Analytical Sensitivity:

The analytical sensitivity of Artron Influenza A&B Test is:

For Influenza A: 2×10^4 pfu/ml

For Influenza B: 7×10^4 pfu/ml

Analytical Specificity:

Artron Influenza A&B Test is specific to influenza type A virus and influenza type B virus; cross reactivity was not found with the following pathogens at 1.0×10^9 organisms/ml.

Adenovirus Type 1
Adenovirus Type 2
Adenovirus Type 3
Adenovirus Type 6
Coxsackievirus B2
Coxsackievirus B3
Coxsackievirus B4
Coxsackievirus B5
Echovirus Type 6
Echovirus Type 11
Echovirus 30
Measles Virus
Mumps Virus (Enders Strain)
Parainfluenza Virus Type 1
Parainfluenza Virus Type 3
Parainfluenza Virus Type 4B
Rhinovirus 3
Rhinovirus 7
Respiratory syncytial virus
Coronavirus 229E
Coronavirus OC43
SARS-coronavirus
Picornavirus
Polio virus I
Polio virus II
Polio virus III
Escherichia coli
Giardia lamblia
Salmonella B, C
Salmonella infantis
Salmonella typhi
Shigella sonnei
Shigella flexneri

Shigella dysenteriae
Vibrio parahemolytica
Trichuris trichiura

Diagnostic Sensitivity and Specificity

An evaluation study was carried out during flu season at multiple hospitals. Clinical specimens were recruited from patients with flu-like symptoms including fever, dry cough and myalgia. Nasal swab specimens from a total of 247 subjects were tested with RT-PCR for confirmation and then examined with Artron Influenza A&B Test (Flu A&B).

Influenza Type A	RT-PCR		
Artron Flu A&B Test	A(+)	A(-)	Total
Flu A Positive	91	8	99
Flu A and B Positive	2	0	2
Negative	15	131	146
Total	108	139	247

Diagnostic Sensitivity: (91+2)/108 = 86.1%
Diagnostic Specificity: 131/139 = 94.2%
Overall Accuracy: (93+131)/274 = 90.7%

Influenza Type B	RT-PCR		
Artron Flu A&B Test	B(+)	B(-)	Total
Flu B Positive	79	11	90
Flu A and B Positive	2	0	2
Negative	20	135	155
Total	101	146	247

Diagnostic Sensitivity: (79+2)/101 = 80.2%
Diagnostic Specificity: 135/146 = 92.5%
Overall Accuracy: (81+135)/247 = 87.4%

Interference Testing

The following substances and conditions were found not to interfere with the test. List of potentially interfering chemical analytes and concentrations tested are as follows:

Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Ascorbic acid	20 mg/dl
Caffeine	20 mg/dl
Gentesic acid	20 mg/dl
Phenylpropanolamine	20 mg/dl
Salicylic acid	20 mg/dl
Benzoylecgonine	10 mg/dl
Atropine	20 mg/dl
Cannabinol	10 mg/dl
Ethanol	1%

Repeatability and Reproducibility

The precision was determined by replicate assays of both positive and negative samples with devices from three different production lots. The resultant data indicated no appreciable variation

between lots and within lots when testing both positive and negative samples by three different lots.

Expiration Date: 18 months from Date of Manufacture