

LEGIONELLA URINARY ANTIGEN TEST

Test Notes	None
Test Method	Immunoassay
Alternative Test Name(s)	Not applicable
Specimen Container	Sterile screw capped container or boric acid tube
Preferred Specimen	1st morning urine specimen 3 – 5 mL (Midstream Clean Catch, Indwelling Catheter, Straight In and Out Catheter, Kidney, Pediatric Bag or Suprapubic Aspirate Urine)
Minimum Volume	1 milliliter (1 mL)
Instructions	Inform the laboratory of the patient's recent antimicrobial therapy history and/or suspected pathogens.
Transport Temperature	Immediately upon collection; if delayed, refrigerate the specimen (2 – 8 degrees Celsius)
Stability	<ul style="list-style-type: none"> • Room Temperature (20 – 25 degrees Celsius): < 24 hours; • Refrigerated (2 – 8 degrees Celsius): >24 hours to < 14 days; • Frozen (- 10 to -20 degrees Celsius): > 14 days
Rejection Criteria	<ul style="list-style-type: none"> • Unlabeled or mislabeled specimens • Non-sterile or leaking containers • Inadequate specimen quantity • Specimens collected with swabs or specimens unsafe to handle (sharps) • Specimens containing additives or fixatives other than boric acid

Test Performed	Sun – Sat; All Shifts						
Report Available	Within 1 hour of specimen processing						
Interfering Substances	None Noted						
Limitations	This test does not detect infections caused by other Legionella pneumophila serogroups or other Legionella species. A negative antigen result does not exclude infection with the target antigen. A positive result can occur due to current or past infection. The performance of this test on diuretic urine has not been evaluated.						
Reference Range	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Normal Value</td> <td>Negative</td> </tr> <tr> <td colspan="2"><hr/></td> </tr> <tr> <td>Critical Value</td> <td>Any detection of Legionella pneumophila serogroup 1 antigens</td> </tr> </table>	Normal Value	Negative	<hr/>		Critical Value	Any detection of Legionella pneumophila serogroup 1 antigens
Normal Value	Negative						
<hr/>							
Critical Value	Any detection of Legionella pneumophila serogroup 1 antigens						
Performance Characteristics of the Test	Overall agreement of BinaxNOW Legionella with laboratory diagnosis was 95%. Sensitivity and specificity were each 95%.						
References	Product Insert – Abbott Binax NOW Legionella Urinary Antigen, IN852050 Rev.10; January 4, 2021						