Hepatitis C Virus (HCV)

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KENTUCKY ADULT HCV SCREENING, TESTING AND REFERRAL MATRIX

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Have certain medical conditions, including persons : • who received clotting factor concentrates produced before 1987 • who were ever on long-term hemodialysis • who have HIV infection • who have Hepatitis B infection		**Option 2- Syringe Exchange Programs** **2). HCV Rapid Test for Screening Individuals** 1). Conduct onsite rapid HCV test 2). Receive test results **HCV Rapid test** **If Positive HCV antibody results:** 1.) Provide on-site rapid test results and counseling 2). During same visit or later visit, draw blood for HCV RNA Quantitative testing using the "*HCV Antibody and HCV RNA Quantitative Specimen Collection and Handling Guidance"* 3). Receive lab results from lab **If Negative HCV rapid results:** A). Provide test results and counseling B). Counsel regarding meaning of test results C). Counsel regarding HCV transmission and ways to prevent spread	**HCV RNA Quantitative Test Results** **If positive HCV RNA Quantitative results:** A). Provide HCV RNA test results -Counsel regarding meaning of test results, avoiding transmission to others and next steps of follow up B). Recommend follow up to: -Primary care provider -HCV Provider Specialist - Hepatologist -Gastroenterologist -Infectious Disease Specialist **If negative HCV RNA Quantitative results:** A). Provide test results and counseling B). Counsel regarding meaning of test results and C). Counsel regarding HCV transmission and ways to prevent spread

Clinical Information and Instructions for Screening and Testing for Hepatitis C Virus (HCV) Infection

The Kentucky Department for Public Health (KDPH) encourages all Local Health Departments (LHDs) to begin offering hepatitis C virus (HCV) education, prevention, screening, and testing to all at risk persons. To avoid a missed opportunity, please offer HCV screening and testing services during all healthcare encounters when persons are identified as being at risk.

Hepatitis C, a blood-borne disease, is primarily spread through intravenous drug use; however HCV can be contracted in other ways from contaminated blood. Hepatitis C usually is a chronic viral infection with few early symptoms, and danger signs may not appear for decades. Ultimately, patients endure liver scarring, liver cancer, or total liver failure.

HCV is transmitted primarily through large or repeated percutaneous (i.e., passage through the skin) exposures to infectious blood. Populations identified at risk for HCV infections include persons who inject drugs, persons with HIV infection; persons with sexual contact with an infected person; sharing personal items contaminated with infectious blood, such as razors or toothbrushes (rare but can occur); perinatal HCV infection; individuals with a history of incarceration; needle stick injuries in healthcare setting and persons that have experienced unsafe injection practices in healthcare settings. Persons born between 1945 and 1965, i.e., Baby Boomers, are also at high risk for chronic HCV infection and should be tested,
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a2.htm?s_cid=mm6417a2_w

Approximately 15%-20% of persons exposed to HCV clear the virus from their bodies without treatment and do not develop chronic infection; the reasons are not well known. HCV infection becomes chronic in approximately 75%-85% of cases. Chronic infection is the leading indication for liver transplants in the United States. Prior infection with HCV infection does not protect against later infection with the same or different genotypes of the virus. Presently no vaccine for Hepatitis C is available.

Approximately 2.2 to 3.2 million persons are living with chronic HCV infection in the United States. The Center for Disease Control (CDC) has reported that up to 1.2% of Americans have been chronically infected with HCV. In Kentucky, cases of acute hepatitis C have dramatically increased in both rural and urban communities. The reported incidence rate of acute HCV infection was 1.5 cases per 100,000 in 2009 and rose to an alarming 5.1 cases per 100,000 in 2013. In Kentucky, between 2009 and 2013; reported rates of acute hepatitis C increased by 240%.

The hepatitis C epidemic among people who inject drugs continues to spread throughout Kentucky and the US, especially among people in their 20's. In April 2015, the CDC issued a Health Advisory; Outbreak of Recent HIV and HCV Infections among Persons Who Inject Drugs. In May 2015, the Morbidity and Mortality Weekly Report (MMWR) released a report: "Increases in Hepatitis C Virus Infection Related to Injection Drug Use among Persons Aged ≤30 Years — Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012," http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a2.htm?s_cid=mm6417a2_w.

The Indiana State Department of Health and the Centers for Disease Control and Prevention (CDC) are currently investigating a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs. It has been reported that 90% of nearly 200 newly diagnosed HIV cases are co-infected with HCV infection.

Testing and Diagnosis

Who should be tested for HCV infection? Refer to the Teaching Sheet Section: **Kentucky Testing Recommendations for Hepatitis C Infection** and the **Kentucky Hepatitis C Virus (HCV) Infection Risk Assessment**.

HCV testing is recommended for anyone at increased risk for HCV infection, including:

- Adults born during 1945 through 1965 (http://www.cdc.gov/hepatitis/populations/1945-1965.htm) should be tested once (without prior ascertainment of HCV risk factors)
- Persons who have:
    - Current injecting or intranasal drug use
    - Ever injected drugs, including those who injected/ intranasal once or a few times many years ago
    - Unregulated body piercing or tattoos
    - Sexual contact with a known HCV-positive person
    - History of high risk sexual behavior
    - History of sexually transmitted infection
    - History of incarceration (http://www.cdc.gov/hepatitis/Resources/PDFs/hiv_comm_planners.pdf)
- Persons who have certain medical conditions, including persons:
    - who received clotting factor concentrates produced before 1987
    - who were ever on long-term hemodialysis
    - who have persistently abnormal alanine aminotransferase (ALT) levels
    - who have HIV infection
    - who have Hepatitis B infection
- Persons who were prior recipients of transfusions or organ transplants, including persons who:
    - were notified that they received blood from a donor who later tested positive for HCV infection
    - received a transfusion of blood, blood components or an organ transplant before 1992
- Persons with a **recognized exposure,** including:
    - Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
    - Children born to HCV-positive women

For collection guidance, refer to the **1-Hepatitis C Virus (HCV) Antibody and Quantitative HCV RNA Specimen Collection and Handling Guidance.**

Testing for HCV infection begins with a laboratory-conducted assay for HCV antibody in blood. See the **Kentucky Adult HCV Screening, Testing and Referral Matrix**. The KDPH recommends that Local Health Departments (LHD) use venipuncture to obtain a specimen for HCV Antibody (anti-HCV) testing. Offer the HCV Rapid test only for offsite HCV Outreach Programs or in Syringe Exchange programs. Refer to the **2-Screening and Referral Guidance for Hepatitis C Virus (HCV) Infection among High Risk Individuals** and **3- Outreach or Syringe Exchange Programs: Hepatitis C Virus (HCV) Rapid Test and Follow Up Guidance**. A nonreactive HCV antibody result indicates no HCV antibody detected.

A reactive result indicates one of the following: 1) current HCV infection, 2) past HCV infection that has resolved, or 3) false positivity. A reactive result should be followed by a HCV confirmation test using HCV RNA Quantitative tests to detect amount (viral load) of the virus. That confirmation test is done automatically (i.e., reflex testing) for HCV tests submitted to the Division of Laboratory Services.

If HCV RNA is detected, that indicates current HCV infection. If HCV RNA is not detected, that indicates either a past, resolved HCV infection, or false positive HCV antibody. A table on the interpretation of results of tests for Hepatitis C Virus (HCV) infection and further actions is available at: http://www.cdc.gov/hepatitis/HCV/PDFs/hcv_graph.pdf . CDC has not expressed a preference for which HCV infection test to use.

How soon after exposure to HCV can anti-HCV be detected?

HCV infection can be detected by anti-HCV screening tests (enzyme immunoassay) four to ten weeks after infection. Anti-HCV can be detected in >97% of persons by 6 months after exposure.

How soon after exposure to HCV can HCV RNA be detected?

HCV RNA appears in blood and can be detected as early as two to three weeks after infection.

For more information about the CDC HCV recommendations, see the "Testing for HCV infection: An Update of Guidance for Clinicians and Laboratorians- http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm

Local Health Department Guidance for HCV Screening & Testing:

1. Local Health Departments seeking to participate in the **Kentucky HCV antibody Screening and Testing with HCV RNA Quantitative Confirmation Program** should email the KY AVHPC Program to advise about participation and contact KY Division of Lab Services (DLS) dphlabkits@ky.gov to order PPT tubes and shipping/collection information and shipping materials.

   HCV Rapid Testing
   The KDPH recommends HCV Rapid test only for offsite HCV Outreach Programs or in Syringe Exchange programs. Training on the HCV Rapid can be arranged by contacting the rapid test manufacturer. Call the KY DLS for the contact information. HCV Rapid testing should not start until this training has occurred. Any Syringe Exchange Program using the HCV rapid test must have a Quality Control (QC) Plan. QC Plans can be reviewed by the DLS. Test kits and controls have a defined shelf life and must not be used beyond their expiration dates. The rapid tests have defined storage and temperature guidelines that must be followed.

2. Identify Linkage to Care in your region to ensure referrals for further evaluation for those with HCV RNA positive test results. Refer to the: **Kentucky HCV Providers Guidance.** Local Health Departments should confirm these providers have the capability to provide medical evaluation and treatment for individuals with HCV infection. Report any updates of providers in your region to the KY AVHPC Program.

3. Identify HCV screening, educating, and testing healthcare personnel at your LHD who will provide HCV screening and testing services. The KY Adult Viral Hepatitis Prevention and Control Program will provide an **HCV Introductory Training** as a public health nursing ITV. The HCV Introductory Training will include screening, collection and handling, data and epidemiology data surveillance reporting and analysis, and appropriate counseling messages, with referral and linkage to care guidance.

4. LHD's identified healthcare staff should follow recommended guidance in this document for HCV testing; this includes: Confidentiality; Staff training on identifying who is at risk for HCV infection, and the ability to provide screening, education, and testing; HCV Epidemiology Data Analysis using the **Kentucky HCV RNA Quantitative Testing Patient Information Log** (In the Forms Section) with the ability to report and email the KY AVHPC the data analysis monthly; HCV Counseling and Referral tracking to HCV diagnostic testing, care, treatment and other supportive services. LHDs should request data management assistance from your Regional Epidemiologist.

Referral for HCV Management and Treatment

What should be done for a patient with confirmed HCV infection?

HCV-positive persons should be evaluated (by referral or consultation, if appropriate) for presence of chronic liver disease, including assessment of liver function tests, evaluation for severity of liver disease and possible treatment, and determination of the need for Hepatitis A and Hepatitis B vaccination.

Hepatitis A and hepatitis B vaccines are recommended for persons with HCV infection to prevent additional damage to the liver that infections from these other hepatitis viruses may cause.

When might a specialist be consulted in the management of HCV-infected persons?

Any physician or medical provider who manages a person with Hepatitis C should be knowledgeable and current on all aspects of the care of a person with Hepatitis C; this can include specialists such as infectious disease physicians, gastroenterologists, or hepatologists. Refer to the: **Kentucky HCV Providers Guidance.**

Referral appointments can be tracked to ensure follow through by the client. Linkage agreement/MOU can include specific language on the process for tracking referrals to ensure efficient tracking of referrals. LHDs should obtain a signed release of information from individuals to ensure that they may obtain all necessary information from the referral provider.

Partnerships with local substance abuse service providers

LHDs are encouraged to work with local substance abuse services that treat IDUs to develop anti-HCV testing services for their clients. A current list of Kentucky Opioid Treatment programs can be found at: http://kbml.ky.gov/Documents/Resources%20SA%20Kentucky%20Opioid%20Treatment%20Programs.pdf

Counseling Patients

What topics should be discussed with individuals who have HCV infection?

- Individuals should be informed about the low but present risk for transmission to sex partners.
- Sharing personal items that might have blood on them, such as toothbrushes or razors, can pose a risk to others.
- Cuts and sores on the skin should be covered to keep from spreading infectious blood or secretions.
- Donating blood, organs, tissue, or semen can spread HCV to others.
- HCV is not spread by sneezing, hugging, holding hands, coughing, sharing eating utensils or drinking glasses, or through food or water.
- Individuals may benefit from a joining a local HCV support group.

What should HCV-infected persons be advised to do to protect their livers from further harm?

- HCV-positive persons should be advised to avoid alcohol because it can accelerate cirrhosis and end-stage liver disease.
- Viral hepatitis patients should also check with a health professional before taking any new prescription pills, over-the counter drugs (such as non-aspirin pain relievers), or supplements, as these can potentially damage the liver.

Pregnancy and HCV Infection

Since pregnant women have no greater risk of being infected with HCV than non-pregnant women and interventions to prevent mother-to-child transmission are lacking, routine anti-HCV testing of pregnant women is not recommended. Pregnant women should be tested for anti-HCV only if they have HCV risk factors. Refer to the **4- Screening and Referral Guidance for Hepatitis C (HCV) Infection among High Risk Pregnant Women**. HCV infection in pregnant women is reportable to public health officials. Complete the EPID 394 Kentucky Reportable Disease Form and fax to 502-564-4760.

What is the risk that an HCV-infected mother will spread HCV to her infant during birth?

Approximately 6 of every 100 infants born to HCV-infected mothers become infected with the virus. Transmission occurs at the time of birth, and no prophylaxis is available to prevent it. The risk is increased by the presence of maternal HCV viremia at delivery and also is two to three times greater if the woman is co-infected with HIV. Most infants infected with HCV at birth have no symptoms and do well during childhood. More research is needed to find out the long-term effects of perinatal HCV infection.

There is no evidence that breastfeeding spreads HCV. However, HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding.

Infants born to mothers with HCV infection

The KDPH recommends HCV RNA testing for Infants born to mothers infected with HCV at the infant's well-child visit at age two months or four months. HCV RNA testing should then be repeated at a subsequent visit in four to six months, independent of the initial HCV RNA test result if the first test is reported as negative.

An Infant born to mothers with HCV infection is reportable to public health officials in Kentucky. Complete the EPID 394 Kentucky Reportable Disease Form and fax to 502-564-4760. An alternative anti-HCV antibody test (anti-HCV) can be offered no sooner than age 18 months because anti-HCV from the mother might last until this age. See the **5-Screening and Referral Guidance for Infants Born to Mothers with Hepatitis C Virus (HCV) Infection**. Refer children with positive HCV test results to identified HCV pediatric specialists in your region.

HCV Testing Provided at LHDs

Perform HCV high risk screening and offer HCV testing to individuals identified high risk by LHD personnel. LHDs should refer an individual identified with HCV risk factors whose health insurance coverage will cover the cost of HCV testing to a private provider for anti-HCV testing and follow up. If the individual is uninsured or has insurance that will not pay for the cost of the HCV test, the LHD personnel qualified in venipuncture will collect and submit a specimen to the Kentucky Division of Lab Services (DLS) following guidance from the **1-Hepatitis C Virus (HCV) Antibody and HCV RNA Quantitative Specimen Collection and Handling Guidance**. The process includes:

- Email dphlabkits@ky.gov to obtain PPT tubes from DLS (Division of Laboratory Services)
- Collect a specimen from the patient using one 8.5mL PPT tube. Spin tube within 6 hours of collection. Those sites previously lacking a centrifuge should have received one from DLS. Specimen should be at least 3mL plasma
- Send spun PPT tube to DLS using ice packs. Specimens collected on Friday should be frozen over the weekend and sent the following workday to DLS on ice packs or dry ice. When possible, send specimens using overnight mailing system to ensure that the specimens meet the shipping guidelines. Specimens will be stable refrigerated for 72 hours and if frozen, 6 weeks.
- DLS will perform the HCV antibody testing. If the antibody testing is positive, DLS will automatically reflex to Quantitative HCV RNA testing for confirmation. **No second specimen is needed.**

  Simply collect the specimens using PPT tubes, spin them down, and ship to DLS using ice packs. If you have any questions about specimen collection and/or shipping, please contact DLS at dphlabkits@ky.gov. **Please do not send DLS whole blood for the HCV antibody testing.**

  Please note that confirmatory testing will be performed by HCV RNA Quantitative testing. If you need assistance interpreting the HCV RNA Quantitative test results, please contact the DLS Supervisor of the Virology Section at 502-564-4446.

1 Hepatitis C Virus (HCV) Antibody and HCV RNA Quantitative Specimen Collection and Handling Guidance

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Order PPT Tubes from Division of Lab Services (DLS)
dphlabkits@ky.gov

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Collect specimen using one 8.5 mL PPT Tube.

Spin specimen with centrifuge within 6 hours of collection.

Send spun PPT tube to DLS using ice packs. If specimen is collected on Friday, freeze and send specimen on ice packs or dry ice to DLS the next business day.*

When possible, send using overnight mailing system. This will help ensure that specimens meet the shipping guidance.

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DLS will perform HCV Antibody testing.

If the HCV antibody test is positive, DLS will reflex to HCV RNA Quantitative testing for confirmation. No additional specimen collection is needed. **

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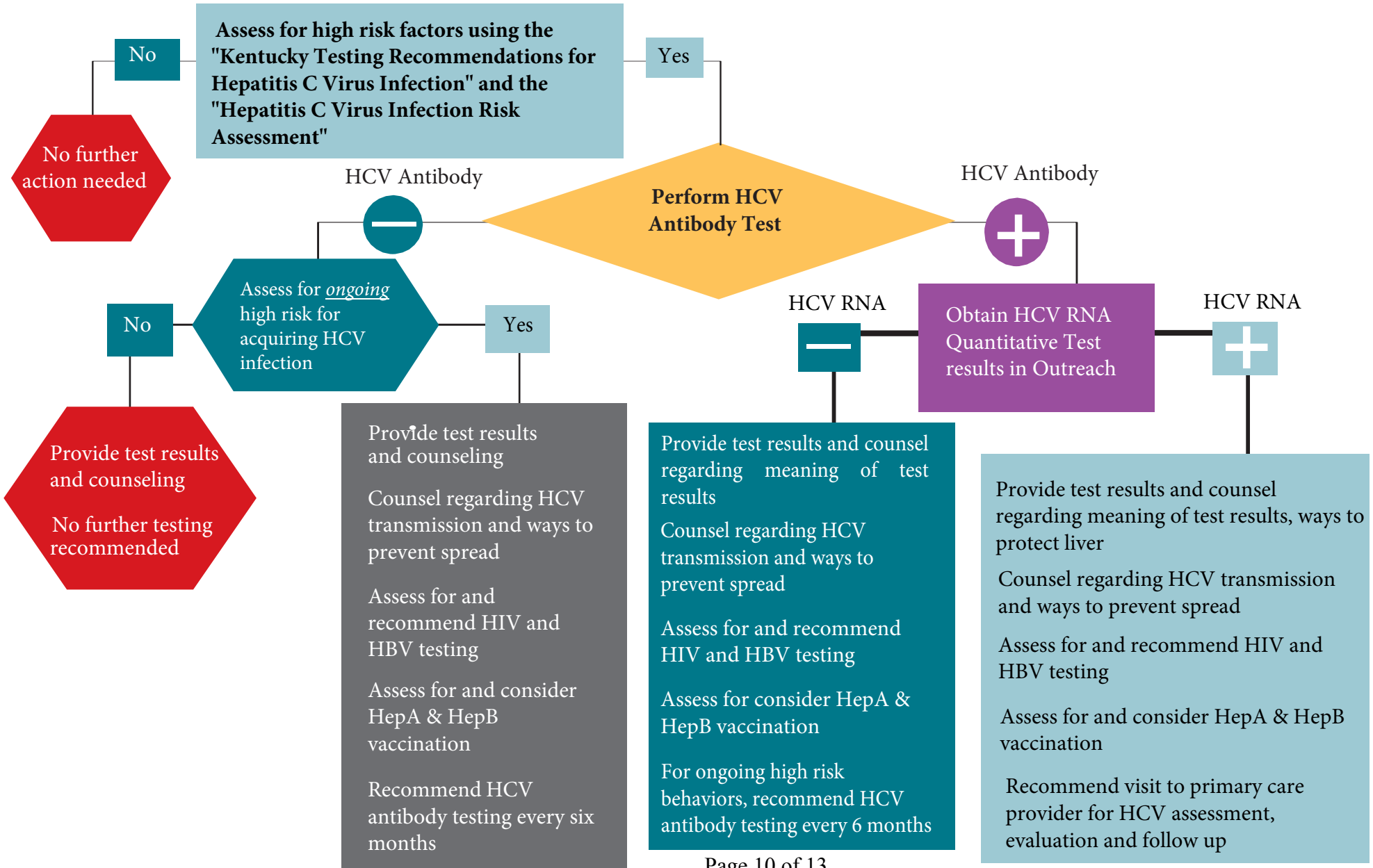
For specimen collection and or shipping information, contact dphlabkits@ky.gov

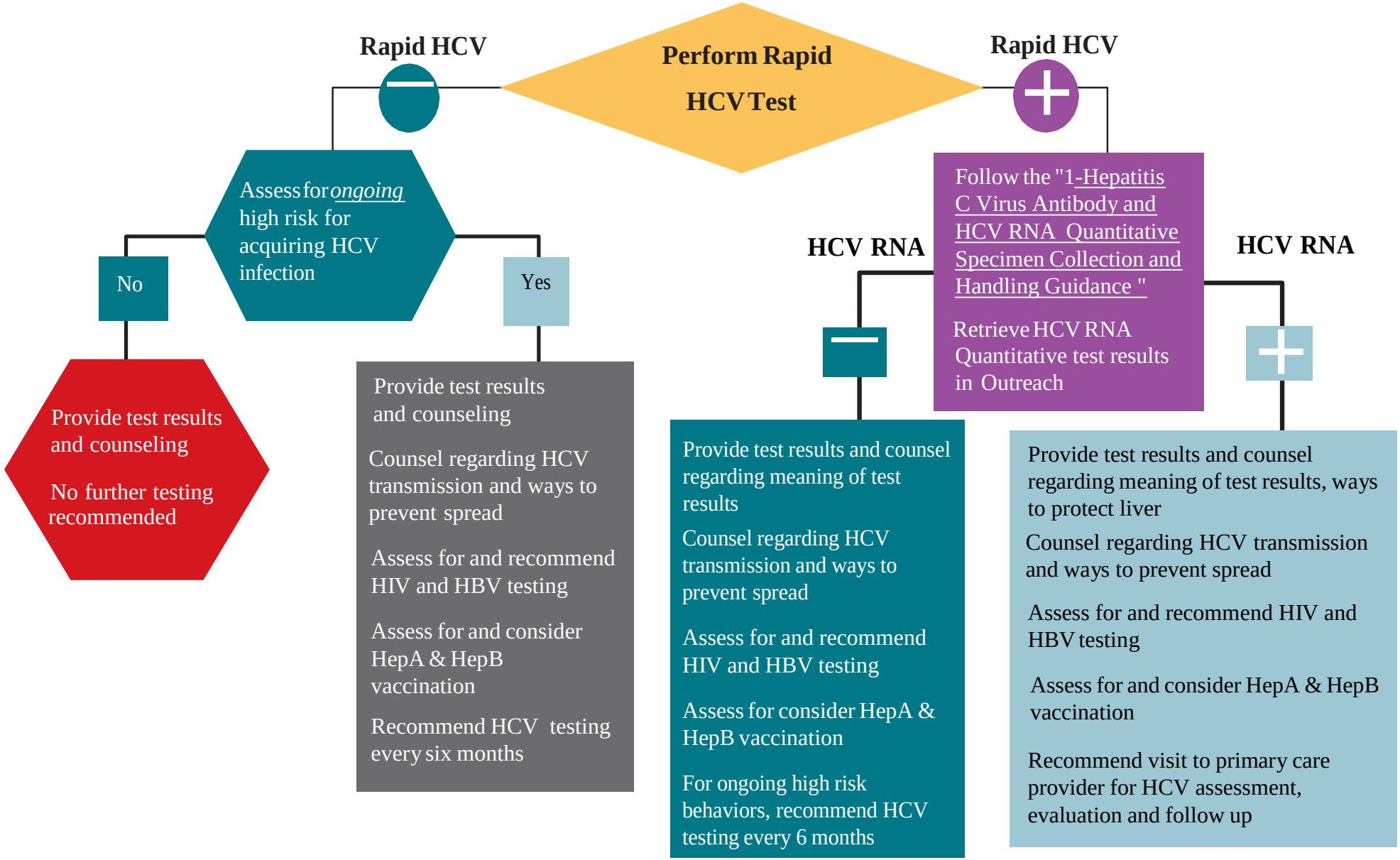
* Specimens will be stable refrigerated for 72 hours and if frozen, 6 weeks.

** For Quantitative HCV RNA testing interpretation questions, contact DLS at 502-564-4446

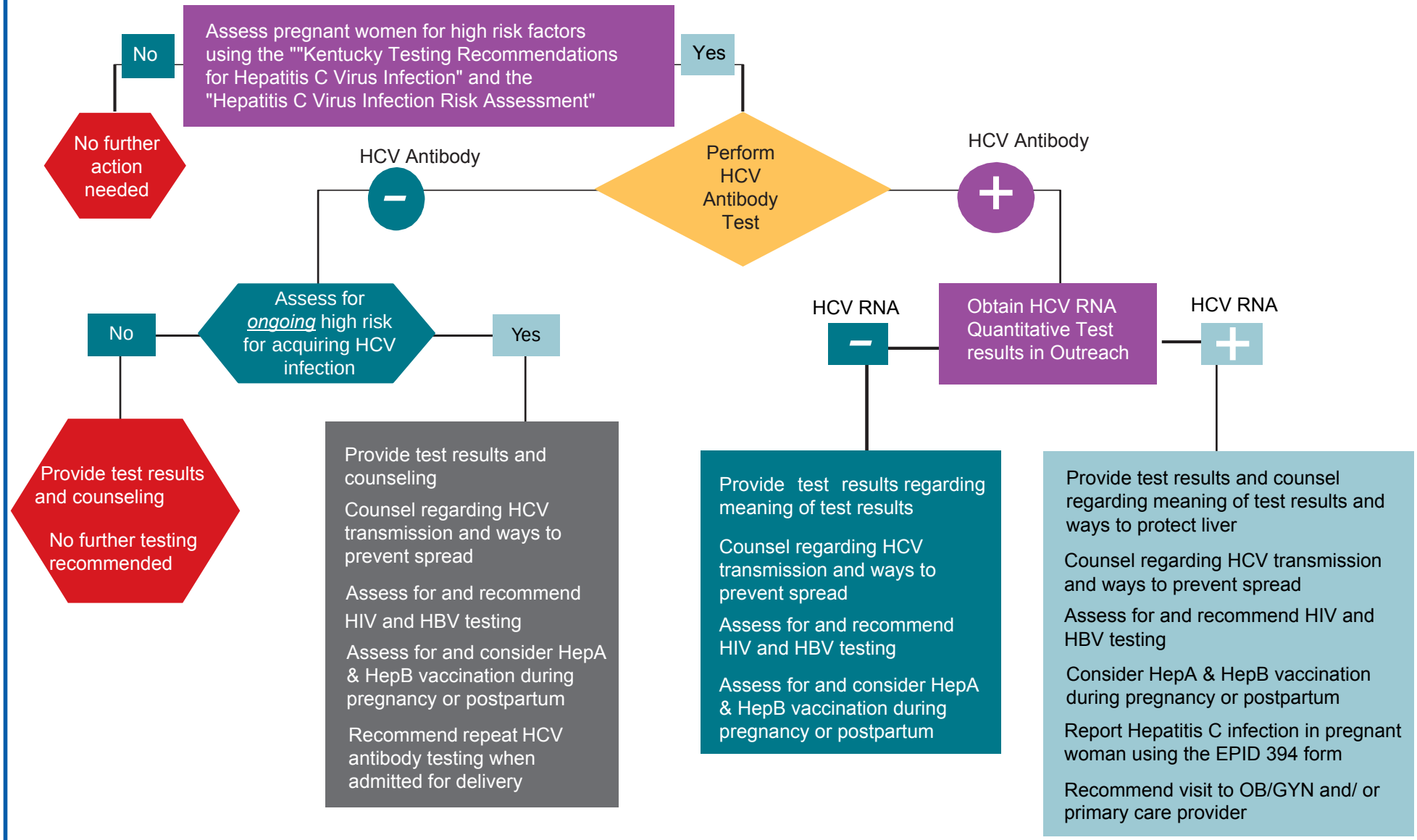
2 Screening and Referral Guidance for Hepatitis C Virus (HCV) Infection among High Risk Individuals



3 Outreach or Syringe Exchange Programs: Hepatitis C Virus (HCV) Rapid Test and Follow Up Guidance



4 Screening and Referral Guidance for Hepatitis C Virus (HCV) Infection among High Risk Pregnant Women



5 Screening and Referral Guidance for Infants Born to Mothers with Hepatitis C Virus (HCV) Infection

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