



Hepatitis C OraQuick Rapid Antibody Test



*Putting people first, with the goal of helping all Michiganders lead healthier and more productive lives,
no matter their stage in life.*

None of the presenters have declared a relevant financial relationship with an ineligible company.

Hepatitis C 101

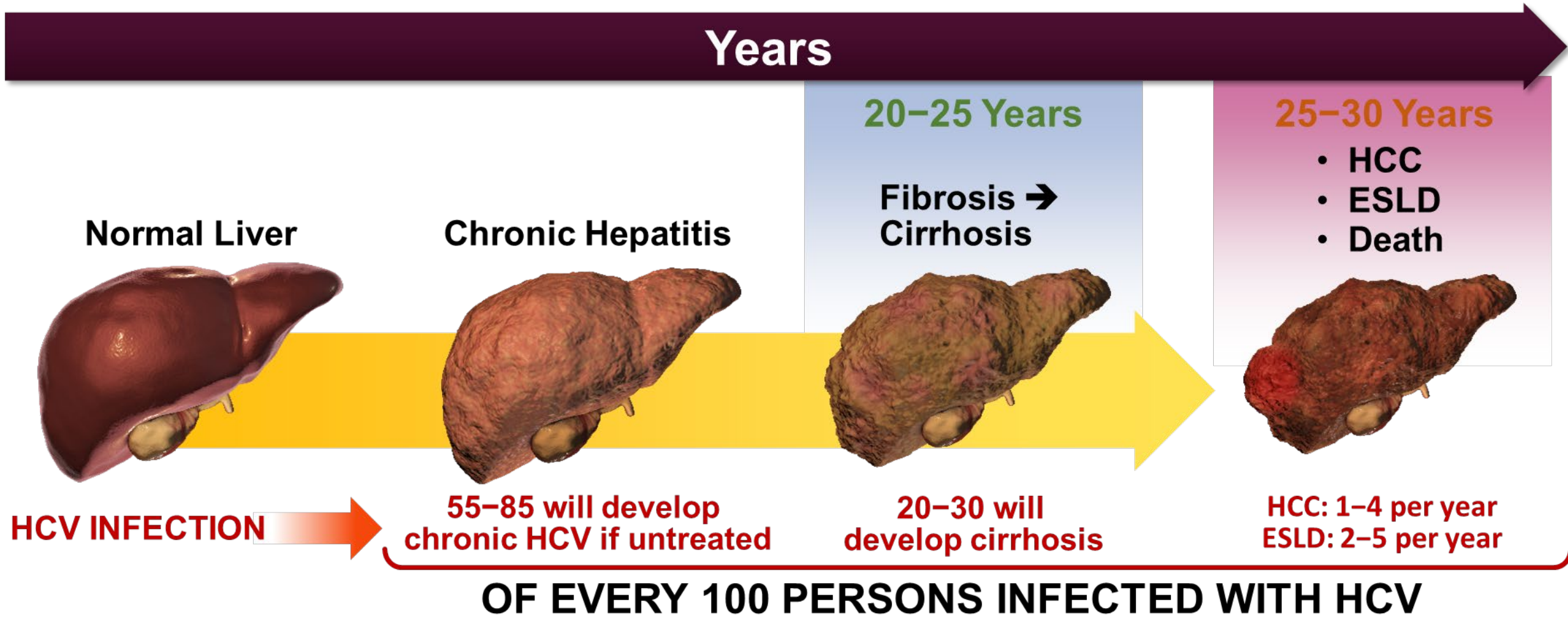
Hepatitis C

- Liver infection caused by the Hepatitis C Virus (HCV) and transmitted through contact with blood from an infected person
 - Sharing of drug injection or preparation equipment, e.g., needles, syringes, snorting straws, cottons, cookers
 - Traumatic sexual practices, e.g., receptive unprotected anal sex
 - Blood transfusions or organ transplants before 1992
 - During birth delivered by an HCV-positive person (~6% of pregnancies)
 - Unregulated body art
 - Healthcare exposures (e.g., needlestick injury)
- HCV **not** transmitted through breastmilk, food, water, or casual contact (e.g., hugging, kissing, sharing food/drink with someone living with HCV)
- People with HCV are often asymptomatic. When symptoms do appear, they often are a sign of advanced liver disease
- There is no vaccine for HCV

Acute vs. Chronic HCV

- HCV infection can range from an acute, mild illness, lasting a few weeks, to a serious, lifelong chronic infection
- Signs and symptoms of acute HCV include jaundice, elevated liver enzymes (ALT >200 IU/L), fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain
- >70% of acutely infected persons are asymptomatic
- >75% of acute HCV cases develop chronic HCV infection
- Chronic HCV infection can result in serious, even life-threatening health problems such as cirrhosis (severe liver scarring/damage) and liver cancer

Natural History of the Disease



HCV Testing

It takes two tests to see if you are living with hepatitis C!

ANTIBODY

- An antibody test detects if you have been exposed to HCV
- A positive result only means that you have been exposed to HCV
- If Ab test is + you need take a RNA test to know if you are currently infected
- Regardless of clearing the virus or receiving treatment, HCV Ab result will ALWAYS be positive!

RNA

- An HCV RNA test can tell if you are currently living with HCV.
- If you test +, there are all-oral medications that can cure you.
- Genotype test – identifies the specific strain of virus and is equivalent to an RNA test.

By law hepatitis C
is a reportable
condition in
Michigan!

HCV Testing Recommendations (CDC, 2020)

Universal HCV screening

- HCV screening at least once in a lifetime for all adults aged ≥ 18 years
- HCV screening for all pregnant persons during each pregnancy

One-time HCV testing regardless of age or setting prevalence among persons with recognized conditions or exposures

- Persons living with HIV
- Persons who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
- Children delivered by a person with HCV infection

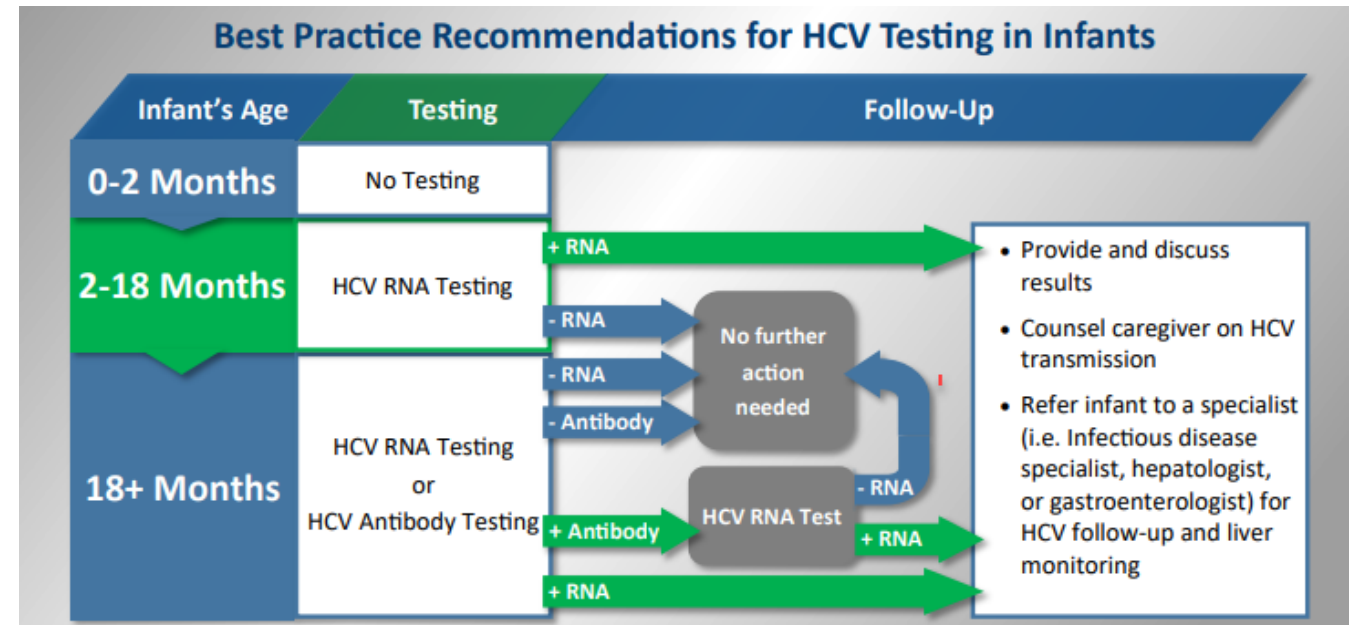
Routine periodic testing for persons with ongoing risk factors, while risk factors persist

- Persons who inject drugs and share needles, syringes, or other drug preparation equipment
- Persons with select medical conditions, including persons who ever received maintenance hemodialysis

Any person who requests HCV testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks

Perinatal HCV Testing Recommendations

- All children delivered by a person with HCV **should be tested for HCV**.
- Maternal HCV antibodies transfer efficiently to infants at birth and may not clear for up to 18 months.
- Therefore, the **American Association for the Study of Liver Diseases (AASLD)** recommends testing infants according to the following algorithm:
 - HCV Ab testing at or after **18 months** of age (maternal antibodies)
 - HCV RNA can be considered as early as at **2 months** of age



Why is HCV a Major Public Health Threat??

THE NUMBERS:

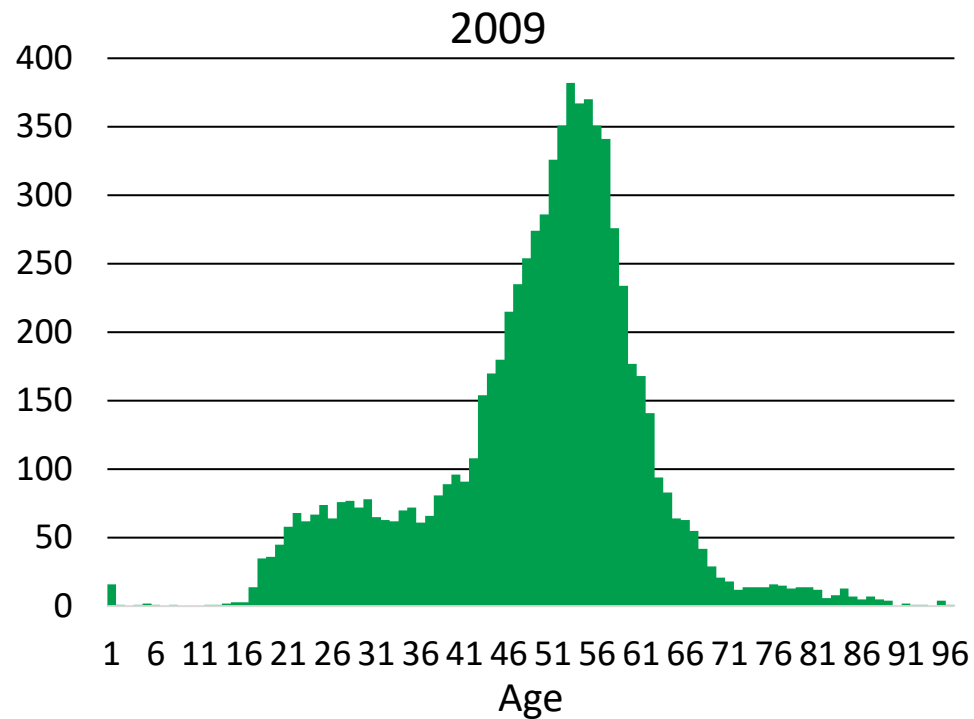
United States

- 2.4 million people are estimated to be living with HCV
 - The actual number may be as high as 4.7 million or as low as 2.5 million
- The rate of new HCV infections reported to CDC in 2018 was four times as high as it was in 2010

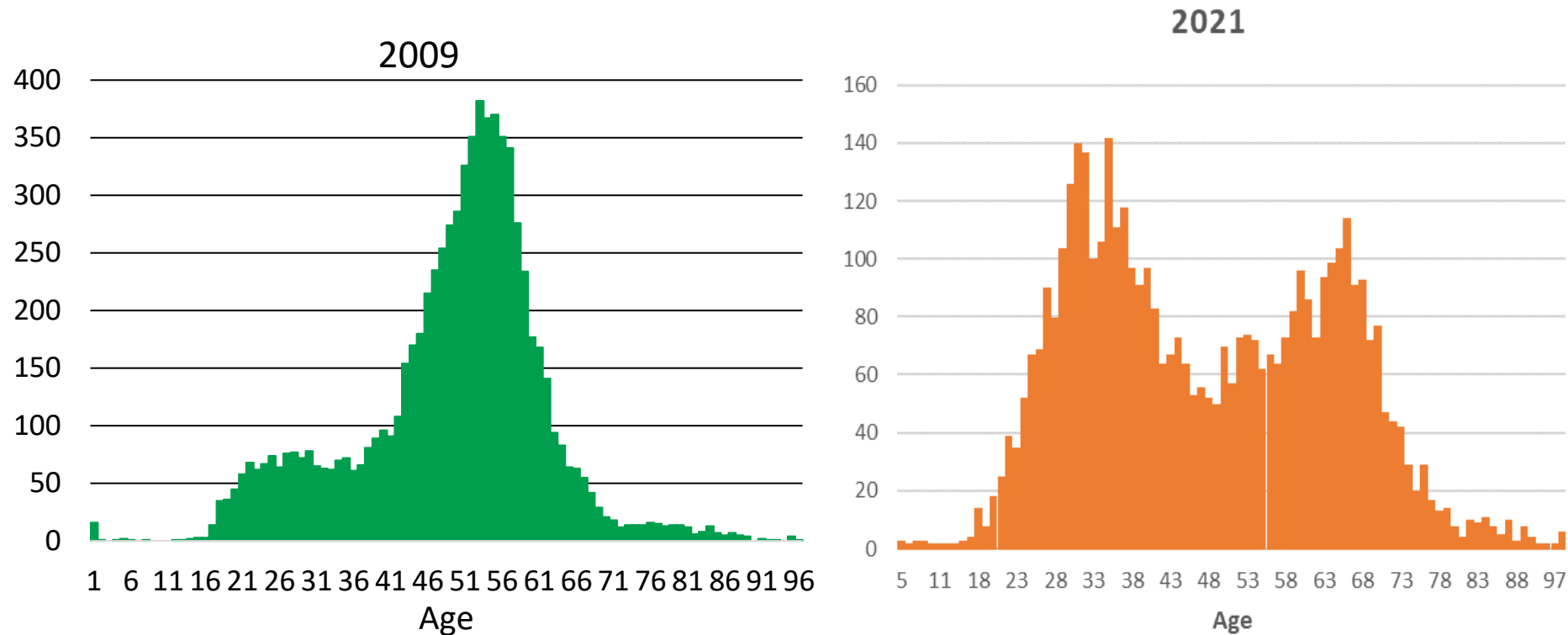
Michigan

- In 2021, a total of 4,412 new chronic HCV diagnoses
- In 2019, HCV prevalence of 69,100 – which ranks Michigan 7th among all states in the U.S
- Estimates of 200,000 + Michiganders living with HCV

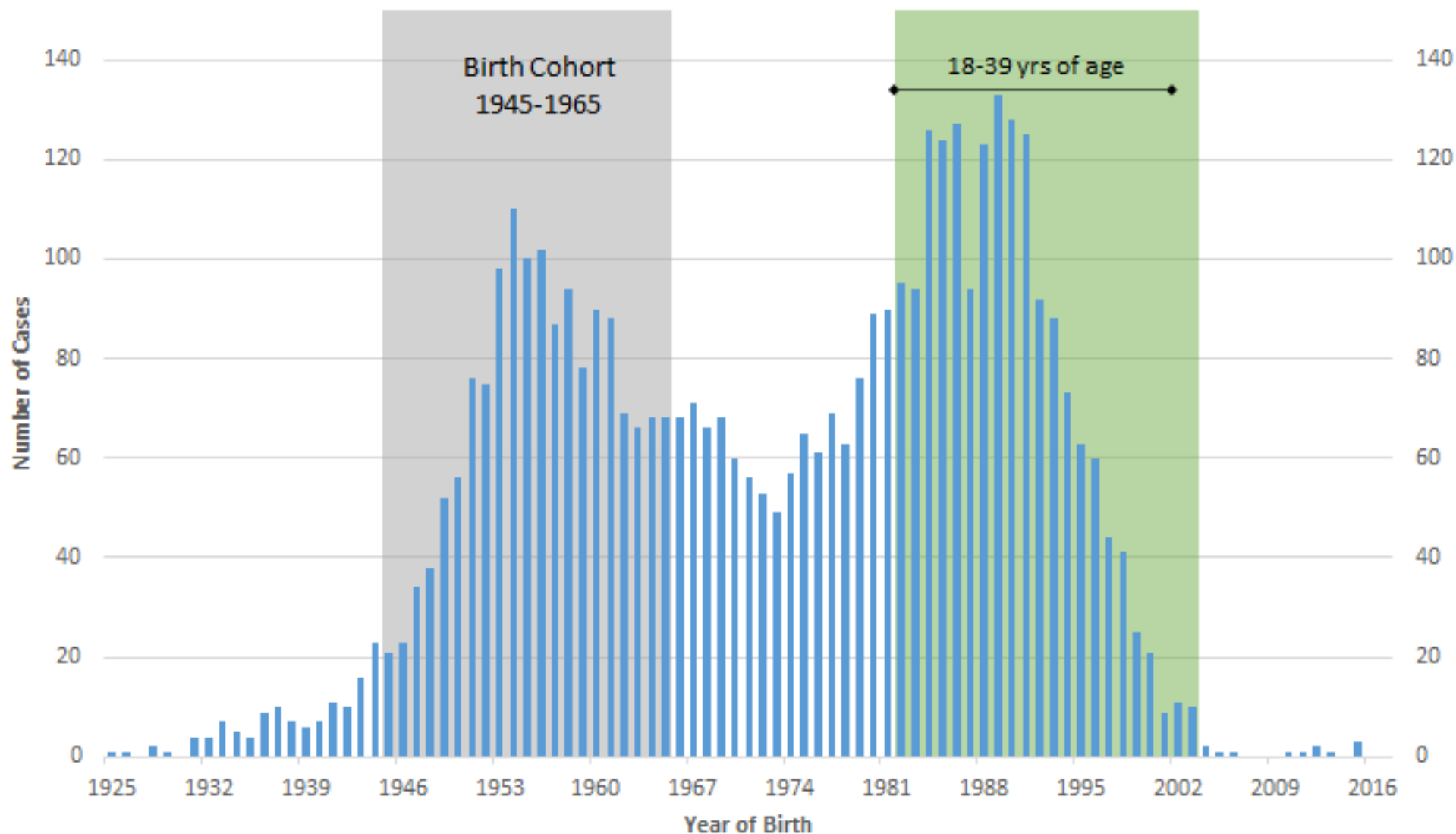
Distribution of New HCV Diagnoses by Year of Birth in Michigan, 2009



Distribution of New HCV Diagnoses by Year of Birth in Michigan, 2009 vs. 2021



Number of Chronic Hepatitis C Reported to MDHHS by Year, 2021

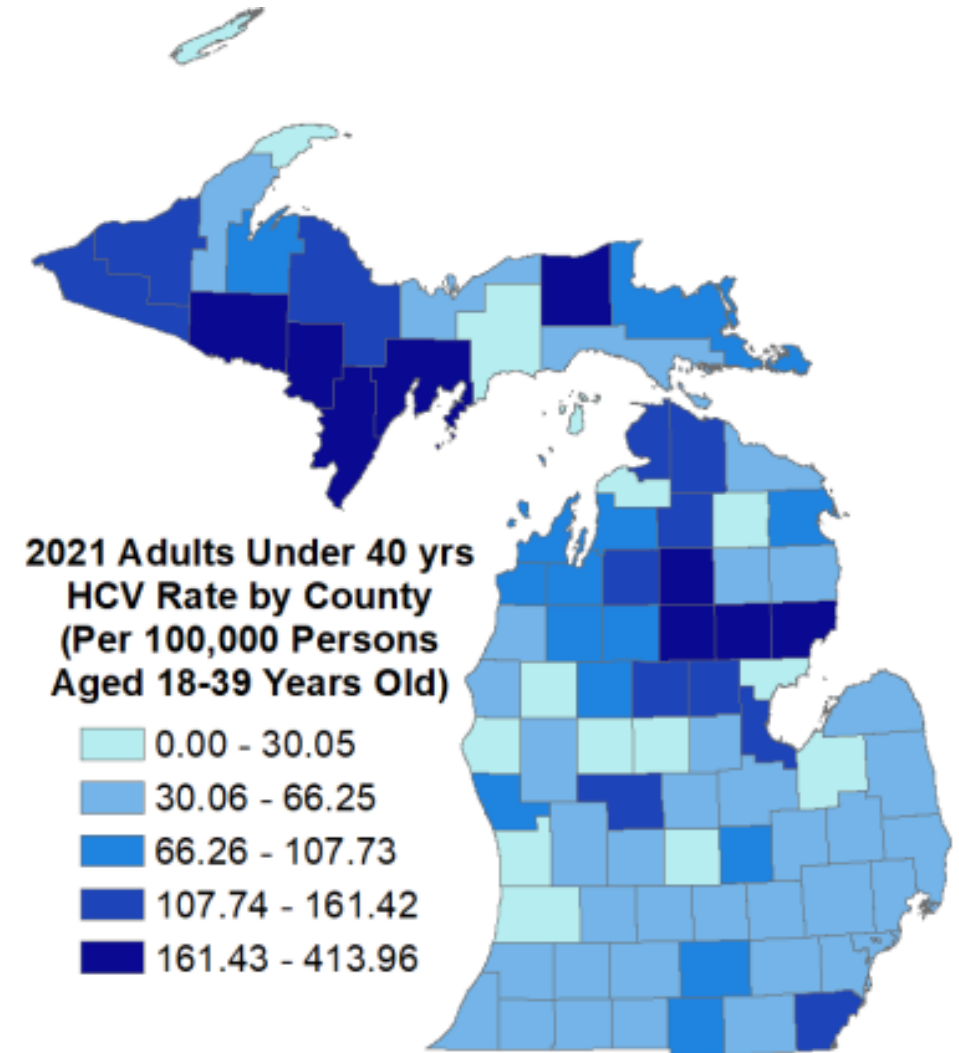


Demographics & County Rate Map 2020

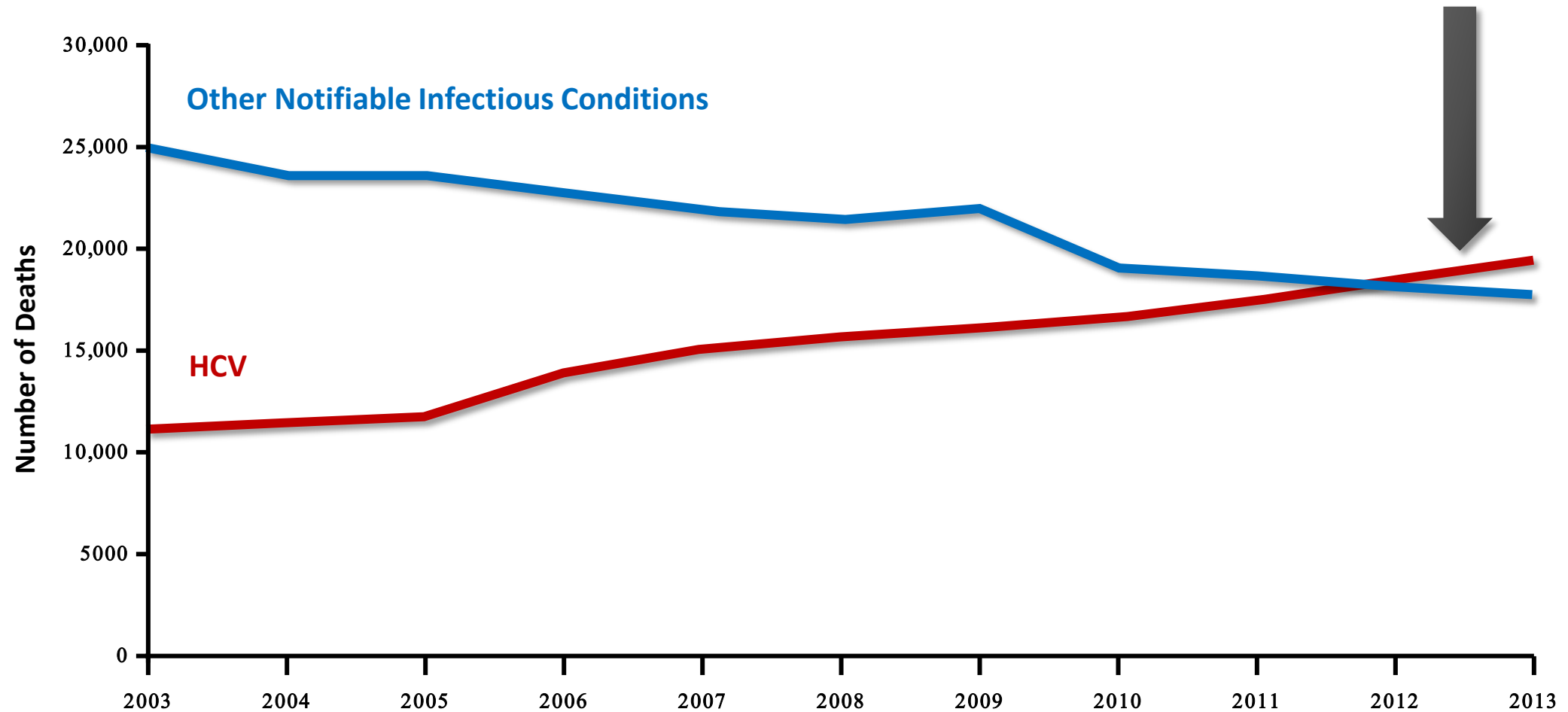
Chronic HCV Cases Aged 18-39 Years Old

Table 7.2 Epidemiologic Summary of 2021 Chronic HCV Cases Aged 18-39 Years Old

Age (n = 1,747)		
Median	32	
Mean	31.31	
Range	18 - 39	
Sex (n = 1,742)		Rate per 100,000
Female	763 (43.8%)	54.38
Male	979 (56.2%)	67.93
Race (n = 1,460)		Rate per 100,000
White	1184 (81.1%)	58.28
Black	138 (9.5%)	29.79
American Indian or Alaskan Native	18 (1.2%)	79.90
Asian	19 (1.3%)	14.11
Other Race	100 (6.9%)	Not Available
Hispanic Ethnicity (n = 1,178)		Rate per 100,000
Hispanic or Latinx	43 (3.7%)	22.49
Not Hispanic or Latinx	1135 (96.3%)	42.78
Arab Ethnicity (n = 526)		Rate per 100,000
Arab Ethnicity	7 (1.3%)	Not Available
Non-Arab	519 (98.7%)	Not Available
History of IVDU (n = 495)		
Yes	386 (78.0%)	
No	109 (22.0%)	

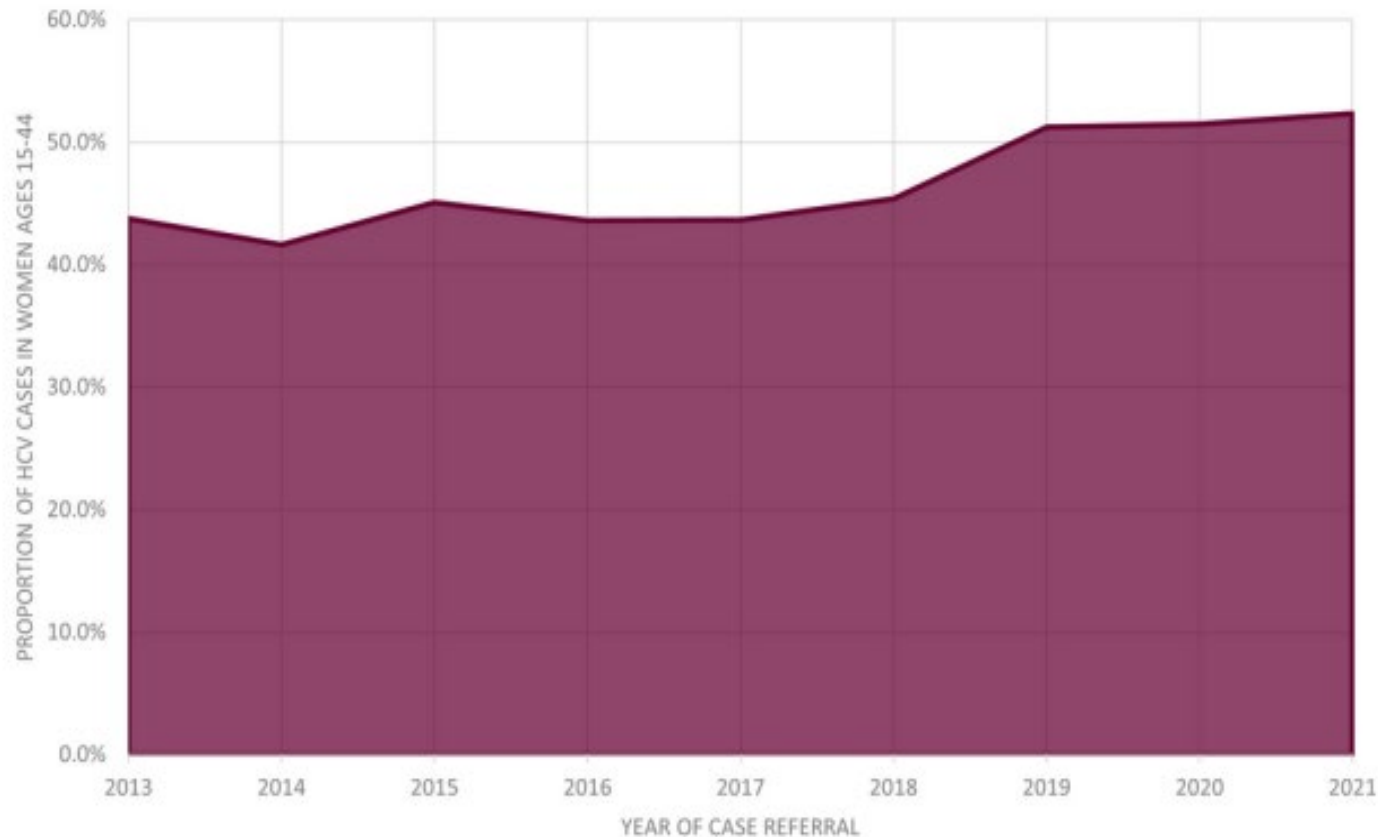


HCV Mortality



Proportion of HCV cases in women ages 15-44 compared to all HCV cases in women 2013-2021, MDSS

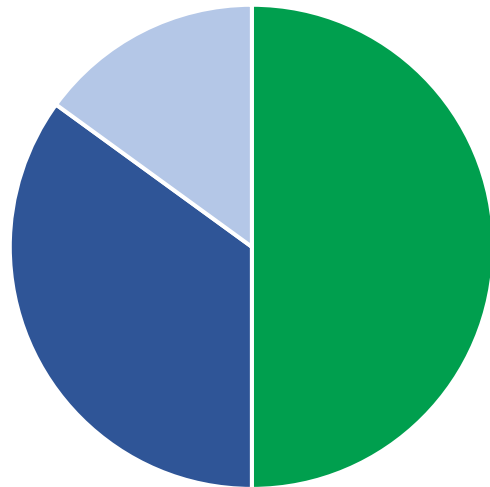
Proportion of HCV cases in women ages 15-44 compared to all HCV cases in women, Michigan, 2013-2021



- Hepatitis C treatment is contraindicated for pregnant people and people who are breastfeeding
- Hepatitis C treatment is approved for children 3 years and older

Liver Cancer & Viral Hepatitis

**Factors Contributing to Liver Cancer
Incidence in the U.S.**



■ Hepatitis C Related ■ Other* ■ Hepatitis B Related

Hepatitis C
is curable.

*Other: Excessive alcohol use, obesity, diabetes, hemochromatosis, consumption of foods with aflatoxin

Benefits of Treatment and Cure

Curative treatment reduces:

- Risk of liver cancer by 75%
- Risk of all cause mortality by 50%

What does it mean to be cured?

- No longer have the virus active in their body
- No risk for transmitting the virus
- Will ALWAYS be HCV Ab positive/reactive
- Past liver damage may heal some
- Re-infection is possible!

HCV is Curable!

PAST

- Interferon-based
- Low efficacy against the most common HCV genotype (treatment often was not curative)
- Patients often experienced significant side effects

PRESENT

- Direct-Acting Antivirals (DAAs) first received FDA approval in 2013
- Curative (95%) for most patients and most genotypes
- Improved patient quality of life: fewer side effects and shorter treatment duration (8-12 weeks)
- Downside: previously very expensive
- Since HCV is a fairly prevalent condition, this caused payers to strategize on how to curtail costs without an infinite budget

WE TREAT HEP C

Increasing access to hep c treatment to pave the way to elimination



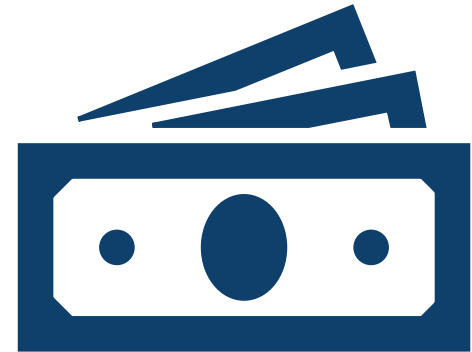
Michigan Medicaid HCV Coverage Background



- **2013** - The first HCV DAA receives FDA approval
- **2015** - Medicaid covers HCV DAAs on a case-by-case basis
- **2016** - Initiated formal coverage of HCV DAAs in January of 2016
 - F3/F4 Fibrosis
 - Prescription must be written by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist
 - Patient must demonstrate 6 months of sobriety
- **2017** – Fibrosis score lowered to F2
- **2018** – Fibrosis score lowered to F1
- **2019** – Fibrosis score lowered to F0, thereby removing fibrosis score requirement

Common Strategies to Curtailing Costs

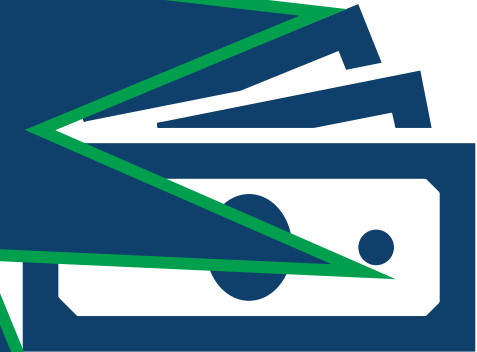
- **Prior Authorization:** Before medications can be prescribed, a provider must submit paperwork to gain approval for writing the script
- **Fibrosis Restrictions:** Limiting prescriptions to only those patients with severe liver damage (e.g., F3 or F4 fibrosis score)
- **Provider Restrictions:** Prescriptions must be written by, or in consultation with, a specialist (e.g., gastroenterologist, hepatologist, or infectious disease)
- **Sobriety Restrictions:** Patient must be sober from drugs or alcohol for 6 months to be eligible for treatment



Common Strategies to Curtailing Costs

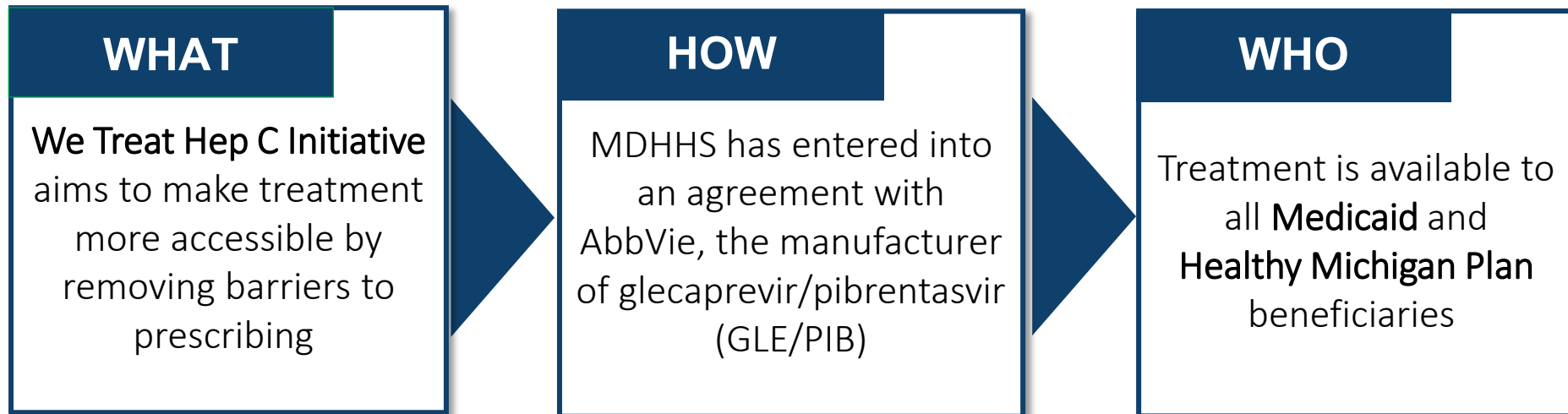
- **Prior Authorization:** Before medications can be prescribed, a provider must submit paperwork to obtain approval for writing a prescription
- **Fibrosis Restrictions:** Patients must have a liver biopsy (or a Fibroscan score) to be eligible for treatment
- **Provider Restrictions:** Patients must be seen by, or in consultation with, a specialist (hepatologist, gastroenterologist, or infectious disease specialist)
- **Sobriety Restrictions:** Patient must be sober from drugs or alcohol for 6 months to be eligible for treatment

Eliminated for
Medicaid beneficiaries
through We Treat Hep C!



WE TREAT HEP C INITIATIVE

MDHHS launched the **We Treat Hep C Initiative** on April 1, 2021, as a strategy to increase access to HCV treatment and eliminate HCV in Michigan



WE TREAT HEP C INITIATIVE



- GLE/PIB no longer requires prior authorization (PA), effective April 1, 2021
 - PA requirements for non-preferred DAAs have been streamlined
- Removal of all HCV DAA restrictions: documentation of recent/current substance use and specialist requirement have been removed
- **Any prescriber with prescriptive authority can treat HCV!**

- Pangenotypic
- For treatment-naïve persons and those with compensated cirrhosis
- Three tablets, once daily for eight weeks
- No limitation regarding renal function
- Approved for adults and children 3+
- Cure rates of 95-99%
- Adverse reactions: >10% of subjects reported headache and fatigue

PROVIDER CAPACITY



- Removing prior authorization means that any provider who can prescribe will be able to prescribe GLE/PIB and other DAAs
- DAAs are safe and have few contraindications or side effects. In most cases, treatment can be prescribed by a PCP, opioid use disorder treatment specialist, etc.
- However, many providers do not have experience treating HCV due to historical prior authorization requirement limiting treatment to specialists
- Program's success depends on getting more providers to treat HCV

PROVIDER OUTREACH



- Provider Letter L 21-21
- Tribal Health Directors
- Academic Detailing
- Professional Medical Societies, Associations, and various conferences
- Licensing and Regulatory Affairs
- Press releases, proclamations, social media
- Medicaid Health Plans



Michigan Department of Health and Human Services
Program Policy Division PO Box 30479
Lansing MI 48909



April 6, 2021

<Provider Name>
<Provider Address 1>
<Provider Address 2>
<City> <State> zipcode5-zipcode4

Dear Provider:

Re: Removal of Prior Authorization for Hepatitis C Treatment

The Michigan Department of Health and Human Services (MDHHS) is removing administrative barriers to improve access to a hepatitis C virus (HCV) treatment for program beneficiaries. This policy is part of the MDHHS We Treat Hep C Initiative to eliminate HCV in Michigan.

Effective April 1, 2021, the product MAVYRET® (glecaprevir/pibrentasvir) will no longer require clinical prior authorization (PA) when prescribed in accordance with Food and Drug Administration (FDA)-approved labeling. This includes removal of the requirement that HCV medications must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist. All providers who have prescriptive authority will be able to prescribe this treatment to their patients with HCV.

MDHHS seeks the assistance of the clinical community to eliminate HCV as a health threat in Michigan by:

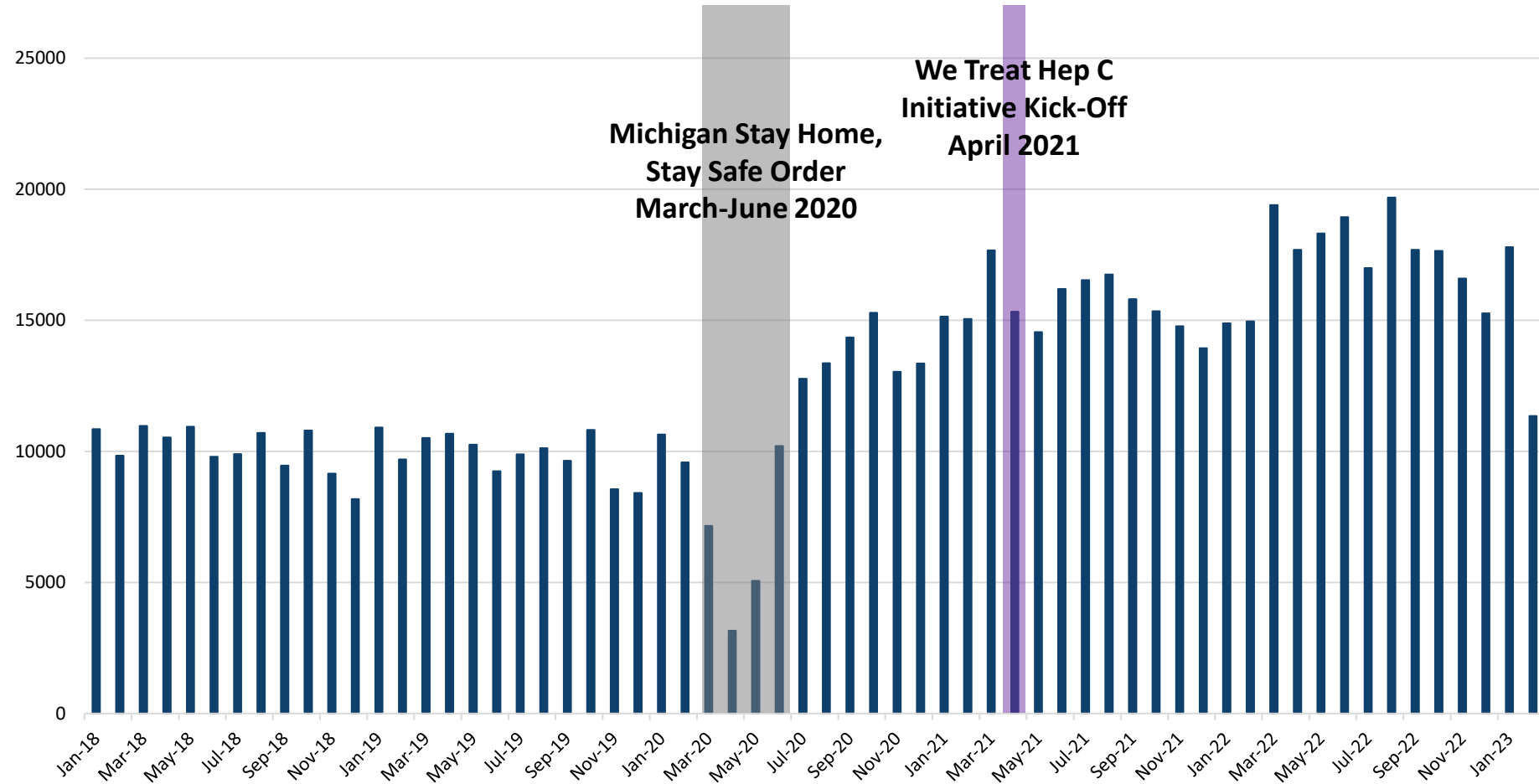
- Screening¹ all adults for HCV infection at least once in their lifetime
- Evaluating those with confirmed HCV infection for treatment
- Prescribing curative therapies for any beneficiary infected with HCV

FROM APRIL 2021 (LAUNCH OF WE TREAT HEP C) – FEBRUARY 2023

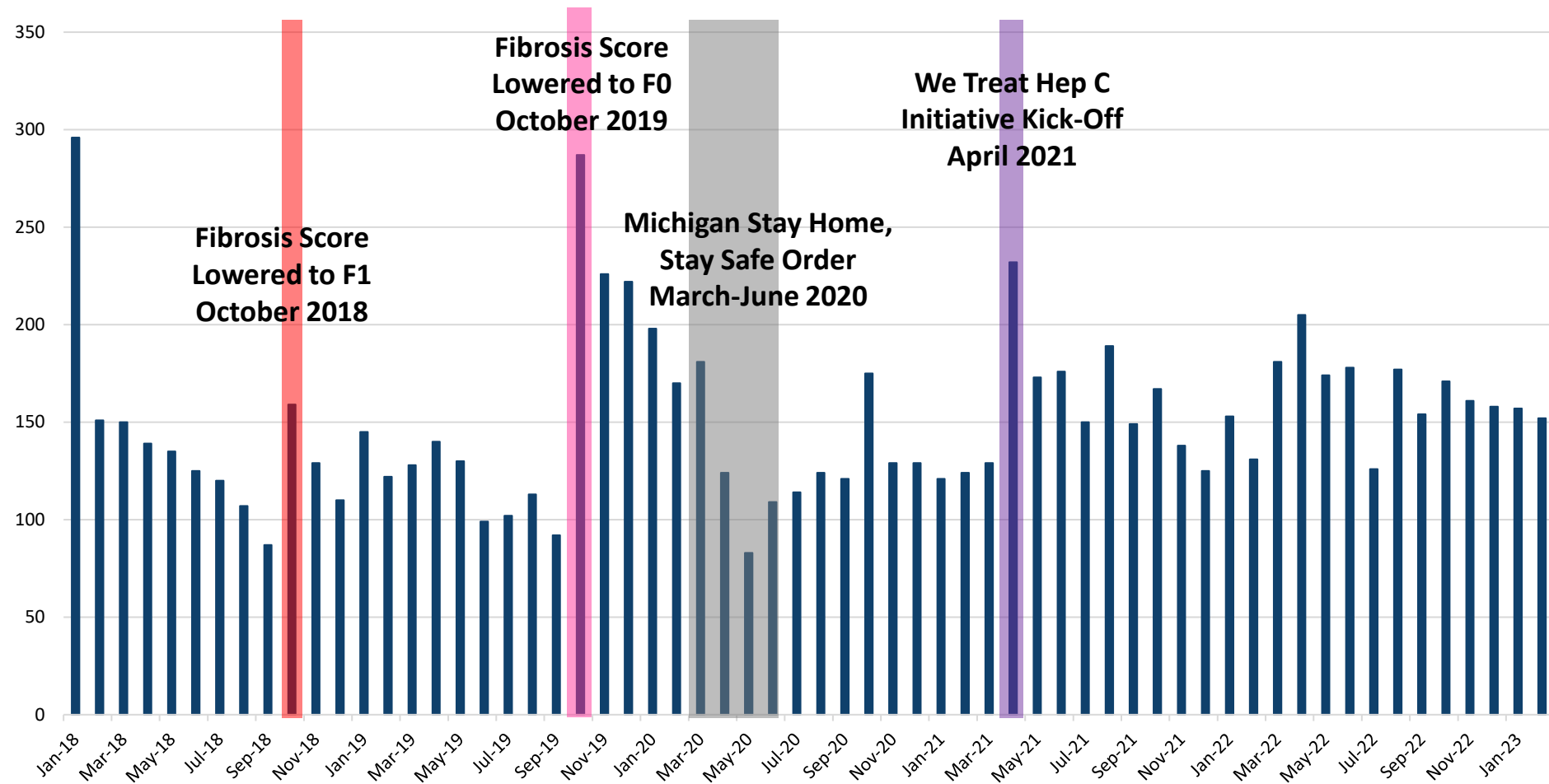


- Added **352** new HCV treatment prescribers
- Screened **288,854** Medicaid beneficiaries for HCV
- Treated **3,469** total Medicaid beneficiaries for HCV

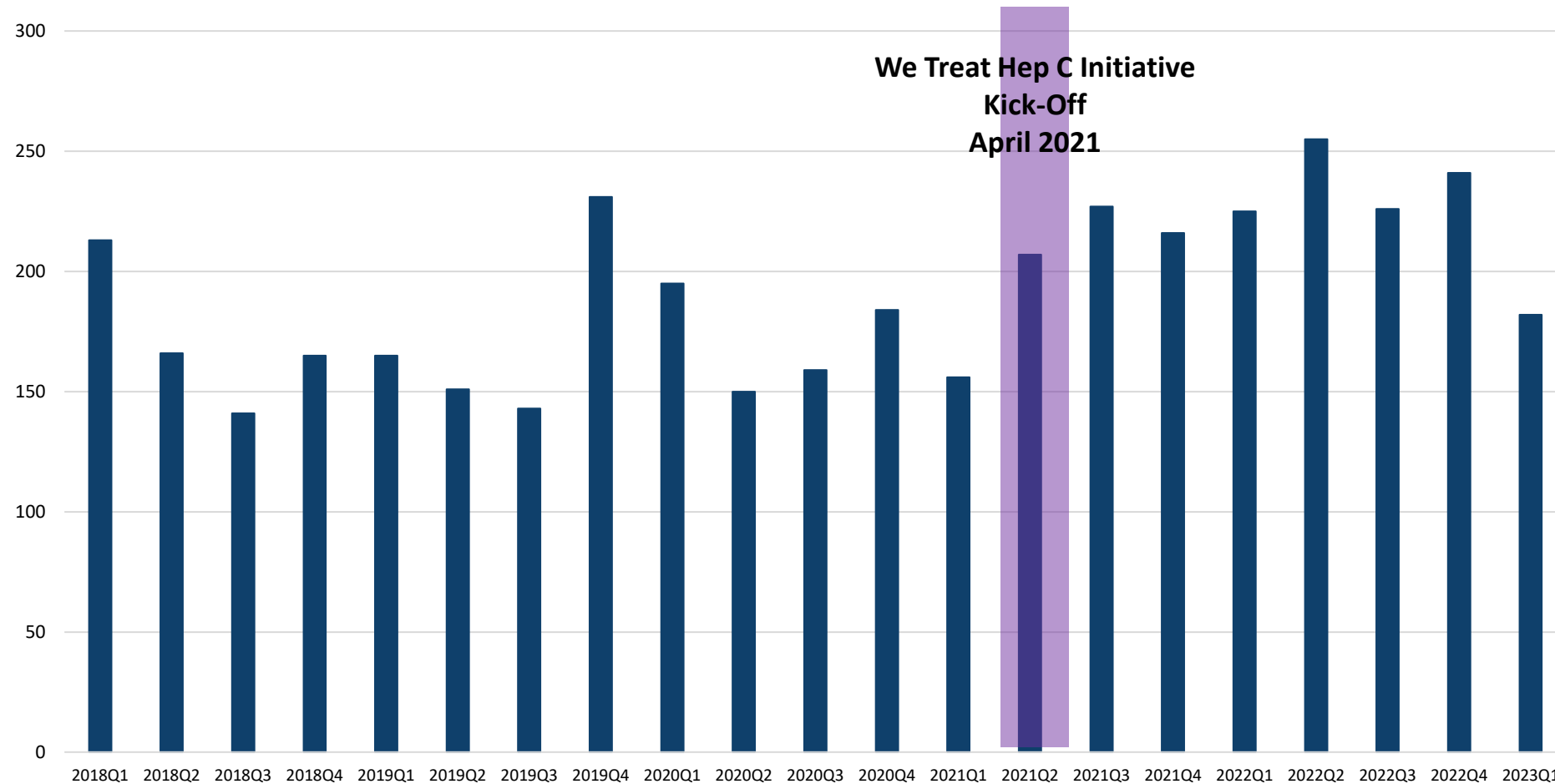
MEDICAID BENEFICIARIES TESTED BY MONTH, 2018-2023, MI



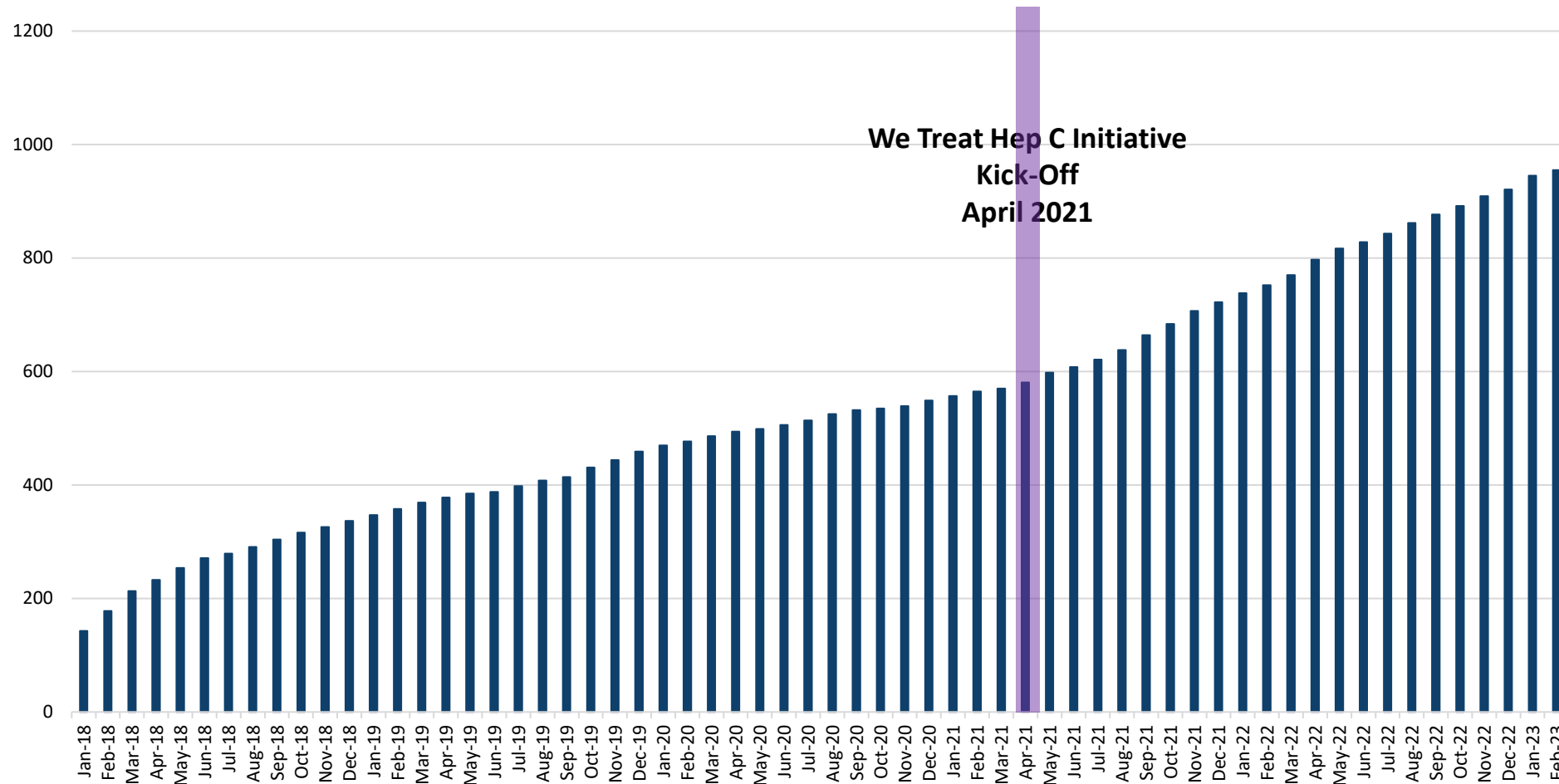
MEDICAID BENEFICIARIES THAT STARTED HCV TREATMENT, 2018-2023, MI



HCV TREATMENT PROVIDERS PRESCRIBING TREATMENT FOR MEDICAID BENEFICIARIES EACH QUARTER, 2018-2023, MI



CUMULATIVE TOTAL OF NEW PROVIDERS WHO PRESCRIBED HCV TREATMENT FOR MEDICAID BENEFICIARIES, 2018-2023, MI



CLINICAL CONSULTATION RESOURCES



- **HENRY FORD HEALTH SYSTEM:** Complimentary clinical consultation line and e-mail box for health care professionals with questions about HCV treatment. Operated from 8 A.M. – 5 P.M. M-F (313) 575-0332
- **WAYNE STATE UNIVERSITY/MIDWEST AIDS TRAINING AND EDUCATION CENTER (MATEC):** On-demand didactic webinars, live training events, office hours, and monthly case discussions. Available for all health care professionals at (313) 962-2000
- **MICHIGAN OPIOID COLLABORATIVE:** Biweekly HCV education and case consultation to support primary care and community providers with diagnosis, treatment planning, and medication management of people living with HCV
- **MSU & MICHIGAN CENTER FOR RURAL HEALTH:** Assist providers and members of the health care team throughout Northern Michigan and the Upper Peninsula to manage infectious disease patients more effectively and confidently. Free CME for health care professionals.
- Additional trainings and resources available at Michigan.gov/WeTreatHepC
- Join the We Treat Hep C listserv by e-mailing MDHHS-Hepatitis@Michigan.gov!

PROVIDER RESOURCES



✕ Testing + Treatment

[CDC Recommendations for Hepatitis C Testing](#)

[ACOG Routine Hepatitis C Virus Screening in Pregnant Individuals](#) this practice advisory includes updated hepatitis C screening guidance to recommend screening for all pregnant individuals during each pregnancy during the first prenatal blood assessment.

[MATEC + WSU Simplified Guidelines for Hepatitis C Treatment in Adults](#) a step-by-step outline to managing HCV patients from testing, assessing liver status, ordering labs, prescribing and monitoring during treatment, to post-treatment evaluation.

[AbbVie Quick Reference Guides](#) for pre-treatment assessment, on-treatment monitoring, and post-treatment follow-up guide

AASLD + IDSA [Hepatitis C Treatment Algorithm for Treatment-Naive Adults Without Cirrhosis](#)

AASLD + IDSA [Hepatitis C Treatment Algorithm for Treatment-Naive Adults With Compensated Cirrhosis](#)

[University of Liverpool - Hep Drug Interaction Checker](#) tool for determining drug-drug interactions with hepatitis C medications

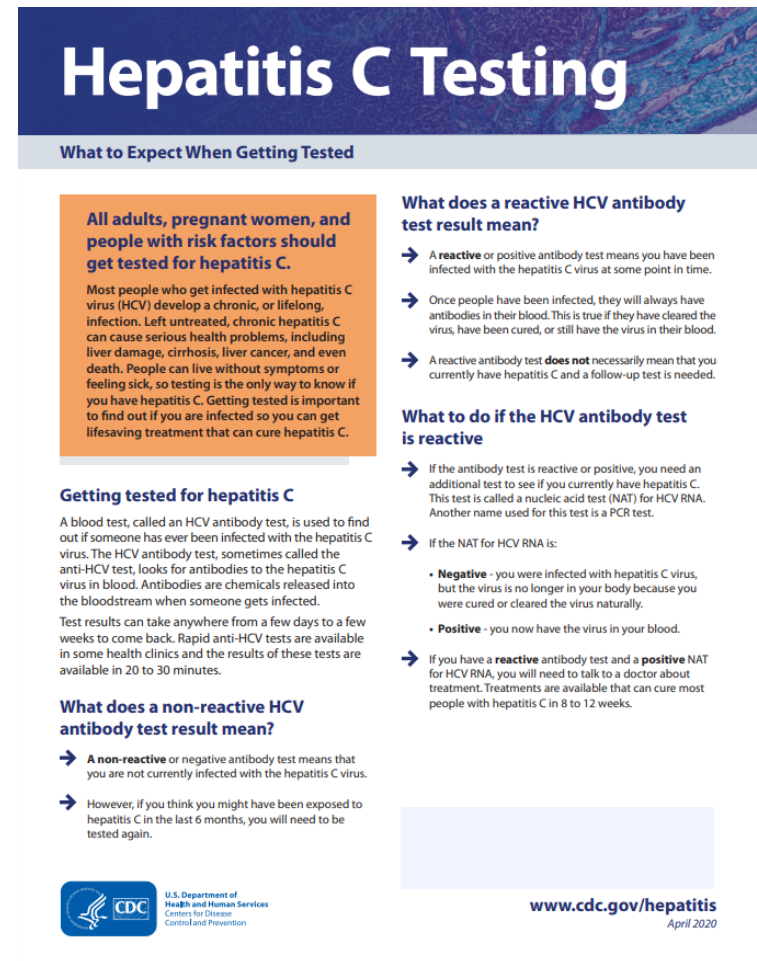
[HCV in Adults Under 40](#) - fact sheet includes epidemiology of hepatitis C among adults under 40, testing recommendations, and information on the We Treat Hep C Initiative

[We Treat Hepatitis C: Clinical Fact Sheet](#) - clinical fact sheet summarizing hepatitis C, the We Treat Hep C Initiative, CDC hepatitis C testing recommendations, and provider trainings and resources

[We Treat Hepatitis C: Patient Fact Sheet](#) - patient fact sheet summarizing hepatitis C, the We Treat Hep C Initiative, CDC hepatitis C testing recommendations, hepatitis C treatment, and resources for the public

PATIENT RESOURCES

- **Hepatitis C Testing Brochure**
- **Help-4-Hep**: Toll-free, confidential, peer-to-peer hepatitis C support line that provides information and resources where you live. (877) 435-7443, M-F from 9 A.M. – 9 P.M. ET
- **Doctor Discussion Guide**: Includes sample template to guide conversations with provider if you either (a) know you have hepatitis C or (b) think you are at risk for hepatitis C. Questions to ask doctor, symptoms experienced, diagnosis date, treatments taken, etc.
- **We Treat Hep C Initiative Fact Sheet – Patients**: Fact sheet which explains what HCV is, who should be tested, information about treatment, information on what the We Treat Hep C Initiative is, and additional resources and contact information.
- ***Some materials also available in Spanish as well.***



Hepatitis C Testing

What to Expect When Getting Tested

All adults, pregnant women, and people with risk factors should get tested for hepatitis C.

Most people who get infected with hepatitis C virus (HCV) develop a chronic, or lifelong, infection. Left untreated, chronic hepatitis C can cause serious health problems, including liver damage, cirrhosis, liver cancer, and even death. People can live without symptoms or feeling sick, so testing is the only way to know if you have hepatitis C. Getting tested is important to find out if you are infected so you can get lifesaving treatment that can cure hepatitis C.

Getting tested for hepatitis C

A blood test, called an HCV antibody test, is used to find out if someone has ever been infected with the hepatitis C virus. The HCV antibody test, sometimes called the anti-HCV test, looks for antibodies to the hepatitis C virus in blood. Antibodies are chemicals released into the bloodstream when someone gets infected.

Test results can take anywhere from a few days to a few weeks to come back. Rapid anti-HCV tests are available in some health clinics and the results of these tests are available in 20 to 30 minutes.

What does a non-reactive HCV antibody test result mean?


- A **non-reactive** or negative antibody test means that you are not currently infected with the hepatitis C virus.
- However, if you think you might have been exposed to hepatitis C in the last 6 months, you will need to be tested again.

What does a reactive HCV antibody test result mean?

- A **reactive** or positive antibody test means you have been infected with the hepatitis C virus at some point in time.
- Once people have been infected, they will always have antibodies in their blood. This is true if they have cleared the virus, have been cured, or still have the virus in their blood.
- A reactive antibody test **does not** necessarily mean that you currently have hepatitis C and a follow-up test is needed.

What to do if the HCV antibody test is reactive

- If the antibody test is reactive or positive, you need an additional test to see if you currently have hepatitis C. This test is called a nucleic acid test (NAT) for HCV RNA. Another name used for this test is a PCR test.
- If the NAT for HCV RNA is:
 - **Negative** - you were infected with hepatitis C virus, but the virus is no longer in your body because you were cured or cleared the virus naturally.
 - **Positive** - you now have the virus in your blood.
- If you have a **reactive** antibody test and a **positive** NAT for HCV RNA, you will need to talk to a doctor about treatment. Treatments are available that can cure most people with hepatitis C in 8 to 12 weeks.

 U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

www.cdc.gov/hepatitis
April 2020

HCV TREATMENT PROVIDER MAP + DIRECTORY

Michigan.gov/WeTreatHepC

Find a Hepatitis C Treatment Provider

To find a hepatitis C treatment provider in Michigan, zoom in on the map below. Use the search function to identify providers within a city, zip code, or county. Location markers on the map have been color coded to denote service provider type.

Disclaimer: Listings in the Hepatitis C Treatment Provider Map are for informational purposes and is not a complete list of all hepatitis C treatment providers in the state of Michigan. Inclusion in the map is for providers who have given consent to be added and MDHHS' endorsement or recommendation of, or for, any individual, service, treatment, or organization. Phone numbers, addresses, and service information are subject to change.



To add, remove, or update the information about a medical facility or provider, e-mail MDHHS-Hepatitis@Michigan.gov.

For a printable listing of the Hepatitis C Treatment Provider map above, please download the [Hepatitis C Treatment Provider](#)

HEPATITIS C TREATMENT PROVIDER DIRECTORY

ALPENA COUNTY

1. Alpena Express Care and Family Practice
109 S Thirteenth Avenue, Alpena, MI 49707
Phone: 989-356-2400 | Providers: Dr. David Dargis, Dr. Douglas King

2. Alcona Health Center
1185 U.S. 23 North, Alpena, MI 49707
Phone: 989-356-4049 | Providers: Dr. Maureen Mead

ARENAC COUNTY

3. Sterling Area Health Center
725 East State Street, Sterling, MI 48659
Phone: 989-654-3501; 989-654-2491 | Providers: Dr. Linda Runyon, Elizabeth Kitchen, NP, Joshua Leonard, NP, Vivian Gallofin, NP

4. Ascension Standish Hospital
805 West Cedar Street, Standish, MI 48658
Phone: 989-846-3500 | Providers: Dr. Ibrahim Shamieh

BARAGA COUNTY

5. Health and Education Center KBIC Med Clinic
102 South Superior Avenue, Baraga, MI 49908
Phone: 906-353-8787 | Providers: Dr. Edward Lelonek, Jody Jinkerson, NP, Jennifer Scott, NP, Brittany Wadaga, NP

BARLY COUNTY

6. Spectrum Health Clinic General Surgeon—Hastings Surgeons PC
1005 West Green Street Suite 300, Hastings, MI 49058
Phone: 269-948-8411 | Providers: Dr. David Dargis

BRANCH COUNTY

7. Charles Whitaker, MD Family Medicine
436 Marshall Street, Coldwater, MI 49036
Phone: 517-278-6600 | Providers: Dr. Charles Whitaker

CALHOUN COUNTY

8. Digestive Health Center
3770 Capital Avenue SW Suite B, Battle Creek, MI 49015
Phone: 269-385-9900 | Providers: Amy Ball, PA, Dr. Tarun Sharma, Dr. Silviu Locovei, Dr. Aljaz Turk, Dr. Brij Dewan

9. Calhoun County Health Department
190 East Michigan Avenue, Battle Creek, MI 49014
Phone: 269-969-6363 | Providers: Michelle Thorne, MSN, FNP-BC

10. Calhoun County Health Department
214 East Michigan Avenue, Albion, MI 49224
Phone: 517-629-9434 | Providers: Michelle Thorne, MSN, FNP-BC

DELTA COUNTY

11. Bellin Health Escanaba
610 S Lincoln, Escanaba, MI 49829
Phone: 906-786-6488 | Providers: Stephen Young, PA, Brian Guindon, PA

DETROIT

12. Wayne Health—Multispecialty Clinic
4160 John R Suite 917, Detroit, MI 48201
Phone: 313-745-4525 | Providers: Jennifer Gideon, NP, Dr. Milton Mutchnick, Dr. Katherine Wong, Dr. Thomas Kelley, Dr. Bashar Mohamad, Sharlet Geevarughese, NP

13. Wayne Health—Tolan Park
3901 Chrysler Drive Suite 4A, Detroit, MI 48201
Phone: 313-966-7601 | Providers: Dr. Jonathan Cohn, Dr. Prateek Lohia, Dr. Gretchen Snoeyenbos Newman

DISCLAIMER: Listings in the Hepatitis C Treatment Provider directory are for informational purposes and is not a complete list of all hepatitis C treatment providers in the state of Michigan. Inclusion in the directory is for providers who have given consent to be added and does not constitute MDHHS' endorsement or recommendation of, or for, any individual, service, treatment, or organization. Phone numbers, addresses, and service information are subject to change.

MAIN TAKEAWAYS

- **OPTIMIZE HCV TESTING!**

- Implement **new** universal HCV testing recommendations
- Implement opt-out HCV testing (all patients get tested, individuals have to decline)
- Adopt HCV reflex testing (automatic confirmatory testing for HCV RNA if HCV Ab is positive)

- **LINK TO CARE INDIVIDUALS WITH HCV OR TREAT HCV!**

- Provide education and link individuals with HCV to care
- Implement HCV treatment in the LHD setting, or collaborate with local providers to treat HCV

- **RAISE AWARENESS OF HCV!**

- Educate providers on WTHC Initiative and ability to treat MI Medicaid/HMP beneficiaries for HCV
- Issue press releases and social media posts, put up posters and educational materials
- Update website to include up-to-date information on HCV (background, transmission, testing recommendations, treatment options, etc.)

Hepatitis C Rapid Testing

Information, Administration, and MORE!



HCV Rapid Antibody Test

- The first FDA-approved, CLIA-waived rapid HCV test
- Detects HCV antibodies via a fingerstick
- Point-of-care testing results in 20 minutes
- Greater than 98% accurate



What is a CLIA-waived test?

- Clinical Laboratory Improvement Amendments
- By the CLIA law, waived tests are those tests that are determined by CDC or FDA to be so simple that there is little risk of error
- A person or entity that is not federally certified to test and report on human specimen testings may report on the results of human specimen tests if the test is a CLIA waived test
- When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver
- More information on applying for Certificate of Waiver:
<https://www.michigan.gov/lara/bureau-list/bchs/providers/clia>

Hepatitis C Screening Recommendations

- At least once in a lifetime for all adults 18 years and older
- All pregnant people during each pregnancy
- Routine periodic testing for persons with ongoing risk factors (substance use)
- Any person who requests HCV testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks

Hepatitis C Testing

IT TAKES TWO TESTS TO SEE, IF YOU HAVE HEPATITIS C.

ANTIBODY



An Antibody test detects if you have **been exposed** to hepatitis C.

A positive result only means that you have **been exposed** to hepatitis C.

If your Antibody test is positive, you need to take and RNA test to know if you are currently infected with hepatitis C.

RNA



An RNA test can tell if you are **currently** infected with Hepatitis C.

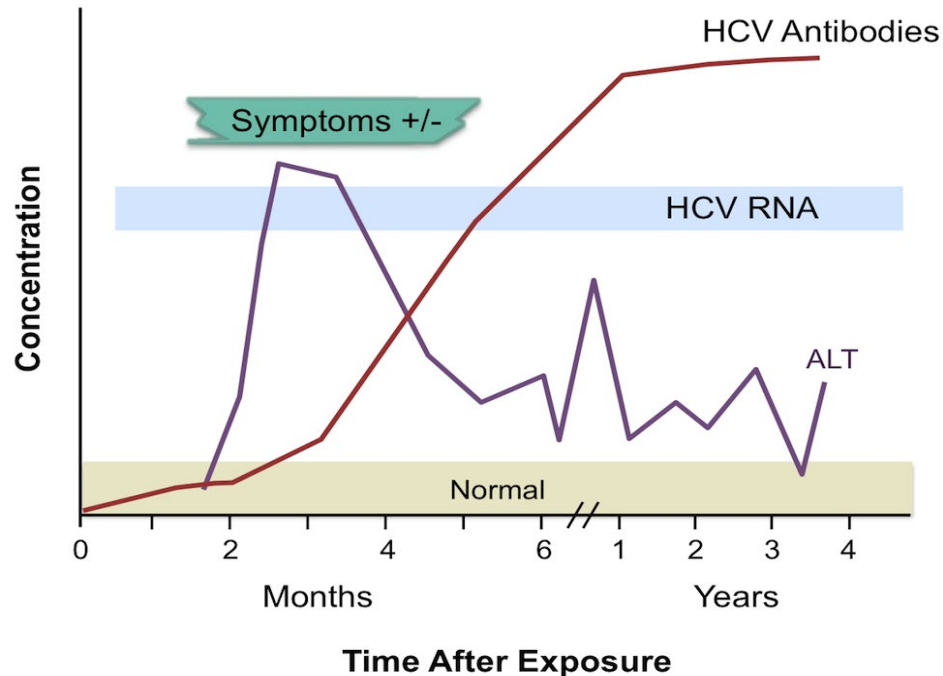
If you test positive, there are new medications that can **CURE** your hepatitis C infection with very minimal side effects!

A negative test result means that your body fought off the infection **without** medical help.

Reminders:

- Rapid HCV POC test only detects antibodies and positive result does not confirm HCV infection. Linkage to HCV confirmatory testing (blood draw) process will need to be established.
- If exposed to HCV, HCV antibody test will ALWAYS be positive!!

Hepatitis C Detection Timeline



- HCV RNA levels first become detectable, followed by increases in ALT levels, and then detectable HCV antibody.
- In most patients, HCV RNA is detectable in blood within 1 to 2 weeks after infection
- HCV antibodies to HCV typically become detectable at about 50 to 60 days after infection (range 20 to 150 days)
- The use of only an HCV antibody test to diagnose acute HCV is not reliable, since only approximately 50 to 70% of patients have detectable HCV antibodies at the onset of symptoms. Further, a positive HCV antibody test does not differentiate acute from chronic HCV infection.
- “Gold standard” of HCV detection is through a blood draw (HCV RNA PCR)

How to use the OraQuick HCV Rapid Test

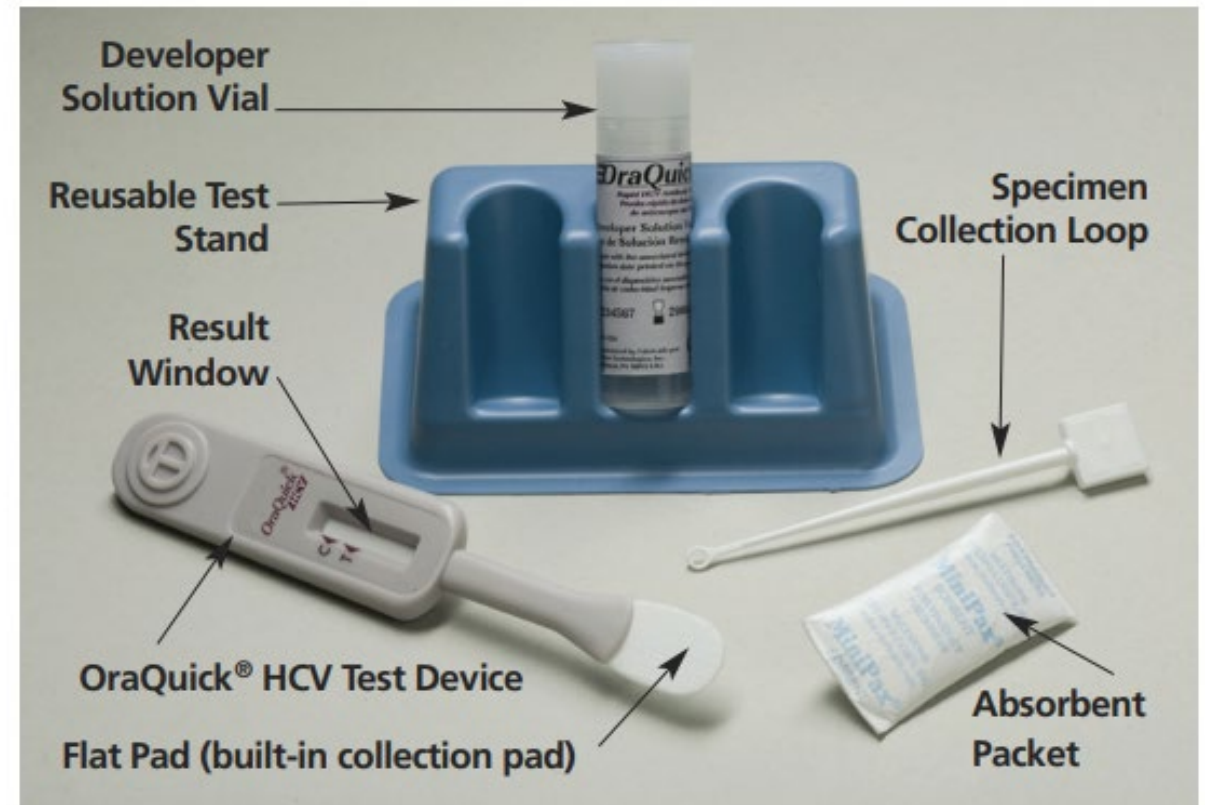
Prior to Testing

- Observe “Universal Precautions” at all times
- Confidential space
- Set up workspace cover and reusable test stand on a flat level surface
 - Additional materials required, but NOT provided:
 - Lancet
 - Gauze pad
 - Gloves
 - Bandage
 - Timer or watch
 - Biohazard waste container
 - Disposable, absorbent workspace cover

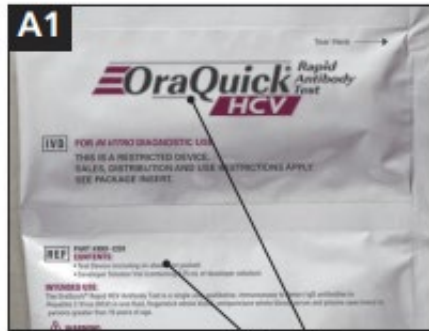


OraQuick HCV Rapid Antibody Test Kit

- Single-use testing device with built-in procedural control
- Single-use test developer solution vial
- Reusable test stand
- Disposable single-use specimen collection loop



General Test Preparation



Two Chambers



- Check expiration date on the OraQuick HCV pouch
- Place reusable test stand on your workspace
- Set timer for 20 mins, but don't start
- Do not open the pouch until are ready to perform test
 - Discard if damaged
- After opening pouch, check for absorbent packet
 - Discard if it's not present/damaged
- Hold developer solution firmly in your hand. Remove cap by rocking it back forth while pulling it off and set cap aside and slide the vial into the tops of one of the slots on the stand.
- Leave the OraQuick HCV Test Device in the pouch until testing is started

General Test Preparation



- Ensure you have all supplies on hand
- Gain informed consent
- Complete all pre-requisite paperwork and clear testing space
- Wash or sanitize hands
- Put on gloves
- Avoid touching any objects/surfaces, as much as possible, after gloves are on
- Ensure correct operating temperature (59°-99°F)

Simple, 3-step procedure

1) Collect



2) Mix

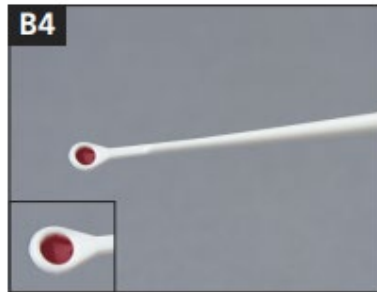
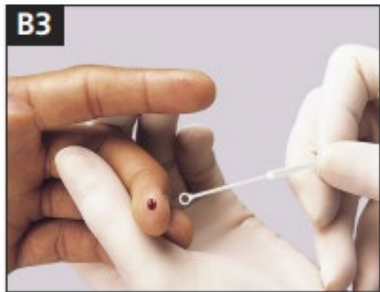
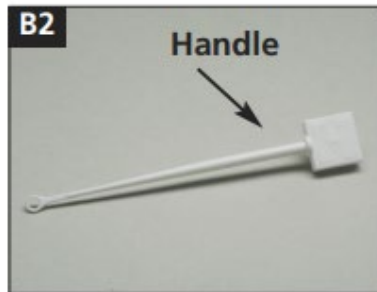


3) Read



*See "OraQuick HCV Step-by-Step"

Step 1: Specimen Collection



NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

- Remove test device from Pouch
 - Do not touch the flat pad
- Label device if necessary →
- Using an antiseptic wipe, clean the finger of the person being tested. Allow to air dry
- Using a sterile lancet, puncture skin off center of finger pad
- WIPE the first droplet with gauze. Hold the hand downward for new droplet. Gently apply pressure to express if needed
- With the new specimen collection loop, touch the droplet
- Make sure the loop is completely filled with blood

DO NOT cover the 2 holes on the back of the OraQuick HCV Test Device with labels or other materials. Blocking the holes may cause invalid result.



Step 2 – Mix



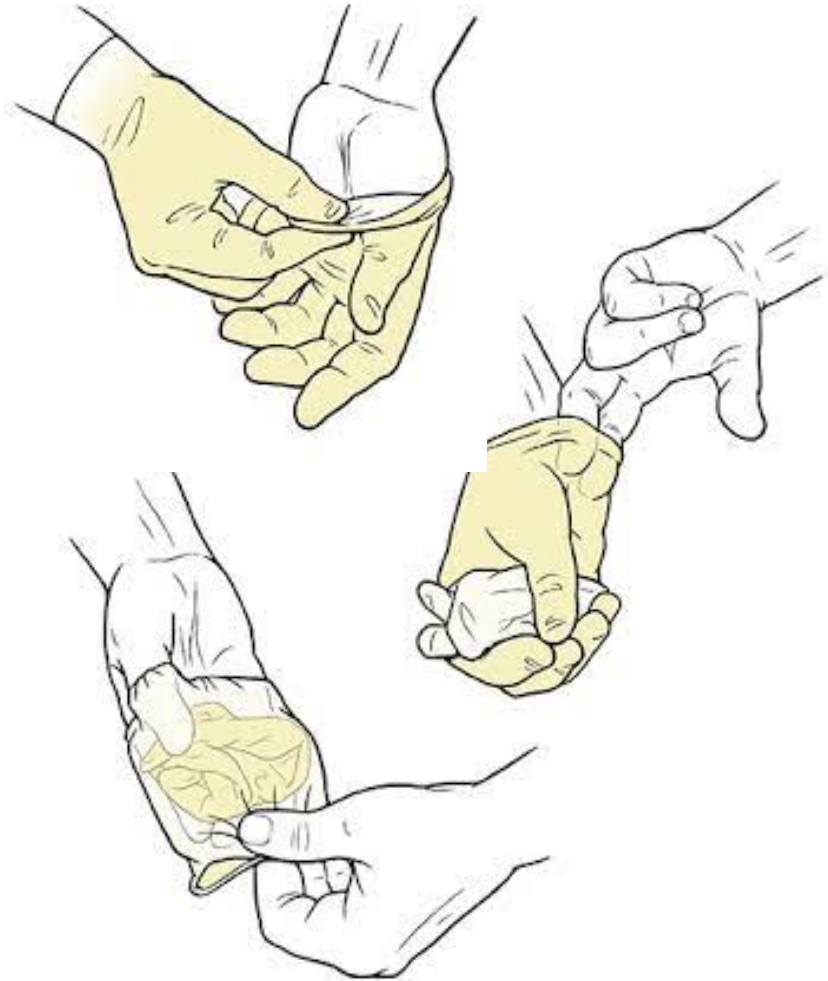
- Insert blood-filled end of loop into the vial. **Be careful not to touch the sides of the vial**
- Use the loop to stir sample in vial. Dispose of used loop in biohazard waste container
- Check solution to make sure it appears pink in color

Step 3 - Test



- Insert flat pad of device into the bottom of developer vial
- Start timing test
- Pink fluid will travel up result window. Fluid disappears as test develops. **DO NOT** remove device while test is running
- Read results after 20 minutes but ***not more*** than 40 minutes. Adequate lighting must be available!

After Test Has Started



- Remove gloves
 - Avoid contact between inside and outside of gloves
 - Pinch one glove near wrist and peel off of hand
 - Hold removed glove in other, gloved hand
 - With ungloved hand, put two fingers inside of other glove and peel to turn inside-out while holding other glove
 - Dispose of gloves in acceptable hazmat container
 - Wash or sanitize hands
- Complete any necessary paperwork
- Provide counseling and answer questions

Reading & Interpreting a Non-Reactive Test



A test is **NON-REACTIVE** if:

- A line appears in the “C” zone and no line appears in the “T” zone.

A **Non-Reactive** test result means that HCV antibodies were not detected in the specimen.

Patient is presumed not to be infected with HCV.

Reading & Interpreting a Reactive Test



A test is **REACTIVE** if:

- A line appears in the “C” zone and a line appears in the “T” zone. Lines may vary in intensity

NOTE: The test is reactive if any line appears in the “T” zone and in the “C” zone, no matter how faint.

A Reactive test result means that HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV.

Individuals with a reactive result should undergo appropriate clinical follow-up according to CDC recommendations for supplemental testing.

Reading an Invalid Test



A test is INVALID if:

- No line appears in the “C” zone **or**
- A pink background in the result window makes it difficult to read the result during the 20 to 40 minute read times, **or**
- If any of the lines are **partially developed** on one side of the “C” or “T” zones

An Invalid result cannot be interpreted. Repeat the test with a new pouch and new specimen. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.

Demonstration

Delivering Results



Invalid

- Offer to re-test client or refer for RNA blood draw

Non-reactive (negative)

- Review “window period” with client and advise re-test if risk occurred within 2 months
- Provide counseling on risk reduction

Reactive

Reactive should be treated as if client was living with active HCV infection. Provide information and linkage to follow-up testing and care. Refer for HAV and HBV vaccination.

Report test to Local Health Department or through MDSS!

*See “Script for Delivering Reactive Hepatitis C Antibody Results”

Kit Controls

External Kit Controls

- Positive and Negative Kit Controls provide:
 - Quality Control to:
 - Assure test performance
 - Provide for user proficiency
- Positive Controls
 - Are calibrated specifically to a very low assay reactivity level (challenge line)
 - Low assay performance reaffirms assay functionality (assay chemistry)
 - Provide better training tool for user proficiency



Positive Control

- Purple-capped vial – inactivated human plasma positive for antibodies to HCV.

Negative Control

- White-capped vial – human plasma negative for antibodies to HCV.

Sufficient volume to perform 25 tests

It is important that test operators read the OraQuick® HCV Rapid Antibody Test Kit, Kit Control and Visual Reference Panel Package Inserts prior to performing the test procedure. This training is not intended to replace this requirement.

Test Kit Control Contents

#1001-0182 OraQuick® HCV Rapid Antibody Test Kit Controls	
Positive HCV Control Vial (Purple Cap)	(1) 0.2mL
Negative Control Vial (White Cap)	(1) 0.2mL
Package Insert	1
Storage Requirements	2-8° C (36-46° F)
Shelf-Life	1 Year from Date of Manufacture or 8 weeks after initial opening of packaging

Note: Kit Controls do not have to be brought to operating temperature prior to performing quality control testing.

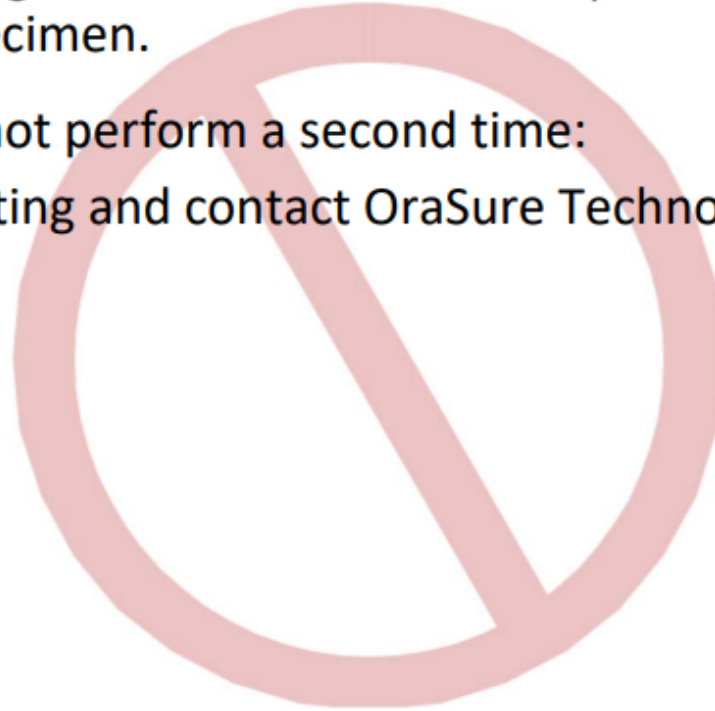
Test Kit – Kit Controls

Run one positive HCV control (+), and one negative control (-) for:

- Each new operator
- Each new lot of test kits
- Each new shipment of test kits
- Test kit storage temperature falls outside 2-30°C; 36-86°F
- Testing area temperature falls outside of 15-37°C; 59-99°F
- At periodic intervals dictated by user facility

Kit Control Failure

- If test result does not perform as expected:
 - Repeat test using new Test Device, Developer Solution Vial, and Control Specimen.
- If test result does not perform a second time:
 - Discontinue testing and contact OraSure Technologies Customer Care.



Process for Ordering HCV Rapid Test Kits

1. Email MDHHS-Hepatitis@Michigan.gov with request
2. You will receive a one-page form to complete and send back
3. You will receive an email confirming order has been placed

OraQuick Rapid Hepatitis C Test Kit Order Form

Please complete all areas of the request form.
Email your request to the MDHHS Viral Hepatitis Unit at:
MDHHS-Hepatitis@Michigan.gov

Date Requested:

Agency:

Contact Person:

Telephone:

Email Address:

Shipping Address:

Quantity Requested (quantities of 25):

Quantity Controls Requested:

Training Requested:

Date Needed:

Target Population:

Please describe the setting which HCV testing will be conducted (e.g., type of outreach, clinic, jails, festivals, etc.):

Reporting HCV + Ab Results

- By law hepatitis C Ab results are required to be reported to public health.
- Two ways:
 1. If you have access to MDSS, please manually enter this lab. Please reach out to MDHHS-Hepatitis@Michigan.gov if you need assistance.
 2. Please complete the HCV Rapid Test Report Form and fax to our secure line at [517-335-8263](tel:517-335-8263) and MDHHS Viral Hepatitis Unit will manually enter this lab into MDSS.

Hepatitis C Reporting Form (Rapid Test)

INSTRUCTIONS: Please complete the following case report form for each person being tested for hepatitis C by rapid test. Upon completion, please submit the completed form to the **Michigan Department of Health and Human Services' Viral Hepatitis Unit** by secure fax at 517-335-8263.

For questions, please contact MDHHS-Hepatitis@Michigan.gov or call 517-335-8165 (Monday-Friday, 8 A.M. – 5 P.M.).

Case Information and Demographics		
First: Click or tap here to enter text.	Last: Click or tap here to enter text.	Middle: Click or tap here to enter text.
Street Address: Click or tap here to enter text.		
City: Click or tap here to enter text.	County: Click or tap here to enter text.	Zip Code: Click or tap here to enter text.
Home Phone: Click or tap here to enter text. <input type="checkbox"/> Cell <input type="checkbox"/> Home <input type="checkbox"/> Work	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	Date of Birth: Click or tap to enter a date.
Other Phone: Click or tap here to enter text.		
Race (check all that apply): <input type="checkbox"/> White/Caucasian <input type="checkbox"/> Black/African American <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Hawaiian/Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> Unknown <input type="checkbox"/> Refused to answer <input type="checkbox"/> Other (specify): _____		
Hispanic Ethnicity: <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Non-Hispanic/Latino <input type="checkbox"/> Unknown <input type="checkbox"/> Refused to answer		
Laboratory Test Results		
Testing Agency: Click or tap here to enter text.		
Testing Date: Click or tap to enter a date.	Test Type: <input checked="" type="checkbox"/> OraSure OraQuick HCV Rapid Antibody Test	Test Result: <input type="checkbox"/> Reactive <input type="checkbox"/> Non-Reactive
Linkage to Care		
If individual is positive, will your agency be providing navigation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Navigation		
Notes		
Click or tap here to enter text.		

Summary and Things to Consider for HCV Testing



- Venous blood draw for HCV RNA testing is the “gold standard”
- HCV Ab will always be positive after someone has been exposed. Regardless if they were treated or cured on their own.
- How will you communicate result to client/patient if they don’t want to wait the 20 mins? What if they don’t have a phone?
- HCV Ab + = doesn’t necessarily mean the person is actively living with hepatitis C. You will want to come up with a process to get client/patient linked to confirmatory testing (HCV RNA blood draw)
 - Most Local Health Department’s HIV/STI clinics perform FREE HCV testing via a blood draw. Specimen gets sent to the State Public Health Lab (BOL) in Lansing and they will do reflex testing → If Ab is + then automatically reflex to RNA
 - We can onboard sites to become a submitter to BOL and results will get faxed directly to you. Please contact MDHHS-Hepatitis@Michigan.gov for more information
- Questions or trainings regarding HCV 101 and linkage to care? Please contact MDHHS-DIS@Michigan.gov

Linkage to Care and Case Management

To what extent will your staff navigate people through the system?

Referral to
Confirmatory
Testing

Referral to
Treatment

Case
Management
through SVR

Linkage to Confirmatory Testing

Can your organization draw blood for specimen submission?



Will you refer participants to another organization?



Be able to communicate or address:

Hours of operation and
locations

Appointment requirements
(walk in, scheduled, etc.)

Cost to participant

Barriers to access:
transportation, phone
access, etc.



Make sure to track all tests and referrals in the SUP!

Linkage to Treatment

Will your organization link to treatment?

- Can your organization treat for HCV?
- Will you refer participants to another organization?
- If another organization is conducting confirmatory testing, will they link the participant to treatment?

Be able to communicate:

- Hours of operation, locations, and appointment requirements.
- Myths about HCV treatment (reinfection, DAAs, costs, sobriety)
- Barriers to access: transportation, phone access, etc.

Case Management through SVR

Will your organization or partner organization follow up to get RNA- result after treatment?

If a case needs long term follow up, will someone provide that (such as incarceration, pregnancy, etc.)?

Successes and Challenges in Implementing Rapid Testing in an SSP Setting



Thank you!!

Teresa Juridico,
WongT@Michigan.gov

Zekiye Lukco,
SalmanZ@Michigan.gov

Lauren Hodson,
HodsonL@Michigan.gov