

The background of the entire page is a black surface with white puzzle pieces scattered across it. The puzzle pieces are of various shapes and sizes, some of which are partially visible at the top and bottom edges of the frame.

# **PARTS & PIECES: HCV SCREENING & COUNSELING**

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**The Bigg Elimination  
Tribute Project**



## Executive Summary

This tool is part of the Bigg Elimination Tribute Project, a collaborative project between the Caring Ambassadors Program and the Chicago Recovery Alliance. The goal of the project is to influence the health practices of people living with chronic hepatitis C with a focus on people who use drugs (PWUD), while building the capacity of community service programs to serve people living with HCV. The Project honors Dan Bigg, the godfather of naloxone, a fierce advocate for HCV elimination, and a harm reduction pioneer who died in August 2018.

Hepatitis C is the largest, chronic infectious disease outbreak of our time and is responsible for more deaths than all other 59 nationally notifiable conditions combined, including HIV.

Here's what's true:

- Diagnosing HCV is easy and inexpensive.
- Short-term, highly effective curative treatments are available.
- Undiagnosed and untreated hepatitis C causes cirrhosis. Cirrhosis can cause liver cancer.
- Stigma, fear, discrimination, and a misunderstanding of HCV's dramatic changes over the past 6 years has caused more confusion.

There are ample opportunities to diagnose and prevent HCV infection with proper tools for screening and counseling, providers can better and more comfortably engage with their clients. This tool has been developed to supplement existing materials, and provides the comprehensive parts and pieces to implement HCV micro-elimination, screening, and education programs.

**Parts & Pieces: HCV Screening & Counseling** is a tool that was developed to influence ANY POSITIVE CHANGE. Let's harness Dan's spirit, ingenuity, and energy to stand up, step in, and eliminate HCV. Together we can do this.

# The Parts of and HCV Counseling Education Session

1. Prep
2. Pre-test Counseling
3. Test/Screen
4. Lab
5. Post-test Counseling

## 1. Prep

Get prepared for rapid, point-of-care HCV screening. This section will detail program needs and formalities for a comprehensive HCV screening initiative.

- a. Physician Standing Order (PSO)
  - This is system-specific (hospitals, primary care, FQHC, etc.) and used to share in the responsibility of providing comprehensive, prevention-based patient care.
- b. Clinical Laboratory Improvement Amendment (CLIA) Waiver
  - A must-have before providing any screening
  - If you already have a CLIA waiver, be sure to update it by adding HCV screening to your certificate of waiver.
- c. Reporting requirements and structure
  - State-specific guidelines dictate reporting, as HCV is a nationally notifiable condition that mandates reporting.
  - Requirements
    - Be sure to review state law for specifics.
  - Structure:
    - Who in your program reports reactive/positive tests? Consider reporting both reactive/positive AND non-reactive/negative tests to the Department of Health for more accurate surveillance.
    - Be sure to submit risk information to assist the Department of Health in matching the risk profile to electronic laboratory reports.

- What measures does your program take to monitor program outcomes, including: reactive/positive AND non-reactive/negative, # of referrals, or # of cured patients?
- d. Data collection, processes, and paperwork/consent
  - Ensure data collection/consent forms capture all the data required by the State for reporting. (Sample provided in Appendix I)
  - Identify processes for coordination between screening results, data collection, and reporting.
- e. Quality Control with rapid tests and Staff Training
  - Important to run controls each time you move the tests (at 1<sup>st</sup> use of lot, at a climate or temperature change, new instructor, etc.).
  - Identify ways to use technology to support staff training in HCV prevention.
  - Ensure staff understand the HCV screening processes and how it is different than HIV screening processes.
- f. Integrating Parallel Testing
  - **Rapid:** Great additional screening added to HIV testing, and rapid glucose testing.
    - Mind the additional consent forms and resources needed for rapid screening kits.
  - **Lab-based:** Use of electronic medical records (EMR) and best practice alerts (BPA) to add HCV testing as standard-of-care.
    - Be sure to use an opt-out testing model.
- g. Determine lab set-up for rapid testing
  - Lab set-up
    - Batch testing = all specimen tubes are collected and run at one time by the lab technician (\*best used during high volume rapid testing)
    - One-by-one testing = each specimen tube is run at time of collection
    - 'Batch testing' vs. 'one-by-one'
      - Lab set-up is based on testing circumstances including space, the # of staff, the # of consumers; the length of the event, etc.
      - Once the specimen is collected in the specimen tube, you will have sixty (60) minutes until the testing stick needs to be inserted into the specimen tube

- Results Delivery:
  - In-person results
    - Results may be provided at the event - consider using log numbers vs. names for participants to pick up results.
      - When delivering results in person, the Caring Ambassadors Program has had the best success with using log numbers and envelopes and instructing participants to return with their log number when obtaining results.
    - See appendix for sample result letters
  - Follow-up by mail/phone results
    - It may not be appropriate or feasible to deliver results at some events. In these cases, results may be provided after the event via phone for reactive/positive results, and/or mail for nonreactive/negative results.

#### Things to Consider:

1. How many testers are needed to manage the event?
2. Do you have a 'lab tech' to monitor specimens and results?
3. Referral options for positive results

## 2. Pre-test Counseling

Pre-test counseling orients participants to the testing process and, through counseling, identifies the need for HCV antibody screening. The general process includes the following steps:

- a. Welcome the participant and explain the rapid HCV screening.
  1. "Welcome, I am glad you are here. Today we're screening a small drop of your blood to determine if you've ever been exposed to hepatitis C. This test will NOT determine if you have hepatitis C, it will only tell us about exposure."
  2. Ask the participant: "have you ever been screened or treated for HCV?"
    - i. This helps to identify the true need for antibody screening and maximizes expensive resources.

- ii. **\*NOTE\***: Avoid unnecessary alarm to participant - once someone has been exposed to HCV, the rapid HCV antibody screening will ALWAYS be reactive/positive!
- b. Complete paperwork and sign consent
  - 1. Instruct participant to complete the consent form including the identification of risk behaviors, contact information for follow-up, and demographics for data and reporting.
    - i. “HCV is a reportable infectious disease and therefore, if you’ve been exposed, we will link you to care, and are required by State law to report the results to the department of health.”
- c. Maximize Time: While participant is completing the consent form and paperwork, prepare for test by setting up the work area with supplies.
- d. Provide general HCV education and answer questions
  - 1. Ask the participant if they have any questions about HCV.
- e. Prepare and support the participant by asking them:
  - i. “Are you on blood thinner or do you take a daily aspirin?”
    - 1. These questions will help the tester to best prepare by using extra absorbent pads, gauze, Band-Aids, and paper towel (\*blood thinner may produce significant blood flow upon skin puncture).
  - ii. Faints at the site of blood
    - 1. Prepare by having additional people to support, and be sure participant breathes deeply through the test
  - iii. Has a preferred finger for testing
    - 1. Help identify the best location - tends to be on the side of the finger where there are less callouses, etc.

### Things to Consider:

Explain the process of delivering results

- 1. in-person/at event
- 2. via phone (reactive/positive results)
- 3. via snail mail (non-reactive/negative results)

\*See appendix for screening set up

### 3. Test/Screen

All technicians should complete a training on the use of the testing technology. Below are step-by-step instructions to conduct a hepatitis C antibody screening using the Orasure HCV rapid point-of-care test.

- a. Review paperwork to ensure participant requires testing and has signed consent form. The counselor should sign and date the paperwork, too.
- b. Place unique ID labels on the specimen test tube, the consent form, and one for the logbook.
  - a. \*consider providing participants the log number if providing on-site results\*
- c. Prepare your work area with supplies.
- d. Place closed specimen tube in tray holder and 'lock' tube into place.
- e. Prepare participant's hand by identifying the best finger (not calloused, injured, etc.) Wipe the finger with alcohol swab in one direction and let it air dry or dry with clean gauze.
- f. While locked in the tray holder, gently remove the specimen tube cap by gently 'snapping' the cap back. Be careful not to tip or spill specimen tube.
- g. Use the lancet on the preferred finger to puncture skin and wipe away the first drop of blood with the gauze.
- h. Squeeze the finger to provide another drop of blood and without touching the loop to the skin, 'pull' the drop of blood into the specimen loop.
- i. Put the specimen loop with the blood sample into the opened test tube.
- j. Gently swirl the specimen loop trying not to touch the inside walls of the tube with the loop.
- k. Place the gauze on the punctured finger and have the participant place pressure with their thumb to stop the bleeding.
- l. Remove the loop, properly dispose of it, and replace the test tube cap.
- m. Place a bandage on the participant's finger and remind them of the process for obtaining results.
- n. Properly dispose of materials and clean testing station.

#### Things to Consider:

- Tracking the specimen with the consent form - stickers with log numbers tent to work best.
- Warmer hands are easier to produce blood from -having participants warm their hands before screening may help with blood flow.

- “Milking” participants’ hands after the puncture can help to produce a large enough drop of blood for the loop to ‘pick up’.
- When testing at events with tight spaces or higher foot traffic, consider waiting to submerge the screening /test kit into the specimen tube until in ‘the lab’ to minimize the chances of spilling the specimen, wasting resources, and re-sticking a participant.

## 4. Lab

For the purposes of rapid HCV screening, a ‘lab’ is referred to as the space where the test kits are placed within the specimen tube and let to stand, undisturbed, for 20 minutes. Ideally, your lab is placed somewhere with minimal foot traffic and out of direct sunlight. Be sure to consider the best process for setting up your lab. There are a number of factors that influence this: the number of staff/testers, the size of the event, the length of the event, the temperature if testing outside, space, and how many tests you have.

1. Test must be read after 20 minutes but NO MORE than 40 minutes after sitting in solution
2. The specimen may sit in test tube for 60 minutes until the test kit must be submerged

### **Things to Consider:**

There is no right way to set up a lab because it depends on the flow and size of the event. Consider the following questions as you think about the flow of your lab.

- How will you manage multiple tests and not confuse specimens?
- Do you have plenty of room and timers to run multiple tests at one time?
- Are you able to set up space (a table or shelving unit) where the specimen can stand undisturbed?
- How’s the lighting? Do you need a magnifying glass and a lamp to effectively read the tests?
- What is the temperature? Will you need a refrigerator for test kits? A fan for lab works?

## 5. Post-test Counseling

Post-test counseling offers an opportunity to explain screening results to participants and provide next steps. The delivery of results will change based on the event set up and whether or not results are provided in-person at the event or following the event via phone or mail. It is generally best to provide positive/reactive results in-person or via phone so that you can answer any questions and provide referrals to care and follow-up support. Understanding and interpreting HCV screening results are vital to providing next-step counseling when necessary.

### Key counseling messages for results with nonreactive/negative participants:

- There is no history of exposure to HCV
- You have never been infected with HCV
- You do not need to be retested unless you have exposure (if exposed, re-test at 12 week post exposure)
- Practice universal precautions

### Key counseling messages for results with reactive/positive participants:

- You have a history of exposure to HCV
- We need to determine if you have chronic, active HCV infection through an HCV RNA confirmatory test (also known as PCR or viral load)
- Practice universal precautions
- Your next step is to ask your doctor for an HCV RNA (or PCR) confirmatory test to determine the presence of active infection (provide referral when necessary)

### **Things to Consider:**

- Is the set-up of the event conducive to delivering in-person results?
- Do you have enough staff and volunteers to support in-person results?
- Using envelopes with log numbers on them are useful in delivering results in an organized fashion that maintains respect of personal health information.

## Appendix I

Page 11 - Sample Consent Form

Page 12 - Sample Department of Health HCV Reactive Reporting Form

Page 13 - Sample Patient letter

Page 14 - Image of areas set up for rapid testing

## Could You Have Been Exposed to the Hepatitis C Virus?

Please check all that apply to you:

- ☐ I was born between 1940 and 1970.
- ☐ I am a hemophiliac.
- ☐ I am a military veteran.
- ☐ My mother has/had hepatitis C.
- ☐ I have had injections, surgery, or dental work done outside the U.S.
- ☐ I have had a blood transfusion (blood, plasma, or platelets) before 1992.
- ☐ I received blood products (immunoglobulin, anti-Rh factor, or clotting factors) before 1992.
- ☐ I have injected substances, even once, even if it was many years ago (drugs, steroids, hormones, silicone, etc.).
- ☐ I have shared snorting straws for drugs, even once, even if it was many years ago.
- ☐ I have (or have had) a job that exposed me to blood (examples include medical and dental workers, police officers, fire fighters, paramedics, and EMTs).
- ☐ I have been exposed to another person's blood through a contaminated needle stick injury, blood splash to the eyes, mouth, or on to broken skin.
- ☐ I have shared personal hygiene equipment such as a razor, toothbrush, or nail clippers with others.
- ☐ I have a tattoo from an unregulated facility (home, jail, with friends, etc.).
- ☐ I have been exposed to blood during sexual activity.
- ☐ None of the above applies to me, but I would still like to be screened for hepatitis C.

### Contact Information: Please PRINT Clearly

First & Last Name:	
Date of Birth:	
Gender:	
Race	<input type="checkbox"/> Caucasian <input type="checkbox"/> African-American <input type="checkbox"/> Asian <input type="checkbox"/> Pacific Islander <input type="checkbox"/> Native American <input type="checkbox"/> Other
Ethnicity	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino
Mailing Address:	
City, State, ZIP	
Telephone #	OK to leave message? <input type="checkbox"/> yes <input type="checkbox"/> no

### Informed Consent

**The hepatitis C antibody test is a screening test to find out if you have ever been exposed to the hepatitis C virus. It cannot determine whether you still have the hepatitis C virus in your system. If your test result is indeterminate or positive, you must have additional testing to see if the hepatitis C virus is still in your system. This testing can be performed by your doctor.** Hepatitis C is a reportable condition under the Control of Communicable Disease Code of Illinois, Title 77, Chapter I, Subpart C, Section 690.200 and subpart D, section 690.452. Reactive tests will be reported to the Department of Health.

I authorize the Caring Ambassadors Hepatitis C Program to collect blood for hepatitis C antibody testing, and to the best of our abilities provide in-person results; otherwise, my test results will be received by mail if negative, or by telephone if the results are positive or indeterminate.

Client Signature: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Counselor Signature: \_\_\_\_\_ Log # \_\_\_\_\_

Event: \_\_\_\_\_

# Hepatitis C Provider Reporting Form - Chicago Department of Public Health

2160 W Ogden Ave, Chicago, IL 60612 | 312.746.6388 (fax)

Hepatitis C is a reportable condition under the Control of Communicable Disease Code of Illinois, Title 77, Chapter I, Subpart C, Section 690.200 and Subpart D, Section 690.452. Disease reports can be faxed to 312.746.6388 or submitted electronically using the Illinois National Electronic Disease Surveillance System (INDESS) through the Illinois Department of Public Health (IDPH) web portal (<http://portalhome.dph.illinois.gov/>).

The health department requires additional information for the individual listed below. Please complete this form and return it to our office no later than 7 days from when this was received.

If you have any questions please contact: \_\_\_\_\_ at (312) \_\_\_\_\_

## PATIENT INFORMATION

Patient's name: \_\_\_\_\_  
first last

Parent's name (if patient is a child): \_\_\_\_\_  
first last

Address: \_\_\_\_\_  
street apt  
\_\_\_\_\_  
city state zip code

Telephone 1: \_\_\_\_\_ Telephone 2: \_\_\_\_\_  
☐ home ☐ cell ☐ work ☐ home ☐ cell ☐ work

## DEMOGRAPHICS

Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_

Status (check one):

- ☐ Alive  
☐ Deceased → date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
☐ Unknown

Sex/gender (check one):

- ☐ Male  
☐ Female → is patient pregnant? ☐ Yes ☐ No  
☐ Transgender

Race (check all that apply):

- ☐ American Indian or Alaskan Native  
☐ Asian  
☐ Black or African American  
☐ Native Hawaiian or Pacific Islander  
☐ White  
☐ Unknown

Ethnicity (check one):

- ☐ Hispanic  
☐ Non-Hispanic  
☐ Unknown

## REPORTING FACILITY

Facility name: \_\_\_\_\_

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Provider name: \_\_\_\_\_

Phone number: \_\_\_\_\_

Reporter name: \_\_\_\_\_

Fax number: \_\_\_\_\_

## TRANSMISSION RISK HISTORY *(Check all that apply)*

- |   |  |
|---|--|
| <input type="checkbox"/> Ever inject drugs<br><input type="checkbox"/> Heroin<br><input type="checkbox"/> Prescription (e.g. OxyContin, Methadone)<br><input type="checkbox"/> Other: _____ | <input type="checkbox"/> Ever a contact of a person who had Hepatitis C<br><input type="checkbox"/> Sexual<br><input type="checkbox"/> Household (non-sexual)<br><input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Ever had a tattoo<br>Most recent venue: _____  | <input type="checkbox"/> Ever treated for a sexually transmitted infection (STI)<br>_____ # of life-time sex partners  |
| <input type="checkbox"/> Ever had a body part pierced<br>Most recent venue: _____   | Sexual preference <i>(check one)</i> :<br><input type="checkbox"/> Heterosexual<br><input type="checkbox"/> Homosexual<br><input type="checkbox"/> Bisexual<br><input type="checkbox"/> Unknown        |
| <input type="checkbox"/> Ever incarcerated longer than 6 months<br>Year of most recent incarceration: _____   |  |
| <input type="checkbox"/> Ever on long-term hemodialysis<br>Most recent location: _____  |  |
| <input type="checkbox"/> Ever employed in a medical or dental field involving direct contact with human blood   |  |

## PATIENT HISTORY *(Check all that apply)*

### Symptoms:

- |                                   |   |
|-----------------------------------|---|
| <input type="checkbox"/> Jaundice | <input type="checkbox"/> Nausea         |
| <input type="checkbox"/> Fever    | <input type="checkbox"/> Vomiting       |
| <input type="checkbox"/> Headache | <input type="checkbox"/> Diarrhea       |
| <input type="checkbox"/> Malaise  | <input type="checkbox"/> Abdominal pain |
| <input type="checkbox"/> Anorexia |   |

Symptoms onset date: \_\_\_\_/\_\_\_\_/\_\_\_\_

### Hepatitis C care:

- ☐ Is the patient currently under your care for Hepatitis C?  
☐ If no, was a referral for Hepatitis C care made?  
Where: \_\_\_\_\_  
☐ Has the patient ever received medication for Hepatitis C?  
Specify: \_\_\_\_\_  
Year: \_\_\_\_\_

## LABORATORY RESULTS

- ☐ Did the patient have a previously (unreported) diagnosis for Hepatitis C?  
Year: \_\_\_\_\_

Test type	Test result	Test method	Reference Range	Specimen collection date
Antibody (anti-HCV)	<input type="checkbox"/> Positive <input type="checkbox"/> Negative			____/____/____
RNA	<input type="checkbox"/> Positive <input type="checkbox"/> Negative			____/____/____
Quantitative PCR				____/____/____
ALT	IU/L			____/____/____
AST	IU/L			____/____/____
Genotype	<input type="checkbox"/> 1 <input type="checkbox"/> 3 & <input type="checkbox"/> A <input type="checkbox"/> 2 <input type="checkbox"/> 4 <input type="checkbox"/> B			____/____/____
Signal to cut-off ratio				____/____/____
Surface antigen	<input type="checkbox"/> Positive <input type="checkbox"/> Negative			____/____/____

# Company Letter head

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Sample Negative Letter

Date

Hello,

Thank you for your recent participation in the **Name of Event**. We are pleased to bring you free hepatitis C screening services to your area.

We are glad to report that your hepatitis C rapid screening test result was **negative**. While no test is 100% accurate, a negative hepatitis C screening test indicates that it is **highly likely you have not been exposed** to the hepatitis C virus.

**Info about you program here:** The Caring Ambassadors Hepatitis C Program and our volunteers were pleased to be able to offer you free hepatitis C screening and work to continue to provide this free service. If you would like to make a donation to our organization to help us provide hepatitis C services to others, please consider making a donation online at <http://caringambassadors.org/get-involved/>. The Caring Ambassadors Hepatitis C Program is a 501(c)(3) nonprofit organization; all donations are tax-deductible to the fullest extent allowed by law. Please visit <http://caringambassadors.org> for more information.

Once again, we are pleased to bring you this good news about your health. If you have any questions, please feel free to contact us at any time.

Sincerely,

Your info here

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CaringAmbassadors.org

The Caring Ambassadors Program, Inc. is a 501(c)(3) nonprofit public charity.

Company Letterhead Here

## Sample Positive/Reactive Screening Letter

DATE

Dear

Thank you for your recent participation in the **insert event here**. We are pleased to bring you free hepatitis C screening services to your district.

The laboratory has reported that your rapid hepatitis C screening result was **preliminarily positive**. This means that you have been exposed to the hepatitis C virus and have produced antibodies to hepatitis C that our test was able to detect. However, the test does **not** tell us whether you **currently** have active hepatitis C virus. Approximately 25% of people exposed to the hepatitis C virus clear the virus from their body on their own; the other 75% of people exposed to the virus remain infected. **It is very important to find out if you currently carry the hepatitis C virus in your body as it may pose a threat to your health.**

To determine whether you **currently** have the hepatitis C virus (HCV RNA), you will need to have an additional test that looks for the virus itself in your blood. This test is known by several names such as **“hepatitis C viral load”, “hepatitis C PCR”, and “HCV RNA”**. You will need to see a doctor to have this blood test or follow the instructions on the enclosed resource sheet for discounted confidential testing.

We are able to assist you in connecting to care to address your liver health. We realize that there is often uncertainty and worry when it comes to news about your health. **You Org Name Here** is here to help should you have questions or concerns.

**You Org Name Here** were pleased to be able to offer you free hepatitis C screening and work to continue to provide this free service. If you would like to make a donation to our organization to help us provide hepatitis C services to others, please consider making a donation online at <http://caringambassadors.org/get-involved/>.

Sincerely,

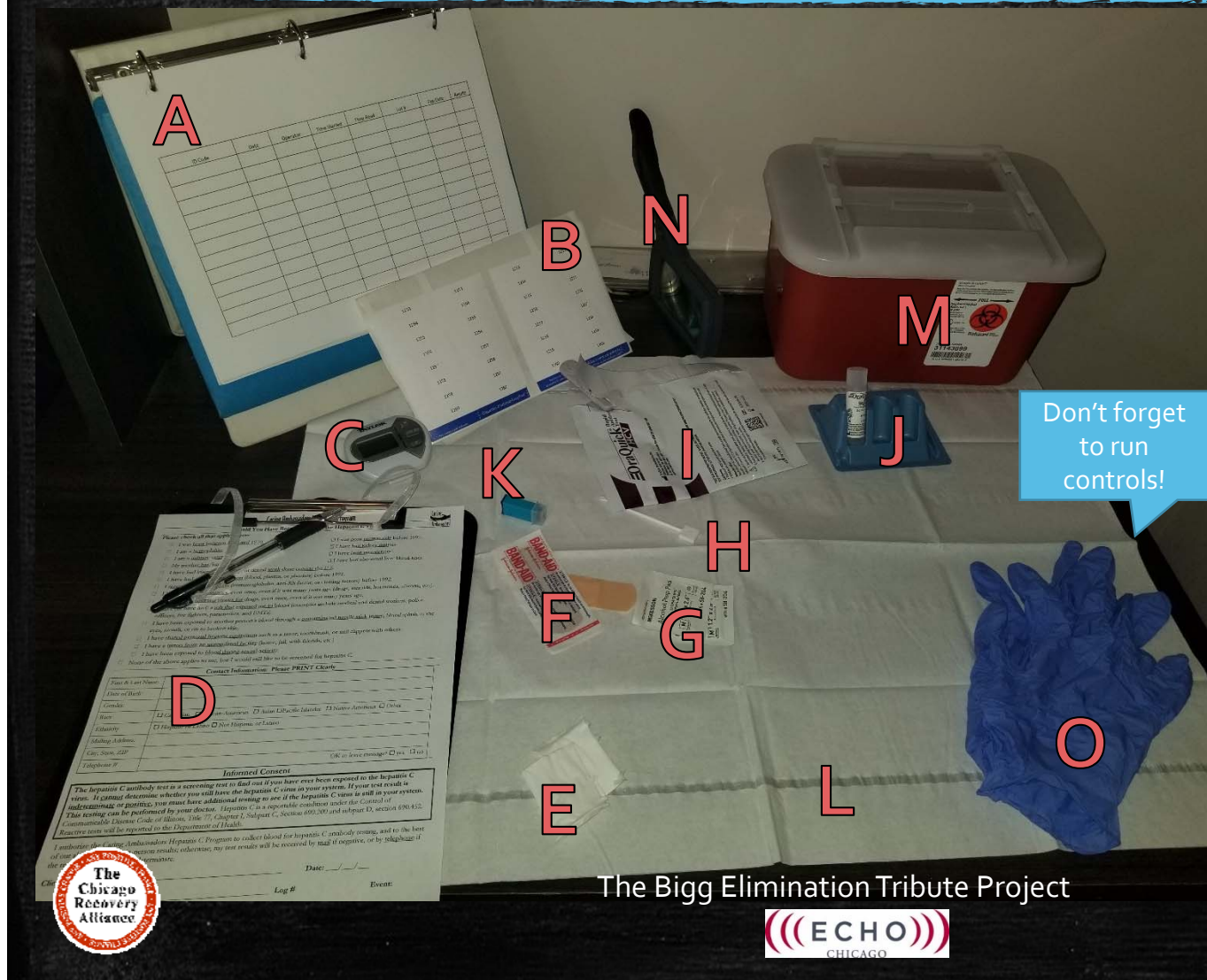
Your Info

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CaringAmbassadors.org

*The Caring Ambassadors Program, Inc. is a 501(c)(3) nonprofit public charity.*

# Screening & Testing – Rapid Test Set Up



- A- Testing log/Lab Record
- B- Tracking labels
- C- Timer
- D- Consent Form
- E- Gauze
- F- Band-Aid
- G- Alcohol swab
- H- Specimen Loop
- I- OraSure HCV Test Kit
- J- Test tube & stand
- K- Lancet
- L- Absorbent pad/'chuck'
- M- Sharps container
- N- Magnifying glass
- O- Gloves

The Bigg Elimination Tribute Project

