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| Purpose or Principle or Introduction | The Binax NOW**®** *Streptococcus pneumoniae* Test is a moderately complex *in vitro* rapid immunochromatographic [ICT] assay for the detection of *Streptococcus pneumoniae [S. pneumoniae]* antigen in the urine of patients with pneumonia |

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| Policy | It is our policy to run external positive and negative controls with the test to assure functionality of reagents and proper performance of assay procedure **at least every** **new box opened**. |

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| |  |  | | --- | --- | | Workplace Safety |  | | All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures.   * For standard precautions and safety practices in the laboratory; see **Safety Practices**, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE). * For Universal Body Substance precautions, see **Universal Body Substance Precautions**, specifically, but not limited to, exposure to body fluids. * For proper hand-washing, see **Hand washing Policy**, specifically, not limited to, proper hand-washing. * For proper infection control, see **Infection Control**, specifically, but not limited to, proper use of gloves. * For proper handling of regular and infectious waste, see **Handling of Regular and Infectious Waste**, specifically, but not limited to, proper disposal of regular and biohazardous waste. * For proper cleaning of work area, see **Cleaning Work Areas**. * For proper handling of chemicals and reagents, see the Chemical Hygiene Plan. * For proper storage and disposal of chemical hazardous waste, see **Storage & Disposal of Chemical Hazardous Waste**. All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures. |

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| Materials provided in kit | * Test Devices * Reagent A: Citrate/Phosphate buffer with sodium lauryl sulfate, Tween 20 and sodium azide. * Swabs: Designed for use in the Binax NOW**®** *Streptococcus pneumoniae* Test. * Positive Control Swab for S.pneumoniae * Negative Control Swab for S.pneumoniae |
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| Materials not provided in kit | * Clock, timer or stopwatch * Standard urine collection containers or urine transport tubes with boric acid preservative |

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| Kit Storage Requirements | * Store kit at room temperature [59-86°F, 15-30°C]. * The Binax NOW**®** *Streptococcus pneumoniae* test kit and reagents are stable until the expiration dates marked on their outer packaging and containers. |

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| Assay Procedure for control testing | Follow these steps to perform control testing. Perform external controls with each new box of Streptococcus pneumonia Antigen cards.   |  |  | | --- | --- | | Step | Action | | 1 | Just prior to use open pouch and remove test device, and lay it flat | | 2 | Label devices as negative and positive control. | | 3 | There are two holes on the right panel of the device. Insert negative control swab into the bottom hole of the device labeled negative control. Firmly push upwards so the swab is fully visible in the top hole. DO NOT REMOVE SWAB. | | 4 | Hold reagent A vial vertically, ½ to 1 inch above the device. Slowly add 6 free falling drops to the bottom hole. | | 5 | Immediately peel off adhesive liner from the right edge of the test device. Close and securely seal device. Read result in window 15 minutes after closing the device. Results read beyond 15 minutes may be inaccurate. | | 6 | Repeat for positive control. Insert positive control swab into the bottom hole of the device labeled negative control. Firmly push upwards so the swab is fully visible in the top hole. DO NOT REMOVE SWAB. | | 7 | Hold reagent A vial vertically, ½ to 1 inch above the device. Slowly add 6 free falling drops to the bottom hole. | | 8 | Immediately peel off adhesive liner from the right edge of the test device. Close and securely seal device. Read result in window 15 minutes after closing the device. Results read beyond 15 minutes may be inaccurate. | | 9 | Record control results in the control log. | | 10 | If controls do not yield expected results repeat testing. If problem is not resolved. Do not proceed with patient testing until problem is resolved. Notify supervisor for further advice. | |

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|  | Appearance of  Test Device Window | Interpretation |
| **Two** pink-to-purple colored lines will appear in the window. | *S. pneumoniae* antigen was detected. |
| A **single** pink-to-purple colored line will appear in the top half of the window. | Control line means that the detection part of the test was done correctly, but no *S. pneumoniae* antigen was detected. |
| **No** lines are seen, or just the sample line is seen. | Assay is invalid  **Repeat the test**. |

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| Reporting Quality control Results | Record control results for internal and external controls in the QC log book each time external control is tested.   |  |  | | --- | --- | | Result | Description | | **Positive** | Streptococcal pneumoniae antigen detected. | | **Negative** | Streptococcal pneumoniae antigen detected. | |

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| Procedure Notes | | * **Invalid results**, **indicated by no control line, can occur when** **an insufficient volume of Reagent A is added to the test device.** * To ensure delivery of an adequate volume, hold vial vertically, ½ to 1 inch above the swab well, and slowly add free falling drops. * The test device is sealed in a protective foil pouch. * Do not use if pouch is damaged or open. * Remove test device from pouch just prior to use. * Do not touch the reaction area of the test device. * Do not use kit past its expiration date. * Do not mix components from different kit lots. * Swabs in the kit are approved for use in the Binax NOW**®** Test. **Do not use other swabs**. * Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls, and test devices should be handled as though they could transmit disease. Observe established precautions against microbial hazards. * Clean catch urine is not necessary for the NOW**®** test. Therefore, urine specimens for this test may not be appropriate for bacteriological culture. | | |
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| Non-Controlled Documents | The following non-controlled documents support this procedure.   * NOW® *Streptococcus pneumoniae* Test product instructions [package insert]. |

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| Controlled Documents | |  |  | | --- | --- | | **Document Number** | **Document Name** | | LAMC-PPP-0123 | Safety Practices | | LAMC-PPP-0127 | Infection Control | | LAMC-PPP-0128 | Universal Body Substance Precaution | | LAMC-PPP-0129 | Handling of Regular and Infectious Waste | | LAMC-PPP-0130 | Cleaning Work Areas | | LAMC-PPP-0132 | Hand-washing Policy | | LAMC-PPP-0134 | Storage and Disposal of Chemical Hazardous Waste |   See below the list of controlled documents |

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