Event Name:	HEPC
Event Time Period:	Lifelong

Clinical Criteria (CSTE 2020):	All hepatitis C virus cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally. One or more of the following: • Jaundice, **OR** • Peak elevated total bilirubin levels ≥ 3.0 mg/dL, **OR** • Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L, **AND** The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)	
CSTE Event Classification (2020):	*Acute Confirmed*	A case that meets clinical criteria **AND** ▪ Has positive Nucleic Acid Test (NAT) for HCV RNA (including qualitative, quantitative or genotype) alone or within 12 months of a positive HCV antibody result, **OR** ▪ Has a positive test indicating the presence of HCV antigen(s) **OR** ▪ Has a negative HCV antibody followed within 12 months by a positive HCV antibody test (anti-HCV test conversion) in the absence of a more likely diagnosis **OR** ▪ Has a negative HCV antibody or negative hepatitis C virus detection test (in someone without a prior HCV infection diagnosis) followed within 12 months by a positive hepatitis C virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis.
	Acute Probable	A case that meets clinical criteria **AND** Has a positive test for antibodies to hepatitis C virus (anti-HCV) **AND** Does not have a hepatitis C virus detection test reported within 12 months of the positive HCV antibody result **AND** Has no documentation of anti-HCV or HCV RNA test conversion within 12 months

	Chronic Confirmed	A case that does not meet clinical criteria OR has no report of clinical criteria **AND** ▪ Has positive Nucleic Acid Test (NAT) for HCV RNA (including qualitative, quantitative or genotype) alone or within 12 months of a positive HCV antibody result, **OR** ▪ Has a positive test indicating the presence of HCV antigen(s) **AND** ▪ Has no documentation of anti-HCV or HCV RNA test conversion within 12 months
	Chronic Probable	A case that does not meet clinical criteria OR has no report of clinical criteria **AND** Has a positive test for antibodies to hepatitis C virus (anti-HCV) **AND** Has no documentation of anti-HCV or RNA test conversion within 12 months **AND** Does not have an HCV RNA test reported within 12 months of the positive HCV antibody result.
MA Event Classification (2021):	Same as CSTE event classification with the addition of the revoked case classification below.	
	Revoked	Any case less than or equal to 2 months of age with or without clinical criteria and regardless of laboratory results **OR** Any case greater than 2 months of age and less than 18 months of age, with or without clinical criteria, with evidence of anti-HCV antibodies, but no report of a NAT for HCV RNA or HCV antigen by 36 months of age **OR** A case with or without clinical criteria with: ▪ Evidence of anti-HCV antibodies, but no report of a positive NAT for HCV RNA or HCV antigen within 12 months of a positive HCV antibody result AND ▪ Evidence of a negative Nucleic Acid Test (NAT) for HCV RNA within 12 months of the HCV antibody positive result (NOT including a negative genotype) AND ▪ No evidence of test conversion
	Unclassified	Case created when negative laboratory results are received for an individual who has no existing hepatitis C event or positive labs in MAVEN.

Perinatal Hepatitis C

Clinical Criteria (CSTE 2018):	Perinatal hepatitis C in pediatric patients may range from asymptomatic to fulminant hepatitis.	
CSTE Event Classification (2018):	*Perintal Confirmed*	Any case greater than or equal to 2 months and less than or equal to 36 months with a positive test for HCV RNA (NAAT), HCV antigen, or detectable HCV genotype and is not known to have been exposed to HCV via a mechanism other than perinatal.
MA Event Classification (2018):	Same as CSTE event classification with the addition of the probable case classification below.	
	Perinatal Suspect	Any case greater than or equal to 18 months and less than or equal to 36 months of age, with or without clinical criteria, with evidence of anti-HCV antibodies, but no report of a NAT for HCV RNA or HCV antigen

HEPATITIS C VIRUS (continued)

Note: If any other viral hepatitis results are included (for Hepatitis A, B, D or E) refer to the appropriate CCM for guidance on how to enter. Any Hepatitis C negative test results should be entered into an existing Hepatitis C event only. If platelet count, bilirubin, ALT or AST are available, enter in the Lab Section.

Report Type	Test Type	Source	Result	New event or beyond report period?	Data Entry
Laboratory report	EIA (only) HCV Ab Anti-HCV	Serum	Positive	Yes	New event PROBABLE
				No	Same event
Select:	Hep C virus Ab: ACnc: Pt: Ser: Ord: EIA				
Laboratory report	HCV IgG	Serum	Positive	Yes	New event PROBABLE
				No	Same event
Select:	Hepatitis C virus IgG Ab [Presence] in Serum or Plasma by Immunoassay				
Laboratory report	PCR for HCV RNA OR bDNA OR RT-PCR	Serum	Results may be positive or negative (no numeric result included)	Yes	New event CONFIRMED if positive
				No	Same event
Select:	Hep C virus RNA: ACnc: Pt: xxx: Ord: Probe.Amp.Tar				
Laboratory report	PCR for HCV RNA OR bDNA OR RT-PCR OR Viral Load	Serum	Results may be positive, negative or trace. Select "trace" if the numeric result appears negative (e.g., shown as <615 or <43) but a comment or interpretation is included stating that the virus was detected but could not be quantified.	Yes	New event CONFIRMED if positive or trace result
				No	Same event
Select:	Hep C virus RNA: ACnc: Pt:Ser/Plas:Qn:Probe.amp.sig				
Laboratory report	EIA signal to cutoff ratio	Serum	Positive (ex. >3.8)	Yes	New event PROBABLE
				No	Same event
Select:	Hep C virus Ab: ACnc: Pt: Ser: Ord: EIA Signal-to-cutoff ratio				
Laboratory report	HCV rRNA	Serum	Positive	Yes	New event CONFIRMED
				No	Same event
Select:	Hep C virus rRNA: ACnc: Pt: xxx: Ord: Probe				

HEPATITIS C VIRUS (continued)

Note: If any other viral hepatitis results are included (for Hepatitis A, B, D or E) refer to the appropriate CCM for guidance on how to enter. Any Hepatitis C negative test results should be entered into an existing Hepatitis C event only. If platelet count, bilirubin, ALT or AST are available, enter in the Lab Section.

Report Type	Test Type	Source	Result	New event or beyond report period?	Data Entry
Laboratory report	HCV Viral RNA NS3 Genotype** HCV Viral RNA Genotype 1 NS5a***	Serum	Genotype (usually number/letter combination)	Yes	New event CONFIRMED
				No	Same event
Select:	Hep C virus genotype: Type: Pt Ser/Plas: Nom:Probe.Amp.Tar				
Laboratory report	Rapid Hepatitis C Antibody Test	Whole Blood	Reactive	Yes	New event PROBABLE
				No	Same event
Select:	Rapid Hep C antibody test				
Death Certificate			"Hepatitis C"	Yes	New event SUSPECT
				No	Same event

Data entry notes

** Quest is running a test called HCV Viral RNA NS3 Genotype. This test detects a mutation that is associated with resistance to some available treatments (boceprevir, telaprevir and simeprevir). Results from this test should be noted as either 1a or 1b, followed by results noted for example as "Boceprevir resistance – Not Predicted", "Telaprevir resistance – Not Predicted" or "Simeprevir – Predicted". This can be entered as a genotype test with the appropriate letter/number combination. You do not need to enter the resistance results.

This test has also been reported on paper by Quest Chantilly; however, the result listed is only "HCV NS3 Subtype" as opposed to 1a or 1b. If you come across this test type with the only result being "HCV NS3 Subtype", enter the genotype result as 1a/1b.

*** Quest is also running a test called HCV Viral RNA Genotype 1 NS5a. This test is also used to determine if the virus has developed specific treatment resistances. Results from this test should be noted as either 1a or 1b, followed by resistance results. This can be entered as a genotype test with the appropriate letter/number combination. You do not need to enter the resistance results.

When entering ALT results, select: ALT SerPl-cCnc
When entering AST results, select AST SerPl-cCnc
When entering platelet results, select Platelet # Plas Auto
When entering bilirubin results, select Bilirub SerPl-mCnc

When entering results from Eurofins/VRL labs:
Ultrio Elite test results noted as non-discriminatory mean that the sample tested positive for HBV/HCV/HIV but this particular assay does not differentiate between the three viruses. It's a screening test done to see if further testing is warranted. Positive non-discriminatory results will be followed up by specific tests for each of the three viruses. These may include repeat Ultrio Elite tests with discriminatory results or tests for HBV core Ab, HBV surface antigen and HCV antibody. Do not enter any results noted as "non-discriminatory".