EvaluationWeb Data Entry Training for Counseling and Testing (CTR)

Minnesota Edition

July 2014

Table of Contents

EVALUATIONWEB BASICS

EvaluationWeb 4.0 is an online data collection and reporting system specifically for HIV Counseling and Testing. EvaluationWeb collects the same data required by and is replacing the CDC's (decommissioned) Program Evaluation Monitoring System (PEMS).

SYSTEM REQUIREMENTS

- Browser Versions: IE 9+; Firefox 3.0 +; Chrome 2.0 +; Safari 3.0 + (No Cost)
- Flash Player 10.2 Or Higher (No Cost)
- Pop Up Blockers Must Be Disabled for .lutherconsulting.com domain;
- Each Tool Bar Has its Own Pop Up Blocker

E-AUTHENTICATION

- E-authentication is electronic authentication. Authentication is a process closely related to identification. In online environments, the username identifies the user, while the password authenticates that the user is who he claims to be.
- Grantees will need to be e-authenticated by CDC. MDH will coordinate this process for all Minnesota grantees. A Minnesota ID and e-mail access is required.
- Step by step process can be found at http://www.health.state.mn.us/divs/idepc/diseases/hiv/evaluationweb/eauthentication.html

- Grantee will receive an email from SAMS (example below). Be aware that this can easily be mistaken for SPAM.
    - **From:** sams-no-reply@cdc.gov [mailto:sams-no-reply@cdc.gov]
      Subject: U.S. Centers for Disease Control: SAMS Partner Portal - SAMS Account Notification
- E-authenticated grantee users are assigned a unique user name, password, and specified level of access.
- Initial passphrase will come from info@lutherconsulting.com in an email
- You will then need to read and sign the Employee Confidentiality Agreement and Rules of Behavior found at http://www.health.state.mn.us/divs/idepc/diseases/hiv/evaluationweb/index.html

EMPLOYEE CONFIDENTIALITY AGREEMENT (sample)

I acknowledge that during the course of performing my assigned duties at _____ I may have access to, use, or disclose confidential health information. I hereby agree to handle such information in a confidential manner at all times during and after my employment and commit to the following obligations:

A. I will use and disclose confidential health information only in connection with and for the purpose of performing my assigned duties

B. I will request, obtain or communicate confidential health information only as necessary to perform my assigned duties and shall refrain from requesting, obtaining or communicating more confidential health information than is necessary to accomplish my assigned duties

C. I will take reasonable care to properly secure confidential health information on my computer and will take steps to ensure that others cannot view or access such information. When I am away from my workstation or when my tasks are completed, I will log off my computer or use a password-protected screensaver in order to prevent access by unauthorized users.

D. I will not disclose my personal password(s) to anyone without the express written permission of my department head or record or post it in an accessible location and will refrain from performing any tasks using another's password

E. I will document all disclosures of confidential health information, including those authorized by clients of_____and any accidental disclosures, in the appropriate client's file.

I understand that as an employee of_____, I have an obligation to complete Client Confidentiality or HIPAA training on an annual basis, and in signing this agreement, I confirm that I have completed confidentiality training within the past twelve months.

I also understand and agree that my failure to fulfill any of the obligations set forth in this Agreement and/or my violation of any terms of this Agreement shall result in my being subject to appropriate disciplinary action, up to and including, termination of employment.

Employee Signature: _____

Employee Printed Name: _____

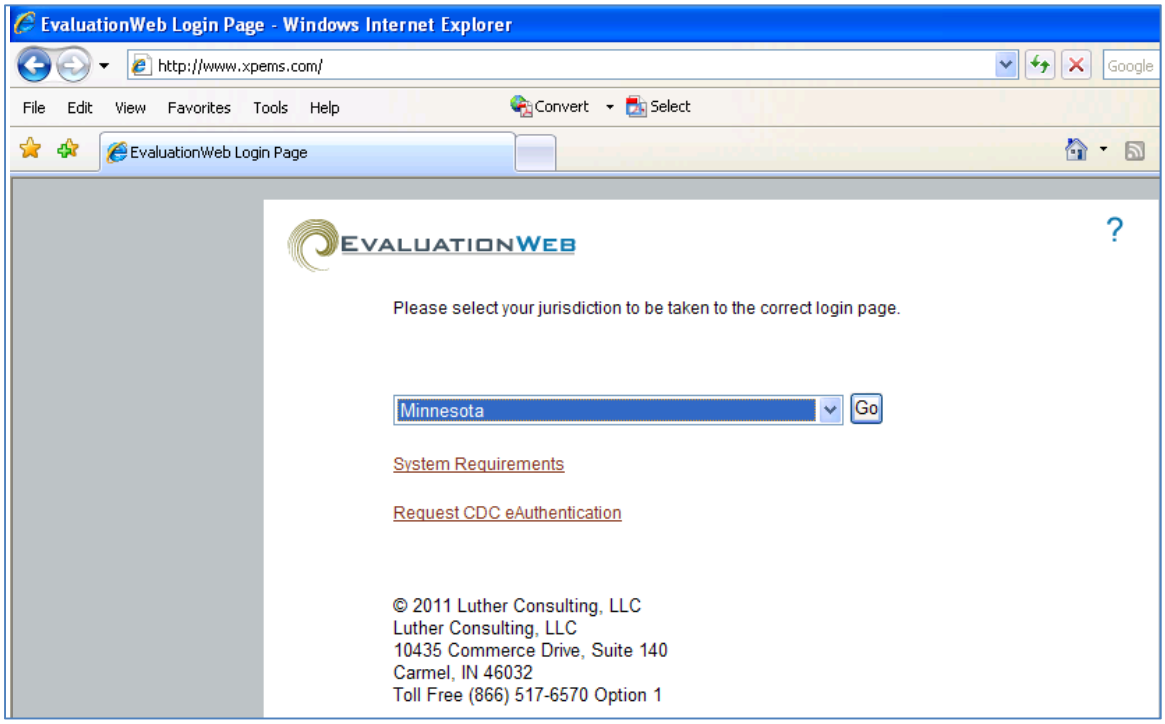
Date: _____

TIME SCHEDULES

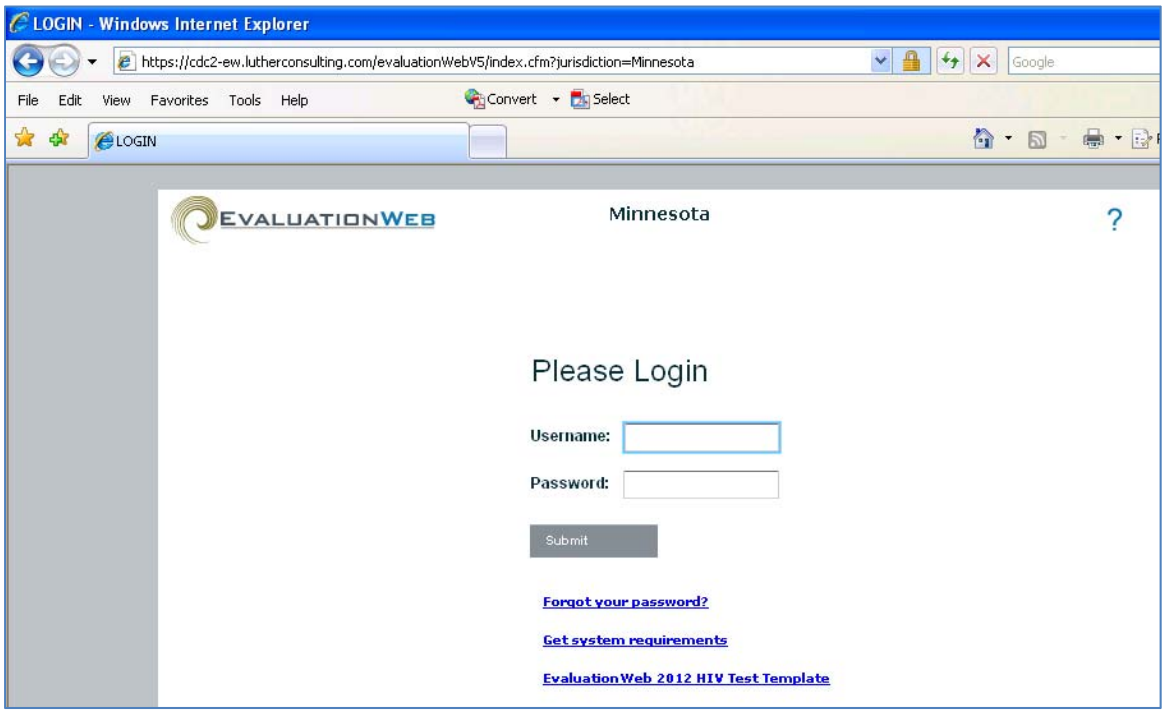
By the twenty-fifth (25th) of each month, forms are to be received by entered into EvaluationWeb for tests performed during previous month. CDC recommends that data be entered into the system at least weekly to avoid a back-log of data.

ACCESSING EVALUATIONWEB

http://www.xpems.com/



LOGGING IN

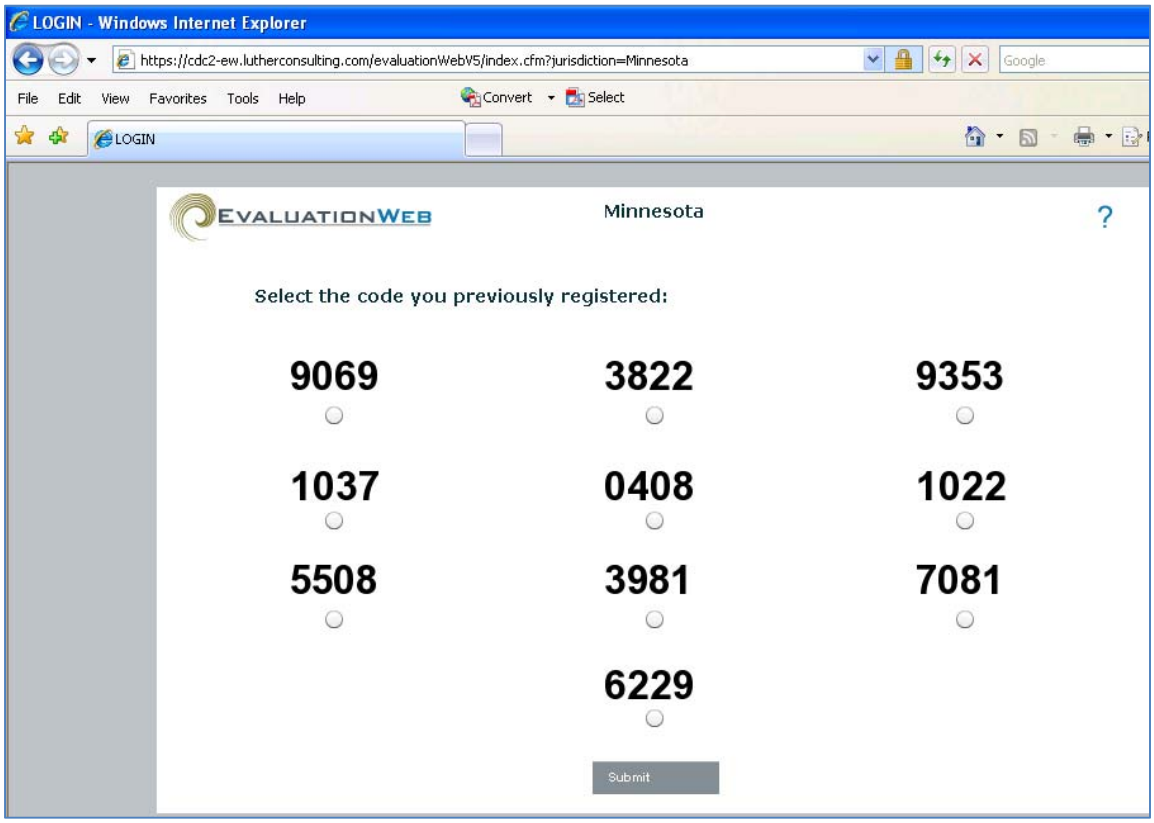


PASSWORD REQUIREMENTS

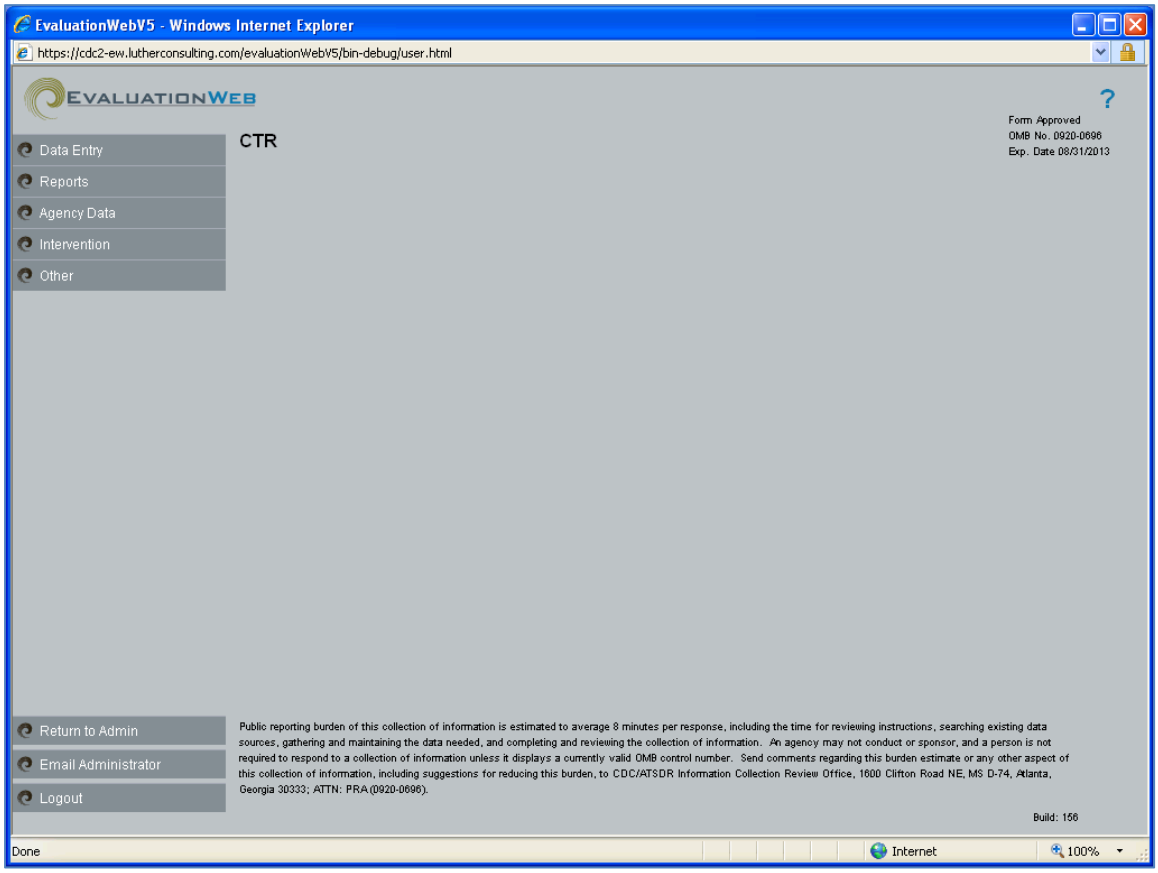
- Initial passphrase will come from info@lutherconsulting.com in an email
- You will then establish a permanent password
- Password phrases must adhere to the following guidelines:
    - Minimum of 9 characters
    - Minimum of one uppercase and one lower case letter
    - Must contain at least one numeric character or at least one of the following special characters:

      ! @ $ % ^ & * ( ) _ - + = < > ? /
    - Must contain at least 1 space
    - Cannot contain your user name
    - Cannot contain your name
    - Change every 60 days
- Pass "phrase" goal – easier to remember, harder for someone to guess:
    - "My love 4 chocolate"
    - "It's too cold 2 snow!"
- Create a four digit pin code for your account
- You will then need to read and sign the User Agreement and Rules of Behavior found at http://www.health.state.mn.us/divs/idepc/diseases/hiv/evaluationweb/index.html

PASS CODE



MAIN SCREEN



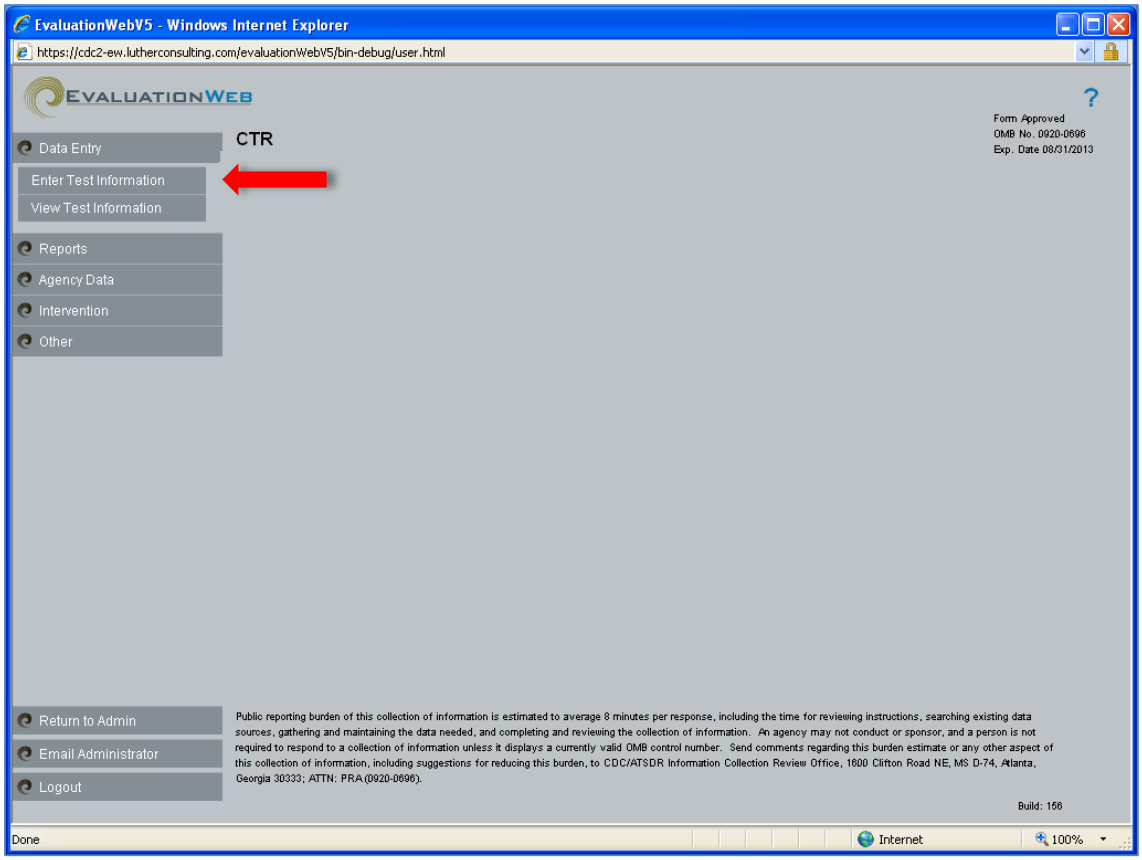
The HIV testing event form template was designed by CDC to facilitate documentation of required test-level variables. Data are collected for each HIV testing event. Each testing event is associated with one unique HIV testing form ID.

To download and print a PDF version of the form, see http://www.health.state.mn.us/divs/idepc/diseases/hiv/evaluationweb/index.html.

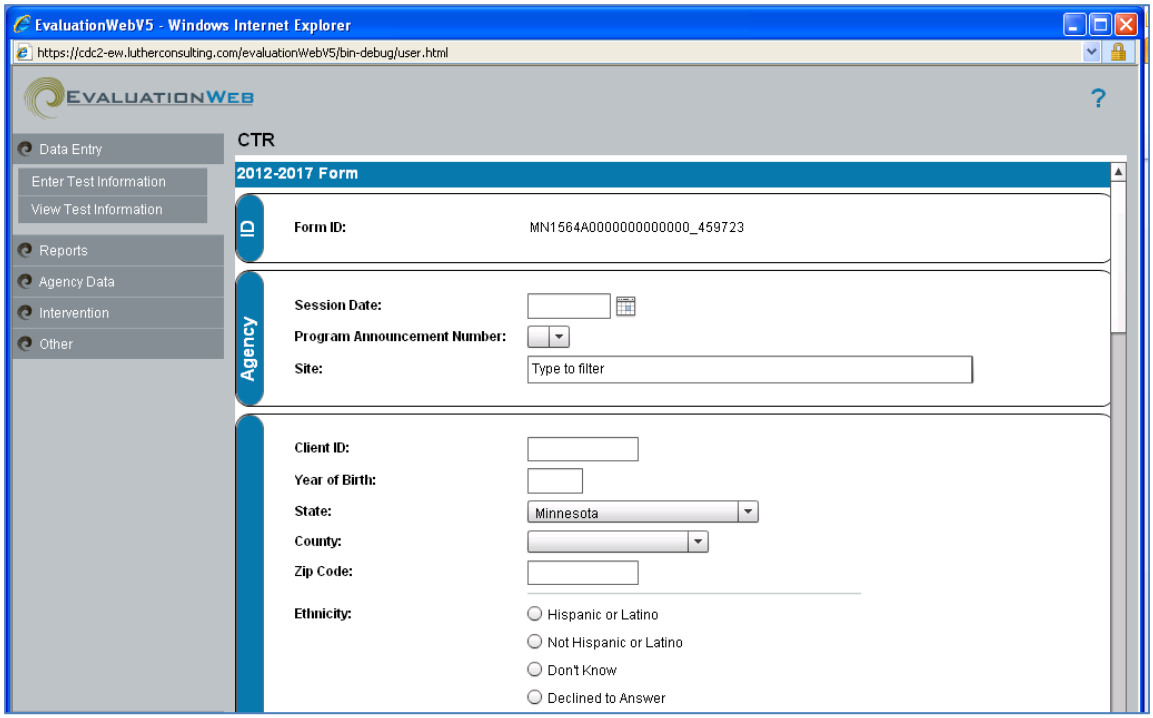
SETTING DEFAULTS

MDH prohibits the use of default settings for patient demographic information.

ENTERING TEST INFORMATION



ID, AGENCY AND CLIENT INFORMATION



TEST ID / FORM ID is auto-generated. If not, please check your preferences within EvalWeb.

SESSION DATE is the date the test was administered. The date can be typed in or chosen from the calendar widget.

AGENCY INFORMATION

Agency Name	Agency ID	Site Name	Site ID	Site Type Code	Site Zip/County	Program Announcement
African American AIDS Task Force (AAATF)	**56525**	***AAATF***	***56781***	***F06.88***	***55404/053***	*Ryan White*
African Health Action (AHA)	**1482**	***African Health Action***	***9058***	***F06.88***	***55406/053***	*PS 12-1201-Category A*
Face to Face Counseling Service, Inc.	**55998**	***Safe Zone***	***56750***	***F06.88***	***55101/123***	*PS 12-1201-Category A*
Hennepin County Public Health (HSPHD)	**27076**				***55415/053***	*PS 12-1201-Category A*
Programs Offered		*Red Door Clinical Services*	*30429*	*F10*		
		Red Door Special Events	*9151*	*F10*		
		CAPS Program - Clinic	*9086*	*F10*		
		CAPS Program - Community	*9087*	*F06.88*		
		CAPS Program - HRSA	*9094*	*F10*		
		HIM Program - Clinic	*9090*	*F10*		
		HIM Program - Community	*9091*	*F06.88*		
		HIM Program - HRSA	*9095*	*F10*		
		HIM YMSM Program - Clinic	*13028*	*F10*		
		HIM YMSM Program - Community	*13029*	*F06.88*		
		HIM Program - PrEP	*9096*	*F10*		
		Disease Intervention Specialist	*30430*	*F10*		
Indigenous Peoples Task Force (IPTF)	**6621**				***55406/053***	10—1003 Direct CDC funding; or *PS 12-1201-Category A*
Programs Offered		*IPTF Main Office*	*463*	*F06.88*		
		Metro - Community	*523*	*F06.88*		
		Metro - Treatment	*527*	*F02.19*		
		Four Winds / Brainerd - Treatment	*543*	*F02.19*		
		Thunder Bird / Wren House - Duluth	*646*	*F06.88*		
		Mille Lacs Lake - Community	*647*	*F06.88*		
		Mille Lacs Lake - Treatment	*648*	*F02.19*		
		White Earth - Community	*11964*	*F06.88*		
		White Earth - Treatment	*11949*	*F02.19*		
		Leech Lake - Community	*11950*	*F06.88*		

Agency Name	Agency ID	Site Name	Site ID	Site Type Code	Site Zip/County	Program Announcement
Indigenous Peoples Task Force (IPTF) continued	**6621**				***55406/053***	10—1003 Direct CDC funding; or *PS 12-1201-Category A*
		Leech Lake - Treatment	*11951*	*F02.19*		
		Red Lake - Community	*11952*	*F06.88*		
		Morton - Treatment	*11956*	*F02.19*		
		Granite Falls - Community	*11957*	*F06.88*		
		Shakopee - Community	*11958*	*F06.88*		
		Fond du Lac - Community	*11959*	*F06.88*		
		Bois Forte - Community	*11960*	*F06.88*		
		Grand Portage - Community	*11961*	*F06.88*		
		Prairie Island - Community	*11962*	*F06.88*		
Lutheran Social Service of Minnesota (LSS) – Duluth	**27601**		***276011***	***F06.88***	***55802***	*PS 12-1201-Category A*
Minneapolis Medical Research Foundation	**1488**	***Positive Care Center***	***9039***	***F08***	***55415/053***	*PS 12-1201-Category A*
Minnesota AIDS Project (MAP)	**56208**				***55404/053***	10—1003 Direct CDC funding; or *PS 12-1201-Category A*
Programs Offered		*Pride Alive*	*56752*	*F06.88*		
		Young Pride Alive	*14052*	*F06.88*		
		AIDSLine (CDC-funded)	*18859*	*F06.88*		
		IDU CTR	*14055*	*F06.88*		
Minnesota Department of Health	**20**	***Partner Services***	***9148***	***F14***	***55155/123***	*PS 12-1201-Category A*
Neighborhood House	**56301**		***563011***	***F06.88***	***55107***	*PS 12-1201-Category A*
Pillsbury United Communities	**56215**				**55407**	*PS 12-1201-Category A*
Programs Offered		*Pillsbury United Communities*	*56754*	*F06.88*		
		21 Barbershop	*13061*	*F06.88*		
Rural AIDS Action Network	**2092**	***RAAN HERR CTR***	***13033***	***F06.88***	**56304**	*PS 12-1201-Category A*
Sacred Spirits	**2108**	***Sacred Spirits - Project***	***13136***	***F06.88***	**56557**	*PS 12-1201-*

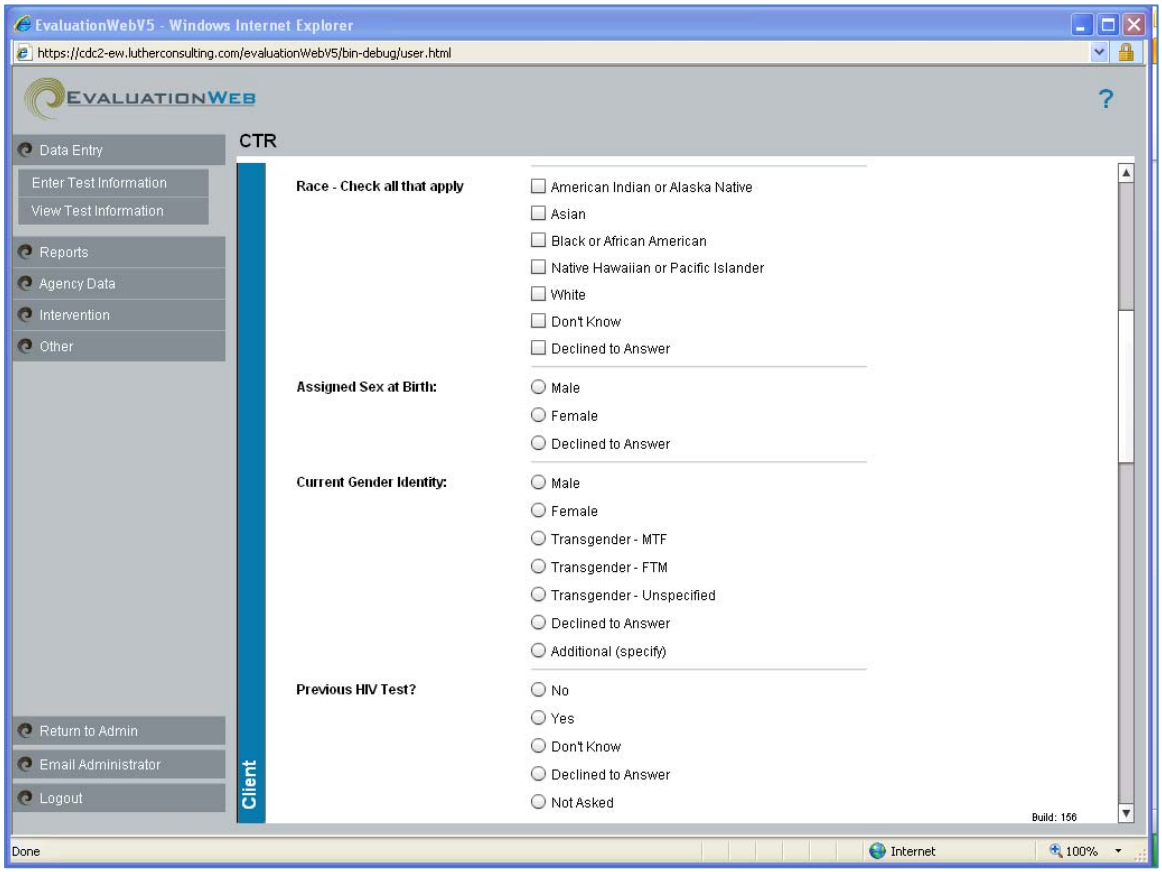
Agency Name	Agency ID	Site Name	Site ID	Site Type Code	Site Zip/County	Program Announcement
		CEDAR				*Category A*
St. Paul Ramsey County PHD	**56278**	***Clinic 555***	***56764***	***F10***	***55101/123***	*PS 12-1201-Category A*
Sub-Saharan African Youth & Family Services of Minnesota (SAYFSM)	**27501**		***275011***	***F06.88***	***55104***	*PS 12-1201-Category A*
The Aliveness Project	**27201**		***27201***	***F06.88***	***55407/053***	*Ryan White*
Turning Point, Inc.	**63599**				***55411/053***	*Other: NOT FUNDED*
Programs Offered		*Turning Point*	*64235*	*F02.19*		
		Turning Point - Community	*9055*	*F06.88*		
U of M - Office of Sponsored Projects Administration	**56245**	***North Memorial - Broadway Family Medicine***	***9051***	***F02.51***	***55411/053***	*PS 12-1201-Category A*
West Side Community Health Services	**56519**				***55107/123***	*PS 12-1201-Category A*
Programs Offered		*Clinic 7*	*56590*	*F02.51*		
		No Tengas Miedo CTR	*9054*	*F06.88*		
Youth and AIDS Project (YAP)	**27401**		***274011***	***F06.88***	**55408**	*PS 12-1201-Category A*

CLIENT ID is your local patient identification number. No names or full birthdates can be transmitted to CDC.

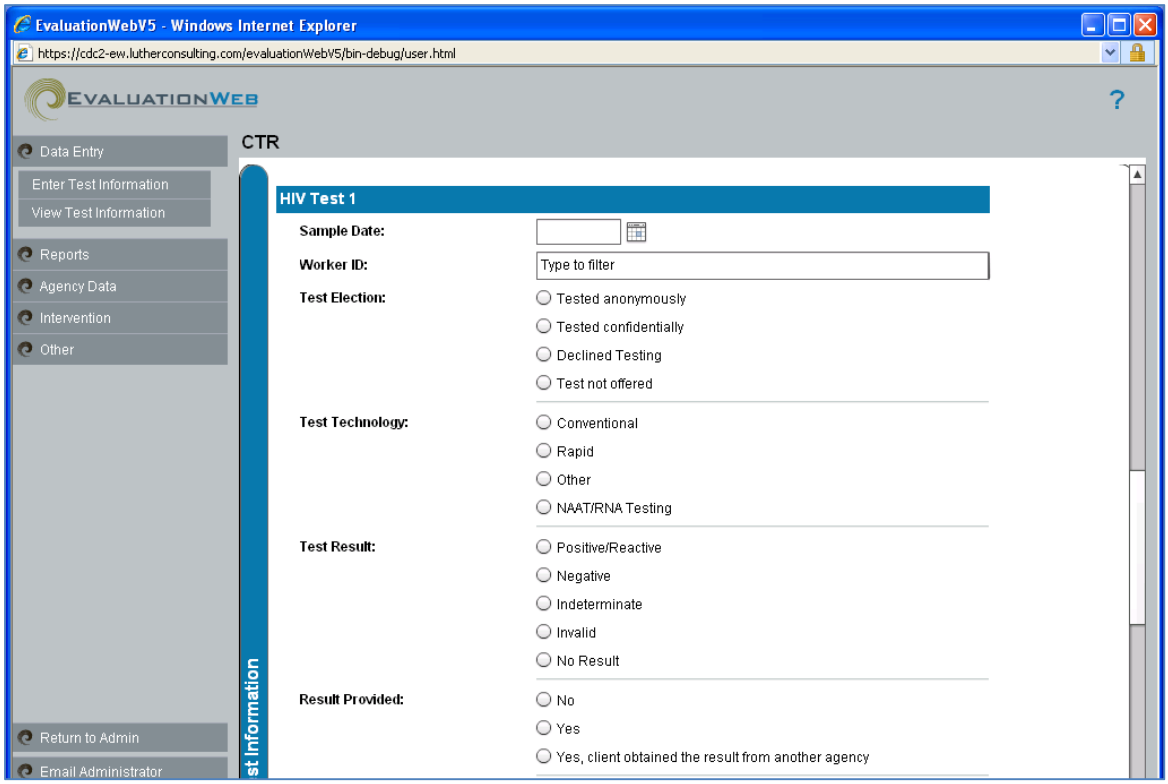
When you do your mandated report of a new HIV diagnosis to MDH Surveillance, you must give Surveillance staff (Sue Bedard-Johnson 651-201-4006 or Adrianna DiStaolo 651-201-3866) the 6-digit Evaluation Web unique form ID.

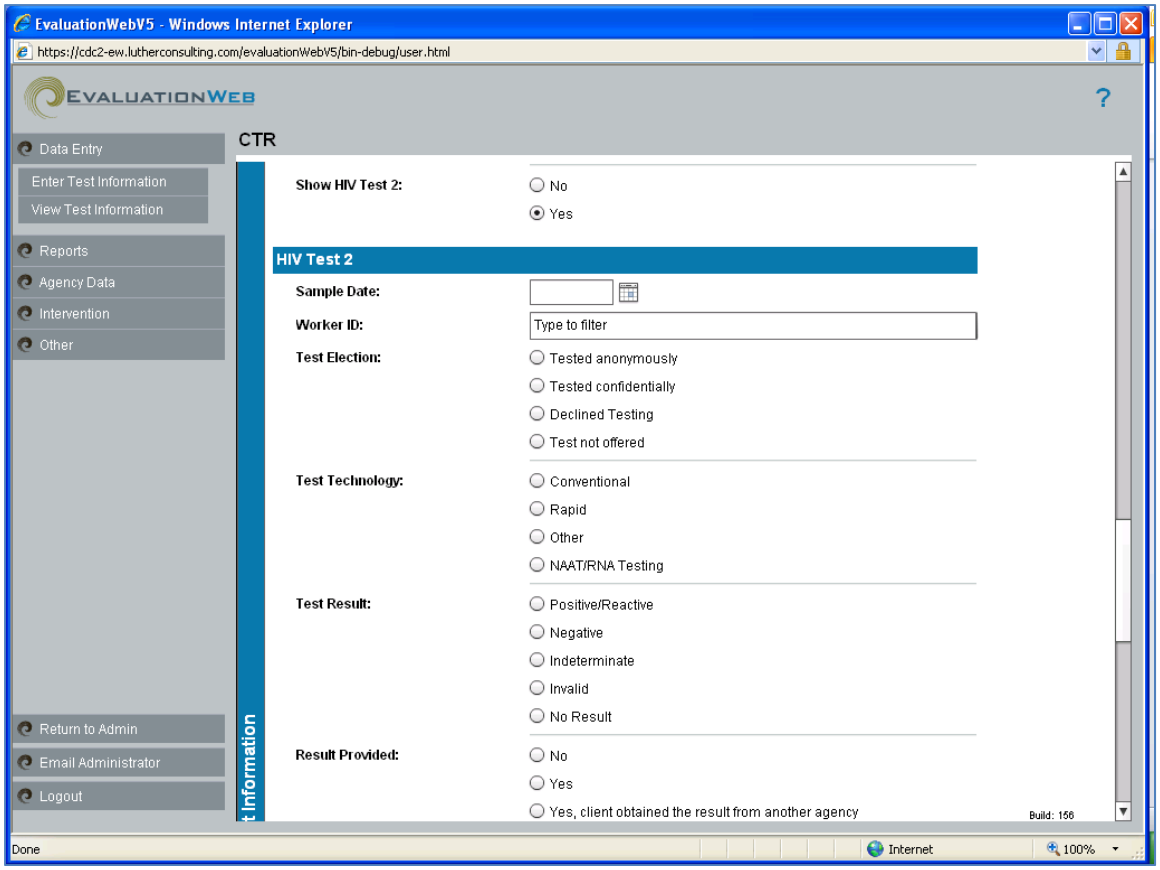
This is the **last 6 digits of the auto-assigned unique form ID**, the first line of the test form, that you see when you open a new form for data entry. It is only through this connection to our Surveillance data that we will be able to provide you with the dates to answer to the required fields in EvalWeb Form 2 (Partner Services interview within 30 days and first medical appointment within 90 days).

Your mandated report to MDH Surveillance will be the last positive test you conduct on a patient/client. For community-based sites, this is most likely the reactive rapid test and for clinic-based sites, this is most likely a confirmatory test.

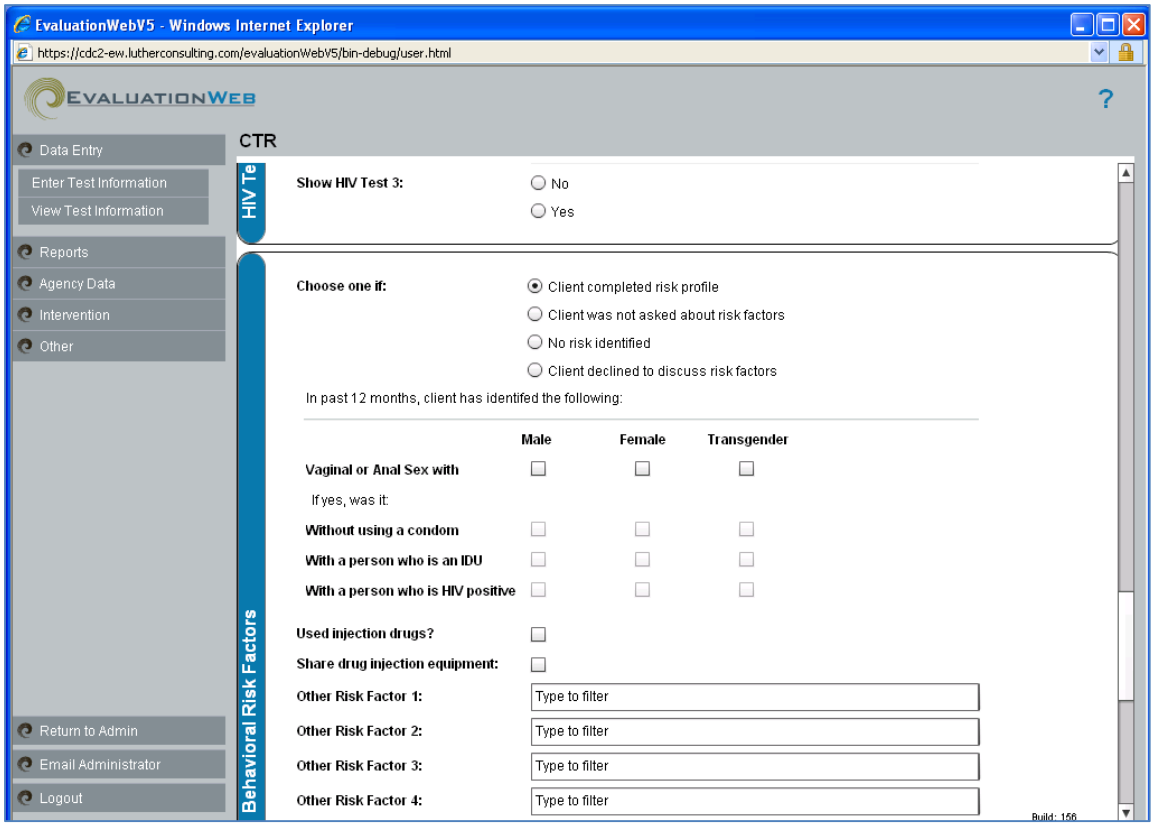


HIV TEST INFORMATION




EvaluationWebV5 - Windows Internet Explorer
https://cdc2-ew.lutherconsulting.com/evaluationWebV5/bin-debug/user.html
EVALUATIONWEB
?
Data Entry
Enter Test Information
View Test Information
Reports
Agency Data
Intervention
Other
Return to Admin
Email Administrator
Logout
CTR
Show HIV Test 2:
No
Yes
HIV Test 2
Sample Date:
Worker ID:
Type to filter
Test Election:
Tested anonymously
Tested confidentially
Declined Testing
Test not offered
Test Technology:
Conventional
Rapid
Other
NAAT/RNA Testing
Test Result:
Positive/Reactive
Negative
Indeterminate
Invalid
No Result
Result Provided:
No
Yes
Yes, client obtained the result from another agency
Build: 156
Done
Internet
100%

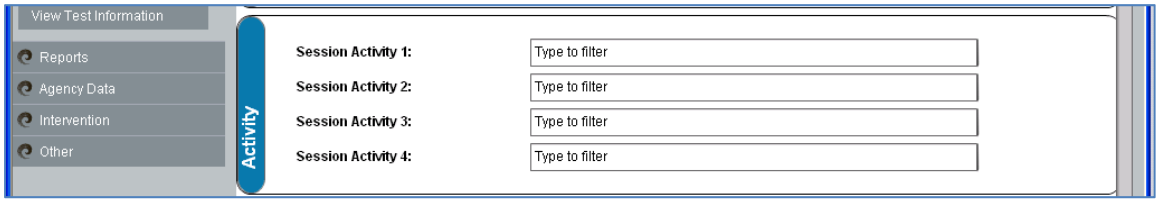
BEHAVORIAL RISK FACTORS

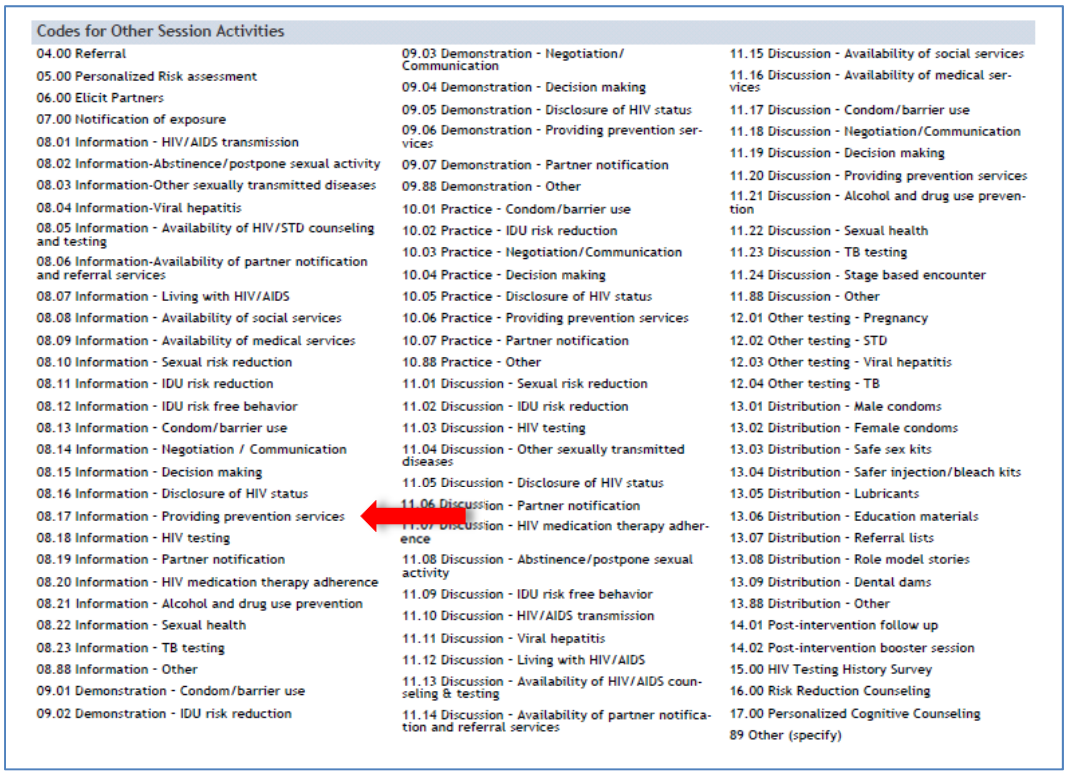


Codes for Other Risk Factor(s)

01 Exchange sex for drugs/money/or something they needed
02 While intoxicated and/or high on drugs
05 With person of unknown HIV status
06 With person who exchanges sex for drugs/money
08 With anonymous partner
12 Diagnosed with a sexually transmitted disease (STD)
13 Sex with multiple partners
14 Oral sex (optional)
15 Unprotected vaginal/anal sex with a person who is an IDU
16 Unprotected vaginal/anal sex with a person who is HIV positive
17 Unprotected vaginal/anal sex in exchange for drugs/money/something needed
18 Unprotected vaginal/anal sex with a person who exchanges sex for drugs/money/something needed
19 Unprotected sex with multiple partners

SESSION ACTIVITIES



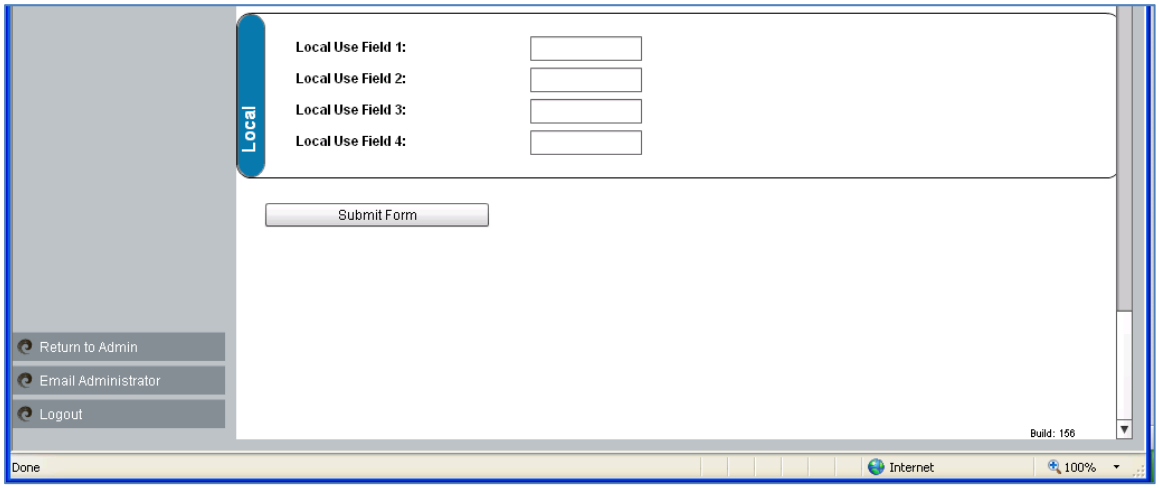


Codes for Other Session Activities

04.00 Referral
05.00 Personalized Risk assessment
06.00 Elicit Partners
07.00 Notification of exposure
08.01 Information - HIV/AIDS transmission
08.02 Information-Abstinence/postpone sexual activity
08.03 Information-Other sexually transmitted diseases
08.04 Information-Viral hepatitis
08.05 Information - Availability of HIV/STD counseling and testing
08.06 Information-Availability of partner notification and referral services
08.07 Information - Living with HIV/AIDS
08.08 Information - Availability of social services
08.09 Information - Availability of medical services
08.10 Information - Sexual risk reduction
08.11 Information - IDU risk reduction
08.12 Information - IDU risk free behavior
08.13 Information - Condom/barrier use
08.14 Information - Negotiation / Communication
08.15 Information - Decision making
08.16 Information - Disclosure of HIV status
08.17 Information - Providing prevention services
08.18 Information - HIV testing
08.19 Information - Partner notification
08.20 Information - HIV medication therapy adherence
08.21 Information - Alcohol and drug use prevention
08.22 Information - Sexual health
08.23 Information - TB testing
08.88 Information - Other
09.01 Demonstration - Condom/barrier use
09.02 Demonstration - IDU risk reduction
09.03 Demonstration - Negotiation/ Communication
09.04 Demonstration - Decision making
09.05 Demonstration - Disclosure of HIV status
09.06 Demonstration - Providing prevention services
09.07 Demonstration - Partner notification
09.88 Demonstration - Other
10.01 Practice - Condom/barrier use
10.02 Practice - IDU risk reduction
10.03 Practice - Negotiation/Communication
10.04 Practice - Decision making
10.05 Practice - Disclosure of HIV status
10.06 Practice - Providing prevention services
10.07 Practice - Partner notification
10.88 Practice - Other
11.01 Discussion - Sexual risk reduction
11.02 Discussion - IDU risk reduction
11.03 Discussion - HIV testing
11.04 Discussion - Other sexually transmitted diseases
11.05 Discussion - Disclosure of HIV status
11.06 Discussion - Partner notification
11.07 Discussion - HIV medication therapy adherence
11.08 Discussion - Abstinence/postpone sexual activity
11.09 Discussion - IDU risk free behavior
11.10 Discussion - HIV/AIDS transmission
11.11 Discussion - Viral hepatitis
11.12 Discussion - Living with HIV/AIDS
11.13 Discussion - Availability of HIV/AIDS counseling & testing
11.14 Discussion - Availability of partner notification and referral services
11.15 Discussion - Availability of social services
11.16 Discussion - Availability of medical services
11.17 Discussion - Condom/barrier use
11.18 Discussion - Negotiation/Communication
11.19 Discussion - Decision making
11.20 Discussion - Providing prevention services
11.21 Discussion - Alcohol and drug use prevention
11.22 Discussion - Sexual health
11.23 Discussion - TB testing
11.24 Discussion - Stage based encounter
11.88 Discussion - Other
12.01 Other testing - Pregnancy
12.02 Other testing - STD
12.03 Other testing - Viral hepatitis
12.04 Other testing - TB
13.01 Distribution - Male condoms
13.02 Distribution - Female condoms
13.03 Distribution - Safe sex kits
13.04 Distribution - Safer injection/bleach kits
13.05 Distribution - Lubricants
13.06 Distribution - Education materials
13.07 Distribution - Referral lists
13.08 Distribution - Role model stories
13.09 Distribution - Dental dams
13.88 Distribution - Other
14.01 Post-intervention follow up
14.02 Post-intervention booster session
15.00 HIV Testing History Survey
16.00 Risk Reduction Counseling
17.00 Personalized Cognitive Counseling
89 Other (specify)

Use code 08.17 for Other Session Activity to indicate “Information – Providing Prevention Services”

LOCAL USE FIELDS



Local Use L1

Use this field to indicate the "Country of Origin" if the client is born outside of the USA. In Local Use L1, write in the client's Country of Origin, but do not worry if the entire name of the country does not fit.

NOTE: Grantees funded to reach new immigrant populations; you must use this field to ensure the data reflects you are reaching your funded target population.

Local Use L2

Use this field to indicate if your client identifies as "MSM" yet the risk profile does not indicate such risk. For example, the client identifies as MSM yet has no risk of anal sex with male, or indicates only sexual risk was oral sex only (which is not identified by gender). In Local Use L2, write in the letters "MSM" to ensure your data reflects you are reaching your target population of MSM.

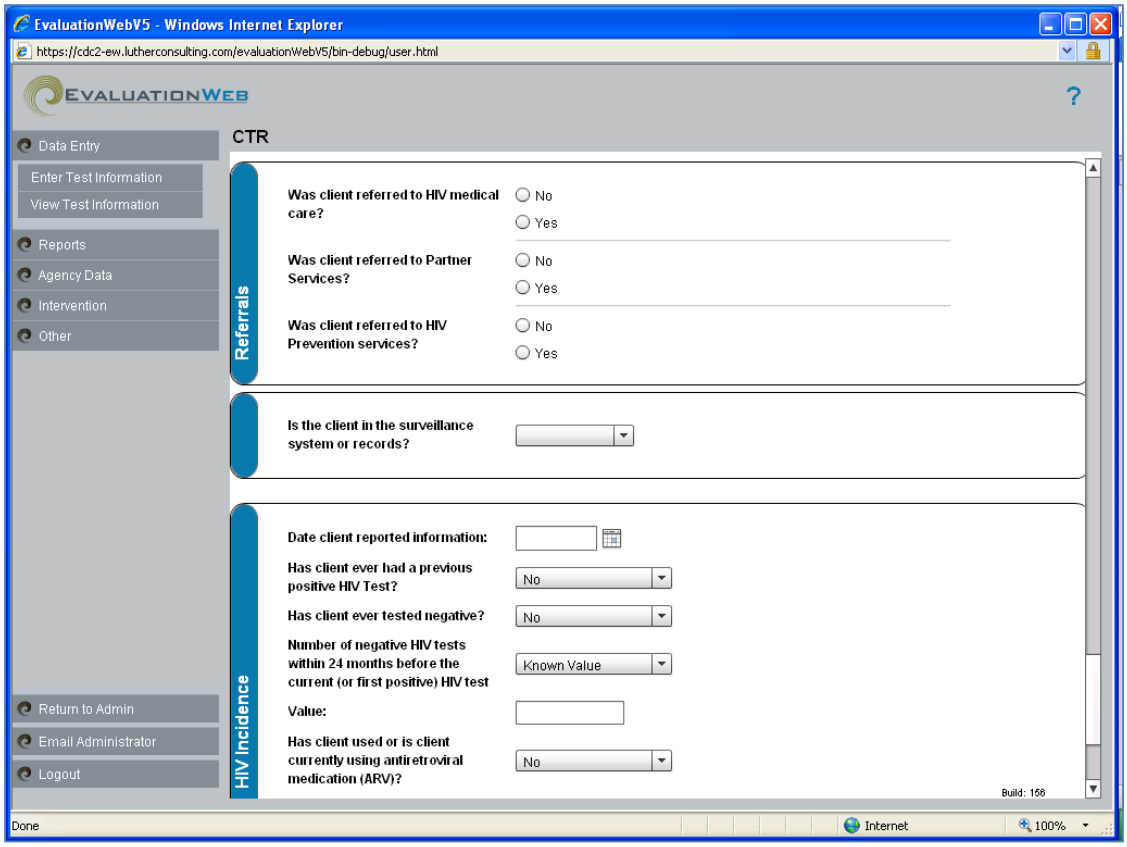
Local Use L3

Please leave this field blank.

Local Use L4

Use this field to indicate if your client was given a Pre-Exposure Prophylaxis (PrEP) referral by entering "PREP".

FOR CONFIRMED POSITIVE CASES ONLY:



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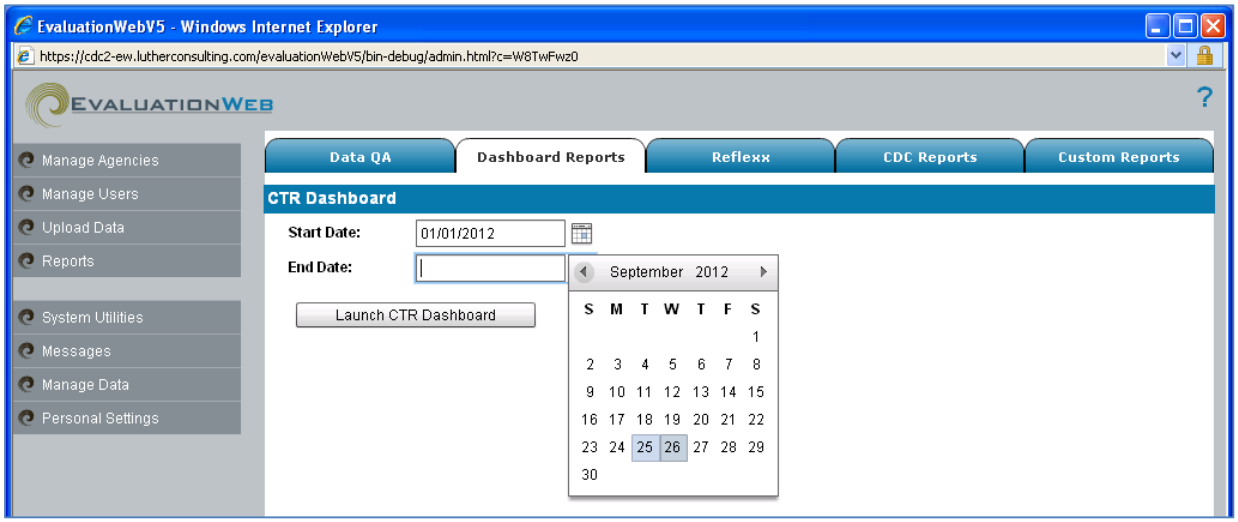
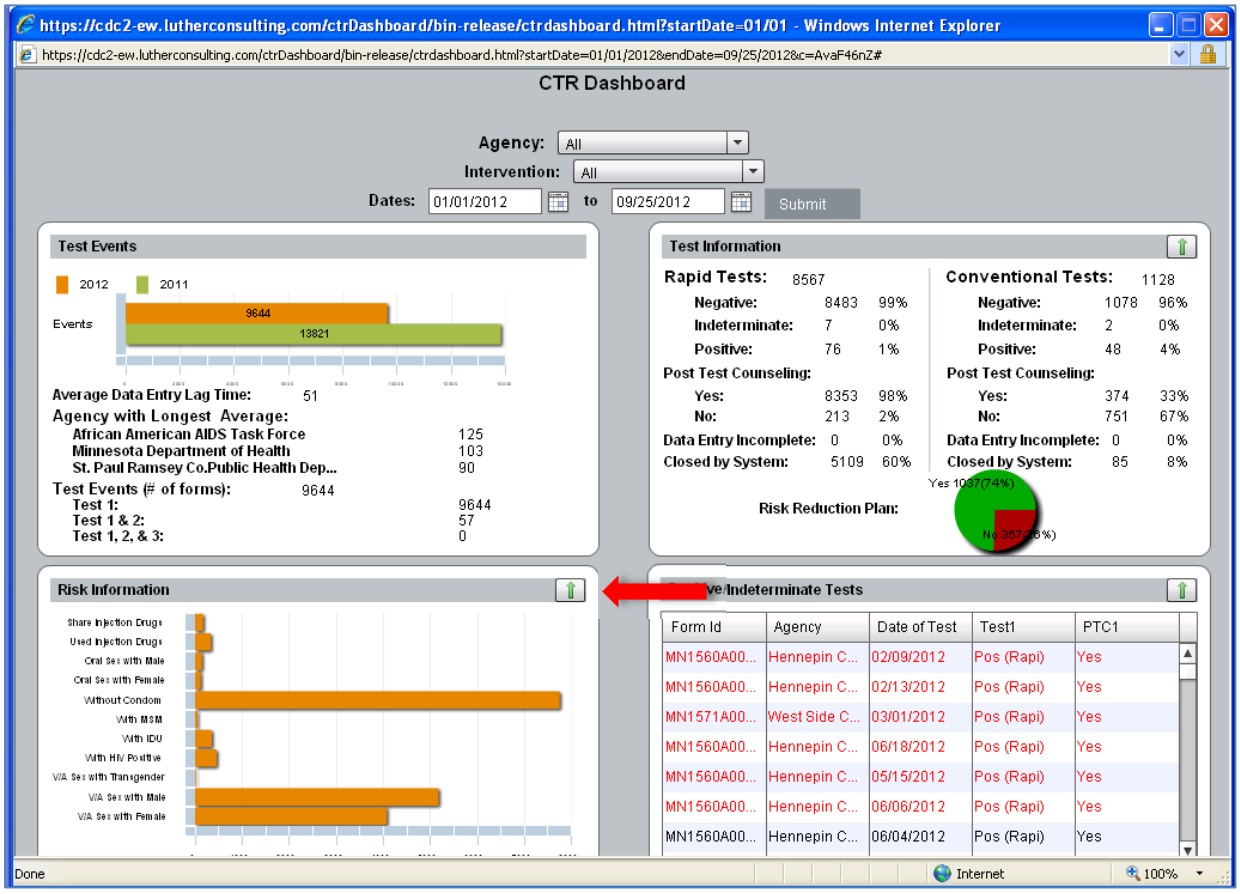
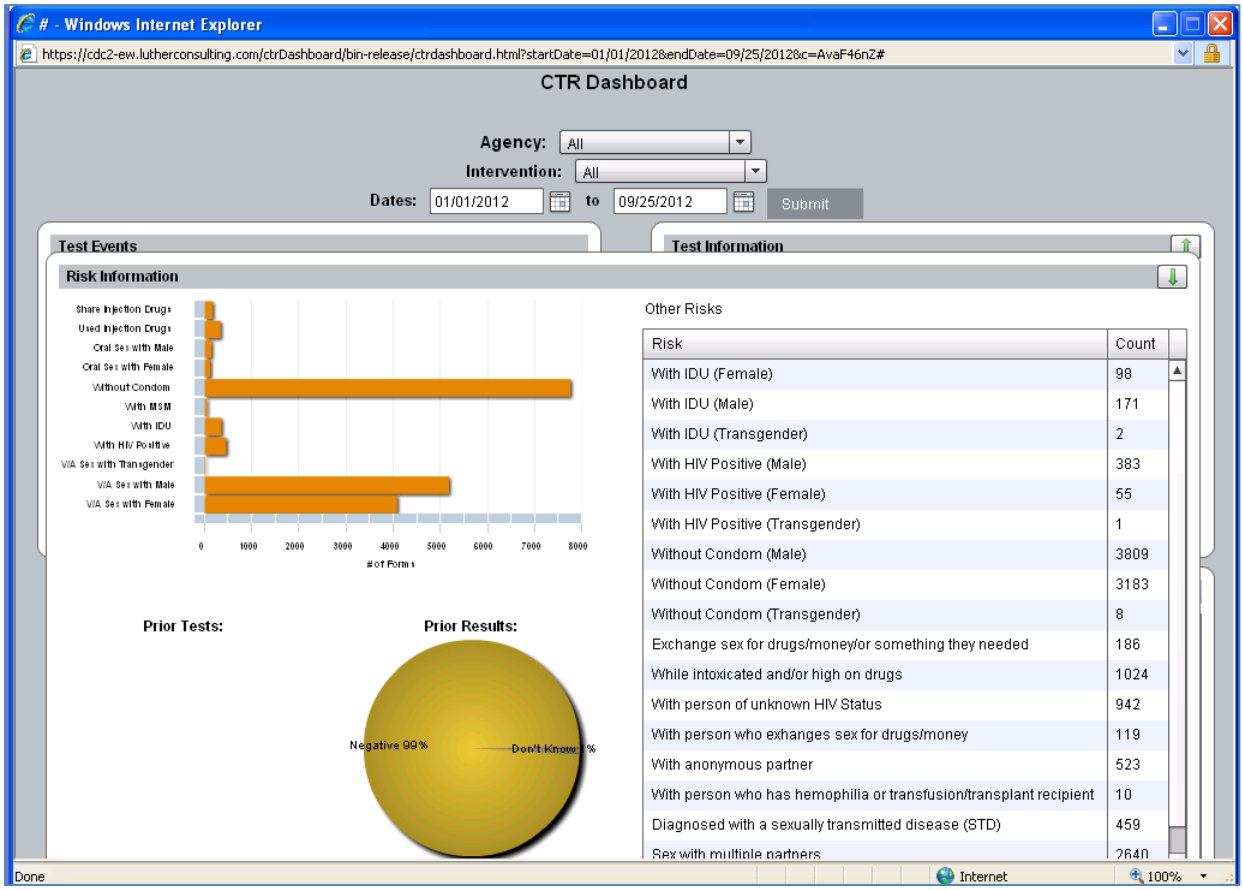
REPORTS

Dashboard Reports:



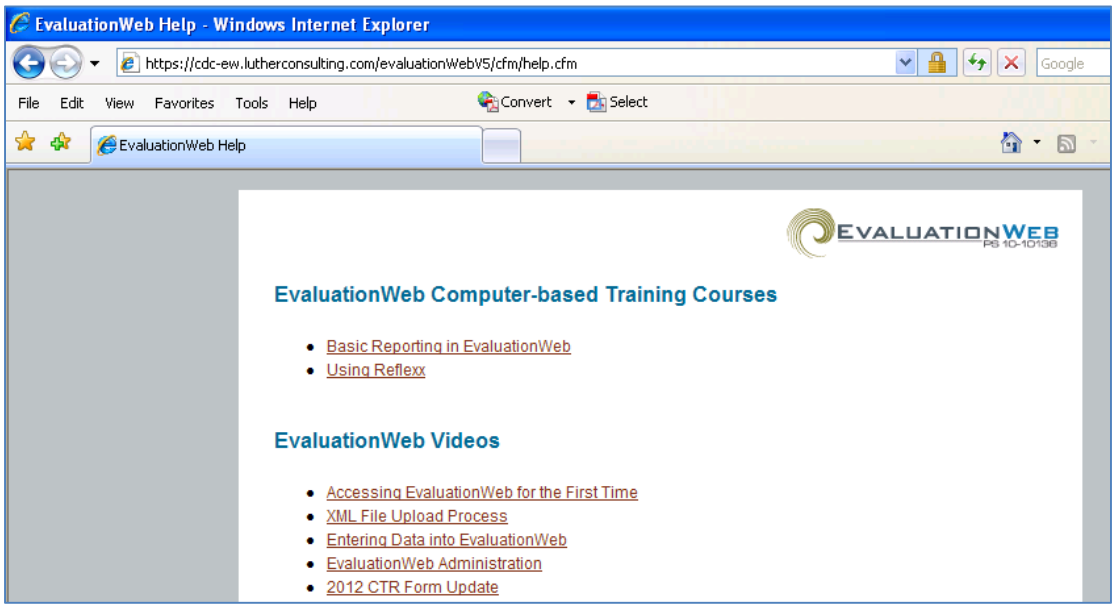


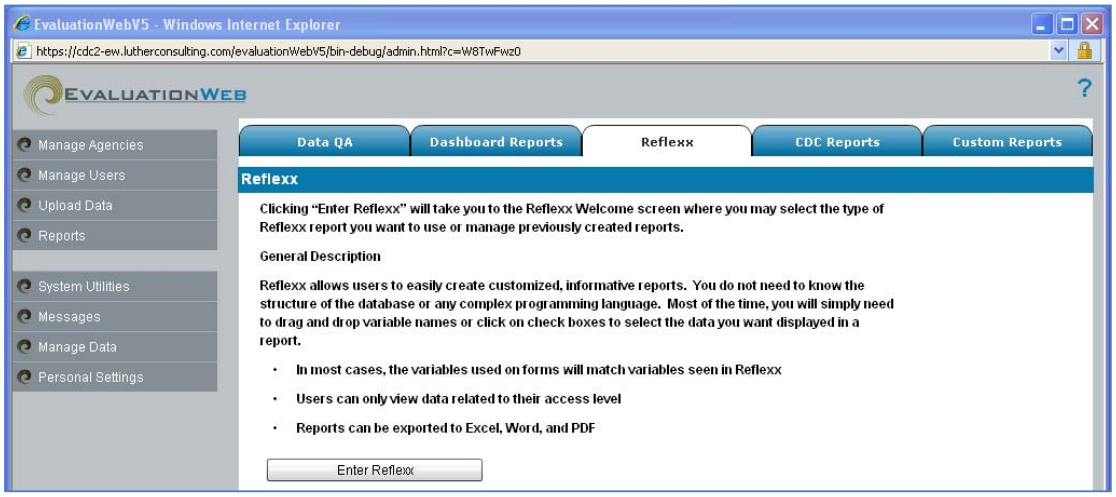

- Windows Internet Explorer
https://cdc2-ew.lutherconsulting.com/ctrDashboard/bin-release/ctrdashboard.html?startDate=01/01/2012&endDate=09/25/2012&c=AvaF46nZ#
CTR Dashboard
Agency: All
Intervention: All
Dates: 01/01/2012 to 09/25/2012 Submit
Test Events
Test Information
Risk Information
Share Injection Drugs
Used Injection Drugs
Oral Sex with Male
Oral Sex with Female
Without Condom
With MSM
With IDU
With HIV Positive
V/A Sex with Transgender
V/A Sex with Male
V/A Sex with Female
0 1000 2000 3000 4000 5000 6000 7000 8000
# of Forms
Other Risks
Risk | Count
With IDU (Female) | 98
With IDU (Male) | 171
With IDU (Transgender) | 2
With HIV Positive (Male) | 383
With HIV Positive (Female) | 55
With HIV Positive (Transgender) | 1
Without Condom (Male) | 3809
Without Condom (Female) | 3183
Without Condom (Transgender) | 8
Exchange sex for drugs/money/or something they needed | 186
While intoxicated and/or high on drugs | 1024
With person of unknown HIV Status | 942
With person who exhanges sex for drugs/money | 119
With anonymous partner | 523
With person who has hemophilia or transfusion/transplant recipient | 10
Diagnosed with a sexually transmitted disease (STD) | 459
Sex with multiple partners | 2640
Prior Tests:
Prior Results:
Negative 99%
Don't Know 1%
Done
Internet
100%

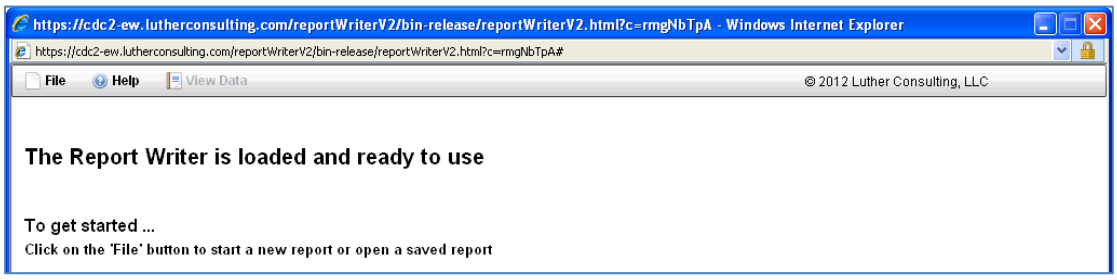
REFLEXX REPORTS

Queries can be built on any of the form variables. For training on using Reflexx, please see Luther Consulting's training list:

https://cdc-ew.lutherconsulting.com/evaluationWebV5/cfm/help.cfm







HELP?!?

Contact MDH First

http://www.health.state.mn.us/divs/idepc/diseases/hiv/evaluationweb/index.html

http://www.health.state.mn.us/hiv then click on EvaluationWeb on left navigation for reference guides or to submit a help desk ticket.

Minnesota Department of Health Contact Information

<table>
<tr><td colspan="2"><u>Program Information</u>
TBA
HIV CTR Coordinator
Minnesota Department of Health
625 North Robert Street
PO Box 64975
St. Paul, MN 55164-0975
Phone: 651-201-4011; Fax: 651-201-4000
Health.hivprevention@state.mn.us (subject line HIV Testing)</td></tr>
<tr><td><u>Data Collection/Form Information</u>
Kathy Melaas
HTS Data Specialist
Minnesota Department of Health
625 North Robert Street
PO Box 64975
St. Paul, MN 55164-0975
Phone: 651-201-4001; Fax: 651-201-4040
kathy.j.anderson@state.mn.us</td><td><u>Test Results/Lab Information</u>
Sara Vetter
Public Health Labs
Minnesota Department of Health
601 North Robert Street
PO Box 64899
St. Paul, MN 55164-0899
Phone: 651-201-5255
sara.vetter@state.mn.us</td></tr>
<tr><td colspan="2"><u>Reporting Positive Test Results – MANDATORY</u>

Sue Bedard-Johnson
Epidemiology and Surveillance Unit
Minnesota Department of Health
625 North Robert Street
PO Box 64975
St. Paul, MN 55164-0975
Phone: 651-201-4006 (Sue)
651-201-3866 (Adrianna)
Case form available online: http://www.health.state.mn.us/divs/idepc/dtopics/reportable/hiv.html

MARK ENVELOPES OF ALL HIV CASE REPORTS “CONFIDENTIAL”</td></tr>
</table>

help@lutherconsulting.com or www.lutherconsulting.com
(317) 808-0200; Option #1 [Toll Free (866) 517-6570 Option #1]

SAMS / e-Authentication: Toll Free: 1-877-681-2901, Email: samshelp@cdc.gov

Grantee Contact Information

Please see http://www.health.state.mn.us/divs/idepc/diseases/hiv/hivgrantees.html for the updated list of HIV Prevention Grantees.

Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate of Waiver

When is a CLIA Certificate of Waiver Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

WHAT IS A LABORATORY?

Under CLIA, a laboratory is defined as a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.

I AM A PHYSICIAN PERFORMING URINE DIP STICKS AND FINGER STICKS FOR BLOOD GLUCOSE IN MY OFFICE AS PART OF THE PATIENT'S VISIT. AM I CONSIDERED TO HAVE A LABORATORY AND DO I NEED A CLIA CERTIFICATE?

Yes, the testing you perform qualifies as waived laboratory testing and you need a CLIA Certificate of Waiver. This testing requires a CLIA certificate regardless of how many tests you perform and even if you do not charge the patient or bill Medicare or other insurances.

WHAT IS A WAIVED TEST?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

WHERE CAN I FIND A LIST OF WAIVED TESTS?

For a list of waived tests sorted by analyte name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm.

CAN I PERFORM TESTS OTHER THAN WAIVED TESTS IF I HAVE A CERTIFICATE OF WAIVER?

No, only those tests that are CLIA-waived can be performed by a laboratory with a Certificate of Waiver.

HOW DO I ENROLL IN OR APPLY TO THE CLIA PROGRAM?

You can enroll your laboratory in the CLIA program by completing an application (Form CMS-116) available online at www.cms.hhs.gov/clia or from your local State Agency. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located. A list of State Agencies is available at the web site listed above. If you do not have online access and do not have information about your State Agency, you may contact the CLIA program at 410-786-3531 for the address and phone number of your State Agency.

IF I HAVE MORE THAN ONE OFFICE AND PERFORM WAIVED TESTING AT MORE THAN ONE SITE, DO I NEED ADDITIONAL CERTIFICATES?

You will need a CLIA certificate for **each** site where you perform testing **unless** you qualify for one of the exceptions listed below.

- Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing may file a single application.
- Laboratories within a hospital that are located at adjoining buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Contact your State Agency if you have questions or you are filing a single application for more than one testing site.

WHEN CAN I START PERFORMING THE WAIVED TESTING?

After you apply for your certificate, you will receive a fee coupon assessing a fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate. You also need to check with your State Agency since some states have additional requirements.

IF I ONLY PERFORM WAIVED TESTS, WHAT DOES CLIA REQUIRE THAT I DO?

For waived testing, CLIA requires that you:

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturers' instructions for the waived tests you are performing;
- Notify your State Agency of any changes in ownership, name, address or director within 30 days, or if you wish to add tests that are more complex; and
- Permit inspections by a CMS agent, such as a surveyor from the State Agency. However, your laboratory is not subject to a routine survey or inspection.

WHAT DOES IT MEAN TO FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR PERFORMING THE TEST?

To follow the manufacturer's instructions for performing the test means to follow **all of the instructions in the product insert from "intended use" to "limitations of the procedure.**" The manufacturer's instructions can be found in the product insert for each test. It is good laboratory practice and important to read the entire product insert before you begin testing. Be sure the product insert is current for the test system in use, the correct specimen type is used, the proper reagents (testing solutions) are added in the correct order, and the test is performed according to the step by step procedure outlined in the product insert.

Some waived tests also have quick reference instructions included, which are cards or small signs containing diagrams or flow charts with essential steps for conducting testing. Be sure that quick reference instructions are current for the test system in use and are available to the individuals performing the test.

HOW DO I KNOW IF I HAVE CURRENT MANUFACTURER'S INSTRUCTIONS?

Always use the product insert or quick reference instructions that come with the test system you just opened. If you are unsure whether you have current instructions, contact the manufacturer at the telephone number listed in the product insert.

WHY IS IT IMPORTANT TO FOLLOW THE CURRENT MANUFACTURER'S INSTRUCTIONS?

It is important to always follow the current test system's instructions precisely to be sure your results are accurate. This includes performing any quality control procedures that the manufacturer recommends or requires. Over time, a manufacturer may make modifications to a test system that result in changes to the instructions. Failure to use the current instructions could cause inaccurate results that may result in a misdiagnosis or delay in proper treatment of a patient.

DO I NEED TO FOLLOW ALL THE MANUFACTURER'S INSTRUCTIONS ON HOW TO PERFORM THE TEST?

Yes, **all** the information in the test product insert instructions is considered part of the manufacturer's instructions and must be followed. Some examples of this information are:

- Observing storage and handling requirements for the test system components;
- Adhering to the expiration date of the test system and reagents, as applicable;
- Performing quality control, as required by the manufacturer;
- Performing function checks and maintenance of equipment;
- Training testing personnel in the performance of the test, if required by the manufacturer;

- Reporting patients' test results in the units described in the package insert;
- Sending specimens for confirmatory tests, when required by the manufacturer; and
- Ensuring that any test system limitations are observed.

CAN I FOLLOW THE QUICK REFERENCE GUIDE INSTEAD OF FOLLOWING THE PRODUCT INSERT?

No, the quick reference guide is only a synopsis of the entire product insert.

WHEN PERFORMING WAIVED TESTING, AM I REQUIRED TO DO EVERYTHING IN THE INSTRUCTIONS, EVEN IF SOME OF THE ITEMS ARE MANUFACTURER'S RECOMMENDATIONS OR SUGGESTIONS?

Yes, you must follow all the instructions when such terms as **"always"**, **"require"**, **"shall"**, and/or **"must"** are used by the manufacturer. You have the option to follow the recommendations or suggestions of the manufacturer. However, adhering to the manufacturer's recommendations and suggestions will help assure the accuracy and reliability of the test and is considered good laboratory practice.

AS A LABORATORY DIRECTOR, WHAT KINDS OF THINGS CAN I DO TO HELP ASSURE THE ACCURACY AND RELIABILITY OF THE WAIVED TESTING IN MY LABORATORY?

In order to assure the accuracy and reliability of waived testing in your laboratory, you should develop and maintain good laboratory practices. Some examples are listed below:

- Provide specific training to the testing personnel so that you are certain they:
    - Collect specimens appropriately;
    - Label and store specimens appropriately;
    - Understand and then follow the manufacturer's instructions for each test performed;
    - Know how to perform the testing;

- Know how to document and communicate the test results; and
- Are able to identify inaccurate results or test system failures.

- Observe and evaluate your testing personnel to make certain the testing is accurate.
  - Do they positively identify the patient and specimen?
  - Do they collect a proper specimen?
  - Do they know how the specimen should be preserved, if applicable?
  - If the specimen needs to be transported, do your testing personnel understand and adhere to the transport requirements?

- Check for extreme changes in such things as humidity, temperature, or lighting; as these may affect test results.

- Make sure that the patient specimen is handled properly from collection to test completion.

WHERE CAN I FIND MORE INFORMATION ABOUT GOOD LABORATORY PRACTICES?

The Centers for Disease Control and Prevention has published recommendations for good laboratory practices for waived testing sites in *Morbidity and Mortality Weekly Reports (MMWR) Recommendations and Reports*. The MMWR publication provides comprehensive recommendations for facilities that are considering introducing waived testing or offering a new waived test, and good laboratory practices to be followed before, during, and after testing. You can find this article on the CDC website at http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf.

You may also find helpful information on the CLIA web site at www.cms.hhs.gov/clia under "Certificate of Waiver Laboratory Project."

CAN I MAKE ANY CHANGES TO THE TEST SYSTEM INSTRUCTIONS?

No, it is not acceptable for you to make changes to the current instructions provided with the test system. This could change the "intended use" of the test system as approved by FDA and result in a test that is **no longer waived**. For example, if a test specifies urine as the waived specimen type and you test a different body fluid, then you are no longer performing a waived test and your laboratory is subject to an inspection and additional CLIA requirements. You must be sure that testing personnel follow the directions exactly and add the proper reagents in the correct order and amount given by the manufacturer to assure correct test results.

HOW AND WHEN WILL I BE INSPECTED?

Laboratories with a Certificate of Waiver are not subject to a routine inspection (survey) under the CLIA Program but may be surveyed in response to a complaint or if they are performing testing that is not waived. Also, CMS is currently conducting a project whereby a small percentage of laboratories that perform waived testing may receive an educational visit at no charge. CMS representatives provide helpful information to the waived testing sites. This project has been extremely well received by the laboratory community.

NOTE: This brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings.

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March 2006