

### BACKGROUND

The Department of Homeland Security (DHS) Science and Technology Directorate's (S&T) Plum Island Animal Disease Center (PIADC) became part of DHS in 2003. PIADC has been protecting the nation's agriculture against the accidental, natural, or intentional introduction of transboundary animal diseases (TAD)—including Foot-and-mouth disease (FMD) and African Swine Fever (ASF)—for over 65 years. PIADC is the only federal laboratory in the nation that can conduct diagnostics and research using live FMD virus (FMDV) and live ASF virus (ASFV).

To execute its agricultural defense mission, PIADC operates as a partnership between S&T, the United States Department of Agriculture (USDA) Agricultural Research Service (ARS), and the USDA Plant and Animal Health Inspection Services (APHIS).

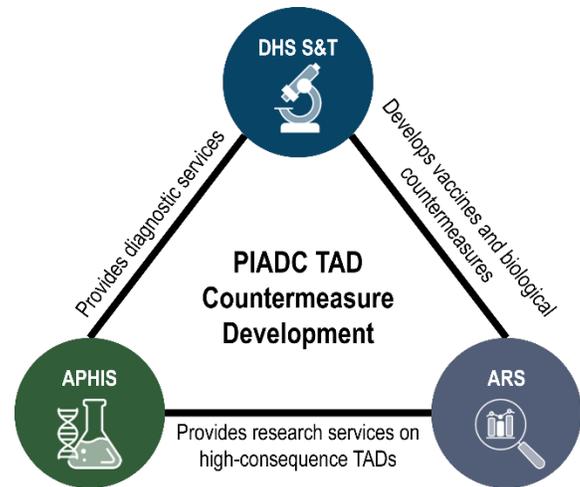
### MISSION

PIADC's mission is to protect U.S. agriculture through countermeasure research on high-consequence livestock pathogens, foundational research for the veterinary community, and essential diagnostics to the global community.

### EXPERTISE

PIADC requires dedicated expertise and lab infrastructure to maintain modern capabilities for countermeasure development to support the DHS agriculture defense mission. PIADC's scientific subject matter experts (SMEs) serve the broader homeland security enterprise by:

- Performing advanced development of vaccines and other biological countermeasures to TADs
- Co-developing TAD vaccines in partnership with veterinary biologics companies for product licensure and manufacturing
- Establishing cooperative research and development agreements (CRADAs) with global animal health biopharmaceutical companies, veterinary biotech, and animal agriculture industry stakeholders
- Filing and receiving United States Patent and Trademark Office (USPTO) patents related to TAD novel vaccine compositions, methods of production, and use
- Publishing peer-reviewed scientific papers



### IMPACT

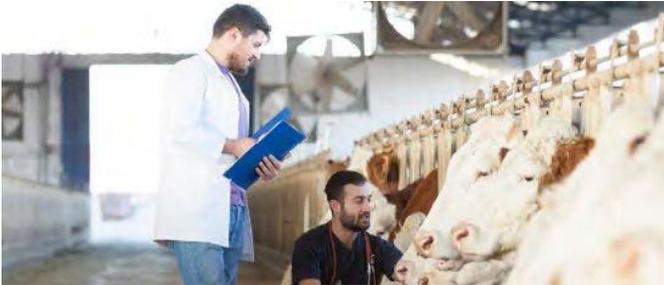
Since 1956, PIADC has defended the nation against TADs—such as FMD and ASF—that cause food insecurity and impact export trade markets for animal products. While the United States has been FMD-free for almost 100 years, the cost of an outbreak could exceed \$50 billion in only one year.

ASF is a highly transmissible disease with up to a 100 percent mortality rate in swine with no licensed vaccines or effective disease treatments currently available. ASF outbreaks have reduced the number of pigs in China—the global leader in pork production—by at least 40 percent since 2018. ASF outbreaks have now been reported in over 50 countries, including most of Asia and, most recently, Haiti and the Dominican Republic. The U.S. pork industry has an annual value of around \$25 billion and it is the global leader in pork exports, exporting around a fourth of its pork products. While the U.S. has never had a case of ASF, a domestic outbreak would significantly impact its ability to export pork and could cost billions in disease outbreak control.

### PATENTS RELATED TO TAD VACCINES

PIADC research & development has resulted in numerous patents granted by the USPTO. In 2018 alone, PIADC scientists received six USPTO granted patents and there are currently several patents pending.

The World Intellectual Property Organization published a patent application titled "Modified Picornavirus 3C Proteases and Methods Thereof" to PIADC inventors in 2019. The PIADC inventions support more efficient production of next generation,



molecular-based FMD vaccines, including more rapid manufacturing for novel, emerging FMD strains. Other scientists may be able to create animal or human vaccines against diseases caused by picornaviruses in a fraction of the time it takes now by following this blueprint.

### INDUSTRY PARTNERSHIPS AND CRADAS

PIADC has established CRADAs with industry partners for FMD and ASF vaccine development. In 2019, PIADC fulfilled a CRADA with the National Pork Board to evaluate commercial disinfectants for use against ASF and entered into a CRADA with MatMaCorp for evaluation of a field-deployable ASFV test.

In 2020, PIADC and MatMaCorp successfully conducted the laboratory evaluation of a field-deployable genetic test to detect ASFV in infected pigs and pork products.

MatMaCorp's device detected ASFV in clinical tissue samples obtained from ASFV-infected laboratory pigs. As ASF continues to rapidly spread in many parts of the world, this field-deployable technology can help in outbreak response to the threat posed by accidental, natural, or intentional introduction of ASF in the United States.

### ESTABLISHED ASF TASK FORCE

In response to ASF's increasing global threat, PIADC established an interagency ASF Task Force. To date, it has met its primary objectives, including:

- Performing advanced development of vaccines and other biological countermeasures to TADs
- Improving diagnostic test surge capacity to support national surveillance and outbreak response
- Increasing national preparedness and response

- Evaluating commercially available disinfectants to determine their efficacy to decontaminate ASF virus-contaminated surfaces
- Fast-tracking development and scale-up production of an emergency-use ASF vaccine

### ASF MASTER QUESTION LIST (MQL)

In 2021, as a result of significant contributions from SMEs at PIADC, the S&T Probabilistic Analysis for National Threats Hazards and Risks Program and the S&T Hazard Awareness & Characterization Technology Center published an [ASF MQL](#), which is intended to:

- Quickly present the current state of available information to government and industry stakeholder decision-makers during a possible operational response to an ASF outbreak
- Allow structured and scientifically guided discussions across the federal government and industry stakeholder without burdening them with the need to review scientific reports
- Prevent duplication of efforts by highlighting and coordinating ASF research

The MQL will undergo periodic updates to ensure it remains current.