



## ***Frequently Asked Questions*** ***November 2021***

# **HIV & STI Home Testing, Take Me Home, Dried Blood Spot Testing, & Rapid Syphilis**

### **Home-based self-collection of specimens for HIV/STI testing**

While home-based self-collection of samples for HIV/STI testing has been around for several years, the number of online companies and laboratories offering home-based self-collection of specimens for HIV/STI testing and the number of people accessing these services has increased dramatically since the advent of the COVID-19 pandemic. This fact sheet is a primer for local public health authorities (LPHAs) on home-based self-collection of samples for HIV/STI testing.

We differentiate between home-based **self-testing** and home-based **self-collection** of samples for HIV/STI testing. **Self-testing** means that the client administers the test on their own and receives a result within minutes (e.g., an oral fluid HIV test). In contrast, **self-collection** means that the client collects the necessary specimens for testing (e.g., urine, pharyngeal and rectal swabs, blood samples) and then sends them to a laboratory for analysis and resulting within about 7 days. For this fact sheet, we will focus on home-based **self-collection**.

#### **1. What companies are offering home-based specimen collection for HIV/STI testing?**

	Tests offered	Cost	Notes
Molecular Testing Labs (MTL) ( <a href="http://moleculartestinglabs.com">moleculartestinglabs.com</a> )	Several kits offering combinations of: <ol style="list-style-type: none"><li>1. HIV Ag/Ab</li><li>2. HCV EIA</li><li>3. Hepatitis B surface antigen</li><li>4. HSV-2 EIA</li><li>5. Syphilis EIA</li><li>6. GC/CT (urine/vaginal, rectal, and pharyngeal)</li><li>7. Trichomonas</li><li>8. Mycoplasma</li><li>9. Ureaplasma</li><li>10. HPV (oral, anal, genital)</li></ol>	\$79.00- \$399.00	Uses dried blood spots (MTL) No medical support Online results
EverlyWell ( <a href="http://everlywell.com">everlywell.com</a> )	Single kit offering: <ol style="list-style-type: none"><li>1. HIV Ag/AB</li><li>2. HCV EIA</li></ol>	\$149.00	Uses dried blood spots (MTL) Provider outreach

	<ol style="list-style-type: none"> <li>3. HSV-2 EIA</li> <li>4. Syphilis EIA</li> <li>5. GC/CT (urine for people with penises, vaginal swab for people with vaginas)</li> <li>6. Trichomonas</li> </ol>		for positive tests App-based client results
Let's Get Checked ( <a href="http://letsgetchecked.com">letsgetchecked.com</a> )	<p>Three options:</p> <ol style="list-style-type: none"> <li>1. CT/GC (urine only)</li> <li>2. HIV, syphilis (RPR and EIA), GC/CT (urine only), Trichomonas.</li> <li>3. HIV, syphilis (RPR and EIA), GC/CT (urine only), Trichomonas, Mycoplasma, Ureaplasma, Gardnerella (BV)</li> </ol>	<p>\$99.00 (1)</p> <p>\$149.00 (2)</p> <p>\$249.00 (3)</p>	<p>Uses microtainer tube for blood collection</p> <p>Provider line 24/7, outreach for positive tests</p> <p>Oral treatment can be prescribed and sent to client's home</p> <p>App-based client results</p>
MyLabBox ( <a href="http://www.mylabbox.com">www.mylabbox.com</a> )	<p>Several kits offering combinations of:</p> <ol style="list-style-type: none"> <li>1. HIV Ag/Ab</li> <li>2. HCV EIA</li> <li>3. HSV-2 EIA</li> <li>4. Syphilis EIA (treponemal only)</li> <li>5. GC/CT (urine/vaginal, rectal, and pharyngeal)</li> <li>6. Trichomonas</li> <li>7. Mycoplasma</li> <li>8. Ureaplasma</li> <li>9. Yeast</li> <li>10. BV</li> <li>11. HPV for women 30+ (genital only)</li> <li>12. Additional PrEP labs (hepatitis B surface antigen), creatinine, pregnancy test)</li> </ol>	\$99.00-\$499.00	<p>Uses dried blood spots (MTL)</p> <p>Provider outreach for positive tests; telemedicine consultation for positive HIV tests</p> <p>Oral treatment can be prescribed and sent to client's home</p> <p>Online results</p>
Health Testing Centers ( <a href="http://www.healthtestingcenters.com">www.healthtestingcenters.com</a> )	<p>Several kits offering combinations of:</p> <ol style="list-style-type: none"> <li>1. HIV Ag/Ab</li> <li>2. HCV EIA</li> <li>3. HSV-2 EIA</li> <li>4. Syphilis EIA</li> <li>5. GC/CT (urine/vaginal, rectal, and pharyngeal)</li> <li>6. Trichomonas</li> <li>7. Mycoplasma</li> <li>8. Ureaplasma</li> <li>9. HPV (oral, anal, genital)</li> </ol>	\$79.00-\$349.00	<p>Uses dried blood spots (MTL)</p> <p>Medical team available for questions</p> <p>Online results</p>
iDNA ( <a href="http://www.idna.com">www.idna.com</a> )	<p>Several kits offering combinations of:</p> <ol style="list-style-type: none"> <li>1. HIV Ag/Ab</li> </ol>	\$78.00-\$298.00	<p>Uses dried blood spots (MTL)</p> <p>Free test of cure</p>

	<ol style="list-style-type: none"> <li>2. HCV EIA</li> <li>3. HSV-2 EIA</li> <li>4. Syphilis EIA</li> <li>5. GC/CT (urine for people with penises, vaginal swab for people with vaginas)</li> <li>6. Trichomonas</li> <li>7. Mycoplasma</li> <li>8. Ureaplasma</li> <li>9. HPV (genital only)</li> </ol>		No medical support Online results
Verisana ( <a href="http://www.verisana.com">www.verisana.com</a> )	<p>Several kits offering combinations of:</p> <ol style="list-style-type: none"> <li>1. HIV Ag/Ab</li> <li>2. HCV EIA</li> <li>3. HSV-2 EIA</li> <li>4. Syphilis EIA</li> <li>5. GC/CT (urine for people with penises, vaginal swab for people with vaginas)</li> <li>6. Trichomonas</li> <li>7. Mycoplasma</li> <li>8. Ureaplasma</li> <li>9. HPV (genital only)</li> </ol>	\$89.00- \$299.00	Uses dried blood spots (MTL) No medical support Online results
NuRX ( <a href="http://www.nurx.com/">www.nurx.com/</a> )	<p>Three kits offering:</p> <ol style="list-style-type: none"> <li>1. HIV Ag/Ab, GC/CT (urine), syphilis EIA</li> <li>2. HIV Ag/Ab, GC/CT (urine), syphilis EIA, trich</li> <li>3. HIV Ag/Ab, HCV EIA, GC/CT (urine, pharyngeal, rectal), syphilis EIA</li> </ol>	\$150.00- \$200.00, accepts insurance	Uses dried blood spots (MTL) Provider outreach Oral treatment can be prescribed and sent to client's home
MISTr ( <a href="http://heymistr.com">heymistr.com</a> )	<ol style="list-style-type: none"> <li>1. HIV Ag/Ab</li> <li>2. HCV EIA</li> <li>3. Syphilis EIA</li> <li>4. GC/CT (urine, pharyngeal, rectal)</li> <li>5. PrEP labs: hepatitis B surface antigen, creatinine, pregnancy testing</li> </ol>	Free with PrEP, accepts insurance	Online PrEP provider Uses dried blood spots (MTL) PRISM health providers (CAP, Portland, OR) consultation and outreach for positive tests
PlushCare ( <a href="http://plushcare.com">plushcare.com</a> )	Tests offered not listed on website; test kits sent out after provider consultation. PlushCare is also an online PrEP provider	Not listed, accepts insurance	Telemedicine service that provides STI self-collection kits and PrEP

**2. What reporting rules do companies that offer home-based specimen self-collection for STI testing follow?**

All of the companies that use dried blood spot (DBS) testing, including the OHA STI home self-collection program (TakeMeHome), send specimens to Molecular Testing Labs (MTL) based in Vancouver, WA. MTL reports positive laboratory results to Orpheus electronically.

Oregon law requires laboratories to report positive communicable disease case reports for anyone who is an Oregon resident or temporarily resides in Oregon. Oregon law also requires laboratories who reach a certain threshold of positive case reports to begin reporting electronically. We continue to investigate how well different home-based self-collection providers are complying with this rule and will respond accordingly if compliance becomes an ongoing issue.

**3. When results are reported, what are the expectations of LPHAs? Should they first attempt to track down the ordering provider at the online testing company? Or contact the patient directly about a screening result and help facilitate confirmatory testing/treatment? In other words, does the health department have a role in home/self-testing?**

The ordering provider for home-based self-collection of specimens for STI testing may not have all of the information that LPHAs may need to assess whether a patient has had confirmatory testing or treatment. Some companies provide consultations with a provider who can prescribe oral treatment (e.g., for CT, GC, trichomoniasis, bacterial vaginosis, and candidiasis) or linkage to treatment, some provide outreach for positive tests to facilitate treatment, and some provide no consultation or outreach by a provider. Therefore, we recommend reaching out directly to patients for follow-up to confirmatory testing, linkage to treatment, and if appropriate, partner services.

**4. Can the counties purchase Home STI test kits to hand out when doing outreach in the field and/or at syringe exchange? If so, what is the process/role for the LPHA with home test kits?**

OHA is currently planning & budgeting for future funding for LPHAs and CBOs to distribute home STI test kits in a variety of settings. There is great interest and potential benefits for home STI kit dissemination. LPHAs are best positioned to promote, offer, and distribute home STI test kits based on the needs of their local communities. Agencies interested in implementing such a system will need to ensure that at a minimum, they have the following staffing in place:

- A local medical provider (STD clinic NP, PA or MD, Health Officer, etc.) who can act as ordering provider.
- Staff in place to ensure timely outreach, treatment, and follow-up of positive tests.
- Staff in place to assist clients who need additional help with specimen self-collection or who need reminders/follow-up to return their kits.

If your agency has interest in future funding for purchasing and distributing home-based self-collected STD test kits, please contact Gianna Bortoli (HIV Prevention Specialist) at [gianna.a.bortoli@oha.oregon.gov](mailto:gianna.a.bortoli@oha.oregon.gov).

## Take Me Home

Take Me Home (TMH) is a national platform for ordering and distributing self-test kits that helps public health departments offer access to HIV testing to those who might be hesitant to walk into a clinic. The kits are promoted by dating apps and customized with local resources/care information.

OHA has launched two TMH services. The first provides rapid HIV at-home testing and the other provides mail-in self-collected STI tests. For more information on TMH visit: [takemehome.co](https://takemehome.co).

Current data on uptake of TMH in Oregon can be accessed at our online dashboard at: [oregon.gov/oha/PH/DISEASES/CONDITIONS/HIVSTDVIRALHEPATITIS/Pages/countyleveldata.aspx](https://oregon.gov/oha/PH/DISEASES/CONDITIONS/HIVSTDVIRALHEPATITIS/Pages/countyleveldata.aspx)

**TMH rapid HIV at-home test program** – offers a rapid HIV self-test utilizing the OraQuick In-Home HIV Test, an FDA approved test which allows an individual to complete the entire testing process in their home (or other private location), including interpretation of the test result. The test requires an oral sample and produces a result in 20 minutes. Individuals receive information in their test kits about what to do in the case of a positive result. This includes information on how to obtain a confirmatory test at a local clinic as well as links to geo-targeted testing and care services. All users receive basic information about STI testing, PrEP, condoms, and U=U.



### Sample collected in HIV Test

<b>Sample Type: Oral Fluid</b>
Human Immunodeficiency Virus (HIV)

**THM home-based STI self-collection-** STI testing includes 3-site (genital, rectal, pharyngeal) chlamydia and gonorrhea, syphilis, HCV, and HIV (ordered under a medical order by a licensed provider) which allow an individual to collect specimens in their home (or other private location) to be mailed to a laboratory that processes the test and reports the test result to the ordering provider. The participant

can access their test results through a secure self-service results portal. Participants with positive test results are encouraged to receive follow-up locally and are provided with links to geo-targeted testing and treatment/care services. All users receive basic information about STD testing, PrEP, condoms, and U=U. All positive results are automatically reported to the LPHA via Orpheus.



### Samples and STI testing:

<b>Sample Type: Urine</b>
<i>Chlamydia trachomatis</i> (CT)
<i>Neisseria gonorrhea</i> (GC)
<b>Sample Type: Dried Blood Spot Card</b>
Hepatitis C Virus Antibody
Human Immunodeficiency Virus (HIV)
Syphilis EIA
<b>Sample Type: Oral Swab</b>
<i>Chlamydia trachomatis</i> (CT)
<i>Neisseria gonorrhea</i> (GC):
<b>Sample Type: Anal Swab</b>
<i>Chlamydia trachomatis</i> (CT)
<i>Neisseria gonorrhea</i> (GC)

1. Who is the ordering provider for TMH tests, and what is their role in following up on results and referring patients for confirmatory testing?

HIV/STD/TB section Medical Director, Tim Menza, MD, PhD, is the ordering provider for all TMH STI home self-collected tests. Before MTL was reporting results electronically, as the ordering provider he followed up with LPHAs on all positive tests and created Orpheus cases. Now that MTL is reporting electronically, the LPHA is responsible for follow-up of positive tests and treatment or referrals to treatment, as is standard with other reportable STDs. Dr. Menza is also the ordering provider for the TMH HIV self-testing program. Rapid HIV testing performed at home is not reported to Orpheus;



however, LPHAs may receive phone calls from clients with a positive rapid home tests for advice on next steps, confirmatory testing, and care linkage.

### Example of ELR from MTL for a self-collected STI test:

<b>Laboratory:</b> Molecular Testing Labs		<a href="#">Show ELR</a>
<b>Collection Date:</b>	06/08/2021	
<b>Report Date:</b>	06/22/2021	
<b>Specimen Type:</b>	oral swab	
<b>Test Type:</b>	Neisseria gonorrhoeae	
<b>Result:</b>	Detected	
<b>Interpretation:</b>	Interpretation...	
<b>Accession ID:</b> Accession ID...		
<b>Pathogen:</b>	300	
<b>OSPHL:</b>	OSPHL...	
<b>Units:</b>	Units...	
<a href="#">Add Lab (same day)</a>		

### List of Results

Specimen Date: 6/8/2021 Lag: 9 days  
Specimen Type/Site: oral swab

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**Order:** N gonorrhoea DNA XXX QI NAA+probe

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**Test:** N gonorrhoea DNA XXX QI NAA+probe  
Detected

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Notes: This message was created from an CSV that was provided to OPHD. Contents were mapped by OR ELR. Oral Swab Expedited partner therapy received: U

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----- Additional Notes -----

This message was created from an CSV that was provided to OPHD. Contents were mapped by OR ELR.  
Oral Swab  
Expedited partner therapy received: U\*\*\*\*\*

ELR Message Date: 6/17/2021

**Example of ELR from MTL for a dried blood spot test:**

<b>Laboratory:</b> Molecular Testing Labs		<b>Show ELR</b>	
<b>Collection Date:</b>	06/16/2021	<b>List of Results</b>	
<b>Report Date:</b>	06/23/2021		
<b>Specimen Type:</b>	Dried blood spot		
<b>Test Type:</b>	Treponema pallidum		
<b>Result:</b>	Reactive		
<b>Interpretation:</b>	Interpretation...	Specimen Date: 6/16/2021 Lag: 7 days Specimen Type/Site: Dried blood spot specimen Order: T pallidum IgG+IgM Ser QI IA ----- Test: T pallidum IgG+IgM Ser QI IA Reactive ----- Notes: This message was created from an CSV that was provided to OPHD. Contents were mapped by OR ELR. Blood Expedited partner therapy received: U ----- ----- Additional Notes ----- This message was created from an CSV that was provided to OPHD. Contents were mapped by OR ELR. Blood Expedited partner therapy received: U*****	
<b>Accession ID:</b>	Accession ID...		
<b>Pathogen:</b>	700		
<b>OSPHL:</b>	OSPHL...		
<b>Units:</b>	Units...		
<b>Add Lab (same day)</b>			

**2. How do participants learn they have a positive result if they participate in the THM STI testing program?**

Below are examples of messages participants receive when logging into the TMH system to retrieve their results. Participants are directed to the CDC's HIV and STD geo-locator services finder and OHA HIV and STD Prevention websites for information and resources on further testing and treatment. Participants are also reminded that a local health department staff person may follow-up with them regarding their positive result and the need for additional testing or treatment.

## RESULT DETAILS

### CHLAMYDIA

You have tested positive for Chlamydia. This infection is quite common and can be easily treated. You can get more information about Chlamydia here. It is recommended not to have sex for 7 days, or, if you have a 7-day treatment, until your treatment is completed, as you could pass Chlamydia to your partner.

## RESULT DETAILS

### GONORRHEA

You have tested positive for Gonorrhea. This infection is quite common and can be easily treated. You can get more information about Gonorrhea here. It is recommended not to have sex for 7 days, or, if you have a 7-day treatment, until your treatment is completed, as you could pass Gonorrhea to your partner.



## RESULTS

PROCESSED ON DECEMBER 17, 2020



GONORRHEA (URINE)	NEGATIVE
CHLAMYDIA (THROAT)	NEGATIVE
SYPHILIS	QUANTITY NOT SUFFICIENT
HEPATITIS C VIRUS (HCV)	NON-REACTIVE
GONORRHEA (RECTAL)	NEGATIVE
CHLAMYDIA (RECTAL)	NEGATIVE
CHLAMYDIA (URINE)	NEGATIVE
HUMAN IMMUNODEFICIENCY VIRUS (HIV)	FOLLOW-UP NEEDED
GONORRHEA (THROAT)	NEGATIVE



Additional follow-up is needed.

Click [here](#) for more information.

You may be contacted by your local health department for additional follow-up.

### 3. Does the syphilis part of the DBS test reflex to an RPR if it is positive?

No, the DBS only offers a treponemal-specific test (EIA) for syphilis. An individual who tests positive for syphilis with DBS must be offered additional syphilis testing including an RPR for appropriate staging and treatment. When initially ordering a test through TMH, users are asked about prior syphilis infection. If they indicate they have previously had syphilis, the syphilis option is not included in their testing package.

### 4. Are there tools available for individuals who may be unfamiliar with self-collection?

The TMH website includes an array of instructional videos on self-collection for users at [takemehome.org/instructional-videos/](https://takemehome.org/instructional-videos/).

The TMH website also includes an extensive frequently asked questions section at [takemehome.org/faqs/](https://takemehome.org/faqs/).



**5. What is the immediate plan for TMH STI testing program?**

The STI testing arm of Take Me Home will remain in a pilot stage with limited availability through the beginning of 2022. There may be short periods when users are unable to access the STI home test kit feature on the TMH website as availability of kits is temporarily removed as an option during periods of heavier advertising on apps such as Grindr. This is done in order to avoid depleting our stock of kits in the pilot. LPHA promotion of this testing program will become possible upon additional evaluation and funding in 2022. Right now, only the HIV oral fluids self-testing program is being advertised more widely given its more robust funding.

**6. Will there be an evaluation of the STI pilot to improve home testing?**

An evaluation of the pilot phase of the TMH home-based self-collection of specimens for STI testing is ongoing. We are evaluating the program with the following metrics: uptake, return rate positivity rates, and overall participant feedback evaluation.

## **Outreach Dried Blood Spot (DBS) Testing**

### **1. What tests are included in DBS testing?**

HIV, Hepatitis C antibody, and syphilis EIA.

### **2. Should someone with a previous syphilis infection be offered DBS testing for syphilis?**

DBS testing for syphilis should not be conducted for individuals who report a previous syphilis infection. It is a treponemal-specific syphilis assay and cannot differentiate between a prior treated infection and a new one. The individual should be offered a standard blood draw for a syphilis RPR.

### **3. Does the syphilis part of the DBS test reflex to an RPR if it is positive?**

No, the DBS only offers a treponemal-specific test (EIA) for syphilis. An individual who tests positive for syphilis with DBS must be offered additional syphilis testing including an RPR for appropriate staging and treatment.

### **4. Where is DBS being utilized currently?**

The Oregon LPHAs currently approved to order and administer DBS testing are Multnomah, Washington, and Lane.

### **5. Why have we not seen more uptake of DBS?**

DBS testing is predominantly focused on the diagnosis of HIV, HCV, and syphilis in resource-limited settings and among certain populations including pregnant women, people who use drugs, people experiencing homelessness and people involved in the criminal justice system. Overall, there has been a slower start and implementation due to the local administrative burden of starting such an outreach testing program that requires approval of protocols and procedures and staff training. Furthermore, COVID-19 shuttered many outreach programs limiting its implementation.

### **6. What does it take to do DBS testing?**

In order to administer DBS, LPHAs/CBOs need to have protocols and processes related to the following in place:

- Staff training on conducting DBS testing, including relevant safety precautions.
- Handling and shipping specimens to the MTL lab in Vancouver, WA, along with a system in place for data entry using the MTL electronic lab interface.
- Notification of individuals with positive test results, and for conducting follow-up testing or administering treatment as needed.

### **7. Is DBS being tracked/evaluated?**

An evaluation of DBS is ongoing. We are evaluating the program with the following metrics: uptake and HIV, treponemal EIA, and HCV positivity rates.

**8. What are the funding constraints around DBS?**

Funding has been primarily through the use of state general funds; past reductions on these funds have affected this program. Future CDC funding will allow for the expansion to counties seeking to implement DBS.

**9. Are we encouraging more partners to use DBS? I'm interested in adopting DBS testing and would like to be considered for future expansion of DBS.**

There have been several counties who have expressed in utilizing DBS. We are in the process of creating technical assistance and guidance to assist in implementation process of DBS. If your agency has interest in being added as a site for future DBS expansion efforts, please contact Gianna Bortoli (HIV Prevention Specialist) at [gianna.a.bortoli@oha.oregon.gov](mailto:gianna.a.bortoli@oha.oregon.gov).

## **Rapid Syphilis Testing**

**1. What funding can be used to purchase rapid syphilis tests (RST)? What are the funding constraints?**

In Fall 2021 we are adding RST to our rapid testing reimbursement program which allows LPHAs to be reimbursed for the purchase of rapid testing technology. At this time, this is the only funding source from OHA which can be used to pay for these tests.

**2. Can LPHAs use rapid syphilis tests and provide them to jails, drug treatment centers, homeless outreach services, etc.?**

Yes, RST is effective within these populations and settings where syphilis is new and will generally indicate an active, untreated infection, including pregnant women, people who use drugs, people experiencing homelessness and people involved in the criminal justice system. Please refer to [OHA Rapid Syphilis Testing Guidance](#).

**3. If we encourage partners to increase rapid syphilis testing, what are the expectations of LPHAs to follow up on results with patients and facilitate confirmatory testing and treatment?**

It is highly encouraged to have treatment available at the time of rapid testing, draw blood for confirmatory testing and arrange for treatment on the spot. Alternatively, provide transportation to a clinic that can provide confirmatory testing and treatment after a positive rapid test. Confirmatory testing should be routine for positive rapid results. Please refer to [OHA Rapid Syphilis Testing Guidance](#).

**4. Are there any plans for us to pilot the Chembio combination HIV/Syphilis rapid test (DPP HIV-Syphilis)? Will OHA provide funding to purchase these kits?**

The DPP HIV-Syphilis rapid test has been approved by the FDA but has not received a CLIA-waiver which is necessary for the test to be administered by non-laboratory staff. We are in communication with Chembio and have received pricing and information regarding their dual rapid test. We will fund the purchase DPP HIV-Syphilis rapid test once the test receives CLIA-waiver.

For the time being the Syphilis Health Check is the only CLIA-waved rapid syphilis testing option.

## RAPID SYPHILIS TESTS SUITABLE FOR USE IN NON-CLINICAL SETTINGS

Brand		<a href="#">Trinity Biotech Syphilis Health Check</a>	<a href="#">Diagnostics Direct Syphilis Health Check</a>
<b>COST</b> (Public health pricing. Contact distributor for further details.)	<b>Control kits</b>	\$29.25	\$49.00
	<b>Test kits</b>	\$200.00 per box of 20 plus shipping & an additional \$25 handling fee	\$200.00 per box of 20 plus \$15 flat rate shipping
<b>Contact</b>		Heidi Maxwell 800-325-3424 Option 3 <a href="mailto:heidi.maxwell@trinityusa.com">heidi.maxwell@trinityusa.com</a>	Jeff Tobias 866-358-9282 ext. 102 <a href="mailto:jtobias@dd-2u.com">jtobias@dd-2u.com</a>
<b>Ordering</b>		Contact Heidi Maxwell	Contact Jeff Tobias or Order on <a href="#">Website</a>
<b>Training</b>		Provided	Provided