Louisiana Office of Public Health Laboratories	
Test Name	Trioplex Real Time rt-PCR
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	87798 x 3
Synonyms	Zika, Chik, Dengue
Brief Description of Test	**Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.** The Trioplex Real-Time RT-PCR assay is used on the ABI 7500 Fast Dx Real-Time PCR Instrument. This assay tests for the presence of Zika, Chikungunya and Dengue virus.
Possible Results	**Trioplex rRT-PCR Interpretation and Reporting Instructions for Whole Blood, Serum and CSF Specimens**

ZIKV	DENV	CHIKV	RP	Interpretation	Reporting	Actions
-	-	-	+	Negative	No Zika, dengue, or chikungunya RNA detected by rRT-PCR	Report results to CDC. No further testing required. Note: If date of onset of symptoms is in doubt or if patient is asymptomatic, serological testing may be recommended. Refer to CDC algorithm.*
-	-	-	-	Inconclusive	Specimen inconclusive for the presence of Zika, dengue, and chikungunya RNA by rRT-PCR. An inconclusive result may occur in the case of an inadequate specimen.	Repeat extraction and rRT-PCR. If unable to resolve inconclusive result for a serum specimen, request collection of additional serum from the patient. Report inconclusive results to CDC.
-	+	-	+/-	Positive for DENV, but negative for ZIKV and CHIKV.	Dengue RNA detected by rRT-PCR. No Zika or chikungunya RNA detected.	Report results to CDC. Forward specimen to CDC. Refer to CDC algorithm.*
-	-	+	+/-	Positive for CHIKV, but negative for ZIKV and DENV.	Chikungunya RNA detected by rRT-PCR. No dengue or Zika RNA detected.	
+	-	-	+/-	Positive for ZIKV, but negative for DENV and CHIKV.	Zika RNA detected by rRT-PCR. No dengue or chikungunya RNA detected.	
-	+	+	+/-	Positive for DENV and CHIKV, but negative for ZIKV.	Dengue and chikungunya RNA detected by rRT-PCR. No Zika RNA detected.	
+	+	-	+/-	Positive for ZIKV and DENV, but negative for CHIKV	Zika and dengue RNA detected by rRT-PCR. No chikungunya RNA detected.	
+	-	+	+/-	Positive for ZIKV and CHIKV, but negative for DENV	Zika and chikungunya RNA detected by rRT-PCR. No dengue RNA detected.	
+	+	+	+/-	Positive for ZIKV, DENV, and CHIKV	Zika, dengue, and chikungunya RNA detected by rRT-PCR.	

Trioplex rRT-PCR Interpretation and Reporting Instructions for Urine and Amniotic Fluid Specimens

ZIKV	RP	Interpretation	Reporting	Actions
-	+	Negative	No Zika RNA detected by rRT-PCR.	Report results to CDC. Refer to CDC algorithm.*
-	-	Inconclusive	Specimen inconclusive for the presence of Zika RNA by rRT-PCR. An inconclusive result may occur in the case of an inadequate specimen.	Repeat extraction and rRT-PCR. If repeat testing does not resolve inconclusive result, do not test further. Report results to CDC.
+	+/-	Positive	Zika RNA detected by rRT-PCR	Report results to CDC. Forward specimen to CDC. Refer to CDC algorithm.*

Reference Range	Negative
Specimen Type	For Zika, chikungunya and dengue testing: • Serum (collected in a serum separator tube) • Whole blood (EDTA) • Cerebrosipinal fluid (CSF) For Zika testing only: • Urine • Amniotic fluid **NOTE: Serum is the preferred diagnostic specimen. Whole blood (EDTA), CSF, urine and amniotic fluid may only be tested alongside a patient-matched serum specimen.**
Specimen Container(s):	Blood Serum Collection Tube, EDTA tube and/or Screw-cap aliquot tube
Minimum volume accepted:	Request 1 mL 300 µL minimum
Collection Instructions	Specimen Container – Serum Separator Tubes (SST), EDTA tube 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 each 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	• Freeze at ≤ -20°C then transport/ship human serum, urine, CSF and amniotic fluid specimens in dry ice, if possible; however, using cold packs is acceptable • Refrigerate at 2-8°C then transport/ship human whole blood (EDTA) specimens on cold packs. For whole blood, testing is recommended within one week of collection.

Causes for Rejection	• Unspun • Short Draw/Overfill • Received outside acceptable transport conditions • Incorrect source • Expired collection tubes • Whole blood (EDTA), CSF, urine and amniotic fluid received without a patient-matched serum specimen
Limitations of the Procedure	This assay was approved via an Emergency Use Authorization. This assay is very dependent on the timing of specimen collection. Specimens collected within 7 days of illness onset will yield the best results.
Interfering Substances	N/A
References	Package Insert: CDC Trioplex Real Time RT-PCR Assay Trioplex FDA Letter of Authorization – March 17, 2016
Additional Information	Fact Sheets for Providers can be located at: http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM491588.pdf Fact Sheets for Patients can be located at: http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM491590.pdf Fact Sheets for Pregnant Women can be located at: http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM491591.pdf
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