ESP CASE DETECTION ALGORITHM

Hepatitis C

Acute Hepatitis C, Chronic Hepatitis C

Document Version 3.2

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Modification History

Version	Date	Modification	By
3.2	11/17/2017	• Added criteria to specify which diagnosis codes are allowed on the case date for acute cases. • Added criteria to always classify cases <18 months old as chronic. • Modified medication list and treatment reporting criteria.	MDPH/DPM
3.12	10/11/2017	Added ESP Logo and MDPH branding	DPM
3.11	10/4/2017	Transferred to updated template	DPM
3.1	8/10/2017	• Added acute vs. chronic classification flag • Modified reporting window for symptoms • Added genotype labs to reporting criteria	MDPH/DPM
3.0	6/16/2017	• Included criteria for identifying chronic hepatitis C. • Updated data to include with case report based on revised teleform.	MDPH/DPM
2.1	5/23/2017	• Removed hepatitis A and hepatitis B labs from data included in case reports to DPH.	MDPH/DPM
2.0	2/8/2017	• Updated case report criteria based CSTE 2016 acute hepatitis C case definition. • Added appropriated ICD-10-CM diagnosis codes.	DPM
1.0	6/16/2014	• Original circulated version for *acute* hepatitis C.	DPM

Section 1. *Overview*

The purpose of this document is to describe the criteria used to identify and report hepatitis C cases and their continuum of care from electronic medical records (EMR) using ESP. ESP will identify all patients with a positive hepatitis C laboratory test, report them to the Massachusetts Department of Public Health (MDPH), and provide follow-up reports for subsequent events relevant to the continuum of care (e.g. repeat hepatitis C testing, hepatitis C treatment, etc.). In addition, ESP will make a presumptive classification of whether a case is acute or chronic. This indicator will be added to case reports for MDPH review but final classification is at MDPH's discretion.

Section 2. *Criteria used to identify cases using ESP data*

I. CASE TYPES

This document includes an algorithm to identify hepatitis C cases and to make a presumptive classification of acute hepatitis C or chronic hepatitis C at the time of case detection using each patient's clinical data.

II. TIME WINDOW

A. ACUTE HEPATITIS C

There is no recurrence window for acute Hepatitis C. A case is considered incident if it is the first time the criteria for acute hepatitis C are met and it has not been previously reported.

B. CHRONIC HEPATITIS C

A hepatitis C case is considered chronic if a patient has positive tests for hepatitis C but does not meet criteria for acute hepatitis C. A patient will remain a chronic Hepatitis C case lifelong.

III. CASE CRITERIA

A. CASE COMPONENTS*

1. Diagnosis code for jaundice
2. Alanine aminotransferase (ALT) >200
3. Hepatitis C ELISA = "REACTIVE"
    a. If Hep C ELISA result is quantitative then interpret as follows:
        - If ELISA Index ≥11 then ELISA is positive
        - If ELISA Index ≤0.80 then ELISA is negative
        - If ELISA Index between 0.80 and 10.99 then ELISA is positive only if positive RIBA or positive Hep C RNA or positive ELISA (with index ≥11) within the next 7 days.
4. Hepatitis C Signal Cutoff Ratio ≥3.8
5. Hepatitis C RIBA = "POSITIVE"
6. Hepatitis C RNA = "DETECTED" or viral load above the limit of detection of the test
7. Diagnosis code for unspecified Hepatitis C
8. Diagnosis code for chronic Hepatitis C
9. Total bilirubin > 1.5

*See Section 4 for codes used to define each component.

B. **CRITERIA FOR HEPATITIS C CASES**

Summary of Case Components					
1	Jaundice ICD9/10 Code	4	Signal cut-off ratio	7	Unspecified Hep C ICD9/10 code
2	ALT>200	5	RIBA	8	Chronic Hep C ICD9/10 code
3	ELISA	6	RNA	9	Total bilirubin > 1.5

ACUTE HEPATITIS C:

a) (#1 or #2 or #9) and #3 positive and #4 positive (if done) and #5 positive (if done) and #6 positive (if done)within a 28 day period; AND no prior positive #3 or #5 or #6 ever; AND no diagnosis code for #7 ever prior to this encounter AND no diagnosis code for #8 ever prior to *or on the day of* this encounter

b) (#1 or #2 or #9) and #6 positive and #4 positive (if done) and #5 positive (if done) and within a 28 day period; AND no prior positive #3 or #5 or #6 ever; AND no diagnosis code for #7 ever prior to this encounter AND no diagnosis code for #8 ever prior to *or on the day of* this encounter

c) #6 positive and record of (#3 or #6 negative within the prior 12 months) AND no prior positive #3 or #5 or #6 or #7ever

d) #3 positive and record of (#3 or #6 negative within the prior 12 months) AND no prior positive #3 or #5 or #6 or #7ever

CHRONIC HEPATITIS C:

e) #3 positive, #4 positive, #5 positive, or #6 positive AND does not meet criteria for Acute Hepatitis C

f) Case is <18 months old as of the case identification date, regardless of whether criteria a-d is met

Notes:

- Patients without any orders for tests 4 or 5 or 6 can still meet definition (a) for acute hepatitis C so long as they fulfill the rest of the definitions. Likewise, patients without orders for 4 or 5 can still fulfill definition (b). These criteria are to exclude patients with negative results on these tests but they are not needed to rule in the presence of acute disease.
- Use “date collected” rather than date ordered or date resulted for time period assessments.
- Minimum period between positive and negative tests for definitions (c) and (d) is >1 day.

Section 3. *Specifications for reporting diseases/conditions to the Massachusetts Department of Public Health*

I. INITIAL CASE REPORTING CRITERIA

All cases should be immediately reported to MDPH upon initial detection. Each patient is only reported the first time they meet the case definition.

II. CASE REPORT UPDATE CRITERIA

An updated report should be set to MDPH whenever any of the following occur:

1. Serial hepatitis C RNA results
2. Hepatitis C genotype results
3. Serial ALT, AST, and platelet count results
4. Prescription for hepatitis C medication (new medication, not a renewal)

III. DATA TO INCLUDE IN INITIAL REPORTS TO MDPH

A. Demographic

Name	Last, first, middle
Date of birth	yyyy/mm/dd
Gender	Male / Female
Race	American Indian / Asian / Black / White / Other / Unknown
Ethnicity	Hispanic / Non-Hispanic / Unknown
Address	Line 1, line 2, city, state, zip, country
Phone	xxx-xxx-xxxx
Language spoken	
Medical record number	
PCP	Name, office address, phone number, email
Country of Birth	
Housing Status	

B. Ordering Facility Information

Facility name	
Facility address	Line 1, line 2, city, state, zip
Facility contact person	
Contact person email	
Contact person phone	xxx-xxx-xxxx
Facility phone	xxx-xxx-xxxx

C. Encounter Data

Lab test ordering clinician	Name, office address, phone number, email
Treating clinician	Name, office address, phone number, email

D. Laboratory Results

Most recent result within 28 day period of day on which case established. ***Include test dates.***

HCV Antibody ELISA	
HCV Antibody ELISA prior test	If case established on basis of change in ELISA from negative to positive.
HCV Antibody signal cutoff ratio	All results
HCV signal cutoff interpretation	
HCV RIBA	
HCV RNA	Quantitative and Qualitative.
HCV genotype tests	
ALT	Peak value only in prior 0- 28 days of the report
AST	Peak value only in prior 0- 28 days of the report

Platelet Count	Minimum value only in prior 0- 28 days of the report

E. Pregnancy

Pregnancy flag active	Yes or No
Expected Date of Delivery (EDD)	

F. Diabetes

Diabetes flag active	Either Type 1 or Type 2 diabetes. Yes, No, or Unknown Diabetes algorithm may be leveraged.

G. Symptoms

If any of the following diagnosis codes (see Table 2, below) or vital sign findings are present 28 days before or after case established then report the following symptoms:

Fever	Diagnosis code or measured temperature >100.4 degrees Fahrenheit
Jaundice	
Anorexia	
Fatigue	
Abdominal pain	
Nausea and Vomiting	
Diarrhea	

H. Medications

Report all of the medications from the specified hepatitis C medications list (see Table 4, below) given at any point from 12 weeks (84 days) prior to the case date and anytime after the case date.

Treatment given	Yes or No
Prescription for Hepatic C medication	Text string including medication name, dose, frequency, and duration (calculated using start and end date). See Table 4 for specific medications.
Treatment date	Date on which each prescription was ordered.

I. History of:

Hemodialysis during incubation period	Diagnosis code for hemodialysis (see Table 3) in the 12 months prior to date on which the case was established. Yes, No, or Unknown. Include most recent date.
Hemodialysis ever	Diagnosis code for hemodialysis (see Table 3) in a patient's available history. Yes, No, or Unknown.
Negative HCV antibody ELISA test	Negative result in the 12 months prior to date on which the case was established.

J. Classification:

To be sent 28 days following the case identification date.

ESP classification flag	Acute or Chronic. If case meets case definition a, b, c, or d (see Section 2), then flag = Acute. If case meets case definition e or f,

	then flag = Chronic.

K. Variables requiring further exploration

Explore availability of the following variables of interest at ESP sites:

History of injection of drugs not prescribed by doctor	We will explore feasibility of receiving this information with providers, but will not be prioritized for initial implementation.

IV. CRITERIA TO REVOKE A CASE

None

Section 4. *Codes, laboratory tests, and medications used to identify criteria listed in Section 2 and supplementary reporting information in Section 3.*

I. DIAGNOSES CODES

Table 1. Diagnosis Codes Used to Identify Case Components

Component Name	Code Type	Code	Description
Jaundice (#1)	ICD-9-CM	782.4	Jaundice, not of newborn
	ICD-10-CM	R17	Unspecified jaundice
Unspecified Hepatitis C (#7)	ICD-9-CM	070.70	Unspecified viral hepatitis C without hepatic coma
	ICD-10-CM	B19.20	Unspecified viral hepatitis C without hepatic coma
Chronic Hepatitis C (#8)	ICD-9-CM	070.54	Chronic hepatitis C without mention of hepatic coma
	ICD-10-CM	B18.2	Chronic viral hepatitis C

Table 2. Diagnosis Codes Used to Identify Symptoms

Symptom	Code Type	Code	Description
Fever	N/A	Temperature >100.4	Measured temperature if available, ELSE “fever”.
	ICD-9-CM	780.60	
	ICD-10-CM	R50.9	Fever, unspecified
Jaundice	ICD-9-CM	782.4	Jaundice
	ICD-10-CM	R17	Unspecified jaundice
Anorexia	ICD-9-CM	783.0	Anorexia
	ICD-10-CM	R63.0	Anorexia
Fatigue	ICD-9-CM	780.79	Other malaise and fatigue
	ICD-10-CM	G93.3	Postviral fatigue syndrome
	ICD-10-CM	R53.1	Weakness
	ICD-10-CM	R53.81	Other malaise
	ICD-10-CM	R53.83	Other fatigue
Abdominal pain	ICD-9-CM	789.0*	Abdominal pain
	ICD-10-CM	R10*	Abdominal and pelvic pain
Nausea & Vomiting	ICD-9-CM	787.01	Nausea and vomiting
	ICD-10-CM	R11.2	Nausea with vomiting, unspecified
	ICD-9-CM	787.02	Nausea alone
	ICD-10-CM	R11.0	Nausea
	ICD-9-CM	787.03	Vomiting alone
	ICD-10-CM	R11.10	Vomiting, unspecified

	ICD-10-CM	R11.11	Vomiting without nausea
	ICD-10-CM	R11.12	Projectile vomiting
Diarrhea	ICD-9-CM	787.91	Diarrhea
	ICD-10-CM	K19.7	Diarrhea, unspecified

Table 3. Diagnosis Codes Used to Identify Medical History

Component	Code Type	Code	Description
Hemodialysis	ICD-9-CM	V45.11	Renal dialysis status
	ICD-10-CM	Z99.2	Dependence on renal dialysis
	ICD-9-CM	V56.0	Encounter for extracorporeal dialysis
	ICD-9-CM	V56.1	Fitting and adjustment of extracorporeal dialysis catheter
	ICD-9-CM	V56.31	Encounter for adequacy testing for hemodialysis
	ICD-10-CM	Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter
	ICD-10-CM	Z49.31	Encounter for adequacy testing for hemodialysis
	ICD-9-CM	585.6	End stage renal disease
	ICD-10-CM	N18.6	End stage renal disease

II. MEDICATIONS

Table 4. Hepatitis C Medications*

Brand Name	Generic Name
Copegus, Rebetol, Virazole	ribavirin (RBV)
Daklinza	daclatasvir
Epclusa	sofosbuvir/velpatasvir
Harvoni	ledipasvir/sofosbuvir
Incivek	telaprevir
Infergen	interferon aphacon-1
Intron A	interferon alpha-2b
Mavyret	glecaprevir/pibrentasvir
Olysio	simeprevir
Pegasys	pegylated interferon alfa
Pegintron	interferon alfa-2b
Rebetron	ribavirin/interferon alfa-2b,recomb.
Roferon	interferon alpha-2a
Sovaldi	sofosbuvir
Technivie	ombitasvir/paritaprevir/ritonavir
Victrelis	boceprevir
Viekira Pak	ombitasvir/paritaprevir/ritonavir/dasabuvir
Vosevi	sofosbuvir/velpatasvir/voxilaprevir
Zepatier	elbasvir/grazoprevir

*Medications reflect list of FDA approved therapies to treat Hepatitis C.

III. LABORATORY TESTS LOINCS

Table 5. Laboratory Test LOINC Mapping

Component Name	LOINC	LOINC Name
HEPATITIS C ELISA	16128-1	Hepatitis C virus Ab : ACnc : Pt : Ser : Ord :
HEPATITIS C SIGNAL CUTOFF RATIO	MDPH-144	Hepatitis C virus Ab:Pt:Ser:Ord:EIA Signal-to-cutoff ratio
HEPATITIS C RIBA	5199-5	Hepatitis C virus Ab : ACnc : Pt : Ser : Ord : IB
HEPATITIS C RNA	*See Table 6*	*See Table 6*
GENOTYPE	32286-7	Hep C virus genotype: Type: Pt: Ser/Plas: Nom: Probe.Amp. Tar
ALANINE AMINOTRANSFERASE (ALT)	1742-6	ALT SerPl-cCnc
ASPARTATE AMINOTRANSFERASE (AST)	1920-8	AST SerPl-cCnc
PLATELET COUNT	TBD	TBD

Table 6. Hepatitis C RNA positivity and LOINC Mapping Criteria by Test

Component Name	LOINC	LOINC Name	Positive result*
HEP C RNA PCR (QL)	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	DETECTED
HEP C RNA PCR (QN) NGI	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	≥100
HEP C RNA PCR (QL)	6422-0	Hepatitis C virus rRNA : ACnc : Pt : xxx : Ord : Probe	DETECTED
HEP C RNA QN (IU/ML)	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>Lx_ref_low (50 or 615)
HEP C RNA QN (LOGIU)	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>2.79
HCV RNA (IU/ML)	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HCV RNA (LOG IU/ML)	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.70
HCV RNA PCR, QUANTITATIVE	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HCV RNA PCR, QUANTITATIVE	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.7
HCV RNA, PCR QUANT(LOGIU)	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.7
HCV RNA (IU/ML)	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HCV RNA, PCR, QUANT	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.7
HCV RNA, QUANT, TMA	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>5
HCV RNA, QUANT, TMA	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>0.70
HCV RNA (IU/ML)	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HCV RNA (LOG IU/ML	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.7
HCV RNA (IU/ML)	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HCV RNA (IU/ML)	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HCV RNA PCR QUANT#2	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.7
HEPATITIS C RNA, QUANT (IU/ML)	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HEPATITIS C VIRUS RNA, QUANT IU/ML	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>10
HEPATITIS C VIRUS RNA, QUANT COPIES	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>10
HEPATITIS C VIRUS, QUANT, BDNA	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HEPATITIS C VIRUS LOG, BDNA	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>2.79
HCV PCR INTERPRETATION	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	DETECTED
HCV PCR QUANT	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.7
HEPATITIS C VIRUS PCR	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	DETECTED
HEPATITIS C VIRUS PCR QUANT	34704-7	Hepatitis C virus RNA : ACnc : Pt : Ser/Plas : Qn : Probe.amp.tar detection limit < 50 iu/ml	>50
HEPATITIS C VIRUS PCR QUANT LOG	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.7

HEPATITIC C RNA BRANCH DNA (IU/ML)	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>615
HEPATITIC C RNA BRANCH DNA (LOG IU/ML)	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>2.79
HEPATITIS C VIRUS PCR	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	DETECTED
HEPATITIS C VIRUS PCR QUANT	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>43
HEPATITIS C VIRUS PCR QUANT LOG	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>1.6
HCV PCR INTERPRETATION	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	DETECTED
HEPATITIS C VIRUS, QUANT, BDNA	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>615
HEPATITIS C VIRUS LOG, BDNA	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	>2.79
HCV BDNA INTERPRETATION	5012-0	Hepatitis C virus RNA : ACnc : Pt : xxx : Ord : Probe.Amp.Tar	DETECTED

*May be truncated.

IV. CODE MAINTENANCE STRATEGY

Continuously screen all incoming Lx_Component_Name fields for the text strings: “HEP” or “HCV” or “RIBA” not “CAST” not “FASTING” not “YEAST”.