

# **VetMAX-Gold SIV solutions**

USDA-licensed, real-time PCR screening and subtyping kits that detect influenza virus in pigs with a high degree of specificity and sensitivity

#### **Features**

- First real-time PCR swine influenza virus (SIV) screening and subtyping kits to be licensed by the United States Department of Agriculture (USDA)
- Superior repeatability, reproducibility, and reliability
- Multiple gene targets
- Complete workflow solution
- Faster time to subtyping results

#### **Benefits**

#### Verified and effective test

The Applied Biosystems™ VetMAX™-Gold SIV solutions are USDA-licensed diagnostic tests that have successfully passed the USDA's stringent review process. This process requires demonstration of the effectiveness of the real-time PCR test and manufacturing of the product in a USDA-licensed and USDA-inspected biologics facility.

### Fast and simple to use

- Intended to be used for rapid detection of SIV RNA extracted from porcine nasal swabs and for differentiation between subtypes
- Validated workflow enables excellent sensitivity, specificity, repeatability, and reproducibility

- Applied Biosystems<sup>™</sup> VetMAX<sup>™</sup>-Gold SIV
  Detection Kit
  - Sensitivity of 98.4%
  - Specificity of 99.1%
- Applied Biosystems<sup>™</sup> VetMAX<sup>™</sup>-Gold SIV Subtyping and Detection Kits
  - Sensitivity of 98.2%
  - Specificity of 100%
- Helps increase speed and reduce labor requirements for SIV subtyping, compared to other methodologies

#### Enables consistent performance

- Targets multiple genomic regions, helping to reduce the risk of false negatives caused by genomic mutation, while offering highly sensitive SIV detection
- Consistently detects down to 25 copies of SIV RNA
- Kits are part of a complete workflow solution enabling more consistent performance and results



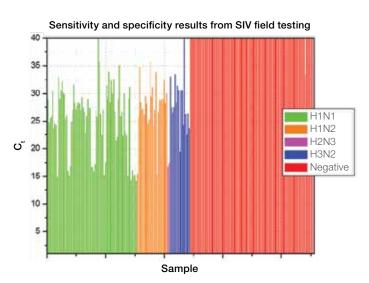
#### **Economical**

Enables greater cost savings—commercially produced, licensed kits help decrease variability in results and allow for greater reproducibility through assay standardization. The built-in internal positive control (IPC) in the screening kit also helps to avoid false negatives. In addition, the use of real-time PCR for subtyping significantly decreases the need for sequencing.

## Confidence in results backed by data VetMAX-Gold SIV Detection Kit

A study was conducted on 226 nasal swab field samples (121 positive and 105 negative) of various SIV subtypes. The complete workflow was carried out by external collaborators as part of the USDA-licensing effort. The SIV status of each sample was determined prior to testing with virus isolation and/or sequencing. The assay produced 98.4% sensitivity and 99.1% specificity. The only discrepant positive samples were from very low-titer samples amplified near the assay's limit of detection, which resulted in inconsistent detection upon retesting. The single discrepant negative sample was confirmed to be negative upon reisolation and repeated analysis by quantitative reverse transcription PCR (RT-qPCR). The original positive test was likely due to cross-

contamination during isolation or RT-qPCR setup.



# VetMAX-Gold SIV Subtyping Kit

The VetMAX-Gold SIV Subtyping Kit produced 98.2% sensitivity and 100% specificity for identifying the SIV subtype from porcine nasal swab samples. This study indicates that RNA isolated from diagnostic porcine nasal swab samples, tested with the VetMAX-Gold SIV Subtyping Kit in conjunction with the VetMAX-Gold SIV Detection Kit, can provide an economical and rapid solution for SIV subtype identification.

Primary testing of 169 characterized positive samples with the VetMAX-Gold SIV Subtyping Kit produced 161 initial positive test results for both hemagglutinin and neuraminidase. 67 samples were called positive for H1N1, 16 samples were positive for H1N2, 77 samples were positive for H3N2, and 1 sample was positive for H3N1.

Of the remaining 8 samples, 5 were identified correctly after completion of the workflow for suspect samples provided in the instructions for use. The resulting sensitivity is 98.2% (Table 1).

In a second study, primary testing of 150 well-characterized negative samples with the VetMAX-Gold SIV Subtyping Kit produced 142 initial negative test results for both hemagglutinin and neuraminidase. 8 samples produced a suspect result for at least one genotype during initial testing. There were no samples that produced a discrepant call in the initial testing.

Of the 8 suspect samples, 5 samples were suspect for the N2 genotype, 1 sample was suspect for H1,1 sample was suspect for H3, and 1 sample was suspect for both H3 and N2. Suspect samples were retested according to the workflow for suspect samples, provided in the instructions for use. All 8 suspect samples produced the correct final call when processed through the workflow for suspect samples, resulting in 100% specificity (Table 2).

Table 1. Results of SIV-positive sample sensitivity testing.

Call	No. of samples
Final call: true positive	166
Final call: false negative	3
Diagnostic sensitivity: 98.2%	

Table 2. Results of SIV-negative sample specificity testing.

No. of samples		
150		
0		

Diagnostic sensitivity: 100%

# applied biosystems

#### Swine influenza virus

The USDA-licensed VetMAX-Gold SIV Detection and Subtyping Kits enable early detection of SIV in pigs and help minimize the spread of the disease caused by the virus. Swine influenza is a highly contagious virus in pigs. The infection is transmitted when an animal comes into contact with secretions containing viral particles, notably in aerosols generated by coughing, sneezing, and the projection of nasal discharge.

SIV causes a respiratory disease characterized by coughing, sneezing, nasal discharge, high rectal temperature, lethargy, difficulty breathing, and loss of appetite. In some cases, SIV infection can cause reproductive problems and abortion.

Symptoms of swine influenza can appear within 24 hours of infection. Although mortality tends to be low, morbidity can reach 100% and secondary bacterial infection can exacerbate the severity of SIV infection.

#### **Ordering information**

Product	Туре	Quantity	Cat. No.
VetMAX-Gold SIV Detection Kit	Real-time RT-PCR	100 reactions	4415200
VetMAX-Gold SIV Subtyping Kit	Real-time RT-PCR	100 reactions	4485541
Workflow products			
MagMAX Pathogen RNA/DNA Kit	Sample prep	480 reactions	4462359
KingFisher Flex Magnetic Particle Processor with 96 Deep-Well Head	Sample prep	1 instrument	5400630
Applied Biosystems 7500 Fast Real-Time PCR System with Dell Notebook	Analysis	1 instrument	4365464
Related products			
VetMAX NA and EU PRRSV Reagents	Real-time RT-PCR	100 reactions	4468465
VetMAX NA and EU PRRSV and Xeno RNA Controls	Real-time RT-PCR	1 kit	4405548
VetMAX PEDV/TGEV/SDCoV Kit*	Real-time RT-PCR	100 reactions	A33402

<sup>\*</sup> For testing of food and environmental samples only.

