



Washington State Department of

**Health**

Revenue Section

P.O. Box 1099

Olympia, WA 98507-1099

206.418.5600

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

## **Certificate of Waiver Medical Test Site (MTS) Application Packet**

### **Contents:**

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2. 505-039.... Certificate of Waiver MTS Application Checklist & Instructions ..... 2 Pages
3. 505-026.... Certificate of Waiver MTS Application ..... 8 Pages

### **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 and fee to:**

Department of Health

Revenue Section

PO Box 1099

Olympia, WA 98504-1099



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## **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 206.418.5600.

### **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, 2011. You will receive a renewal notice for this license approximately 60 days before the expiration date.

Please contact our Seattle office at 206.418.5600 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"/>	April 1, 2009 – June 30, 2011 ..... 150.00

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**

<b>UBI #</b>		<b>Federal Tax ID (FEIN) #</b>	
Legal Owner/Operator Name			
Mailing Address			
City	State	Zip	County
Phone #		Fax #	
Email Address		Web Address:	
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
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.

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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 # for MD, ND, PA, ARNP, RN, LPN, health care assistant, etc.

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 206.418.5600.**

## 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 7/21/09)

### 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, 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)

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

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,  
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 (CO<sub>2</sub>)

Abbott i-STAT CHEM8+ Cartridge

Piccolo xpress & Blood Analyzers (CMP,BMP,lytes, Metlyte 8,  
Renal)

### Catalase, urine

Diatech Diagnostics Uriscreeen (for OTC use)

### Chloride

Abbott i-STAT CHEM8+/6+ Cartridge

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

### 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

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

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

Accu-Stat Diagnostics Drugs of Abuse Home Test

Advantage Diagnostics

Alatech Scientific Peace of Mind Multiple Drugs of Abuse

Alfa Scientific Designs

Amedica Biotech The Amedica Drug Test Cup

American Bio Medica Rapid TOX

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

Drug Detection Devices Multi-Drug Multi-Line Screeners

eScreen, Inc. mCheck Multi-Line Screen Test Device

continued on next page

## Waived Tests (continued)

### Drugs of Abuse, continued

- \_\_\_ 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
- \_\_\_ Syntrol Bioresearch Quikscreen Multiple Drug Cup Test
- \_\_\_ Twin Spirit Inc DrugSmart Cup
- \_\_\_ 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
- \_\_\_ 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

- \_\_\_ 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

- \_\_\_ 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, 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)

### 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
- \_\_\_ 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)
- \_\_\_ 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-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/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)

continued on next page

## Waived Tests (continued)

### ***Helicobacter pylori, continued***

- \_\_\_ 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
- \_\_\_ Stanbio 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
- \_\_\_ EartyDetect 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
- \_\_\_ 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

### **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)
- \_\_\_ 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 Gastrocuilt/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 Gastrocuilt

## Waived Tests (continued)

### 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)
- \_\_\_ 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

### Prottime

- \_\_\_ AvoSure Pro and PT
- \_\_\_ Hemosense INRATIO
- \_\_\_ International Technidyne Corporation Prottime 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

### 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
- \_\_\_ Fertell 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, Metlyte 8, Renal)

### 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 Acceava™ 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
- \_\_\_ IMI Signify Strep A Dipstick
- \_\_\_ Immunostics Immuno/Strep A Detector, Strep A Direct
- \_\_\_ Instant Technologies Istrep Strep A Test
- \_\_\_ Inverness Medical BioStar Acceava 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
- \_\_\_ 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

## Waived Tests (continued)

### 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

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

Biosys Laboratories Optima/Optima II Urine Analyzer

Consult diagnostics Urine Analyzer

Henry Schein OneStepPlus Urine Analyzer

Hypoguard Diascreen 50 Urine Chemistry Analyzer

Jant Pharmacal Corporation Accustrip URS Reader

PSS Select Urine Analyzer

Roche/BMC Mini UA and Chemstrip 101 Urine Analyzer

Roche Diagnostics Urisys 1100 Urine Analyzer

Siemens Clinitek 50/Status Urine Chemistry Analyzers

Teco Diagnostics URITEK TC-101 Urine Strip Reader

ThermoBiostar PocketChem UA

## 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