TEST CHANGE: New Test
NOTIFICATION DATE: 3/24/2025
EFFECTIVE DATE: 4/01/2025

Affected Test Name- LEGIONELLA URINE ANTIGEN AND STREPTOCOCCUS PNEUMONIAE, URINE AG

TESTCODES: LAB304824 AND LAB304860

EXPLANATION: The ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is an in vitro, rapid, lateral flow test, also known as a lateral flow immunochromatographic assay, intended for the qualitative detection of *Streptococcus pneumoniae* and *Legionella pneumophila* antigens in urine specimens from patients with symptoms of pneumonia. The assay is further intended to aid in the diagnosis of *S. pneumoniae* infections by detection of S. pneumoniae antigen in cerebrospinal fluid (CSF). This assay is intended to aid in the diagnosis of *L. pneumophila* serogroup 1 infections, but may also be positive for Legionella serogroup 3, 6, 8, 10 and 12.

Due to the combined nature of this assay, *S. pneumoniae* and *L. pneumophila* Urinary Antigen Tests will no longer be able to be ordered individually. Ordering either test will lead to a combined panel (STREP PNEUMONAI AND LEGIONELLA ANTIGEN PANEL). This will not affect STREP PNEUMO AG-CSF LAB304860.

METHOD: Lateral flow assay

REFERENCE VALUES: Negative

SPECIMEN REQUIREMENTS: Urine in sterile leak-proof container or vacutainer urine culture kit-grey top.

SPECIMEN REJECTION CRITERIA: Non-validated sample type, specimen container not labeled properly, broken specimen container, sample greater than 7 days since collection. Urine with visible blood will be rejected with recollection suggested. False positive results can occur with bloody samples.

SPECIMEN STABILITY INFORMATION: Refrigerated: 7 days

DAYS TEST SET UP: Sunday-Saturday

QUESTIONS ABOUT THIS TESTING

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