Louisiana Office of Public Health Laboratories	
Test Name	Hepatitis C
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86803
Synonyms	HCV Anti-HCV
Brief Description of Test	The ORTHO HCV ELISA Test System is used for the detection of antibody to hepatitis C virus (Anti-HCV) in human serum. The hepatitis C virus (HCV) is now known to be the causative agent for most, if not all, blood-borne non-A, non-B hepatitis.
Possible Results	Nonreactive Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Blood Serum Collection Tube or Screw-cap aliquot tube
Minimum volume accepted:	Request 1 mL 210 µL serum minimum (does not allow for repeat testing)
Collection Instructions	Specimen Container – Serum Separator Tubes (SST) or Screw Cap Aliquot Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number. The same two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Specimens can be shipped refrigerated (2-8°C) or ambient (8-37°C) and can be stored for up to 7 days.

	For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If samples are frozen, document the date and time the sample was frozen.
Causes for Rejection	• Unspun • Short Draw/Overfill • Hemolyzed • Lipemic • Received outside acceptable transport conditions • Incorrect source • Expired collection tubes
Limitations of the Procedure	Specimens with absorbance values greater than or equal to the Cutoff value are considered initially reactive and should be retested in duplicate before final interpretation. Upon retesting an initially reactive specimen, the specimen is considered repeatedly reactive for antibody to HCV if either or both duplicate determination(s) is/are reactive, i.e. greater than or equal to the Cutoff Value. The presence of anti-HCV does not constitute a diagnosis of hepatitis C, but may be indicative of recent and/or past infection by hepatitis C virus. A nonreactive test result does not exclude the possibility of exposure to hepatitis C virus. Levels of anti-HCV may be undetectable in early infection.
Interfering Substances	Clear, nonhemolyzed specimens are preferred. However, no effect on reactivity was observed when specimens were treated with 50-200 mg/dL of hemoglobin and 194-1285 mg/dL of triglyceride. Do not use any heat-treated specimens.
References	ORTHO® HCV ELISA Test System Package Insert EVOLIS™ Operator Manual
Additional Information	None
Release Date	05/18/2018
Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.	