Alere i Isothermal Amplification

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The old thinking. . . “it’s just the flu”

A bit of history

Alere™

There are flu epidemics every 1 to 3 years for at least the last 400 years.

Pandemics (worldwide) occur around every 10 to 20 years.

History

Alere™

Hippocrates described flu back in the 5th century.

Columbus brought a devastating flu on his second voyage to the new world.

Spanish flu of 1918-1919 was the single greatest epidemic in history.

- 50 to 100 million people were killed (3-6% of the world's population!)
- Another 500 million were infected (1/3rd of the world's population)

Influenza Disease Burden

Alere™

Estimated average global burden of **seasonal** influenza

- 600 million cases per year
- 3 million cases of severe illness
- 250,000 – 500,000 deaths

Concern is highest in

- The very young, the elderly
- persons with underlying health conditions
- pregnant women

WHO Report: Acute Respiratory Infections (Update September 2009)

Burden on Healthcare & Industry

Flu causes 30-50% increase in primary care consultations

2-3 fold increase in hospital admissions during epidemics

10% of all sickness absences from work

Impact in industrialised countries:

- US$10-60 million / million population

Lost productivity:

- US$12 billion / annum in US alone

Influenza A versus Influenza B

Influenza A

- More severe disease than B
- Can cause disease in a wide variety of animals

Influenza B

- Causes a milder flu, usually in the spring months

Treating Respiratory Diseases in the Emergency Department

Question	Consideration
Is the pathogen bacterial or viral?	Influenza and pneumonia symptoms can overlap dramatically
Who do you test?	If it is flu season, do you test for other pathogens?
What do you test them for?	Different age groups are linked to different pathogens.
Can treatment be impacted if the appropriate testing is done?	Stop indiscriminate use broad spectrum antibiotics.

Misuse of Antibiotics Can Lead to Other Medical Issues

- Respiratory issues can treated with fluoroquinolone
- Disrupts normal intestinal flora
- O27 strain of *C. difficile* is specifically resistant to fluoroquinolone

Diagnostic Methods for Influenza

- Culture
- DFA
- PCR
- Rapid Tests

Issues with Clinical Samples

Viral titer is highest in first 48 hours

Proper sample collection is necessary

Dilution in transport media

Rapid Tests

Alere

Pro

- Tests take minimal time
- Some tests are so simple that they can be CLIA-waived
- Can be used to triage patients
- Positive results can be used to rule out other issues like pneumonia so don't give unnecessary chest x-ray, antibiotics, etc.

Con

- Performance is not as good as culture, PCR, or DFA

Molecular Assays

Pro

- For respiratory specimens, high performance
- Same day results

Con

- Turn around time from lab may be extensive, especially if batching specimens
- Expensive
- May require experienced technicians, labs, dedicated equipment, etc.

Alere™

The need is a test rapid enough to triage patients like a rapid test with molecular results.

What is Alere i?

What is Isothermal Amplification?

- Alere^{TM} i is a molecular diagnostic test using isothermal amplification
- Isothermal amplification is not PCR but offers similar sensitivity and specificity
- Uses a constant and low temperature so there is no need for thermal cycler
- Very rapid amplification (many targets amplified in only 5-10 minutes)
- Does not require DNA purification step, which adds time, complexity and cost
- Ability to deploy an incredibly sensitive test for infectious diseases at the POC

Definition

NEAR, or **N**icking **E**nzyme **A**mplification **R**eaction, enables the isothermal unwinding and subsequent amplification of very small amplicons using a set of target-specific templates (primers), a nicking endonuclease and a strand displacing DNA polymerase. Amplicon detection can be performed using a variety of probe formats including molecular beacons or by lateral flow sandwich.

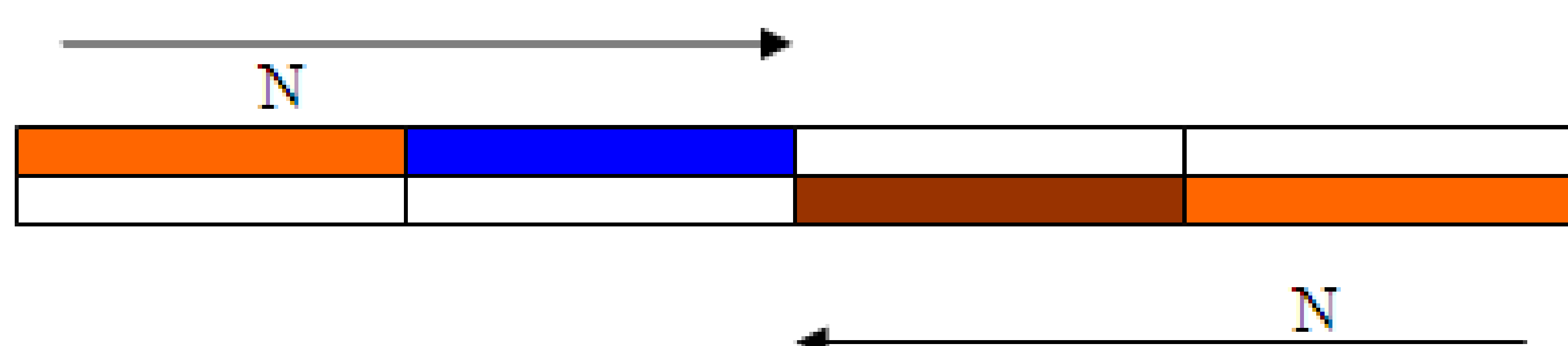
Initial Reaction

- Influenza is RNA virus
  - Perform reverse-transcriptase amplification
  - No purification of the nucleic acid

Amplification

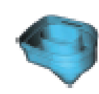
The primed, duplex amplicon:

- blue recognizes a site on one strand of the target
- brown recognizes a nearly adjacent target on the other strand
- orange is an extra piece on each primer with a “nicking” site (N) and other “stabilizing” sequences
- there is a 10-12 bp “gap” between the “templates” (arrows); this enables use of a target-specific probe for product detection.
- after duplex synthesis, nicking at or near “N” enables strand displacement amplification, providing additional product that can be re-amplified using additional templates (primers).

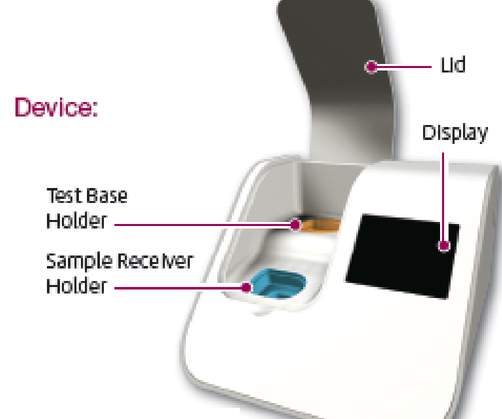


iNAT Flu A/B Workflow

Consumables:



Device:



1. **Touch "Run Test"**
   This will begin the test process.

2. **Enter and confirm patient data**

3. **Open lid and insert Test Base into holder**
   Test Base and holder are color coded.

4. **Confirm test**
   Touch "Confirm" to proceed.

5. **Insert Sample Receiver into holder**
   Sample Receiver and holder are color coded.

6. **Wait 3 minutes for Sample Receiver to warm up**
   Then remove foil from the Sample Receiver.

7. **Take nasal swab from patient and insert into Sample Receiver**

8. **Press Transfer Cartridge onto Sample Receiver**
   Listen for click. Blue indicator on top of Transfer Cartridge will appear to confirm sample has been collected.

9. **Lift and then attach Transfer Cartridge to Test Base**
   Blue indicator on top of Transfer Cartridge will disappear to confirm sample has been dispensed.

10. **Close lid and wait 10 minutes for test results**

Attach Test Base/Cartridge onto Sample Receiver and discard after completing test.

Influenza A/B: First Publications

CLINICAL EVALUATION OF THE ALERE™ i INFLUENZA A&B ASSAY, A POINT-OF-CARE RAPID NUCLEIC ACID AMPLIFICATION TEST FOR DETECTION OF INFLUENZA.

UMKC School of Medicine

Children's Mercy HOSPITALS & CLINICS Kansas City

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ABSTRACT (Revised)

Background. Rapid testing and detection of influenza virus infection in an outpatient setting improves patient management. Although rapid antigen tests for influenza offer quick results, they lack adequate sensitivity. We report data from an ongoing clinical point-of-care (POC) evaluation using a new isothermal nucleic acid test (NAT), the Alere™ i Influenza A&B assay. The assay is a rapid instrumented test for the qualitative detection of influenza A and B viral RNA from respiratory specimens. Results are available within 15 minutes from specimen collection, allowing for a quick turnaround time.

Methods. Specimens were collected during the 2012-2013 respiratory season. During the study 545 specimens were collected from study-eligible subjects (465 children and 80 adults). Two nasal swabs were collected from the same nostril of each subject. One swab was immediately eluted in viral transport media and viral cell culture was inoculated within 72 hrs and analyzed by fluorescent antibody test at 2 days and 5 days post inoculation. The other swab was tested directly with the Alere™ i Influenza A&B instrument within 2 hrs at room temperature following collection or up to 24 hours with refrigeration. Testing with the instrument was performed in a POC setting and completed according to step-by-step instructions provided on the instrument display. These results were compared to viral cell culture as the gold standard. A real-time influenza RT-PCR assay was used for discrepant analysis.

Results. A total of 545 specimens were collected for testing. Of the specimens tested, two were excluded for uninterpretable viral culture results and one was excluded due to conflicting reference results. With testing of the Alere™ i Influenza A&B assay, there were 11 invalid results for influenza A and 15 for influenza B, resulting in invalid rates of 2% and 2.8%, respectively. For 531 valid influenza A and 527 valid influenza B results, the overall performance of the Alere™ i Influenza A&B assay compared to viral cell culture is summarized in Table 1. In children less than 18 years old, the sensitivity was 100% for detection of influenza A and 97.2% for influenza B. The specificities were 98.2% and 100% for influenza A and influenza B in children. For adults greater than or equal to 18 years old, the sensitivity and specificity for detection of influenza A were 100% and 96.6%, while for influenza B the sensitivity and specificity were each 100%.

Conclusions. The Alere™ i Influenza A&B assay was easy to perform and testing results were available within 15 minutes, rather than hours or days as compared to conventional molecular testing and viral cell culture. Overall, the Alere™ i Influenza A&B assay compared well to viral cell culture. The Alere™ i Influenza A&B assay combines the speed of a rapid antigen test with the sensitivity of a NAT in the POC setting and offers the opportunity to improve patient management.

INTRODUCTION

Influenza viruses cause respiratory illnesses that manifest clinically with common symptoms of fever, headache, body aches, extreme tiredness, nausea, stuffy nose or rhinitis, and dry cough (1). Most who have an influenza infection will have a mild illness, will generally not require medical care or antiviral drugs, and will recover in less than two weeks. Some people, however, are more likely to have influenza-related complications that result in being hospitalized and occasionally result in death. Persons at increased risk for severe disease or death include young children (especially those less than two years of age), older adults, and persons of any age with compromised respiratory, cardiac, or immune systems (2-3).

Rapid antigen tests are at the front line of diagnosis of many common infections including respiratory infections such as influenza virus. Though not as sensitive as molecular nucleic acid tests (NAT), these rapid antigen tests provide the quick turnaround time from sample collection to result necessary for patient management in point-of-care (POC) sites such as physician offices and busy emergency departments (4). The decreased sensitivity has long been a tradeoff for the acquisition of rapid results.

Isothermal NAT (iNAT) allow nucleic acid amplification in a very narrow temperature range, eliminating the need for expensive thermal cyclers and allowing for results to be obtained very quickly. The Alere™ i Influenza A&B assay is a rapid and automated in vitro diagnostic test for the qualitative detection of influenza A and B that uses iNAT technology to detect viral RNA from respiratory specimens. Results are available within 15 minutes, allowing for the possibility of turnaround time from sample collection to results reporting in less than half an hour. This technology provides a rapid, sensitive and specific molecular test for influenza virus that can be used in POC settings for timely diagnosis of influenza infections.

MATERIALS & METHODS

Specimens. A total of 545 respiratory nasal swab specimens were collected from study-eligible subjects (465 children and 80 adults) during 2012/2013 respiratory season at clinical sites in distinct regions around the United States. From each subject, two nasal swabs were collected from the same nostril, one for testing with shell vial viral culture and fluorescent antibody testing, and the other for direct testing on the Alere™ i Influenza A&B assay.

Alere™ i Influenza A&B Nucleic Acid Amplification Testing. A schematic of the testing procedure is provided in Figure 1. Briefly, the test base is inserted into the appropriate color-coded receptacle, followed by placing the sample receiver into the corresponding color-coded receptacle. The sample receiver and buffer inside are then heated for three (3) minutes. Following the heating step, specimen is eluted from the swab directly into the sample receiver. The transfer cartridge is then used to transfer sample to the test base. Once this step has been confirmed by the user, the test proceeds and results are available within 10 minutes. All instructions are provided by animated graphics on the instrument display. For the study, positive and negative quality control swabs were processed every day before testing of study specimens. Nasal swabs were tested with the Alere™ i Influenza A&B assay within 2 hours at room temperature following collection or up to 24 hours with refrigeration. All specimens were tested by directly eluting the nasal swab specimen into the buffer in the sample receiver.

Respiratory Viral Culture. Viral culture was performed using shell vials followed by analysis with fluorescent antibodies.

Discrepant Analysis. Prodesse ProFlu+ real-time RT-PCR was performed on discordant specimens.

Specimen Analysis. A total of 545 specimens were enrolled into the study. Two specimens yielded uninterpretable viral culture results. One specimen yielded conflicting reference results. With Alere™ i Influenza A&B testing, there were 11 specimens with invalid Influenza A results and 15 specimens with invalid Influenza B results.

Figure 1. Overview of the Alere™ i Influenza A&B Assay

RESULTS

Table 1. Detection of Flu A and B by Alere™ i Influenza A&B in comparison with viral culture.

Alere™ i Influenza A&B	Influenza Type	TP	FP	TN	FN	Total	% Sensitivity (95% CI)	% Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
vs. Culture	Flu A	90	63	377	1	531	98.9 (93.2-99.9)	85.7 (81.9-88.7)	58.8 (50.6-66.6)	99.7 (98.3-99.9)
	Flu B	67	17	437	6	527	91.8 (82.4-96.6)	96.3 (93.9-97.7)	79.8 (69.3-87.4)	98.6 (96.9-99.4)

RESULTS (cont.)

Table 2. Detection of Flu A and B by Alere™ i Influenza A&B in comparison with viral culture after discrepant analysis.

Alere™ i Influenza A&B	Influenza Type	TP	FP	TN	FN	Total	% Sensitivity (95% CI)	% Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
vs. Culture after PCR discrepant analysis	Flu A	146	8	377	0	531	100 (96.8-100)	97.9 (95.9-99.0)	94.8 (89.8-97.6)	100.0 (98.7-100)
	Flu B	84	0	441	2	527	97.7 (91.1-99.6)	100 (98.9-100)	100.0 (94.6-100)	99.5 (98.2-99.9)

Table 3. Detection of Flu A and B in children and adults by Alere™ i Influenza A&B in comparison with viral culture after discrepant analysis.

Specimen Detection		TP	FP	TN	FN	Total	% Sensitivity (95% CI)	% Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Flu A	Children	128	6	321	0	455	100 (96.4-100)	98.2 (95.9-99.3)	95.5 (90.1-98.2)	100.0 (98.8-100)
	Adults	17	2	57	0	76	100 (77.1-100)	96.6 (87.3-99.4)	89.5 (65.6-98.2)	100 (92.1-100)
Flu B	Children	70	0	379	2	451	97.2 (89.4-99.5)	100 (98.7-100)	100 (93.5-100)	99.5 (97.9-99.9)
	Adults	14	0	62	0	76	100 (73.2-100)	100 (92.7-100)	100 (73.2-100)	100 (92.7-100)

CONCLUSIONS

1. In comparison to viral culture as the gold standard prior to discrepant analysis, overall sensitivity of the Alere™ i Influenza A&B POC test was 98.9% for the detection of Influenza A, and 91.8% for the detection of Influenza B from direct nasal swabs. The specificities were 85.7% and 96.3% for Influenza A and B, respectively.
2. After discrepant analysis with Prodesse ProFlu+ real-time RT-PCR, the overall sensitivity of the Alere™ i Influenza A&B assay was 100% for the detection of Influenza A, and 97.7% for the detection of Influenza B from direct nasal swabs. The specificities were 97.9% and 100% for Influenza A and B, respectively.
3. In children, when compared to viral culture (after discrepant analysis by Prodesse ProFlu+ real-time RT-PCR) overall sensitivity of the Alere™ i Influenza A&B assay for the detection of Influenza A was 100%, and 97.2% for detecting Influenza B from direct nasal swabs. Specificity was 98.2% for Influenza A and 100% for Influenza B in children. In adults, overall sensitivity of the Alere™ i Influenza A&B assay for the detection of both Influenza A and Influenza B was 100%. Specificity was 96.6% for Influenza A and 100% for Influenza B.
4. The Alere™ i Influenza A&B assay is a simple and easy to use molecular diagnostic test with no off-board lysis step. The test has the ability to generate results within 15 minutes from the time of specimen collection. Importantly, the test demonstrates impressive sensitivity for the detection of both Influenza A and B in clinical respiratory specimens obtained from both children and adults.

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http://pascv.ivdnews.net/public/show_abstract/1558

Influenza A/B: First Publications

UMKC School of Medicine

EVALUATION OF THE RAPID ALERE™ i INFLUENZA A&B NUCLEIC ACID AMPLIFICATION TEST USING RESPIRATORY SPECIMENS COLLECTED IN VIRAL TRANSPORT MEDIUM

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ABSTRACT

Background: Molecular nucleic acid-based laboratory tests are among the most sensitive tests available for diagnosis of viral infections. The Alere™ i Influenza A&B assay is a rapid isothermal nucleic acid amplification test for the qualitative detection of influenza A and B in respiratory specimens. Results are available within 15 minutes.

Methods: A total of 226 salvaged frozen respiratory specimens collected from August 2009 through June 2012 were included in the study. The respiratory specimens were nasopharyngeal swabs (NPS) or nasopharyngeal washes/aspirates (NPW/A) collected in 3 ml universal transport medium (UTM) from children. The results of the Alere™ i Influenza A&B assay were compared to R-mix shell vial culture and ProFlu+ real-time RT-PCR assay. All testing was completed within 24 hours of thawing the specimens. The Alere™ i Influenza A&B assay was performed by adding 200 µl of respiratory specimen directly to the instrument for lysis and isothermal amplification. Viral cultures were performed using R-Mix™ shell vials and stained with influenza A/B dual antibody on day 2. Nucleic acids were extracted with the bioMérieux NucliSENS® easyMag® and frozen at -80°C prior to batch-testing by real-time RT-PCR assay.

Results: The performance of the Alere™ i Influenza A&B assay compared to viral culture and PCR testing is summarized in Table 1. A total of 105 influenza A and 58 influenza B were detected by culture and 116 influenza A and 58 influenza B were detected by real-time RT-PCR. The Alere™ i Influenza A&B assay detected 105 influenza A and 58 influenza B specimens. In comparison with culture, the influenza A test results of the Alere™ i Influenza A&B assay were 98 true positives (TP), 7 false positives (FP), 121 true negatives (TN), and 7 false negatives (FN). When compared to PCR, the influenza A results were 103 TP, 2 FP, 115 TN, and 13 FN. The overall invalid rate was low (1.7%).

Conclusions: The test performance of Alere™ i Influenza A&B assay with respiratory specimens collected in UTM compared more favorably with test results from viral culture versus real-time RT-PCR. The Alere™ i Influenza A&B assay test results were available in minutes versus hours for conventional PCR and days ahead of the culture results. The Alere™ i Influenza A&B assay test is simple and easy to perform without the need for off-board nucleic acid extraction. The Alere™ i Influenza A&B assay provides both the speed of a rapid antigen test with the sensitivity of a nucleic acid based molecular test.

INTRODUCTION

Several laboratory methods are available for the diagnosis of influenza infections and will distinguish between influenza A and influenza B. Commonly used methods in the lab include viral culture (1), direct fluorescent antibody (DFA) staining, immunochromatographic viral antigen-based assays (2-4), and nucleic acid amplification assays (5-7). Culture continues to be the gold standard for detection of influenza infection, and shell vial cultures using co-cultured cell lines (R-mix) have been used to increase the rate and rapidity of culture results. However, these results are not available in a timely fashion to impact clinical decisions in an outpatient setting. DFA assays have performed well and have improved the result turnaround time. However, these assays are laborious, subjective, and technically demanding. Real-time reverse transcription polymerase chain reaction (RT-PCR) is becoming increasingly accepted as a gold standard for detection of influenza viruses, but is technically demanding, laborious, and expensive, all limits to the usefulness of the technique in an outpatient setting. Rapid antigen-based assays are available for rapid diagnosis of viral infections from respiratory specimens. These assays show benefit in the Emergency Department and outpatient settings due to their ease of use and rapid turnaround time, generally 30 min or less. For these reasons, most clinical laboratories employ rapid antigen-based assays as their first line diagnostic test for influenza infections. Though generally exhibiting very high specificity and positive predictive values, the major limitation of currently available rapid antigen tests is low and widely variable sensitivity.

A current need in diagnostic Microbiology is for a rapid, molecular-based assay with high sensitivity and quick turnaround time. Isothermal nucleic acid amplification allows nucleic acid amplification in a very narrow temperature range, eliminating the need for expensive thermal cyclers and allowing for results to be obtained very quickly. The Alere™ i Influenza A&B nucleic acid amplification test is a simple to use, automated test for influenza A and B viruses that provides the sensitivity of a molecular test with the quick results that a traditional rapid antigen test provides. The Alere™ i Influenza A&B test can provide results within 15 minutes of initiating the test. Specimen preparation, lysis, and nucleic acid amplification are all accomplished with minimal hands-on time.

MATERIALS & METHODS

Specimens. A total of 226 salvaged frozen respiratory specimens collected in 3 ml of UTM from August 2009 through June 2012 at Children's Mercy Hospitals and Clinics in Kansas City, Missouri, USA, were included in the study. There were 150 NPS and 76 NPWA from children ages 10 months to 18 years that were included. Each specimen was de-identified and given a unique, site-specific study identifier prior to enrollment into the study.

Alere™ i Influenza A&B Nucleic Acid Amplification Testing. A schematic of the testing procedure is provided in Figure 1. Briefly, the test base is inserted into the appropriate color-coded receptacle, followed by placing the sample receiver into the corresponding color-coded receptacle. The sample receiver and buffer inside are then heated for three (3) minutes. Following the heating step, specimen is added directly to the sample receiver. The transfer cartridge is then used to transfer sample to the test base. Once this step has been confirmed by the user, the test proceeds and results are available within 10 minutes. All instructions are provided by animated graphics on the instrument display. For the study, positive and negative quality control swabs were processed every day before testing of study specimens. Specimens were tested with the Alere™ i Influenza A&B assay within 24 hours of thawing. All specimens were tested by adding 200 µl of thawed specimen in UTM directly to the buffer in the sample receiver. The testing procedure described above was then followed.

Respiratory Viral Culture. Viral culture was performed using R-Mix™ shell vials from Diagnostic Hybrids. The viral cultures were stained with Light Diagnostics™ SimulFluor® Flu A/Flu B dual antibody from EMD Millipore on day 2 of culture.

RT-PCR. RT-PCR was performed with the Prodesse® ProFlu™+ Assay for detection of influenza A, influenza B, and RSV (Gen-Probe). The assay was performed on all tested specimens according to the manufacturer's instructions on the Cepheid SmartCycler II Real Time Instrument with Dx Software version 1.7b. Nucleic acids were extracted in batches daily and stored frozen at -80°C until real-time RT-PCR testing. Total nucleic acid was extracted from the specimens along with positive and negative extraction controls with the NucliSENS® easyMAG® automated extractor from bioMérieux.

Figure 1. Overview of the Alere™ i Influenza A&B Assay

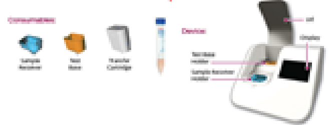


Figure 2. Schematic Representation of Alere™ i Influenza A&B Assay Technology

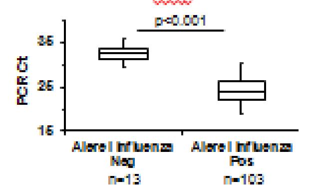
1. Both template strands are cut by nicking enzyme.
2. a) Polymerase sits at nick sites and unravels template. b) Polymerase elongates reaction products throughout test duration.
3. a) Primer binds loosely to template such that b) growing reaction product can be displaced by new primer.
4. Reaction proceed from both directions.
5. Nick-site within primers allows for process to be repeated for rapid amplification of product.

RESULTS

Table 1. Comparison of Alere™ i Influenza A&B Assay versus Respiratory Viral Culture and ProFlu+ RT-PCR

Alere™ i Influenza A&B	Specimen	TP	FP	TN	FN	Total	% Sensitivity (95%CI)	% Specificity (95%CI)	PPV (95%CI)	NPV (95%CI)
vs. Culture	Influenza A	98	7	121	7	233	93.3 (86.3-97.0)	94.5 (88.6-97.6)	93.3 (86.3-97.0)	94.5 (88.6-97.6)
	Influenza B	58	-	174	-	232	100 (92.3-100)	100 (97.3-100)	100 (92.3-100)	100 (97.3-100)
vs. PCR	Influenza A	103	2	115	13	233	88.8 (81.3-93.7)	98.3 (93.3-99.7)	98.1 (92.6-99.7)	89.8 (82.8-94.3)
	Influenza B	58	-	174	-	232	100 (92.3-100)	100 (97.3-100)	100 (92.3-100)	100 (97.3-100)

Figure 3. Comparison of PCR Ct values of Alere i Influenza A&B positive and negative specimens.



CONCLUSIONS

1. Using viral culture as the gold standard, overall sensitivity of the Alere™ i Influenza A&B assay was 93.3% for the detection of influenza A, and 100 % for the detection of influenza B. The specificities were 94.5% and 100% for influenza A and B, respectively.
2. In comparison to PCR, overall sensitivity of the Alere™ i Influenza A&B assay for the detection of influenza A was 88.8 %, and 100% for detecting influenza B. Specificity was 98.3% for influenza A and 100% for influenza B.
3. The PCR cutoff for the detection of influenza A and B viruses for specimens collected in 3 ml of VTM based on the Prodesse ProFlu+ assay was determined to be a Ct of ~30. For the i Influenza Neg specimens the Ct range was 28.4 - 35.8 (1st Quartile 28.4 - 31.2; 3rd Quartile 32.7 - 33.5). For the i Influenza Pos specimens the Ct range was 19.1 - 30.4 (1st Quartile 19.1 - 22.1; 3rd Quartile 24.1 - 26.3).
4. The Alere™ i Influenza A&B assay is a simple and easy to use molecular diagnostic test without off-board lysis step. The assay has the ability to generate results within 15 minutes from the time of initiating the test.

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Acknowledgements

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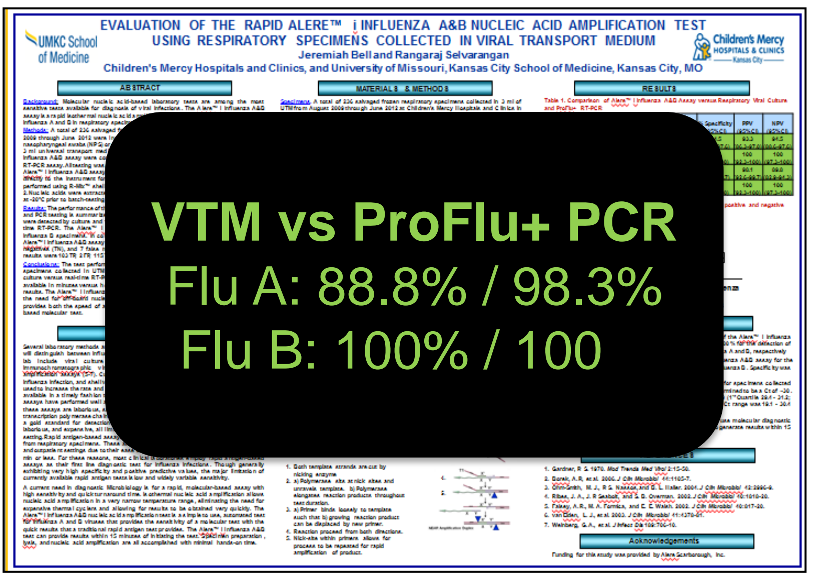
Influenza A/B: First Publications

CLINICAL EVALUATION OF THE ALERE™ i INFLUENZA A&B ASSAY, A POINT-OF-CARE RAPID NUCLEIC ACID AMPLIFICATION TEST FOR DETECTION OF INFLUENZA.

Direct NS vs Culture
Flu A: 100% / 97.9%
Flu B: 97.7% / 100%



Conclusions:

✓ Compared well to viral cell culture

✓ Demonstrates impressive sensitivity

✓ Combines speed of a RAT with sensitivity of a NAT in POC setting

✓ Offers the opportunity to improve patient management

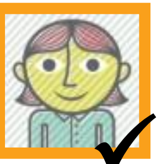
http://pascv.ivdnews.net/public/show_abstract/1558

Advantages of Rapid Flu Tests

Alere™

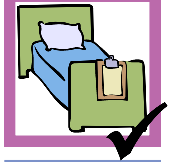
Accurate determination of who needs medication

- Antiviral medication AND antibiotics
- Avoid exacerbation of bacterial & viral resistance
- In pandemic, can help qualify who gets medication



Early treatment of high risk patients, to

- Reduce complications
- Reduce spread
- Reduce healthcare burden



Cost benefits

- Directed therapy
- Reduced morbidity and mortality reduces hospital costs