LEGISLATIVE SERVICES AGENCY
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ISSUE REVIEW

Fiscal Services Division

January 4, 2018

Iowa State University Veterinary Diagnostic Laboratory

ISSUE

This ***Issue Review*** provides an overview of the operations and the facilities of the Iowa State University Veterinary Diagnostic Laboratory (ISU VDL) located in Ames.

AFFECTED AGENCIES

Iowa State University

CODE AUTHORITY

Iowa Code section 163.9

BACKGROUND

The ISU VDL is the State of Iowa's official veterinary diagnostic lab and is the only fully accredited and full-service veterinary diagnostic laboratory in Iowa. The ISU VDL serves to protect animal and human health and advance Iowa's animal agriculture economy. The ISU VDL is a division in the Department of Veterinary Diagnostic and Production Animal Medicine at the College of Veterinary Medicine (CVM). The Laboratory is fully accredited by the American Association of Veterinary Laboratory Diagnosticians and offers diagnostic services for animal species, including necropsy, bacteriology, serology, histopathology, virology, parasitology, molecular diagnostics, and toxicology. In addition, the ISU VDL processes between 75,000 and 85,000 case submissions per year and conducts over 1.25 million diagnostic tests per year. **Photo 1** is a photo of the current facility.

Photo 1
Current Iowa State University Veterinary Diagnostic Laboratory

Mission Statement

The mission statement of the ISU VDL includes:

- Provide comprehensive and cutting-edge diagnostic services agents as fast as possible.
- Deliver accessible, timely, accurate, valid, and consistent test results.
- Detect and identify emerging domestic and foreign animal disease.
- Lead efforts in disease surveillance and eradication.
- Provide educational opportunities to professional and graduate students, scientists, diagnosticians, and practitioners.
- Develop state-of-the-art diagnostic tools and techniques.
- Direct or support studies to provide understanding of pathogenesis, transmission, epidemiology, and control of infectious and toxicological diseases.

Economic Impact of Iowa Animal Agriculture

A recent ISU study estimated that Iowa animal agriculture provides $14.620 billion in direct economic output, and livestock processing provides $17.960 billion in direct economic output.[1] The combined direct economic output of animal agriculture production and processing is $32.580 billion and equates to over $10,000 for each person living in Iowa.

In another study conducted in 2015, Iowa animal agriculture contributed $25.500 billion in economic output; created approximately 115,000 jobs; contributed $1.600 billion in income taxes paid at the local, State, and federal levels; and contributed $473.3 million in property taxes.[2]

CURRENT SITUATION

National Animal Health Laboratory Network

The United States Department of Agriculture National Animal Health Laboratory Network (USDA NAHLN) is part of the Animal and Plant Health Inspection Service under the U.S. Department of Agriculture (USDA) and was established in 2002 with the passage of the Public Health Security and Bioterrorism Preparedness and Response Act. The Network is a partnership of federal, State, and university-associated animal health laboratories that supports early detection, rapid response, and appropriate recovery from high-consequence animal diseases such as Foot and Mouth Disease, Classical Swine Fever, Exotic Newcastle Disease, Highly Pathogenic Avian Influenza, and others. The laboratories within the USDA NAHLN are categorized at different levels and include 14 Level 1 facilities, 28 Level 2 facilities, and eight Level 3 facilities. The ISU VDL is the only facility in Iowa that is a Level 1 laboratory and is involved in the surveillance and implementation of animal health programs at the national level.

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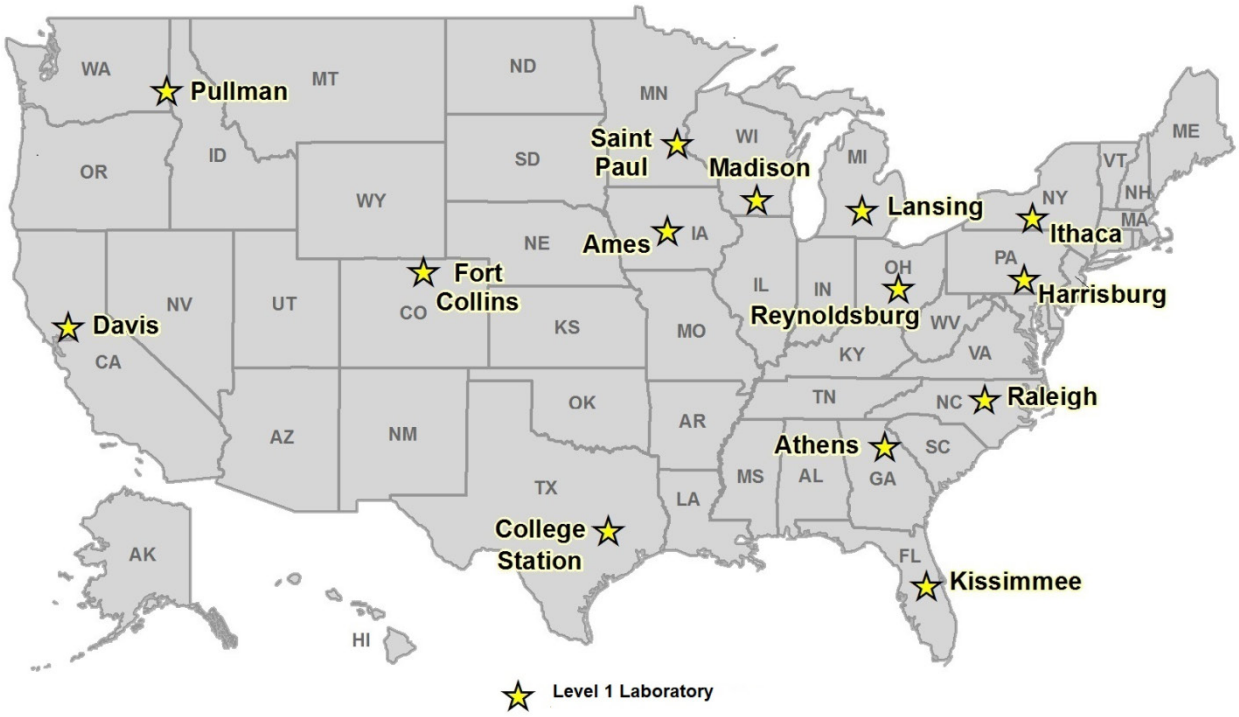
[1] Lee Schulz, David Swenson, Dermot Hays, and Derald Holtcamp, Iowa State University, Economic Contribution of the Iowa State University Veterinary Diagnostic Laboratory (January 30, 2017), vetmed.iastate.edu/sites/default/files/VDL/pdf/ISU-VDL-Report-01-30-17.pdf

[2] Decision Innovative Solutions LLC, Economic Analysis of Animal Agriculture 2005-2015 (September 2016), animal.ag/economics/state-reports/IOWA%20Economic%20Analysis%20of%20Animal%20Agriculture%202005-2015.pdf

For a summary listing of activities for Level 1 through Level 3 USDA NAHLN facilities, refer to **Appendix A**. **Map 1** depicts the location of the Level 1 facilities.

Map 1
National Animal Health Laboratories Network
Level 1 Laboratories



Source: Federal Department of Agriculture
Animal and Plant Health Inspection Service

The ISU VDL provided a leadership role in three recent animal health events, including:

- **Porcine Epidemic Diarrhea Virus (PEDV)** in 2013 – 2015. This virus causes diarrhea in all ages of swine. Mortality rates can approach 100.0% in neonatal pigs. Prior to May 2013, there were no cases in the United States but the virus had previously been actively circulating within China and Southeast Asia. The ISU VDL was the first to identify the transboundary introduction of PEDV into North America and to develop and provide same-day PEDV diagnostic tools in response to this emerging animal health crisis.
- **Highly Pathogenic Avian Influenza Virus (HP-AIV)** in 2015. The HP-AIV is a quickly spreading pathogen that infects wild birds and domestic poultry. Affected flocks are depopulated immediately to decrease the spread of the disease. Iowa experienced a severe outbreak in 2015 and the ISU VDL played a critical role in providing quality and timely test results. Testing was conducted seven days per week throughout the outbreak. The ISU VDL continues to provide ongoing surveillance of HP-AIV to support Iowa's poultry and egg producers.
- **Senecavirus A (SVA)** in 2015 – 2017. This virus causes clinical signs of vesicular lesions on the foot and snout of swine that are visually indistinguishable from Foot and Mouth Disease Virus (FMDV). In 2015, a new and more virulent strain of SVA emerged in United

States swine. A similar SVA outbreak had been described in South America earlier in 2015. Due to the trade-impacting nature of FMDV, all cases of vesicular disease need to be investigated by veterinary medical officials and cleared by official diagnostic testing prior to resuming the movement of animals or meat products from the affected premises.

During each of these emerging disease events, the ISU VDL aided in mitigating losses, maintaining continuity of business, and determining freedom from the disease.

OPERATIONS

Services Provided

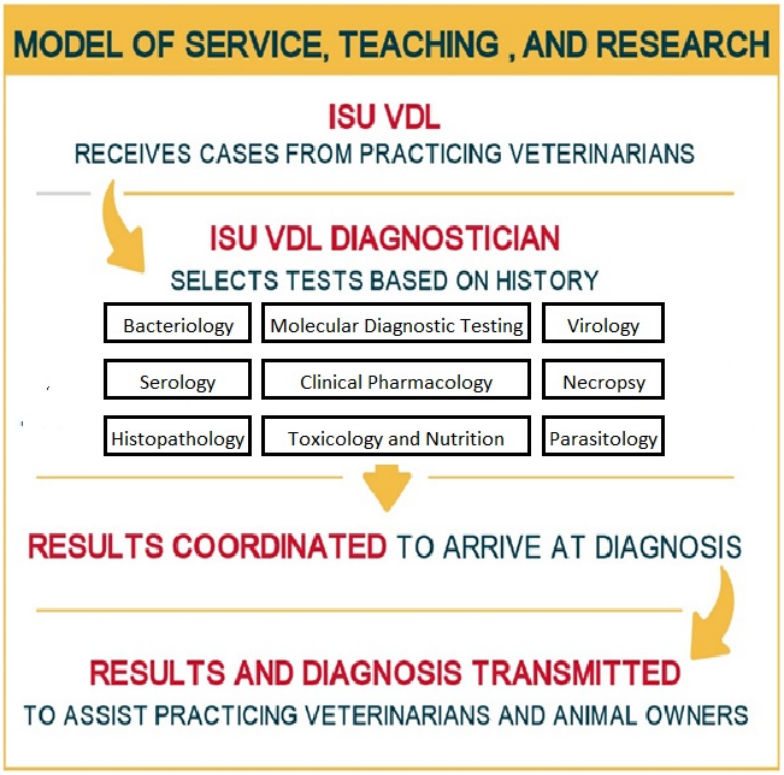
The immediate customers of the ISU VDL are practicing veterinarians who need assistance in either monitoring the health status of animals or in determining the cause of an illness affecting production animals, companion animals, or wildlife. The ISU VDL provides a comprehensive diagnostic service that includes all types of testing, analysis, and services commonly required to deliver a confirmatory diagnosis. The veterinary diagnosticians at the ISU VDL play a central role in selecting the appropriate test, interpreting results, and communicating diagnostic findings to submitting veterinarians.

The following diagnostic tests can be performed by the ISU VDL:

- Serology – Detects antibodies or antigens as indicators for infectious diseases in animal agriculture, companion animals, and wildlife. Information is shared with other stakeholders and new specimens are discovered and used for detecting antibodies.
- Molecular Diagnostic Testing – Uses numerous techniques to analyze biological markers in the genetic code of an animal. This testing investigates and predicts immune function and can assist in determining which treatment will work best.
- Histopathology – Studies the microscopic anatomy of cells and tissues in animals.
- Bacteriology – Identifies bacterial and fungal disease agents affecting companion animals and animal agriculture.
- Toxicology and Nutrition – Analyzes information from the client about specific samples or specimens to confirm a diagnosis. This includes information relating to animal management, feed type, clinical signs, and lesions. Nutrition monitoring is available for production animals.
- Virology – Analyzes biological specimens to identify the presence of viruses in afflicting cattle, horses, swine, and other animals.
- Clinical Pharmacology – Analyzes samples to quantify exogenous and endogenous compounds such as drug toxins or biomarkers. This information will improve the health of a producer's livestock and also safeguards trade agreements and the public's health.
- Necropsy – Examines and dissects dead animals to diagnose the cause of death.
- Parasitology – Studies the organisms that use other organisms as their hosts.

Diagram 1 illustrates the processing of samples received at the ISU VDL.

Diagram 1
Sample Processing at ISU VDL

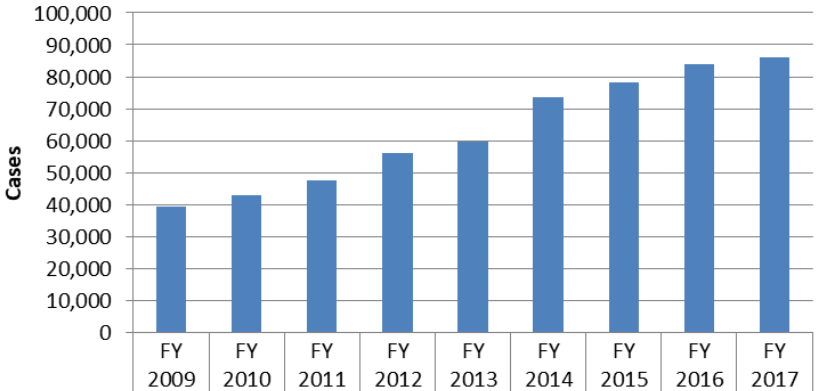


Source: ISU VDL

Cases Submitted and Processed

The volume of diagnostic services at ISU VDL has increased in recent years. Processed case submissions increased by 50.0% over the past five years and 100.0% over the past eight years. **Chart 1** depicts the number of cases submitted and processed by the ISU VDL from FY 2009 through FY 2017.

Chart 1
Iowa State University Veterinary Diagnostic Laboratory
Cases Submitted and Processed



	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Cases Submitted	39,473	42,928	47,618	56,178	59,748	73,505	78,125	83,888	85,923

Teaching and Research

Clinical case submissions serve as the primary source for research questions. The ISU VDL provides a location for teaching the next generation of veterinarians, animal health-related scientists, and veterinary diagnosticians.

BUDGET IMPACT

Funding

The ISU VDL's core diagnostic service operations are funded by clinical diagnostic service fees and contract payments, a General Fund appropriation from the Iowa General Assembly, ISU funding to support salaries, and funding from the USDA NAHLN. The USDA NAHLN funding is approximately $200,000 to $300,000 per year and is provided for ISU VDL's contributions as a Level 1 Facility. Payments by the USDA NAHLN support infrastructure and personnel expenditures at the ISU VDL.

The General Fund appropriation to the ISU VDL has been funded at $4.0 million since FY 2015. The ISU CVM provides additional financial support for faculty salaries and facility expenditures for operations and maintenance. The ISU VDL currently resides within the larger ISU Veterinary Medical Complex at the College of Veterinary Medicine.

Although State and ISU funding levels have been generally flat in recent years, the overall budget and operations at the ISU VDL have grown significantly in response to increased demand for diagnostic services and related research efforts. The key drivers in the increased number of case submissions and associated service fees have been due to ISU VDL's role in responding to emergency diseases affecting animal agriculture and wildlife. This includes USDA's funding of $11.0 million for diagnostic services in FY 2015 through FY 2017, most notably in response to the PEDV and the HP-AIV outbreaks.

The USDA NAHLN is the federal veterinary diagnostic reference and confirmatory laboratory; however, the USDA NAHLN has State or university laboratories perform routine diagnostic tests for native animal diseases as well as targeted surveillance and testing for foreign animal diseases. During an emergency outbreak, the number of tests needed increases and the funding paid by the USDA NAHLN also increases. The USDA NAHLN also asks State and university laboratories to participate in the development of new testing methodologies. However, USDA-funded diagnostic testing has been reduced dramatically in FY 2018 since the emergency animal disease outbreaks.

Table 1 is a five-year overview of the ISU VDL's core diagnostic service operations.

Table 1
ISU VDL Budgetary Operations

Funding	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Revenue					
State General Fund	$ 3,237,636	$ 3,762,636	$ 4,000,000	$ 4,000,000	$ 4,000,000
ISU Salary Support	1,013,917	1,078,282	1,066,093	1,091,010	1,166,865
USDA - NAHLN	182,000	168,667	196,000	202,000	305,333
USDA Funded-Diagnostics	261,500	418,202	3,750,595	5,360,052	1,795,752
Other Contracts & Services	12,585,813	15,619,145	14,626,781	16,597,905	17,837,809
Total Revenue	**$ 17,280,866**	**$21,046,932**	**$ 23,639,469**	**$27,250,967**	**$ 25,105,759**
Expenditures					
Personnel	$ 8,234,935	$ 9,265,264	$ 10,234,907	$10,842,836	$ 11,741,327
Supplies & Services	7,129,505	8,543,166	10,656,474	9,721,749	9,646,010
Capital, Training & Equipment	2,005,695	3,090,951	2,776,235	6,098,269	3,805,504
Total Expenditures	**$ 17,370,135**	**$20,899,381**	**$ 23,667,616**	**$26,662,854**	**$ 25,192,841**
Balance	**$ (89,269)**	**$ 147,551**	**$ (28,147)**	**$ 588,113**	**$ (87,082)**

NAHLN = National Animal Health Laboratory Network
Source: ISU VDL

Personnel

Over the past five years, ISU VDL's staffing levels have increased significantly with the increased caseload.

Table 2 provides a summary of faculty and staff employed at the ISU VDL. While ISU VDL's personnel costs have increased by $3.5 million over the past five years, the average costs per employee (Faculty & Staff) have remained relatively unchanged. Refer to **Table 3**.

Table 2
ISU VDL Faculty and Staff

Description	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Faculty	21	23	22	26	26
Staff	84	106	113	118	126
Total Faculty and Staff	**105**	**129**	**135**	**144**	**152**
Annual Number Change		24	6	9	8
Annual Percentage Change		22.9%	5.7%	8.6%	7.6%
Five Year Percentage Change					44.8%
Grad. Student & Training Pos.	12	12	15	20	23
Student Hourly	30	32	41	35	37
Total Grad. Student & Training Pos.	**42**	**44**	**56**	**55**	**60**
Annual Number Change		2	12	(1)	5
Annual Percentage Change		4.8%	27.3%	-1.8%	9.1%
Five Year Percentage Change					42.9%
Total	**147**	**173**	**191**	**199**	**212**
Annual Number Change		**26**	**18**	**8**	**13**
Annual Percentage Change		**17.7%**	**12.2%**	**5.4%**	**8.8%**
Five Year Percentage Change					**44.2%**

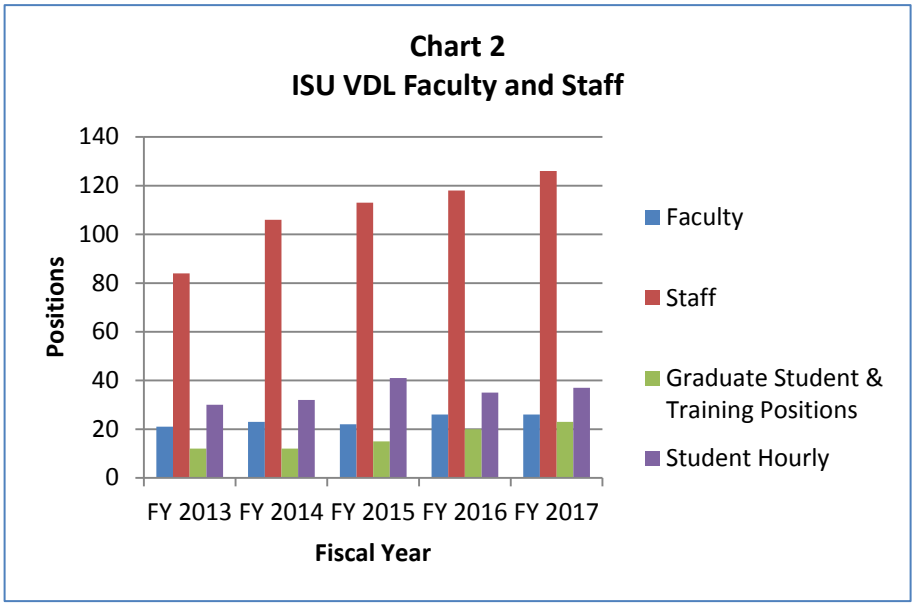
Source: ISU VDL

Table 3
Average Cost of ISU VDL Employee

Description	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Personnel	$ 8,234,935	$ 9,265,264	$ 10,234,907	$10,842,836	$ 11,741,327
Total Employees	147	173	191	199	212
Average Cost Per Employee	$ 56,020	$ 53,556	$ 53,586	$ 54,487	$ 55,384

Source: ISU VDL
Employees include, faculty, staff, graduate students, and training positions.

Chart 2 summarizes the number of employees at the ISU VDL.



Source: ISU VDL

INFRASTRUCTURE ISSUES

Expansion Concerns

The ISU VDL moved into the current location in 1976. While the size, scope, and complexity of ISU VDL's operations have increased significantly in response to the evolving needs of its stakeholders over the course of the past 40 years, ISU VDL's core facility infrastructure has not been substantially expanded or updated since initially occupied. Major challenges as reported by the Director of Operations at the ISU VDL include:

- Compromised biosafety and biocontainment due to the layout, airflow, and overcrowding in the building. The ISU VDL is located in the same building as the large animal and small animal hospitals. Concerns include cross-contamination of a contagious disease from the ISU VDL to animals and people leaving the veterinary hospital.
- Overcrowding of employees in the building. Personnel have limited space to conduct their work. Dated heating, ventilation, and air conditioning (HVAC) systems increase safety concerns for the ISU VDL employees that daily process samples containing a wide variety of disease-causing agents. The inadequate quality and quantity of space has also affected the ability to recruit and retain highly capable diagnosticians, scientists, and trainees.
- There is insufficient space to respond to an outbreak of a serious disease such as Foot and Mouth Disease, Hog Cholera, or African Swine Fever.
- The building has outdated plumbing, electrical systems, and HVAC systems. These will need to be replaced or updated throughout the building.

Outside Opinions

Extensive study of ISU VDL's facilities commenced in the fall of 2012 after significant infrastructure-related concerns were raised by two independent third-party audits. One audit was completed by the Accreditation Committee of the American Association of Veterinary Laboratory Diagnosticians. Concerns from the audit included:

- The limitations of the nearly 40-year-old ISU VDL facility are an area of immediate concern. The space, air-handling, and structural limitations of the aging facility can be expected to have a serious negative impact on the ability of the ISU VDL to continue to develop and incorporate new technologies and state-of-the-art services, to ensure separation of incompatible activities, and to respond to the potential of a disease outbreak or large-scale surveillance program in support of business continuity for the State's animal agriculture industries.
- The ISU CVM public spaces, including hallways that are shared with or in proximity to laboratory areas, cannot be closed off from student and technician traffic or otherwise secured to ensure a high level of biocontainment, biosafety, and laboratory security.

A second audit (External Academic Program Review) was completed by a peer group from five academic institutions that noted the following deficiencies:

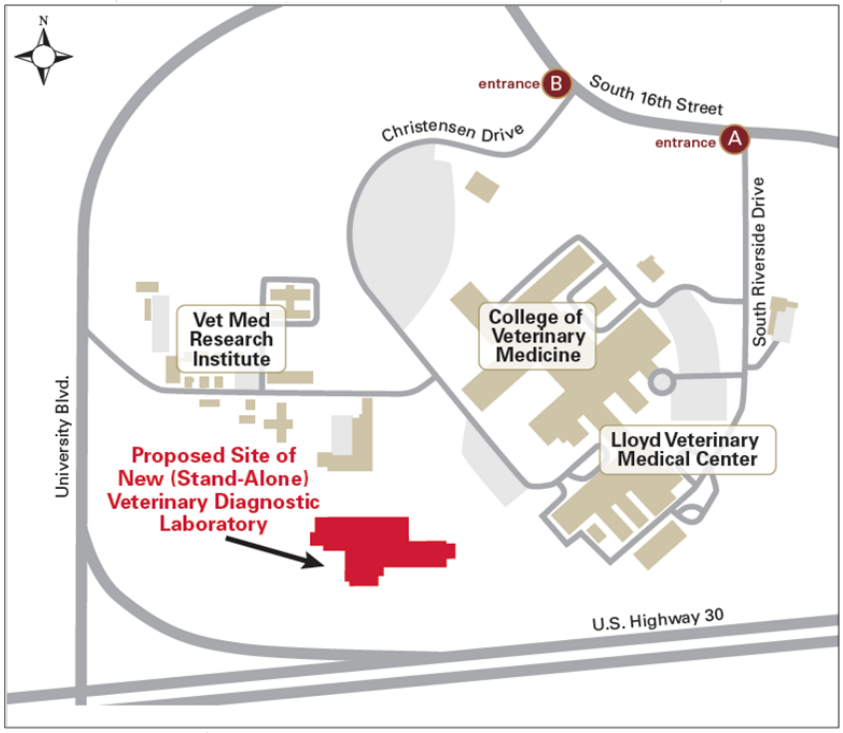
- Insufficient space – Many of the current programs (Molecular, Bacteriology, Virology, Serology) are severely overcrowded with minimal room to expand or add new programs.
- Space configuration – The space has been reconfigured multiple times to meet programmatic needs but the basic design in some areas is flawed.
- Outdated systems and controls – Major facilities systems (HVAC, plumbing, electrical, incinerator) are being challenged to keep up with routine demands and in some cases do not support appropriate biosecurity or programmatic needs.

New Facility Proposal

The State Board of Regents submitted an FY 2019 capital budget request that would fund a new stand-alone ISU VDL building. The total cost is estimated at $124.0 million. In the proposal, the Iowa Legislature would appropriate $20.0 million per year for five years; $20.0 million would be from private donations, and $4.0 million from ISU.

The space assessment identified the need for a total of about 83,000 net square feet to support the current and future needs of the laboratory. The proposed facility would provide approximately 30.0% more space than ISU VDL's current facilities. According to the Director of Operations at the ISU VDL, the development of this new facility would provide optimal process flow and appropriate biocontainment and biosafety, and address the growth in critical programmatic space needs. The facility would be segregated from the working teaching hospital and other public spaces. Building a new facility would allow the existing laboratory to remain in place during construction, minimizing disruption to the operational continuity of the ISU VDL functions and services being provided. The new facility would be located near the existing facility on the CVM Campus. **Diagram 2** is the proposed facility with a northeast view.

Diagram 2
Proposed Site For New Veterinary Diagnostic Laboratory



Source: ISU VDL

The project also proposes to renovate and repurpose approximately 24,000 net square feet of the existing ISU VDL space at the CVM building. This vacated space would provide the college the opportunity to increase research laboratory space and teaching classroom space. The remodel would remove obsolete laboratories and would also reduce deferred maintenance. **Photo 2** is the proposed stand-alone ISU VDL building.

Photo 2
Proposed Building

OTHER STATES

The ISU VDL is one of the most recognized facilities in the world due to the largest animal agriculture caseload in the United States. While the size and scope of animal agriculture economies and veterinary diagnostic lab capabilities can vary significantly among states, the ISU VDL infrastructure is among the oldest. Examples of new laboratories that are being built include:

- The Texas A&M Veterinary Medical Diagnostic Laboratory opened a new laboratory in April 2017. This is a USDA NAHLN Level 1 facility. The cost of the new laboratory was $53.0 million and paid with State funds. Other laboratories serving Texas include Amarillo and two poultry laboratories in Center and Gonzales.
- A new Nebraska Veterinary Diagnostic Center was opened on July 31, 2017, in Lincoln, Nebraska. The facility was also approved as a USDA NAHLN Level 2 facility on April 14, 2017. The cost of the facility was $45.6 million and the funding was 90.0% State funds and 10.0% from the University of Nebraska and private donations.
- A new North Dakota State University Veterinary Diagnostic Laboratory is under construction and will open during the fall of 2017. This facility is a USDA NAHLN Level 2 facility and the new building will enable the laboratory to operate more efficiently and expand services. The estimated cost of the facility is $18.0 million and will be paid with State funding.
- Construction started in August 2017 for the new South Dakota State University Animal Disease Research And Diagnostic Laboratory. This is a USDA NAHLN Level 2 facility with an estimated cost of $58.0 million and the funding will include 90.0% State funds and 10.0% from South Dakota State University and private donations. The project will provide an addition and updates to an existing facility.

CONCLUSION

As the animal agriculture industry expands, so does the demand for veterinary diagnostic testing. The ISU VDL's diagnostic service operations have continued to evolve and grow to meet the needs of stakeholders and industries served. When the current ISU VDL facility opened in 1976, there were 11 faculty and 20 staff members. ISU VDL's present-day operations include 26 faculty and 126 staff members. The ISU VDL now processes between 75,000 and 85,000 diagnostic case submissions and conducts over 1.2 million diagnostic tests each year.

Globalization of the animal agriculture market and the increased movement of people, animals, products, and disease-causing agents throughout the world has a real impact on the demand and need for a comprehensive veterinary diagnostic laboratory infrastructure at ISU.

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Appendix A

United States Department of Agriculture National Animal Health Laboratory Network Tiered Requirements

Any state can sponsor a publicly funded United States Department of Agriculture National Animal Health Laboratory Network (USDA NAHLN) laboratory. However, the participating laboratories must have sufficient laboratory-generated income, state resources, or other public funds to qualify for their level of participation. Qualifying requirements are tiered and based on current understandings of the needs of the overall network. To maintain a USDA NAHLN designation, qualifying laboratories will undergo annual reviews to demonstrate adherence to established policies.

Requirements for a Level 1 Facility

- Have capacity to provide surge testing for disease agents of interest.
- Participate in surveillance testing as requested by the USDA.
- Be fully accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD), the American Association for Laboratory Accreditation (AALA), or by another accrediting body with equivalent standards.
- Perform all work within a quality management system under the direction of a quality manager.
- Have staff members trained and proficiency tested in diseases of interest.
- Possess a functional Laboratory Information Management System (LIMS).
- Have the capability to electronically send diagnostic test results to the Animal and Plant Health Inspection Service (APHIS) databases.
- Report test results within timeframes indicated in USDA NAHLN standard operating procedures.
- Help further develop the NAHLN information systems.
- As requested by the USDA, help other laboratories develop and implement information systems that communicate testing results with USDA NAHLN.
- Provide and maintain Biosafety Level 3 Laboratory (BSL-3) space adequate for work performed. The levels are determined by the Centers for Disease Control and Prevention.
- Possess ongoing state funding adequate to maintain equipment and laboratory space used for USDA NAHLN purposes.
- As requested by the USDA, send staff members to other laboratories or field operation centers during emergency situations.
- As requested by the USDA, provide training for USDA NAHLN test procedures.
- Accept samples that originate from other states affected by disease outbreaks, especially those from Level 2 laboratories.
- Assist with USDA NAHLN test development and validation.
- Participate in USDA NAHLN-related activities such as development of training programs, scenario testing exercises.
- Have an acceptable periodic review conducted under the oversight of USDA.

Requirements for a Level 2 Facility

- Are not required to maintain capacity to provide for surge testing.
- May be provisionally accredited by the AAVLD or by another accrediting body.
- Perform all work within a quality management system under the direction of a quality manager.
- Have no requirement for a BSL-3 space.
- Participate in biosafety requirements as resources allow.

Requirements for a Level 3 Facility

- May participate in surveillance testing if requested by the USDA.
- Work under a USDA NAHLN-approved quality management system overseen by a quality manager.
- Have staff members trained and proficiency tested in diseases of interest.
- Have a functional LIMS.
- Report test results within timeframes indicated in USDA NAHLN standard operating procedures.