

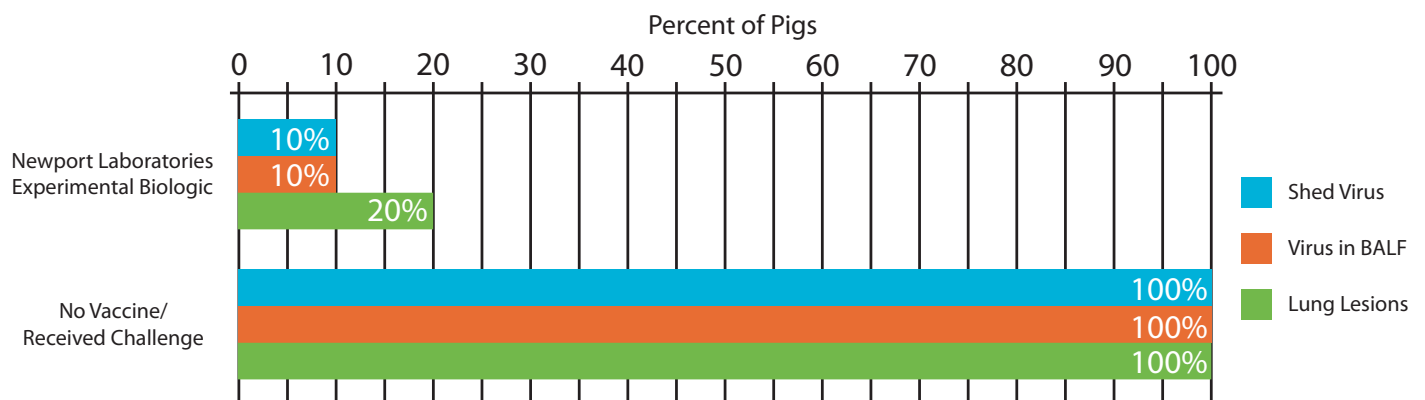
Newport Laboratories' Proprietary Two-Step Isolate Selection Technology Proves Itself in Independent NADC Study¹

Newport Laboratories has developed a proprietary two-step isolate selection technology to identify swine influenza isolates that cross-neutralize novel H1N1 and thus protect pigs from the disease, as demonstrated by an independent NADC study.

An experimental vaccine was produced by Newport Laboratories containing two field SIV isolates selected for cross-neutralization with novel H1N1. The vaccine was submitted to the National Animal Disease Center (NADC) for testing under the direction of Dr. Amy Vincent. Pigs (10 pigs per group) were vaccinated on days 0 and 21 and challenged with novel H1N1 A/CA/04/2009 on day 42.

One hundred percent of non-vaccinated controls showed nasal shedding, presence of virus in bronchoalveolar lavage fluid, and lung lesions. Pigs vaccinated with Newport's experimental vaccine showed a 90% reduction in the number of animals shedding virus in nasal secretions compared to non-vaccinated controls. Pigs receiving Newport's vaccine showed a 90% reduction in the number of animals with virus present in bronchoalveolar lavage fluid (BALF) compared to non-vaccinated controls. Pigs receiving the Newport vaccine showed an 80% reduction in the number of pigs with lung lesions compared to non-vaccinated controls.

Dr. Vincent concluded that Newport Laboratories' vaccine "demonstrated significant protection."



These results confirm the validity of Newport Laboratories' two-step strain selection technology for Swine Influenza Virus vaccine formulation.

Reasons to use Newport Laboratories' proprietary two-step strain selection technology for SIV vaccine production:

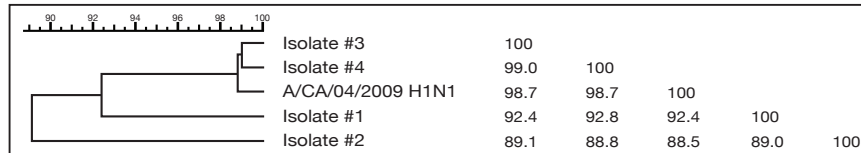
- 1. Do It Now:** Vaccine production can start immediately (no need to wait for a conditionally licensed product for H1N1).
- 2. No Extra Steps:** An isolate that cross-neutralizes in the novel H1N1 HT-SN Assay can be formulated with other contemporary SIV strains and built into existing vaccine.
- 3. Less Cost:** Autogenous multivalent SIV vaccine will be more economical than a monovalent conditionally licensed product.
- 4. Think Ahead:** Newport Laboratories' unique two-step isolate selection technology can be applied to emerging diseases today, tomorrow, and in the future.

¹Vincent, A. Oral presentation. 2009 Sept 30; Ames, IA. (Unpublished).

The strains used in Newport's experimental vaccine evaluated in the NADC study were selected using the following process:

Introducing iNGA[®] - Newport's Isolate Neutralization Genetic Analysis - A Two-Step Process for Isolate Selection

SIV isolates are analyzed using both genetic and antigenic methods. Initial characterization of isolates was completed using sequence analysis.



Traditional vaccine isolate selection stops here.

Step One: TALLYSS[™]

Genetic analysis includes partial hemagglutination gene sequencing and epitope analysis using Newport's TallySS[™] software. Potential cross-reactive isolates are initially identified as those strains having a genetic distance of 7 or less to the novel H1N1. Genetic distance is a measure of amino acid differences at key sites. The lower the genetic distance between an isolate and the novel H1N1, the more genetically similar the two viruses are.

TallySS[™] (Strain Selection Software Analysis)

Compare:	Candidates:	Genetic Distance
A/CA/04/2009 H1N1	Isolate #3	6
	Isolate #4	5
	Isolate #1	5
	Isolate #2	7

Step Two: HT-SN[™]

Isolates with high genetic similarity are then assayed for antigenic similarity using a High Throughput Serum Neutralization assay to determine potential for cross-neutralization. Isolates are antigenically characterized using antisera generated against two different novel H1N1 viruses. Antigenically similar isolates are neutralized by novel H1N1 antisera in the serum neutralization assay. Isolates neutralized by novel H1N1 antisera are antigenically similar to the novel H1N1 and are candidates for vaccine production.

HT-SN[™] (Serum-Neutralization Assay)*

Vaccine Candidates	Antisera	Antisera
	A/CA/07/2009	A/CA/04/2009
Isolate #1	0.99	0.82
Isolate #2	0.92	0.95
Isolate #3	0.11	0.22
Isolate #4	0.05	0.17

Selected for Vaccine

Isolates #1 & #2 were selected based on positive SN results with antisera.

*SN>0.30=Positive

Final Conclusion:

Antisera generated with isolates #1 and #2 cross-react with pandemic H1N1 isolates, further validating Newport Laboratories' two-step isolate selection process.

Two-Way Cross Reaction (Hemagglutination Inhibition Assay) of HT-SN Positive Isolates*

Vaccine Candidates	Antisera Isolate #1	Antisera Isolate #2
A/CA/04/2009	160	320
A/CA/07/2009	320	320

*HI>40=Positive



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