Louisiana Office of Public Health Laboratories	
Test Name	GenMark eSensor Respiratory Viral Panel (RVP)
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	**87633** – infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg. Adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes; 12-25 targets
Synonyms	RVP
Brief Description of Test	The eSensor® Respiratory Viral Panel (RVP) is a qualitative nucleic acid multiplex *in vitro* diagnostic test intended for use on the eSensor XT-8™ system for the simultaneous detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals exhibiting signs and symptoms of respiratory infection. The following virus types and subtypes are identified using the eSensor RVP: Influenza A, Influenza A H1 Seasonal Subtype, Influenza A H3 Seasonal Subtype, Influenza A 2009 H1N1 subtype, Influenza B, Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Human Metapneumovirus, Human Rhinovirus, Adenovirus species B/E, and Adenovirus species C.
Possible Results	Positive or Not Detected for each virus and subtype listed above
Reference Range	Not Detected
Specimen Type	Nasopharyngeal swabs
Specimen Container(s):	Viral Transport Media (VTM)
Minimum volume accepted:	Request 1-3 mL Testing may be performed on as little as 200µL
Collection Instructions	Swab must be placed and mixed well in a viral transport media tube immediately after collection. Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron) and an aluminum or plastic shaft. 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 sample. Lab submission form must be thoroughly completed with patient's first and last

	name, 2nd patient identifier, gender, date of birth, date and time of collection, specimen source, test requested, submitter's name, address, fax and contact number. Additional information regarding patients' address is requested. Transport specimen to laboratory as soon as possible after collection/incubation. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Specimens must be shipped refrigerated (2-8°C) and can be stored for up to 7 days. If sample will be delivered to the laboratory outside of 7 days from collection, the sample must be frozen ≤-15ºC. Freezing the sample must be within 7 days from collection. If the sample is frozen at any point, it must remain frozen and be shipped on dry ice. Specimens are acceptable frozen for up to 1 month prior to extraction and can undergo up to two freeze/thaw cycles.
Causes for Rejection	• Received outside acceptable transport conditions • Incorrect source • Incorrect labeling • Expired collection tubes
Limitations of the Procedure	The eSensor RVP can reliably differentiate Adenovirus species C from Adenovirus B /E. Due to the genetic similarity between Adenovirus species B and E, the eSensor RVP cannot reliably differentiate between Adenovirus species B and E. A positive Adenovirus species B/E result should be followed-up using an alternative method (e.g., sequence analysis). If definitive Adenovirus speciation between species B and E is needed. Adenovirus species C has been experimentally observed to cross react with Adenovirus species D (serotype 9) and F (serotype 41) due to genetic similarity between the species. Cross reactivity of the Adenovirus species C with other serotypes of the Adenovirus species D and F has not been experimentally confirmed. A positive eSensor RVP Adenovirus species C result should be followed-up using an alternative method (e.g., sequence analysis) if definitive Adenovirus speciation between species C, D and F is needed. Due to the genetic similarity between human rhinovirus and poliovirus, the eSensor RVP cannot reliably differentiate them. If a polio infection is suspected, a positive eSensor RVP human rhinovirus (HRV) result should be confirmed using an alternate method (e.g., cell culture). Due to the genetic similarity between human rhinovirus and Enterovirus 68, the eSensor RVP cannot reliably differentiate them. This test is a qualitative test and does not provide the quantitative value of detected virus present.

	The performance of the test has been evaluated for use with human specimen material only. This test has not been validated for testing specimens other than nasopharyngeal swab (NPS) specimens. The performance of this test has not been established for immunocompromised individuals. The performance of this test has not been established for patients without signs and symptoms of respiratory infection. Results from this test must be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient. Analyte targets (viral nucleic acids) may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious, nor are the causative agents for clinical symptoms. The detection of viral nucleic acid is dependent upon proper specimen collection, handling, transportation, storage, and preparation (including extraction). Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false negative values resulting from improperly collected, transported, or handled specimens. There is a risk of false negative values due to the presence of sequence variants in the viral targets of the assay. A negative eSensor RVP result does not exclude the possibility of viral or bacterial infection. A specimen yielding a negative result may contain respiratory viruses not targeted by eSensor RVP. Negative test results may occur from the presence of sequence variants in the viral targets of the assay, the presence of inhibitors, technical error, sample mixup, or an infection caused by an organism not detected by the panel. Test results may also be affected by concurrent antiviral therapy or levels of virus in the specimen that are below the limit of detection for the test. Negative results should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likelyduring peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence is moderate to low.

	Virus and amplicon contamination may produce erroneous results for this test. There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay. Cross-reactivity with respiratory tract organisms other than those listed in the “Cross-reactivity” section may lead to erroneous results. The eSensor RVP Influenza A subtyping reagents target the Influenza A hemagglutinin gene only. The eSensor RVP does not detect or differentiate the Influenza A neuraminidase gene. The test performance was established during the 2010-2011 season. The performance for some viruses may vary depending on the prevalence and population tested. The performance of this test has not been established for monitoring treatment of seasonal influenza A H1, H3 2009 H1N1 or RSV infections. The performance of this test has not been established for screening of blood or blood product for the presence of seasonal influenza A H1, H3 or 2009 H1N1 viruses. The effect of interfering substances has only been evaluated for those listed in the labeling. Interference by substances other than those described in the “Interference” section can lead to erroneous results. Recent administration of a live intranasal influenza virus vaccine may cause false positive results for Influenza A, H1, H3, 2009 H1N1, and/or Influenza B. Variant influenza A H3N2 virus (H3N2v) will be detected as seasonal influenza A H3.
Interfering Substances	No potentially interfering substance or microorganism was shown to inhibit the eSensor RVP at all tested concentrations. See package insert for list of all substances tested.
References	GenMark eSensor RVP Package insert
Additional Information	None

Release Date	06/09/2018

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.