIA number. Your MTS license will contain both your MTS license number and your CLIA number.

In order to process your request:

Return Completed Application (original copy) and fee to:

Department of Health

Revenue Section

PO Box 1099

Olympia, WA 98507-1099



Certificate of Waiver Medical Test Site Application Checklist and Instructions

- Please indicate type of application. New, change of ownership, or change of license type.

Check One:

- Please check your legal owner/operator business structure type according to your Washington State Master Business License.

Section #1: Demographic Information:

Uniform Business Identifier Number (UBI #): Enter your Washington State UBI #. All Washington State businesses must have UBI #'s. City, county, and state government departments also have UBI#'s.

Federal ID Number (FEIN#): Enter your Federal ID Number, if the business has been issued one. **Note:** If the facility FEIN # is different than the Legal Owner FEIN, enter this number on page 2 of the application under Facility Specific Federal Tax ID (FEIN) #.

Legal Owner/Operator Name: Enter the owner's name as it appears on the UBI/Master Business License.

Legal Owner Mailing Address: Enter the owner's complete mailing address.

Phone and Fax Numbers: Enter the owner's phone and fax number.

Email and Web Address: Enter the owner's email and Web addresses, if applicable.

Facility Name: Enter the lab's name as advertised on signs or Web site.

Physical Address: Enter the lab's physical street location including city, state, zip and county.

Phone and Fax Numbers: Enter the lab's phone and fax number.

Facility Mailing Address: Enter the lab's mailing address, if different than physical address.

Section #2: Facility Specific Information:

Site Type: Please check one applicable site type.

Facility Specific Federal Tax ID (FEIN) #. Enter if different from the Owner FEIN on listed on page 1.

Multiple Sites: List multiple sites, if applicable, and test(s) performed at each site

Section #3: Key Individuals:

Lab Director: Enter the lab director's (1) name, (2) Washington State professional license number for MD, DO, ND, PA, ARNP, PA, ARNP, LPN, health care assistant or other professional license category and (3) email address.

Lab Contact: Enter the lab contact's (1) name, (2) Washington State professional license number for MD, DO, ND, PA, ARNP, PA, ARNP, LPN, health care assistant or other professional license category, if applicable, and (3) email address.

Note: The lab contact will receive all information that we mail to your medical test site.

Certificate of Waiver MTS Application Checklist and Instructions (continued)

Section #4: Additional Information – Waived Tests:

Waived Tests: Place a checkmark by all waived tests performed at your facility.

If you perform any tests other than the waived tests listed, do not complete this application. See the LQA website: <http://www.doh.wa.gov/lqa.htm> to help you determine your correct license category or call the LQA office at 253.395.6746.

Section #5 Other Licensure, Certification, or Registration:

Legal Owner: List the names, titles, addresses, and phone numbers of the corporate officers, LLC members or manager, partners, etc. Attach additional sheet, if necessary.

Change of Ownership Information: If applicable, list the previous legal owner name, previous name of facility, previous MTS license #, effective date of ownership change and physical address.

Signature:

Signature of legal owner or authorized representative

Date signed

Print name of legal owner or authorized representative

Print title of legal owner or authorized representative

Your new MTS license will expire on June 30, 2013. You will receive a renewal notice for this license approximately 60 days before the expiration date.

Please contact our Seattle office at 253.395.6746 if you have any questions or need assistance in completing the application form. Additional information is available on our Web site at: <http://www.doh.wa.gov/lqa.htm>.



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<http://www.doh.wa.gov/lqa.htm>

Date Stamp Here

Fee	
<input type="checkbox"/>	July 1, 2012 – June 30, 2013.....75.00

Revenue: 0420030000

Certificate of Waiver Medical Test Site License Application

This is for: New Change of Ownership Change of License Type

Check One

- | | | |
|--|---|--|
| <input type="checkbox"/> Association | <input type="checkbox"/> Limited Partnership | <input type="checkbox"/> Partnership |
| <input type="checkbox"/> Corporation | <input type="checkbox"/> Municipality (City) | <input type="checkbox"/> Sole Proprietor |
| <input type="checkbox"/> Limited Liability Company | <input type="checkbox"/> Municipality (County) | <input type="checkbox"/> State Government Agency |
| <input type="checkbox"/> Limited Liability Partnership | <input type="checkbox"/> Non-Profit Corporation | <input type="checkbox"/> Trust |

1. Demographic Information

UBI #

Federal Tax ID (FEIN) #

Legal Owner/Operator Name

Mailing Address

City	State	Zip	County
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Phone #	Fax #
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Email Address	Web Address:
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Facility/Agency Name (Business name as advertised on signs or website)

Physical Address

City	State	Zip	County
------	-------	-----	--------

Facility Phone #	Fax #
------------------	-------

Mailing Address (If different than physical address)

City	State	Zip	County
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For Office Use Only

Medical Test Site # _____ CLIA # _____

2. Facility Specific Information

SITE TYPE (check one only)

- | | | |
|--|--|--|
| <input type="checkbox"/> 1 Ambulance | <input type="checkbox"/> 12 Home Health Agency | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 2 Ambulatory Surgery Center | <input type="checkbox"/> 13 Hospice | <input type="checkbox"/> 24 Public Health Lab |
| <input type="checkbox"/> 3 Ancillary Test Site | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 4 Assisted Living Facility | <input type="checkbox"/> 15 Independent Laboratory | <input type="checkbox"/> 26 Student Health Service |
| <input type="checkbox"/> 5 Blood Banks | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 27 Skilled Nursing Facility |
| <input type="checkbox"/> 6 Community Clinic | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 28 Tissue Bank/Repository |
| <input type="checkbox"/> 7 Comprehensive Outpatient Rehab | <input type="checkbox"/> 18 ICFMR | <input type="checkbox"/> 29 Other |
| <input type="checkbox"/> 8 End Stage Renal Disease Dialysis | <input type="checkbox"/> 19 Mobile Lab | <input type="checkbox"/> 90 Drug Treatment |
| <input type="checkbox"/> 9 Federally Qualified Health Center | <input type="checkbox"/> 20 Pharmacy | <input type="checkbox"/> 91 Clinic |
| <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 21 Physician Office | |
| <input type="checkbox"/> 11 Health Main. Organization | <input type="checkbox"/> 22 Other Practitioner _____ | |

Facility Specific Federal Tax ID (FEIN)#

Enter if different from the Owner FEIN listed on page 1 _____

Multiple Sites

List number of sites if you have multiple sites **and** the paragraph below applies.

If you qualify as a not-for-profit laboratory or state or local government laboratory that performs limited public health testing (total of 15 or less waived or moderate complexity tests) at different locations, you may apply for one license. Attach a list of names and addresses for each site that will be included under one license, and a list of tests performed at each site. If any of the sites already have a MTS license, include the MTS and CLIA numbers of the sites that will be consolidated under this license. If you are not a state or local government laboratory, you **MUST** include a copy of your federal 501(c)(3) determination letter to be licensed in this manner.

3. Key Individuals

Lab Director (include MD, PhD, BS, etc.)

Name:

WA State Professional License (if applicable):

Email Address

Lab Contact Person

Name

WA State Professional License # for MD, ND, PA, ARNP, RN, LPN, health care assistant, etc.

Email Address

Note: If you perform any tests other than the waived tests listed, do NOT complete this application. See the LQA website: <http://www.doh.wa.gov/lqa.htm> to help you determine your correct license category or call the LQA office at 253.395.6746.

4. Additional Information – Waived Tests

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 01/26/12)

Adenovirus

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)

Arkay 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

Arkay 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)

Arkay 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)

Arkay 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

Arkay 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)

Maritech BladderCheck Test (professional & prescription use)

BUN (Blood Urea Nitrogen)

Abbott i-STAT CHEM8+/6+ Cartridge

Arkay SPOTCHEM EZ Chem Analyzer (WB)

Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP,
Metlyte 8, Renal)

Calcium

Arkay 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,Iytes, Metlyte 8, Renal)

Catalase, urine

Diatech Diagnostics Uriscreen (for OTC use)

Chloride

Abbott i-STAT CHEM8+/6+ Cartridge

Piccolo xpress & Blood Analyzers (CMP,BMP,Iytes,metlyte 8,
Renal)

Cholesterol

Accu-Check InstantPlus Cholesterol test system

Accucheck Instant Plus Dual Testing System

Advanced Care Cholesterol measuring system

Alere Cholestech LDX Cholesterol(WB)

Arkay 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

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 AnalyzersWB (Metlyte 8)

Creatinine

Abbott i-STAT CHEM8+/Crea Cartridge

Arkay 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

Alatech Scientific Peace of Mind Multiple Drugs of Abuse

Alere Toxicology Services iCassetts Dx Drug Screen

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 OneScreen Drug Test Cups/Cards/

Revel Multi-Drug Testing Cups

continued on next page

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

___ Applied Biotech
 ___ Aventir Biotech LLC Home Check Multiple Drug Cup Test
 ___ Biotechnostix Rapid Response Drug Screens
 ___ Branan Medical Corp Fastect II/FasTox/QuickTox/ToxCup
 ___ BTNX Know/Rapid Response Multi-Drug One Step Screen
 ___ CLIA-X Multiple Drug Cup Test
 ___ CLIAwaived Inc. Rapid Drug Test Cup (OTC)
 ___ Confirm Biosciences Drugconfirm Instant Multi-Drug of Abuse
 ___ 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
 ___ First Check Diagnostics Drug Screens
 ___ Forefront Diag. Drug Screen
 ___ Graman Medical Corporation
 ___ Greenbrier Intn'l East SCREEN Marijuana Test Strip
 ___ 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 ER11/Multi-Drug of Abuse
 Urine Test/SplitCup Drug Screen/Test Cup/Cassette.Cup
 ___ LifeSign Home Drug Tests
 ___ Med Direct ProXam Drug Test Cards/Multiple Drug Screen Cups
 ___ Micro Distributing II Ltd Multi-Drug of Abuse Urine Test
 ___ 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
 ___ 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
 ___ Quest Diag. Integrated E-Z Split Key Cup II/Express Results
 ___ QuickTest USA Multi-Drug of Abuse Urine Screen
 ___ Redwood Tox Lab Reditest 6/Reditest Freedom Cup/Reditest
 Home Drug Tests
 ___ RefuAH U120 Urine Analyzer
 ___ Screen Tox Multi-Drug of Abuse Urine Test
 ___ Syntrol Bioresearch Quikscreen Multiple Drug Cup Test
 ___ 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
 ___ UCP Home Drug/Multiple/U-Checker Drug Screening Test
 Cards/Cups
 ___ US Diagnostics ProScreen Drugs of Abuse Cup (OTC)
 ___ WayPoint Biomedical, Inc. Health Essist Multi-Drug Tests
 ___ Wolfe Drug Testing RealityCheck Integrated Specimen Cup
 ___ Wondfo Urine Test Cup and Dip Card
 ___ 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

___ Acon Laboratories Mission Saliva Alcohol Test Strip
 ___ Alfa Scientific Designs Oral-View Saliva Alcohol Test Strip
 ___ 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

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
 ___ 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 201analyzer/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+ (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)

Waived Tests (continued)**HDL Cholesterol**

- ___ 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
- ___ Jant Pharmacal LipidPlus Lipid Profile and Glucose System
- ___ Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)
- ___ Polymer Technology Systems BioScanner Plus and 2000
- ___ PolymerTechnology 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 (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)
- ___ Princeton BioMeditech BioSign *H. pylori* WB OSOM *H. pylori*
- ___ Pro-Advantage by NDC *H. pylori* Device (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)
- ___ Stanbio RELY *H.pylori* (WB) fingertstick only)
- ___ 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
- ___ Alere HemoPoint H2 Hemoglobin Measuring System
- ___ Biosafe 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
- ___ 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

- ___ 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

- ___ 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
- ___ 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
- ___ Nova Max Plus 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

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

Waived Tests (continued)

Mononucleosis

- ___ Aceava Mono II (whole blood)
- ___ 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)
- ___ Consult Diagnostics Mononucleosis Cassette (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)
- ___ 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)

- ___ 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
- ___ Immunostics hema screen ER
- ___ Know Fecal Occult Blood Self Test
- ___ Rapid Response Fecal Occult Blood Self Test
- ___ Siemens Hematest Reagent Tablets
- ___ Smithkline Gastrocult

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)
- ___ 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)
- ___ Quicek QuickVue Advance pH and Amines Test

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 Use)
- ___ 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 Sytems, PT-S Strips, XS, XS PST, **XS Plus Patient Self Test**

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
- ___ 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

continued on next page

Waived Tests (continued)

Strep Antigen Test, continued

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/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 Schein Inc, One Step+ 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
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
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
___ 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

___ Alere Cholestech LDX (triglyceride)(WB)
___ Arkray SPOTCHEM EZ Chem Analyzer (WB)
___ Cholestech LDX
___ Infopia USA LipidPro/Lipid Profile Test Strips
___ 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)
___ 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
___ Acon Mission 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 Urine Analyzer
___ Hypoguard Diascreen 50 Urine Chemistry Analyzer

5. Additional Information

Legal Owner Information—attach additional sheets as needed

List names, addresses, phone numbers, and titles of corporate officers, partners, members, managers, etc.

Name	Address	Phone #	Title

Change of Ownership Information

Previous Name of Legal Owner

Previous Name of Facility

Previous MTS License #

Effective Date of
Ownership Change

Physical Address

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.

Signature of Owner/Authorized Representative of Medical Test Site

Date

Print Name

Print Title