

***A Review and Analysis of the Virginia Department of Agriculture and  
Consumer Services’  
Regional Animal Health Laboratory System***

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**Table of Contents**

Part 1	Executive Summary.....	2
Part 2	Introduction and Purpose.....	5
Part 3	Methodology.....	7
Part 4	Analysis of Current Diagnostic Services of RAHLS.....	11
Part 5	Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis.....	25
Part 6	Comparison of RAHLS to Other State VDLs.....	27
Part 7	Strategic Recommendations.....	33

## Part 1. Executive Summary

The Virginia Regional Animal Health Laboratory System (RAHLS) is composed of four full-service diagnostic laboratories located in Harrisonburg, Wytheville, Warrenton and Lynchburg. The RAHLS is managed by the Virginia Department of Agriculture and Consumer Services (VDACS), Division of Animal and Food Industry Services (AFIS), Office of Laboratory Services (OLS). The system provides essential diagnostic services to the poultry, dairy, beef, swine and sheep industries; as well as to wildlife agencies, zoos, and companion animal and equine owners. The RAHLS also plays a significant role in public health by monitoring zoonotic infectious diseases and conducting food safety testing.

The RAHLS has a long, proud history of providing quality animal health diagnostic services to the citizens of Virginia, especially the food production animal agricultural industry. Since many human pandemics around the world have originated from animal sources (such as COVID), they also play a key role in protecting public health. Laboratories such as the RAHLS are considered essential public services because they are one of three essential components of the *One Health* concept, which states that the holistic health of the planet requires healthy animals, healthy people and a healthy environment. Animal health laboratories across the country and world, such as the RAHLS, assist veterinary practitioners with rapid laboratory diagnoses of infectious, nutritious, toxic or genetic animal diseases and zoonotic diseases (those transmitted readily from animals to humans). They also play a key preventive role as they participate in many monitoring and surveillance programs that help control infectious diseases in populations of animals and people. There have been some recent, unexpected leadership changes for the RAHLS. Current RAHLS and VDACS leaders felt it was time for a comprehensive analysis by outside experts. A Request for Proposals (VA RFP 301-22-065 Vet Lab Consulting Services) was posted late in 2021, seeking a review of the system. The general purpose of the evaluation was to review the current facilities, equipment, staffing and operations of the RAHLS, conduct a strategic analysis, and make recommendations for evolution needed to ensure the future success of the mission of the RAHLS. The review and analysis were conducted by two highly experienced veterinary laboratory diagnosticians with over 70 years of combined experience working in veterinary diagnostic laboratories, including over 30 years' experience managing multiple veterinary diagnostic laboratories in the USA.

Initial virtual meetings were held with AFIS and OLS key leaders to discuss goals of the review and analysis work. Five full days of on-site visits were made and included a review of facilities, equipment and staffing at each of the State's four veterinary diagnostic laboratories as well as meetings with leaders at the Virginia-Maryland College of Veterinary Medicine (VMCVM). One full day was spent at each RAHLS laboratory. All laboratory staff were interviewed, and business and client records were reviewed.

While at the Harrisonburg laboratory, there was a meeting with key State and agricultural leaders and stakeholders. After the site visits, there were ongoing general discussions with AFIS and OLS management for the purpose of clarifying any observations, facts or statements gathered during the site visit, prior to generating a written analytical report.

### **Summary Observations**

The four RAHLS laboratories are small to medium sized units in reasonable condition, built at bio security levels one (BSL1-offices) and two (BSL2-most laboratory space), with a very limited amount of level 3 (BSL3-high containment) space at only the Harrisonburg location. **Virginia is among the last states to still have multiple small to medium sized laboratories scattered across the state.** That geographically dispersed model was popular several decades ago when, due to transportation logistics, getting specimens to the laboratory timely was problematic. The advent of rapid private courier systems (e.g., FedEx, UPS...) has generally removed the main reason for such an operational model. **Nearly all states have transitioned to one or two strategically located laboratories** which is a much more efficient, successful and sustainable model for overall laboratory operations and maximum utilization of expensive equipment and highly skilled staff.

Modern medical diagnostic test laboratories have experienced significant changes in the past 25 years relative to the use of technology within the industry. Laboratories in general are conducting fewer postmortem examinations of whole carcasses and are doing much more preventative monitoring and surveillance work utilizing cutting edge technologies such as molecular diagnostic testing, genetic sequencing, serology, and other highly computerized techniques for identifying microbial pathogens. The cost of purchasing and maintaining redundant expensive technical equipment across many sites quickly becomes cost-prohibitive and inefficient.

Modern diagnostic laboratories need highly skilled and experienced analytical scientists. A critical mass of scientists is often key to an efficient testing laboratory. Under the current RAHLS operational plan with four different sites, **management is having major difficulties in filling key veterinary positions and finding fully qualified candidates for analytical scientist positions.** Significantly, the **RAHLS currently lacks high level subject matter expert (SME) positions in practically every diagnostic discipline.** At other diagnostic laboratories, such SMEs typically have doctoral degrees (DVM and/or PhD) with additional specialized training and even board certification in one or more of the disciplines (e.g. bacteriology, virology...). This recruitment problem is expected to only get worse across the country because of future competition from public health labs and private biomedical industries as well as the drop in population and hence workforce that is already under way. **Laboratories associated with universities can typically cope with these challenges much more readily** due to a larger scientist talent pool and the additional economic and intellectual benefits they can provide to boost recruitment and retention, especially of SMEs.

### **Recommendations**

**Laboratory System Structure – We believe an ideal configuration for the VDACS RAHLS would comprise at most two state-of-the-art facilities, one in Harrisonburg and the other co-located with the CVM in Blacksburg, Virginia.** The RAHLS should continue the trend towards increased collaboration with the CVM. Where along the possible spectrum between separate-but-collaborative and fully-integrated with the CVM the system ends up should be thoughtfully explored with all parties, with the goal to maximize the benefits to all (RAHLS, CVM and stakeholders).

**Staffing – RAHLS' staffing challenges (recruitment, retention, SMEs) will need to be addressed through a combination of changes including development of career ladders, salary adjustments, establishment of SME positions and improved training programs.** Performance management must become a valued and required aspect of supervisory positions at all levels. Besides SMEs, adequate support staff is necessary

to allow the SMEs to spend their time doing scientific analysis and not distracting them with duties able to be effectively performed by other staff.

**Accreditation** - The vast majority of animal health laboratories in the USA are accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD). The AAVLD standard is a holistic accreditation of the entire laboratory operation including biosafety and biosecurity considerations. The AAVLD standard accredits the entire laboratory not just individual tests. Once accredited, all the laboratory's operations, quality system and testing activities fall under the accreditation standard. The *AAVLD Requirements for An Accredited Veterinary Medical Diagnostic Laboratory* is a direct application of ISO Guide 17025, the internationally recognized standard for testing and calibration laboratories. AAVLD laboratory accreditation is the best mechanism to assure those in charge of managing laboratories as well as stakeholders, that all work is being done competently, reliably, accurately and consistently. **We recommend that RAHLS promptly pursues AAVLD accreditation.**

**Operations** – Along with restructuring, the RAHLS should take greater advantage of technologies to **increase automation of processes and enhance the sophistication, accuracy, quality and value of the results it produces.** Changes with potential large returns on investment include consolidation and automation of testing workflows (e.g., sample processing and testing robotics, machine learning and artificial intelligence algorithms) as well as laboratory information management system (LIMS) modernization (e.g., client internet portal, interactive reports, data analytics, data transfers).

## Part 2. Introduction and Purpose

This report is the written summation work product for an RFP initiated by the Virginia Department of Agriculture and Consumer Services (VDACS) of the Commonwealth of Virginia; VA RFP 301-22-065 Vet Lab Consulting Services. The RFP was released late in 2021 and awarded to DHZ Vet Path Consulting, LLC in January 2022. The review was initiated by VDACS leaders including Commissioner Joseph Guthrie, Deputy Commissioner Charles Green, the Director of Animal Food and Industry Services (AFIS)/State Veterinarian Dr. Charles Broaddus and Deputy Director David McGreevy.

The review and analysis were conducted by two experienced veterinary laboratory diagnosticians who brought over 70 years of combined experience working in veterinary diagnostic laboratories, including over 30 years' experience managing veterinary diagnostic laboratories in the USA. The general purpose of the evaluation was to review the current facilities and operations of the Regional Animal Health Laboratory System (RAHLS) of the AFIS' Office of Laboratory Services (OLS), conduct a strategic analysis, and make recommendations for moving forward to ensure the mission of the RAHLS is met. Specifically, some key goals were requested in the RFP:

1. A thorough review of testing and specific recommendations to improve efficiency.
2. An analysis of the resources and equipment in each laboratory and recommending improvements.
3. An analysis of diagnostic capabilities and comparison with other state laboratories to determine areas for improvement, including an analysis of the necropsy services provided and how those compare to other laboratory systems.
4. A thorough review and analysis of staffing capabilities and staff compensation in comparison to other nationally renowned state laboratories. Provide a recommendation of metrics for evaluating the workload of employees.
5. Analysis of the services offered, and the quality of the reports generated at the labs.
6. A detailed assessment of the effectiveness of our current quality system, including comparison to similar labs, and analysis of necessary steps needed to achieve accreditation with the American Association of Veterinary Laboratory Diagnosticians (AAVLD).
7. A detailed assessment of the laboratory system fee schedule including a comparison to fee schedules from other laboratories and providing feedback for improvements.
8. Development and suggestions for opportunities for outreach to increase laboratory submissions and necessary resources needed to complete these tasks.
9. Recommendations of other areas or topics that would be beneficial for VDACS to study for improving the laboratory system.
10. Recommendations to develop and submit a long-term strategic plan for our laboratory system. Offerors should determine and define the appropriate length of the plan in their proposal, such as a five (5) or ten (10) year plan.

The consultants' work to achieve these goals included the following six major activities/deliverables:

1. Meetings with key leaders virtually to discuss particular goals of the review and analysis work prior to visiting the State.

2. On-site review of facilities at each of the State's four veterinary diagnostic laboratories (Harrisonburg, Lynchburg, Warrenton, Wytheville) and meeting with leaders at the VA/MD Regional College of Veterinary Medicine (CVM). Five full days were required to conduct the site visits and visit the Virginia Tech University campus. One full day was spent at each RAHLS laboratory.
3. Meeting with key State Leaders and stakeholders during the week of lab site visits. After the site visit, a general review with leaders for the main purpose of clarifying any observations, facts or statements gathered during the site visit; prior to generating a final written analytical report.
4. Generation of a written analytical report to include these key sections:
  - a. Current overview of the VA animal health laboratory diagnostic services as a system (RAHLS)
  - b. Comparisons to animal health laboratory services in other areas of the USA
  - c. Options for consideration regarding the administration, management, and operation of the RAHLS moving into the future
5. An on-site presentation by the consultants to the VDACS leaders in Richmond to present findings and to facilitate strategic discussions directed towards the future (sooner and longer-term recommendations and next steps).
6. Ongoing follow up discussions via email, phone or virtually as needed and determined by Dr. Broaddus until contract end.

### Part 3. Methodology

The RFP was awarded to DHZ Vet Path, LLC, a private consulting company; two reviewers were assigned to the task. Both have decades of experience as animal health laboratory directors and employees. The reviewers were:

- David H. Zeman, DVM, PhD, DACVP
  - Dr. Zeman has audited over 50 US and Canada animal health laboratories; as such has provided input into operations, physical facilities assessments, and strategic recommendations to over 75% of the animal health labs in the US and Canada. For over twenty years he led one of the nation's premier food animal diagnostic and research laboratories (South Dakota Animal Disease Research and Diagnostic Laboratory at South Dakota State University). He is a board-certified pathologist who has focused on food animal diagnostics and research. He is past president of the American Association of Veterinary Laboratory Diagnosticians (AAVLD) and has served on numerous committees including the Accreditation Committee.
  
- Bruce L. Akey, DVM, MS
  - Dr. Akey has both supervised and participated in the development and implementation of multi-year strategic plans for veterinary diagnostic laboratories, state agencies and universities in Virginia, New York, and Texas. He has also been recruited to serve in multiple scoping and planning efforts for the U.S. Department of Agriculture. He has participated in numerous laboratory operations reviews including for the Animal Disease Diagnostic Laboratory at Purdue University, the Iowa State University Veterinary Diagnostic Laboratory, the USDA National Veterinary Services Laboratory, and the Animal Health Laboratory System of Panama. He is past president of the American Association of Veterinary Laboratory Diagnosticians (AAVLD) and has served on numerous committees.

Following receipt of official notification of the award and permission to proceed, the team began with phone, email, and virtual conversations with VDACS leaders, working mostly with the Director of Animal Food and Industry Services (AFIS)/State Veterinarian Dr. Charles Broaddus, Deputy Director AFIS David McGreevy, and the OLS RAHLS Program Manager, Dr. Jessica Walters. Anne P. Magee, Business Manager, Office of Lab Services, VDACS, was assigned to provide data from the business side of the operation. Information requested and provided ahead of time included an organizational chart, test count summaries, revenue summaries, and personnel lists and salaries by title and duties. The on-site laboratory visits began on Monday, March 14, 2022 and concluded on Friday, March 18, 2022. The schedule for the week of on-site visits is below.

- Monday - Wytheville
  - Meet at Wytheville Laboratory at noon, have lunch.
  - 1:30 PM - Meet with staff, group meeting, introductions and explain why we are there.
  - 1:45 PM - Tour of the lab, ask questions of section leaders and staff on operations as we tour.

- 2:30 - Team meets alone with the Lab Manager
- 3:15 - Team meets alone with section leaders as a group, and begins to meet with bench analysts
- 4:30 PM- Depart
- Tuesday Morning - Wytheville
  - 9 am – Team meets with Quality management group
  - 10:00 am - Team meets with bench scientists as a group
  - 11:00 am – Team reviews records and lab documents (can go back and forth around lab to get answers as needed)
  - 11:30 am – Available for confidential appointments
  - 12:00 pm – Exit gathering with all staff to say goodbye, closing comments on the process.
- Tuesday Afternoon- Blacksburg, Virginia-Maryland Regional College of Veterinary Medicine
  - Drive to Blacksburg- Arrive 1:00 PM, lunch
  - 2:00 PM: Tour ViTALS Lab, Discussions with ViTALS Management
  - 3:00 PM: Meet with Dean of CVM
  - 4:00 PM: Depart for Lynchburg
- Wednesday – Lynchburg
  - 9 am - Arrive at lab
  - 9:15 am - Meet with staff, group meeting, introductions and explain why we are there.
  - 9:30 - Tour of the lab, ask questions of section leaders and staff on operations as we tour.
  - 10:30 - Team meets alone with the Lab Manager
  - 11:15 - Team meets alone with section leaders as a group
  - Noon – 2 pm Lunch and Discussion with Stakeholders as available
  - 2 pm – Team meets with Quality management group
  - 2:30 pm - Team meets with bench scientists as a group
  - 3 pm – Team reviews records and lab documents (can go back and forth around lab to get answers as needed.)
  - 4 pm – Available for confidential appointments
  - 4:30 pm – Exit gathering with all staff to say goodbye, closing comments on the process.
- Thursday – Harrisonburg
  - 9 am - Arrive at lab
  - 9:15 am - Meet with staff, group meeting, introductions and explain why we are there.
  - 9:30 - Tour of the lab, ask questions of section leaders and staff on operations as we tour.
  - 10:30 - Team meets alone with the Lab Managers
  - 11:15 - Team meets alone with section leaders as a group
  - Noon – 2 pm Lunch and Discussion with Stakeholders
  - 2 pm – Team meets with Quality management group
  - 2:30 pm - Team meets with bench scientists as a group
  - 3 pm – Team reviews records and lab documents (can go back and forth around lab to get answers as needed.)
  - 4 pm – available for confidential appointments
  - 4:30 pm – exit gathering with all staff to say goodbye, closing comments on the process.



- Friday – Warrenton
  - 9 am - Arrive at lab
  - 9:15 am - Meet with staff, group meeting, introductions and explain why we are there.
  - 9:30 - Tour of the lab, ask questions of section leaders and staff on operations as we tour.
  - 10:30 - Team meets alone with the Lab Manager
  - 11:15 - Team meets alone with section leaders as a group – standard question list
  - Noon – 2 pm Lunch and Discussion with Stakeholders as available
  - 2 pm – Team meets with Quality management group
  - 2:30 pm - Team meets with bench scientists as a group – standard question list
  - 3 pm – Team reviews records and lab documents (can go back and forth around lab to get answers as needed.
  - 4 pm – Available for confidential appointments
  - 4:30 pm – Exit gathering with all staff to say goodbye, closing comments on the process.

At the Harrisonburg laboratory, two hours were scheduled for a lunch and feedback from laboratory stakeholders. In attendance were:

- VDACS Commissioner Joseph Guthrie
- Dr. Nathaniel Burke, VP Virginia Veterinary Medical Association
- Eric Paulson, Executive Director, Virginia State Dairyman's Association
- Stefanie K. Taillon Virginia Farm Bureau Federation
- Dr. Dan Hadacek, Office of Veterinary Services, AFIS, VDACS
- Hobey Bauhan, Executive Director, Virginia Poultry Federation
- Willie Morris, Virginia Cattleman's Association
- Beck Stanley, Virginia Agribusiness Council
- Dr. Tanya LeRoith, Director, ViTALS, Virginia-Maryland Regional College of Veterinary Medicine
- Dr. Jessica Walters, Program Manager, RAHLS, OLS, AFIS, VDACS
- Anne P. Magee, Business Manager, OLab S, AFIS, VDACS
- Melinda M. Stuart, Quality Manager, OLS, RAHLS, AFIS, VDACS
- Whitney Patrick, Regional Quality Manager, OLS, RAHLS, AFIS, VDACS

In general, at each laboratory the consultants met briefly with staff at the start of the day to inform them of logistics of the visit (the staff was aware ahead of time of the timing and purpose of the visit); an escorted lab tour was provided and questions asked along the way; consultants met privately with the lab leader (Lab Director); met with the Quality Manger and the Regional Quality Manager for the respective labs; met with the Microbiology Supervisors; met with the analysts and support staff as a group without their supervisors; provided opportunities for private one-on-one visits and left our email and phone contact information; collected copies of original submission forms and lab reports to review later; and met again with the staff to say thank you and good-bye.

Within days, the reviewers began working on the written report and continued gathering additional documentary material from RAHLS leaders as needed. Follow up email, phone and virtual visits continued until a draft report was produced.

The draft report was shared with AFIS Director Dr. Broaddus, Deputy Director David McGreevy and Program Manager Dr. Jessica Walters for review of factual accuracy and understandability. The final report was then shared with the same group and an on-site meeting was scheduled for a presentation and strategic discussion in Richmond with VDACS leadership as well representatives from the Secretary's office.

## Part 4. Analysis of Current Diagnostic Services of RAHLS

The statutory authority to operate the animal health laboratory system in the Commonwealth of Virginia is as follows:

**Code of Virginia**  
Title 3.2. Agriculture, Animal Care, and Food  
Subtitle V. Domestic Animals  
Chapter 59. General Provisions  
§ 3.2-5903. Laboratory for diagnosis of diseases

*The Commissioner shall maintain and operate a laboratory system for the diagnosis of diseases of livestock and poultry, and for such other uses and purposes as may be determined by the Commissioner. Code 1950, § 3-567; 1966, c. 702, § 3.1-725; 2008, c. 860.*

The current RAHLS Quality Manual provided some historical information and summarizes the current activities and rationale for the laboratory locations as summarized below:

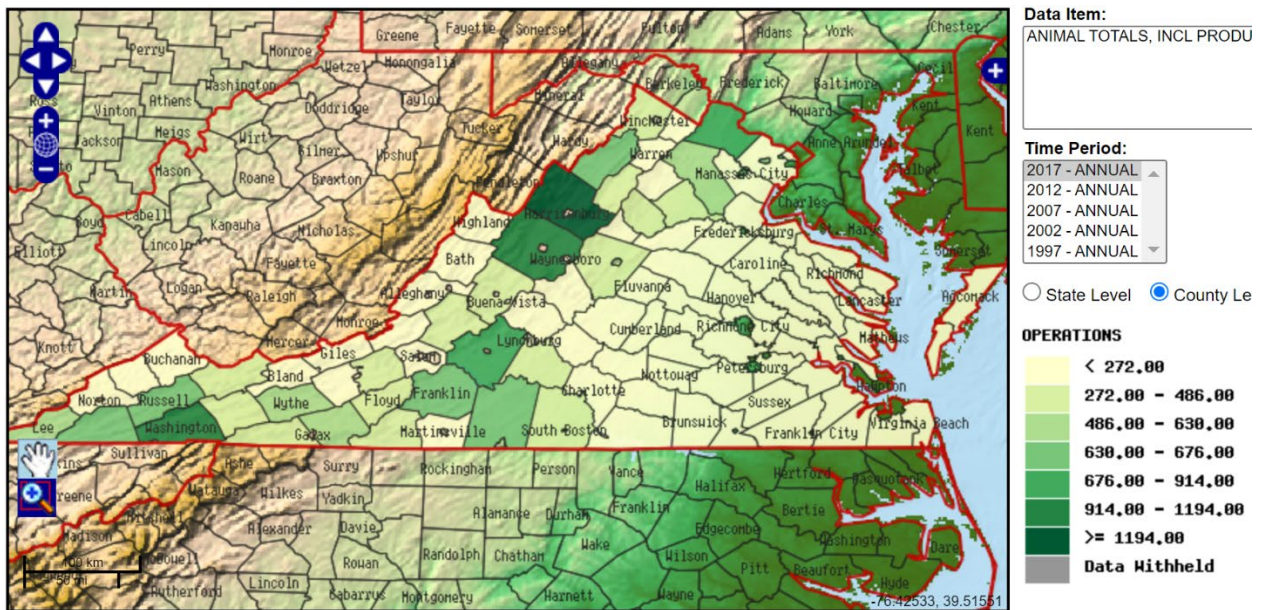
Historically - What is now the Virginia Department of Agriculture and Consumer Services began in 1877 as a fertilizer testing service for Virginia farmers. Over the first 49 years, a central laboratory was established in Richmond, which was responsible for testing fertilizer, paint, gasoline, pesticides, and (during Prohibition) alcohol. When the Livestock and Sanitation Board, previously an independent entity, was incorporated into the Department of Agriculture and Immigration in 1926, the Division of Animal Health was created. Five years later, in 1931, the first laboratory in Virginia devoted to animal health was established in the town of Harrisonburg, in Rockingham County. Over the next 20-30 years, as government efforts to control brucellosis and hog cholera (now known as Classical Swine Fever) intensified, additional regional animal health laboratories were established in eight separate locations around the Commonwealth. By the late 1950's, regional animal health laboratories existed in Accomac (Accomack Co.), Harrisonburg, Ivor (Southampton Co.), Lynchburg (Campbell Co.), Richmond (City), Warrenton (Fauquier Co.), Warsaw (Richmond Co.), and Wytheville (Wythe Co.). Over the next 45 years, the laboratories in Accomac, Richmond, Warsaw, and Ivor closed, while new or expanded facilities were built in the other four locations. Services continued to expand well beyond the original dairy testing and serology offerings, to include necropsy services, sophisticated microbiology testing, and molecular testing techniques such as polymerase chain reaction (PCR).

Current Operational Rationale - "The Virginia Animal Health Laboratory System, Office of Laboratory Services (OLS) is part of the Virginia Department of Agriculture and Consumer Services (VDACS) under the Secretary of Agriculture and Forestry for the Commonwealth of Virginia. The system consists of four regional laboratories located in Harrisonburg, Lynchburg, Warrenton, and Wytheville and a central office located in Richmond, Virginia. The laboratories are distributed so that all agriculture producers, veterinary practitioners and citizens have reasonable access to a facility. All sites provide basic diagnostic services, regulatory services for export and animal/public health programs as well as some site-specific test functions. Management is committed to the regional distribution of laboratories as the system ablest to deliver quality, useful information to our clients."

The RAHLS services support a diverse animal industry sector in Virginia. The sector encompasses:

<u>Commodity</u>	<u>Inventory</u>	<u>National Ranking</u>
Beef Cows <sup>a</sup>	599,000	18 <sup>th</sup>
Dairy Cows <sup>a</sup>	71,000	25 <sup>th</sup>
Swine <sup>b</sup>	249,000	19 <sup>th</sup>
Equine <sup>b</sup>	65,588	12 <sup>th</sup>
Poultry – Broilers <sup>b</sup>	44,683,000	10 <sup>th</sup>
Poultry – Turkeys <sup>b</sup>	5,700,000	6 <sup>th</sup>
Poultry – Egg production (annual) <sup>a</sup>	710,100,000	18 <sup>th</sup>

Sources: <sup>a</sup>VDACs, <sup>b</sup>2017 Census of Agriculture – USDA National Agriculture Statistics Survey



Source: USDA National Agriculture Statistics Services – 2017 Census of Agriculture

As with most states, the RAHLS is funded through a combination of direct state dollars, fee revenues from testing conducted and grants. The following describes the three-year trend in this funding:

<u>Funding Source</u>	<u>FY21</u>	<u>FY20</u>	<u>FY19</u>
State appropriations	\$2,973,063.00	\$2,793,592.00	\$2,643,592.00
Testing Fee Revenue	\$1,773,575.00	\$1,523,075.00	\$1,534,656.00
Grants/Awards	\$176,238.00	\$141,878.00	\$154,793.00
<i>Total</i>	<i>\$4,922,876.00</i>	<i>\$4,458,545.00</i>	<i>\$4,333,041.00</i>

Current RAHLS testing services can be categorized in a number of ways:

<b>% of ACCESSIONS</b>					
3%	State Regulatory	57%	Equine	4%	Companion Animals
0.09%	Federal Regulatory	3%	Small Ruminants	0%	Research
4%	Beef	18%	Poultry	1%	Food Safety
3%	Dairy	0.03%	Zoo/Exotics	0.04%	Aquaculture
0.2%	Swine	0.03%	Wildlife	0.5%	Environmental
<b>% of TESTS</b>					
2%	State Reg. dairy	63%	Poultry serology	1%	Food Safety
3%	Dairy microbiology	4%	Bacteriology	0.5%	Environmental - water
5%	Molecular testing	0.1%	Virology	2%	Pathology
1%	Parasitology	16%	Mammalian ser.	1%	Hematology
0.04%	Aquaculture	0.3%	Federal Regulatory		

<b>Test Count Summary</b>				
	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>%Total</b>
Harrisonburg	237,939	214,607	203,811	71%
Lynchburg	60,187	51,234	26,333	9%
Warrenton	36,661	32,264	30,957	11%
Wytheville	<u>25,876</u>	<u>23,428</u>	<u>27,741</u>	10%
<i>Total</i>	<i>360,663</i>	<i>321,533</i>	<i>288,842</i>	

<b>Test Revenue Summary</b>				
	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>%Total</b>
Harrisonburg	\$646,556	\$741,327	\$827,393	46%
Lynchburg	\$386,743	\$360,289	\$261,732	15%
Warrenton	\$427,003	\$395,497	\$434,885	24%
Wytheville	\$216,672	\$226,298	\$267,338	15%
<i>Total</i>	<i>\$1,676,974</i>	<i>\$1,723,410</i>	<i>\$1,791,348</i>	

Note: An Accession Fee (\$2/accession) was implemented at the start of FY2022. It is estimated it will generate an additional \$100,000 per year of revenue based on historical submission rates.

### **Current Operational Management of the RAHLS**

The RAHLS falls under the Virginia Department of Agriculture and Consumer Services (VDACS), currently led by Commissioner Joseph Guthrie. Deputy Commissioner Charles Green is responsible for four units including the Division of Animal and Food Industry Services (AFIS). AFIS is led by Director/State Veterinarian Dr. Charles Broaddus and Deputy Director David McGreevy (business expert). AFIS has four subunits:

- Dairy and Foods

- Meat and Poultry Services
- Veterinary Services
- Laboratory Services

The RAHLS falls under Laboratory Services and is managed by Program Manager Dr. Jessica Walters. Each of the four RAHLS labs is managed on site by a veterinarian (functional on-site Lab Director) who also serves as lead diagnostician and case coordinator:

- Wytheville – Dr. Chris Halsey
- Lynchburg – vacant
- Harrisonburg – vacant (Dr. Walters is Acting)
- Warrenton – Dr. Jaime Weisman
- ViTALS – Dr. Tanya LeRoith (not part of RAHLS, part of CVM)

In general, at each RAHLS lab, the Lab Director supervises all support staff and the Microbiologist Supervisor. The Microbiologist Supervisor supervises 3 to 6 bench analysts.

The Lab Director is also the one that performs necropsies, orders tests from the necropsy cases, receives and correlates test results including a histopathology report from the pathologists. They then finalize and communicate necropsy case findings to the clients. They also serve, as needed, as case coordinator for other types of case submissions to aid in interpretation of those findings as well.

Animal owners and industry personnel may directly submit case materials to the laboratory without a referring veterinarian's orders. The laboratory personnel refrain from offering treatment, vaccination or management recommendations to clients; instead referring such inquiries to the client's local Veterinary practitioner.

**Current Assessment Summary by Laboratory:**

**a. Harrisonburg**

- i. Service Region – This laboratory naturally serves in large part the west-central portion of the state, with emphasis on the Shenandoah Valley.
- ii. Service to what industries – This laboratory is the primary, and virtually only, poultry industry service laboratory, which constitutes by far the largest share of its workload. The poultry industry is the largest animal industry in the state, by any measure. It also provides a wide variety of testing for cattle, dairy and equine industries.
- iii. Facility summary – The facility is approximately 15 years old, comprises 14,750 sq. ft. of BSL2, BSL3 laboratories and office space. This facility has the only BSL3 testing space in the entire system. The building has additional square footage used for office and meeting space by other VDACS programs (see appendix for lab footprint). In general, testing space is reasonable for current workload, though the layout is not the most ideal or efficient for molecular testing. Overall the facility appears in good operational condition.
- iv. Personnel: See the appendix for a detailed personnel list. The Harrisonburg Lab Director position is currently vacant and being covered by Dr. Walters. There is a necropsy technician on site. Dr. Carvalho, half-time pathologist shared with the

CVM, comes one day a week to do non-poultry necropsies, the rest of the week is covered by VDACS staff. Dr. Walters is still covering poultry necropsies. Jennifer Carickhoff is the Microbiology Supervisor and has been in this role for close to a year. She has seven years of experience at this lab as a serologist. She supervises 6 bench analysts. All analysts except one, have 3 years or less of experience. The other has about 7 years of experience.

- v. Caseload and Revenue: This lab conducted 203,811 test procedures in 2021, which is 71% of the RAHLS total. Harrisonburg test count in 2021 was down 14% compared to 2019. The revenue in 2021 was \$827,393 which represents 53% of the RAHLS total revenue. Harrisonburg revenue in 2021 was up 28% compared to 2019. \*NOTE: Case count and revenue in the RAHLS is typically credited by the original accession site. Therefore, when samples are shipped to other RAHLS labs there is some skewing of the test and revenue data. This data skew is most notable in labs that either ship or receive many specimens to or from other labs.

This lab offers many tests under the following categories (does not imply exclusivity or that some other test categories have no offerings from this lab):

- Necropsy
- Bacteriology
- Dairy Microbiology
- Molecular Diagnostics
- Parasitology
- Pathology
- Poultry Serology
- Water Testing
- Virology

- vi. Accreditation Status
  1. AAVLD – no
  2. A2LA – yes, 14 tests on scope
  3. National laboratory system participation – Harrisonburg is currently the sole RAHLS lab in the NAHLN (USDA’s National Animal Health Laboratory Network), which focuses on surveillance for high consequence foreign animal diseases (e.g. Highly Pathogenic Avian Influenza).
- vii. Summary Comments: The Harrisonburg lab has the most bench analysts and conducts 71% of the testing for the RAHLS. It produces the most revenue, close to double what the next most revenue generating lab produces (Warrenton). It currently has 14 accredited test procedures. . It is the main lab for poultry testing. Three of the RAHLS labs offer extensive Dairy Microbiology testing with considerable duplication among the labs. Harrisonburg offers the most molecular diagnostic tests, compared to other labs with six tests on line.

## **b. Wytheville**



- i. Service Region - this laboratory serves the southwestern and southern portions of the state.
- ii. Service to what industries - Beef cattle constitute the primary industry segment served by this laboratory. They are also unique, being the only lab offering fish disease diagnostic and certification testing services.
- iii. Facility summary – the majority of the laboratory facility is approximately 30 years old, but it shares and uses some space in the rest of the 60 year old structure. The laboratory portion constitutes approximately 11,500 sq. ft. of BSL2 labs and offices (see appendix for lab footprint). Many of the testing sections appear limited by an inefficient space layout. Both molecular testing and fish diagnostics are particularly challenged. While generally appearing to be in good operational condition, lack of appropriate drainage for cleaning and disinfecting the loading dock and area around the incinerator raise concerns for good biocontainment.
- iv. Personnel: See the appendix for a detailed personnel list. The Wytheville Lab Director is Dr. Chris Halsey. There is a necropsy technician on site with about 2 years of experience. The Admin and Office Specialist (Receptionist) position has been vacant for about 2 years, causing frequent distractions for the analysts as they must cover client phone calls and check-ins. Carrie Umberger is the Microbiology Supervisor; started this role about 2 years ago. She supervises 3 bench analysts. Pathologist, Dr. Sheryl Coutermarsh-Ott (DACVP) works out of this lab 4 days a week and spends one day a week at Virginia Tech. She reads most of the histopathology slides for the RAHLS and reports directly to Dr. Walters. A half time pathologist (Dr. Carvallo) also reads slides. Both travel to other labs a few days per month to assist with necropsies when others are away. \*The bench analysts in this laboratory all have between 19 and 31 years of laboratory experience with between 11 and 17 years with VDACS. The Wytheville lab has the least turnover of technical staff. Technical analysts are all certified medical technologists (VDACS edit)\*
- v. Caseload and Revenue  
This lab conducted 27,741 test procedures in 2021, which is 10% of the RAHLS total. The Wytheville test count in 2021 was up 7% compared to 2019. The revenue in 2021 was \$267,338 which represents 17% of the RAHLS total revenue. Wytheville revenue in 2021 was up 23% compared to 2019.

This lab offers many tests under the following categories (does not imply exclusivity or that some other test categories have no offerings from this lab):

- Necropsy
- Bacteriology
- Dairy Microbiology
- Hematology and Clinical Pathology
- Mammalian Serology
- Parasitology
- Pathology



- Molecular Diagnostics
- Virology
- Fish testing

- vi. Accreditation Status
  1. AAVLD – no
  2. A2LA – 15 tests on scope
- vii. National laboratory system participation - none
- viii. Summary Comments: The Wytheville laboratory is clean, tidy and staffed by experienced and dedicated people. Like the other labs, they are doing a broad variety of tests with few personnel. The lab serves many cattle and equine clients. They are to be commended for responding and setting up a fish testing service which serves the state fish hatcheries and VA Department of Wildlife Resources, but this has stretched them further. The two-year absence of a receptionist/office manager has caused much frustration and inefficiencies for analysts due to distractions of handling clients as they arrive or call into the lab for results. Offering full testing services with a small staff is also stressful, requiring many different types of tests to be set up daily. Final report turn-around-time (TAT) for necropsy cases is slow, about 10 working days (5 days for biopsies), although a preliminary report goes out once per week until the case is final. The main reason for this seems to be multiple lag times caused by many different steps including transporting tissues for trimming, slide production, transporting slides to pathologists, and communication of findings back to the case coordinator (lab director). Data shows the slides are in the hands of the pathologists only one day for biopsies and 3.5 days for necropsy cases, which is reasonable. Further investigation shows that slide processing time at the CVM is also within expected norms. The culprit then appears to be excessive time added to the process due to shipping of fixed tissues from the receiving lab to the trimming and slide processing labs, along with additional shipping time of slides from the slide processing lab (CVM) to the pathologists to be read.

**c. Lynchburg**

- i. Service Region - this laboratory serves central and eastern parts of the state.
- ii. Service to what industries- the laboratory's clients include the beef and equine industries. It also specializes in Food Safety testing services, the only lab to do so.
- iii. Facility summary – This 25-year-old facility is approximately 8,400 sq. ft. of BSL2 testing and office space (see appendix for lab footprint). Overall, the facility is in good operating condition. Testing space and layout is challenging for some disciplines, especially molecular testing (PCR) where lack of separation of sample preparation, clean reagent preparation, extraction and replication increases the possibility of cross contamination.
- iv. Personnel: See the appendix for a detailed personnel list. The Lynchburg Lab Director/Diagnostician position is currently vacant. The Microbiologist Supervisor is the *de facto* Director. There is a general feeling by staff that the

former lab director who left the position, did not manage the lab or their professional responsibilities well, to the detriment of the lab's mission. The necropsy technician position is also vacant. Therefore, at this time the laboratory is not offering necropsy services, which has raised concerns from some clients. This lab also has no receptionist/office support staff, which is a major distraction to the analysts as they fill-in and share the handling of client/specimen receiving and communication responsibilities. Marcos Alejos is the new Microbiology Supervisor and has been in this role for about three months. He brings molecular experience to the lab. He supervises 3 bench analysts.

- v. Caseload and Revenue: This lab conducted 26,333 test procedures in 2021, which is 9% of the RAHLS total. Lynchburg test count in 2021 was down 28% compared to 2019. The revenue in 2021 was \$26,304 which represents 2% of the RAHLS total revenue. Lynchburg revenue in 2021 was down over 10-fold compared to 2019. Both of these declines are likely attributable to necropsy services, testing consolidation, and dairy testing no longer being offered at this RAHL.

This lab offers many tests under the following categories (does not imply exclusivity or that some other test categories have no offerings from this lab unless indicated):

- Bacteriology
- Dairy microbiology (fewer test offerings than other labs)
- Food Safety (the exclusive lab for this category in the RAHLS)
- Johne's PCR (the exclusive lab for this (2 tests) in the RAHLS)
- Parasitology
- Poultry serology (5 tests)

- vi. Accreditation Status
  - 1. AAVLD – no
  - 2. A2LA – yes, 12 tests on scope
- vii. National laboratory system participation – this lab is the sole RAHLS participant in the FDA's VetLIRN (Veterinary Laboratory Investigation and Response Network), which focuses on surveillance for problems in animal feeds and drugs.
- viii. Summary Comments: The Lynchburg lab is currently operating differently from the other RAHLS labs. They have not offered necropsy services since October 2020. Clients are referred to other RAHLS laboratories for necropsies. However, the lab does process field-necropsy cases (necropsy in a box) when received. The loss of their primary dairy client, who also owned the specialized dairy microbiology testing equipment, resulted in any remaining dairy microbiology submissions being forwarded to other RAHLS labs (Warrenton and Wytheville). A search for a new lab director (veterinary diagnostician) has failed four times, despite efforts to redefine the role and improve the salary offered. Morale is suffering as this leadership vacancy stretches on. The lack of a receptionist/office support person magnifies the stress. This is the only RAHLS

laboratory that conducts food safety testing (11 test methods offered). They are in the process of building their molecular diagnostic test offerings, for example a bovine abortion panel and bovine respiratory panel are being developed. Quality system implementation seems to be a struggle due to many of the issues raised above which distract bench analysts from their testing duties and their quality system duties. When the Regional Quality Manager visits for a day, she spends 4 hours driving to be in the lab 4 hours.

**d. Warrenton**

- i. Service Region – this laboratory services primarily the northern part of the state, though it also currently provides dairy microbiology services for the Lynchburg laboratory service area.
- ii. Service to what industries – this laboratory’s biggest service segments are for the equine industry and the dairy industry (the latter especially due to current referral of samples from Lynchburg). In addition, this laboratory, compared to the other locations, provides more testing services for companion animals and is unique in its offering of forensic pathology services, primarily on companion animals. These forensic services are used primarily by law enforcement agencies in northern VA, MD and DC in regards to animal cruelty and other criminal investigations.
- iii. Facility summary – this 25-year-old facility encompasses approximately 8,400 sq. ft. of BSL2 testing space and offices (see appendix for lab footprint). Although operationally functional, currently the facility lags significantly behind all other RAHLS locations in terms of custodial maintenance and cleanliness. This is detrimental to the safety and operations of the laboratory as well as negatively impacting staff morale. Testing spaces appear to be very crowded, with equipment, filing cabinets and etc. While problematic in all testing sections, this is especially a threat regarding molecular testing, due to a lack of physical separation of the various steps of PCR preparation and processing, creating a much-increased probability for cross contamination during testing.
- iv. Personnel: See the appendix for a detailed personnel list. The Warrenton Director is Dr. Jamie Weisman, who has received formal pathology training. Dr. Weisman has been director for 11 years; she has a keen interest in forensic pathology and currently receives many forensic cases from Virginia, Maryland and the District of Columbia. There is a necropsy technician on site as well as an office specialist. Others try to cover necropsies on days when Dr. Weisman is called for forensic court appearances; or the cases are held over until the next day. A new Microbiology Supervisor began February 2022, Nabin Rayamajhi BVsc, PhD. He is a veterinarian that has considerable experience in public veterinary practice and molecular diagnostic testing. Dr. Rayamajhi currently supervises 3 bench analysts and there is one serologist vacancy. Two analysts have many years of experience, and the other has been on board for just one year.
- v. Caseload and Revenue: This lab conducted 30,957 test procedures in 2021, which is 11% of the RAHLS total. The Warrenton lab test count in 2021 was

down 15% compared to 2019. The revenue in 2021 was \$434,885 which represents 28% of the RAHLS total revenue. Warrenton revenue in 2021 was up about 2% compared to 2019. The low total test count vs. the higher revenue indicates this lab does more high fee test procedures.

This lab offers many tests under the following categories (does not imply exclusivity unless indicated or that some other test categories have no offerings from this lab):

- Necropsy
- Forensic Necropsy (exclusive offering by Warrenton lab)
- Bacteriology
- Dairy Microbiology
- Hematology and Clinical Pathology (exclusive to this laboratory)
- Mammalian Serology (8 tests offered)
- Molecular Testing (three equine tests on line)
- Parasitology
- Virology

vi. Accreditation Status

1. AAVLD – no
2. A2LA – yes, 11 tests on scope

vii. Summary Comments: The Warrenton laboratory was noticeably crowded and short of bench space. The square footage size is the same as Lynchburg (8,400 sq. ft.) but that is 43% smaller than Harrisonburg and 27% smaller than Wytheville. However, it appeared that the removal of old equipment, files/filing cabinets and some general rearrangement could be helpful. It was also noted that the floors of this lab were significantly dirtier than any of the other labs. The necropsy room was also quite dirty, and in need of a deep scrub, steam cleaning and disinfecting. Biosecurity practices appeared loose. The VDACS facilities supervisor stated that getting janitorial service in this area of the state using state contract bidding limits was very difficult i.e. no one would provide cleaning bids for the facility. The validity of that claim was not verified. In general, staff morale was low; although they understood the mission of the lab well, they felt stretched way too thin. Implementation of the quality system was difficult to work into their daily routines while understaffed. A2LA audits caused extreme stress and concerns about the attitudes and previous auditor competencies were mentioned. Training new employees appeared inadequate, haphazard and disorganized; this was a problem noted throughout the RAHLS. Cost of living differential in this part of the state was another stressor and probably influences recruitment efforts when trying to fill vacancies. All lab employees appeared dedicated to the mission and reported that there never seemed to be a lull in the workload to allow time for non-testing activities, such as ordering and quality duties. The forensic pathology work (mostly small animal and equine) brings some deep customer appreciation to the lab and

RAHLS, especially from law enforcement officials in the state and surrounding region. However, it does seem to add to the stress this lab appears to be under when the director is out for court appearances or when several of these intensive case work ups come in sporadically and demand high amounts of time and attention. These cases also put increased demands on the other pathologists in reading slides and providing legal levels of documentation.

- e. **Virginia Tech Animal Laboratory Services (ViTALS), Virginia-Maryland College of Veterinary Medicine (VMCVM, not part of RAHLS but provides collaborative services)**
- i. Service Region: CVM Teaching Hospital, the New River Valley and many Virginia counties, West Virginia, Maryland, and Pennsylvania.
  - ii. Service to what industries: The College of Veterinary Medicine Teaching Hospital represents 60% of the caseload; small animal, small ruminants, and equine, with fewer submissions from beef and dairy cattle. Poultry and swine submissions are fewer. Clinical pathology is the busiest test section. ViTALS also does Chronic Wasting Disease (CWD) testing for the Virginia Department of Wildlife Resources (VDWR).  
\*NOTE: Currently the CVM lab is sharing one board-certified anatomic pathologist with RAHLS (.5 FTE to each). This person does histopathology and necropsy duty some days in Harrisonburg. The ViTALS also creates all histopathology slides for RAHLS, about 10,000 slides per year. It has also recently begun providing trimming of fixed tissue for some of the RAHLS cases.
  - iii. Facility summary – The lab was built at the same time as the Veterinary Teaching hospital in 1983, and has 4,939 square feet of laboratory space, a total of 9015 square feet if you include offices, conference rooms, and shower facilities, all of which are shared with the hospital and department. The individual lab spaces are BSL2, with access to BSL3 lab space if needed, but the latter is shared with research activities.
  - iv. Personnel - currently 3.0 FTE in anatomic pathology (DVM, DACVP), 1.6 FTE in clinical pathology (DVM, DACVP), 0.5 FTE Clinical Microbiology (DVM, DACVM), 0.5 FTE Parasitology (DVM, DACVM); Staff – 9 FTE not including receiving, all at the HT(ASCP), MT(ASCP), or MS level, 2.0 FTE after hours technicians (DVM students)
  - v. Caseload - approximately 45,000-50,000 tests/year. Necropsies average 700 a year, 50% of which are large animal (average 150 cattle and 150 horses a year), 50% small animals.
  - vi. Accreditation Status - AAVLD accredited full-service laboratory.
  - vii. National laboratory system participation - A member of the National Animal Health Laboratory Network (NAHLN), level 3.
  - viii. Summary Comments: Although this laboratory (ViTALS) predominantly serves small animals and teaching hospital patients, it also performs a significant number of mortality investigations involving cattle, small ruminants, and horses. The breadth of expertise brought to the effort is naturally quite broad at a veterinary college, and this is one of the major strengths of this unit. This expertise includes not only the pathology section, but other diagnostic

specialties including bacteriology, virology, hematology, serology, parasitology, molecular diagnostics, immunohistochemistry, and toxicology. In addition, the ability for diagnosticians to communicate and collaborate with clinical medicine specialists in all the various animal sectors is another advantage for performing quality diagnostic investigative work. Access to and collaboration with researchers at the CVM has also been instrumental in both diagnosing new or unusual diseases as well as development of new or improved diagnostic test capabilities. The laboratory is aging and appears maximized on space utilization, but appears well maintained and organized. This has not stopped them from stepping up and performing important new diagnostic activities by finding room in other areas of their complex, such as the recently expanded CWD surveillance activities contracted to ViTALS by the VDWR. Another advantage this laboratory appears to enjoy is an apparent abundance of available part time labor (student workers). This appears to be a win/win as the laboratory gains more throughput capacity and flexibility as cases surge or wane, and the students expand their diagnostic educational experiences.

**Quality System management**

A copy of the RAHLS Quality Manual was submitted to the consultants. The system Quality Manager (QM) is Melinda M. Stuart, BSMS, MLT, ASCP, who is based at the Wytheville laboratory and travels to the other labs as necessary. Melinda covers on site quality management for Wytheville as well as overall coordination of quality management for the system. There is currently only one other person on the team, Whitney Patrick, Regional Quality Coordinator (RQC), who works out of Harrisonburg and covers quality management for 3 labs (Harrisonburg, Warrenton, Lynchburg). At one point there was an initiative to add one more RQC, splitting the 4 labs evenly between the RQCs for baseline support with the QM supervising system-wide, but this has not been implemented. In general, the point person at each lab for quality system duties is the Microbiology Supervisor, assisted by the quality management team. In summary relative to Quality System management:

- Melinda Stuart
  - System Quality Manager
  - Wytheville Quality Coordinator
- Whitney Patrick
  - Harrisonburg Quality Coordinator (office base)
  - Lynchburg Quality Coordinator (4-hour roundtrip from base)
  - Warrenton Quality Coordinator (3-hour roundtrip from base)
- Microbiology Supervisor at each lab is that lab’s quality leader

The RAHLS laboratories are not full-service accredited laboratories per the AAVLD standard. However, they do have several specific key tests accredited to the ISO 17025 standard through A2LA, a private, ISO-recognized and authorized accrediting body. This allows participation in the NAHLN; the Harrisonburg lab is an approved level 2 NAHLN laboratory. Tests currently approved to be run as part of A2LA Accreditation:

<u>Lab</u>	<u>Accredited Test Scope</u>
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<u>Harrisonburg</u>	<u>Avian Influenza (AI) AGID</u> <u>Avian Influenza (AI) RT-PCR:</u> <u>AI, H5, &amp; H7 using 7500</u> <u>Ambion Magnetic Bead RNA Extraction</u> <u>Avian influenza (AI) ELISA</u> <u>Brucella by Buffered Plate Antigen (BAPA)</u> <u>Colilert Enumeration (MPN)</u> <u>Equine Infectious Anemia (EIA) AGID</u> <u>Equine Infectious Anemia (EIA) ELISA</u> <u>MG/MS/MM ELISA</u> <u>Newcastle Disease Virus RT-PCR</u> <u>APMV-1 using 7500</u> <u>Ambion Magnetic Bead RNA Extraction</u> <u>Salmonella Isothermal PCR</u>
<u>Lynchburg</u>	<u>Equine Infectious Anemia (EIA) AGID</u> <u>Campylobacter VIDAS</u> <u>Campylobacter Positive Confirmation</u> <u>Colilert Enumeration (MPN)</u> <u>Equine Infectious Anemia (EIA) ELISA</u> <u>E. coli O157 (including H7) VIDAS UP</u> <u>E. coli Positive Confirmation VIDAS UP</u> <u>Listeria VIDAS UP</u> <u>Listeria Positive Confirmation VIDAS UP</u> <u>Salmonella VIDAS UP</u> <u>Salmonella Positive Confirmation VIDAS UP</u> <u>Staphylococcus Enterotoxin II VIDAS</u>
<u>Warrenton</u>	<u>Anaplasmosis cELISA</u> <u>Bluetongue cELISA</u> <u>Bovine Leukemia Virus ELISA</u> <u>Bovine Pregnancy Test</u> <u>Brucella by Buffered Plate Antigen (BAPA)</u> <u>CAE/OPP ELISA (Small Ruminant Lentivirus c ELISA)</u> <u>Colilert Most Probably Number (MPN)</u> <u>Contagious Equine Metritis (CEM)</u> <u>Equine Infectious Anemia (EIA) AGID</u> <u>Equine Infectious Anemia (EIA) ELISA</u> <u>Johne's ELISA</u>
<u>Wytheville</u>	<u>Anaplasmosis cELISA</u> <u>Bovine Leukemia Virus ELISA</u> <u>BVDV PI X2 (BVD ELISA)</u> <u>Brucella Card Test (Rose Bengal)</u> <u>Brucella by Buffered Plate Antigen (BAPA)</u> <u>Brucella by Standard Plate Antigen</u> <u>CAE/OPP ELISA (Small Ruminant Lentivirus c ELISA)</u>

	<u>Colilert Enumeration (MPN)</u> <u>Colilert Presence/Absence</u> <u>ELITEST CLA EIA</u> <u>Equine Infectious Anemia (EIA) AGID</u> <u>Equine Infectious Anemia (EIA) ELISA</u> <u>Leptospirosis Microscopic Agglutination Microtiter Test (MAT)</u> <u>Johne's ELISA</u> <u>Pregnancy Test ELISA</u>
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The current test-by-test A2LA accreditation method is an intensive process. A2LA comes once every two years for re-accreditation of each test. Current Quality Staff appear to be on top of the needs but having only two individuals to cover 4 labs is stretching them to the max under their current test-by-test accreditation mode. On top of this, they must coordinate the USDA proficiency test program for NAHLN and other tests of significant importance. The Regional Quality Coordinator, currently based in Harrisonburg, wastes 3–4 hours a day driving each time she visits Warrenton or Lynchburg. The bench analysts are feeling swamped by routine duties, including Quality System chores. Staff have the willingness to implement, and they understand, the need for a functional quality system, but the daily demands of routine bench work while short staffed makes quality system work another burden they have difficulty working into their daily routine. This lack of a fully functional Quality Management System seriously undermines the reliability of the testing services offered by the RAHLS.



## **Part 5. Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis**

Additional feedback on the current state and future directions for the RAHLS was gathered through the use of a typical SWOT analysis. A survey instrument was sent to a cross section of RAHLS staff, AFIS management and a few stakeholders. The survey simply requested each participant to list up to five issues for each of the SWOT categories. A total of 17 replies were compiled with similar issues in each category combined and the number of times an issue was cited tallied. This introspective exercise shows that the RAHLS personnel is well aware of the important issues in the operation of these laboratories. It also appears that although there is a certain level of staff frustration with some of these issues, there is still honest and open communication occurring between staff and leadership. Detailed compiled data is located in the Appendix and highlights can be summarized as follows:

### **Strengths**

By far the most frequently cited strength of the RAHLS currently is its staff, their experience, knowledge, dedication and client service. The responsiveness of the system to its clients, ease of access due to geographic distribution and focus of the facilities and scope of testing capabilities were also significant. Program leadership was also cited positively and repeatedly.

### **Weaknesses**

Staffing issues were far and away the most numerous items cited as weaknesses. These included staff shortages, causing people to feel stressed and lacking sufficient time to maintain high quality services, staff recruitment and retention problems due to salary levels, lack of a career ladder, inadequate training processes as well as ineffective personnel management. Workflow inefficiency was also cited, exacerbated by facility space limitations and, in some cases, the redundant, decentralized logistics of services. The Quality Management System was repeatedly mentioned due to perceived redundancies, insufficient staffing and a perceived time conflict between meeting daily testing demands and getting the additional quality assurance work and documentation done as well. The current Laboratory Information Management System (LIMS) was cited due to multiple factors (lack of a client portal, cumbersome processes, insufficient user support, report deficiencies).

### **Opportunities**

The list of potential opportunities that surfaced was extensive. Many were related to weaknesses identified above, such as improving training programs, both for new hires as well as ongoing training and continuing education of staff. Likewise, many saw opportunities to improve the functioning of the Quality Management System by streamlining processes and requirements, combining Standard Operating Procedures (SOPs) for the same testing from multiple locations into a single, system-wide SOP as well as creating additional SOPs for some processes that currently don't have them. Opportunities to address the many areas related to staffing issues also figured prominently, addressing salaries, career ladders, training, team building, staff recognition and recruitment practices.

A very specific opportunity mentioned was implementing a process for clients to be able to use credit cards at lab locations to pay for services. Continuing to build on current collaborations with the Virginia-

Maryland Regional College of Veterinary Medicine was cited repeatedly as were expansion of advanced technology testing methods and increased outreach to clients.

### **Threats**

Many of the issues surfaced as threats were those also cited as weaknesses related to staffing issues (staffing levels, recruitment, retention, training, workload stress) and the Quality Management System (redundancy, staffing, lack of time). Some external threats, external to RAHLS, were also identified including insufficient state funding, growing competition from other state and private labs, decreasing numbers of new veterinary graduates interested in livestock and poultry as well as a lack of knowledge among clients of the capabilities of the RAHLS.

In summary, this SWOT exercise clearly demonstrated that human resources, the most critical part of any organization, was an area in particular need of attention for the future of the RAHLS. Maintaining full services of all disciplines at all laboratories has stretched the bench analysts extremely thin in each individual lab, leaving most disciplines one deep, tired and stressed. This will only become more acute in future years as the RAHLS faces the demographic changes already in the works (population declines, fewer college graduates, changing workforce expectations and priorities) that will drastically increase competition for the kind of staff needed.

## Part 6. Comparison of the RAHLS to Other State Veterinary Diagnostic Laboratory Systems

### Staffing Levels, Workload and Compensation

Proper staffing level is key to the efficient management of any organization. It is tempting to try and boil down the analysis to some comparable parameter such as tests per analyst per day. However, that exercise does not take into consideration the inherent productivity variables at different laboratories. For example, in one laboratory, clerical staff may input all client and specimen data into the computer to prepare for test resulting, whereas in a different laboratory the bench analysts may be required to perform such time-consuming tasks. For another example, a high-volume testing laboratory may have the luxury of utilizing automation and be able to run their tests at maximum efficiency capacity (like full 96 well plates) whereas a different laboratory may be hand pipetting and running small, inefficient batches due to a lower caseload. Therefore, caution must be used when making interlaboratory efficiency comparisons. Such **comparisons should only be done by knowledgeable managers capable of factoring in all of the variables inherent in the complex testing environments of these types of laboratories**, which is far different than a factory assembly line making widgets. An assessment of productivity must include all of the duties and responsibilities of the staff member e.g. QA, maintenance activities...in addition to numbers of tests performed. The safest comparisons are between positions with the same duties and responsibilities, across the system. To accurately conduct such comparison requires detailed, accurate, granular workload data that correctly attributes testing to the location and even the technician that conducted the test. **The current RAHLS laboratory information management system (LIMS) does not appear to have the ability to provide such data, making such comparisons difficult and unreliable.**

To retain highly skilled staff long term and therefore be able to benefit from their growing experience base, it is important to have opportunities for career progression and advancement. **In comparison to other state's laboratories, the lack of career advancement (ladders or steps) places RAHLS at a significant disadvantage.** Such advancement is typically based on acceptance of additional responsibilities as well as one's growing skills during the course of a career. **Financial rewards for those accepting additional responsibilities must be a part of this career progression plan.** Career ladders help ensure that essential state infrastructure services are staffed, managed and led by experienced people. It also ensures that a critical mass of experienced personnel is available for the training and mentoring of new employees. Lastly, career progression opportunities also make the laboratory staff less vulnerable to raiding by competing industries. Resources for continuing education must also be a part of a progression and retention plan to sustain RAHLS employee excellence. A typical career ladder might include at least 3 levels to reflect beginning, intermediate and advanced knowledge, education, experience or responsibilities. Some systems have found it advantageous to further subdivide each level into 2-3 steps, each requiring advances in knowledge and/or responsibilities and each step accompanied by at least a small salary increase. It has been shown to be most effective when all career advancement is predicated on demonstrable merit and defined metrics and should not be based on longevity in the position. **It is also extremely beneficial to formulate two, parallel but equal career tracks for technical staff, one track based on advancing technical prowess, the other track focused on supervisory/administrative management responsibilities.**

Regarding employee compensation levels, these are highly variable from state to state. Ideally, they should be based in part upon educational requirements to perform their assigned duties. Pertinent experience and additional training should be considered when determining entry salary level. Without career progression opportunities, the **RAHLS' current salary structure is a significant challenge to recruiting and retaining the high caliber of staff required.**

The pay scale at laboratories managed by universities is typically higher than those managed by state agencies. The reasons for that include: higher and more specific educational requirements and broader job duty expectations such as teaching and mentoring skills or research skills. Universities often have an inherent advantage of local access to a highly educated labor market. The pay scale for laboratory workers within private industry is again typically higher than even what universities are able to offer. The pharmaceutical and biologicals industries are always on the hunt for experienced analytical scientists to work in their research and development divisions. Regardless, in establishing reasonable starting and median salary levels for staff, factors such as local/regional cost of living differences, educational requirements or achievements, experience and training must be included and routine surveys of salary levels for other public and private sector positions with similar educational, knowledge or experience levels should be conducted for comparison. For veterinary diagnostic laboratory positions, such comparators typically include similar positions in other state agencies and universities as well as veterinary technicians, human clinical medical laboratory technicians, research laboratory technicians and private industry quality control, testing or research technicians.

The AAVLD is currently in the middle of a comprehensive salary and compensation review of all AAVLD laboratories across the USA. That first-ever comprehensive report is expected to be delivered at the annual meeting of the AAVLD in October 2022. It will be made available to AAVLD members and lab directors when completed. It is expected to be repeated periodically so that trends can be established. It is hoped that it will be a useful management tool for veterinary diagnostic laboratory directors.

### **Accreditation**

At this point we believe it would be beneficial to provide some background regarding the purpose of laboratory accreditation and its evolution over the last 20 years. The general purpose of any accreditation review is to ensure that any complex activity is being conducted in a manner that ensures a quality product or reliable result. The accreditation review team is typically composed of individuals with expertise from multiple disciplines relative to the task being evaluated. The review is conducted against a previously agreed upon accreditation standard, also fit to the purpose, such as the *AAVLD Requirements For An Accredited Veterinary Medical Diagnostic Laboratory*.

When a complex activity is being evaluated for success (e.g., a Medical College, a Law School, a Veterinary College, a full-service diagnostic laboratory) the standard should include an evaluation of all aspects of the program that have an impact on the final product. The unit being evaluated does not have the option of asking the auditors to “please evaluate our anatomy courses for quality but don’t look at our surgery courses”. All essential inputs into the final product must be evaluated for effectiveness.

Animal health diagnostic laboratories in the USA have been providing diagnostic data to animal owners, veterinarians and those in charge of managing animal populations for well over 100 years, many going back to the 1800’s. These laboratories were established within land-grant universities or state

departments of agriculture. Universities were often engaged because they had Cooperative Extension service obligations to assist producers in the production of food. Furthermore, new disease conditions often required researchers to become involved via Agricultural Experiment Stations. Around the middle of the last century, State and Federal veterinarians recognized a rapidly growing need to have reliable diagnostic data to make important herd/flock health decisions for the nation. Reliable data was necessary for the monitoring and surveillance work of disease eradication programs. Many states then formally established animal health laboratories to conduct this work. Currently 3/4 of the state animal health laboratories are affiliated in some way with universities and about 1/4 are managed independently by state agencies.

Since the combined work of these laboratories (being performed across numerous states) collectively create the data that determines our national herd/flock health status, it became increasingly important that tests performed at different laboratories produced similar results. At least as similar as the methodology would permit relative to sensitivity and specificity of the test performance. How could leaders ensure this happens? The answer was having all labs working from the same performance standard and ensuring that quality performance was happening via third-party accreditation audits. In 1967 the American Association of Veterinary Laboratory Diagnosticians (AAVLD) wrote the first standard in the world for the accreditation of animal health diagnostic laboratories. In 1969, the first state labs were accredited under the new standard. The standard was entirely compatible with the mission of AAVLD; to advance the discipline of animal health diagnostic laboratory services. The new standard had an immediate impact on harmonization of test results across the country and advanced the entire system. By the turn of the century all of the major labs in the USA and some provincial labs in Canada were accredited to this AAVLD standard.

Leading up to and during the early years of the 21st century, some significant changes brought about some necessary adjustments. Due to the *globalization of agriculture* and the extensive trading of animals and animal products across country boundaries, international expectations for reliable test results grew considerably. Our trading partners (and the USA inversely) desired an accreditation process that was familiar internationally. The International Standards Organization (ISO) had a new standard for testing and calibration laboratories (ISO Guide 17025) which was suggested to be applied to the business of animal health diagnostic laboratories. It is not a perfect fit when applied to the biological world of complex disease investigations, but is suitable (ISO originated out of the manufacturing world). The ISO 17025 standard only accredits an individual test, it does not look at the entirety of the operations of a laboratory. In 2001, the AAVLD extensively rewrote their accreditation standard, *Requirements For An Accredited Veterinary Medical Diagnostic Laboratory*, to be a direct application of ISO Guide 17025 and has been accrediting to this standard since. The AAVLD accreditation standard is a comprehensive, holistic accreditation process, and considers all disciplines and factors that have a potential impact on a test result, including biosafety and biocontainment. By design, It does not accredit test by test simply because a typical diagnostic laboratory runs hundreds of assays. Rather, the AAVLD accreditation process takes the approach of evaluating competency in all the necessary diagnostic disciplines and overall quality and operational management.

Accreditation status is upper management's most reliable mechanism for knowing whether or not activities for which they are responsible are being conducted properly, reliably, and consistently. Accreditation also adds confidence that the users of the product (lab test data) are making subsequent decisions with the best data available. It is important that this process be holistic and inclusive of all

aspects of the operation because upper management is typically not an expert in all facets of the operation. For example, a lab director may be highly familiar with the discipline of pathology, but not necessarily an expert in molecular diagnostic test performance. When the task at hand is an investigation into an unknown morbidity and mortality situation, the competence of the investigation is reliant upon multiple disciplines to successfully solve the questions (the causes could be pathological, bacterial, viral, parasitic, toxic, genetic, or environmental conditions).

At this point in time, the RAHLS is notably different than nearly all other state animal health diagnostic laboratories in that they are not accredited by AAVLD. They do have some critical tests accredited per the ISO Guide 17025 which has allowed them participation in the National Animal Health Laboratory Network (NAHLN). It is our opinion that adding additional tests by that method will further tax an already stressed system. Test by test accreditation is also expensive both in direct costs (accreditation fees) and manpower energy (auditors come for each test every other year).

In addition, by not being part of the AAVLD group, RAHLS is missing out on significant networking, troubleshooting and mentoring opportunities with colleagues in similar roles in other states. Due to very rapid changes in biomedical technology, 'keeping up' is a significant challenge to isolated laboratories. Laboratories that are not affiliated with a university are even more challenged due to the inherent advantages that Universities have relative to staying on the cutting edge of technology and science.

### **Fee Schedule**

A subset of 32 tests and their associated fees from the current RAHLS Fee Schedule were selected for comparison. The selection was based on overall test volume and importance to clients or the mission of the RAHLS and the AFIS. The tests selected for comparison represent most of the testing disciplines and methods in use, ones that are common to virtually all veterinary diagnostic laboratories. The laboratories chosen for comparison are a cross-section of types including those part of a state agency like RAHLS (NC, MD, PA) and those that are university affiliated (SC, SD, GA, TX, NY) and are also a combination of smaller volume systems like RAHLS (MD, NC, SC, PA) and high-volume systems (SD, GA, NY, TX). The specific laboratories compared to were:

1. *North Carolina Veterinary Diagnostic Laboratory System – North Carolina Department of Agriculture and Consumer Services*
2. *Clemson Veterinary Diagnostic Center – Clemson University, South Carolina*
3. *Pennsylvania Veterinary Laboratory – Pennsylvania Department of Agriculture*
4. *Animal Disease Research and Diagnostic Laboratory – South Dakota State University*
5. *Animal Health Diagnostic Laboratories – Maryland Department of Agriculture*
6. *Texas A&M Veterinary Medical Diagnostic Laboratory – Texas A&M University System*
7. *Animal Health Diagnostic Center – Cornell University, New York*
8. *Veterinary Diagnostic Laboratories – University of Georgia and the Georgia Poultry Laboratory Network (private)*

Of the test fees compared, RAHLS was below the average of the other labs for 60% (19/32) of the tests and at or above the average for 40% (13/32) of the tests.

Some of the RAHLS' highest revenue tests were included in those below the average for other labs:

- EIA AGID
- MG/MS ELISA
- Necropsies – Livestock, Equine and Poultry
- AI ELISA
- Aerobic Culture and ID

Likewise, some of the RAHLS' test fees that are higher than average, some significantly so, include:

- Contagious Equine Metritis Culture
- Avian Influenza RT-PCR
- *Ornithobacterium rhinotracheale* PCR
- EIA ELISA
- Biopsy

This analysis reveals both potentially missed opportunities to increase fee revenue (test fees lower than average) as well as potential threats to the surveillance mission of the RAHLS (test fees higher than average). **These findings emphasize the need for a routine, usually annual, fee review and adjustment process.** The process should include this type of market comparison as well as many other factors (impact on industry segment, impact on disease surveillance mission and etc.) in establishing the fee schedule.

### Organizational Structure

The four RAHLS laboratories are small to medium sized units in reasonable physical condition, built at bio-security levels one (BSL 1-offices) and two (BSL2-most laboratory space), with a very limited amount of level 3 (BSL3-high containment) space at only the Harrisonburg location. **Virginia is among the last states to still have multiple small to medium sized laboratories scattered across the state.** That geographically dispersed model was popular several decades ago when, due to transportation logistics, getting specimens to the laboratory timely was problematic. The advent of rapid private courier systems (e.g., FedEx, UPS...) has generally removed the main reason for such an operational model. **Nearly all states have transitioned to one or two strategically located laboratories which is a much more efficient, successful and sustainable model for overall laboratory operations and maximum utilization of expensive equipment and highly skilled staff.**

The current supervisory structure within the RAHLS, a Director/Diagnostician and one Microbiologist Supervisor (MS) with analysts in each discipline, reflects the relatively small staff complement of each laboratory. There are some major drawbacks to this structure though:

- The MS is expected to be technically proficient in all disciplines in the lab, able to train new staff and provide backup testing services everywhere. Due in part to the ever-growing technical scope of the different scientific disciplines, this is a huge, unreasonable, technical requirement. This is especially exacerbated by the lack of subject matter experts (SMEs) for each testing discipline in the system.
- In several laboratories, individual analysts are expected to maintain technical proficiency in as many as three or more disciplines. This is technically unfeasible and not a common practice. More typically an analyst would be expected to maintain technical competence and proficiency in no more than two disciplines.
- The RAHLS is sorely lacking and technically deficient in SMEs. These SMEs (typically DVM and/or PhD level, some with specialty board certification) are critically important to the technical competence of the system, maintaining state-of-the-art diagnostic capabilities, troubleshooting technical issues and being able to address new or emerging disease threats. In this regard the **RAHLS lags far behind what is considered “industry standard” for veterinary diagnostic laboratories.**
- The staffing issues described above are significantly exacerbated by **ongoing recruitment and retention failures leading to some critical, prolonged vacancies (e.g., Lynchburg Director/Diagnostician) and high turnover of technical staff.**

### Summary

Currently, in comparison to the nationwide norm for US veterinary diagnostic laboratories, the RAHLS would rank as Middle Tier in its strongest areas and Bottom Tier in others. Significant restructuring and other work need to be done to address the weaknesses cited if the RAHLS is to reach the First Tier or “Best in Class” level that the agriculture industry in Virginia needs.



## **Part 7. Strategic Recommendations**

We recognize that there certainly is more than one way to achieve a successful outcome. The strategic recommendations we provide are based on our years of experience with many different animal health diagnostic laboratories. We also recognize that each state is unique in its governance, traditions, and financial resources and therefore their ability to adopt any specific recommendations. These parameters are not unique to any review and analysis situation, and therefore it is unusual when analytical reviewer's recommendations are 100% implementable. Success should be gauged on insights gained that allow an organization to change directions and create momentum in a positive trajectory, frequently taking years to reach major goals with major impacts.

Our approach to writing this section is to first concentrate on major recommendations and paths forward to achieve them. Then we provide some specific operational recommendations which management can consider in the near future, to perhaps gain some immediate efficiencies.

### **Major Recommendations**

#### **Laboratory System Structure**

The RAHLS model of four smaller laboratories scattered across the state is a highly inefficient model for this day and time. The problems this model causes include:

- It magnifies the indirect cost by 4-fold (bench space, equipment, utilities, etc.).
- It disperses the scientific manpower across the state, forcing most of them to be working alone within their discipline within their assigned lab.
- It prevents the formation of a critical mass of scientists for any particular discipline, thus requiring inefficient stressful cross-training schemes to cover sick and vacation days of analysts from other test sections. This approach also creates inherent quality control issues due to inexperience and work overload when analysts must cover more than one section during such times.
- It dilutes the case load to four different sites, thus removing the opportunity for high throughput efficiency; and removing the cost feasibility for implementing high throughput automation; in short it creates inherent analyst inefficiency and replication of identical services across the state.
- It does not allow adequate training and mentoring of new analysts since the experienced staff are dispersed across four sites and stretched too thin to assist new employees.
- It creates inefficiencies in quality management, by increasing the quality system workload both of the testing section and the quality management team; in modern labs, it is estimated on average that 20% of an analyst's duties are related to quality system management which includes SOP management, control management, reagent management, equipment management, educational check tests, required proficiency tests, and audit preparation.

**Recommendation: Develop a multi-year transition plan to move from the current RAHLS structure to one comprised of two, state-of-the-art facilities, at Harrisonburg and Blacksburg in collaboration with the VMCVM.** Part of development will be determining the preferred level of collaboration or integration between the RAHLS and the VMCVM.

- Replace DVM Diagnosticians with DVM board-certified pathologists
- Maintain current total overall state budget for RAHLS operations to provide sufficient funding for investments in SME positions, equipment, facilities expansion and etc.

### **Accreditation**

**Recommendation: The Virginia RAHLS should seek full AAVLD accreditation as quickly as possible.**

Once accredited, advantages include:

- All of the laboratory's diagnostic and testing activities would fall under the total laboratory accreditation umbrella, leaving fewer vulnerable liabilities for the organization
- Laboratory staff, including management and quality system personnel, will immediately have a national network of colleagues to share with and collaborate with to advance the expertise of the system
- RAHLS will have full access to continuing education programs of the AAVLD include the annual meeting, quality symposia, workshops, voluntary educational check tests, diagnostic list serves by discipline, and others
- Overall cost savings relative to accreditation should be anticipated with the AAVLD system vs. the current test by test accreditation process
- The current accreditation plan and quality system appears highly vulnerable to collapse, especially if additional tests are added to their test authorization scope via the current test-by-test accreditation method

One way to bring the RAHLS system into the AAVLD accreditation system (currently 64 labs in the USA and Canada) could be via one of the current stable labs (such as the Harrisonburg lab) assuming status as the 'Primary' laboratory for the system and the other labs becoming 'branch' laboratories. With that model, all labs typically operate under the same quality system and leadership. One advantage is that a satellite lab does not have to provide all the required disciplines that an independent full service accredited laboratory typically must provide, as long as there are referral mechanisms for those testing disciplines not offered at the branch lab (usually those are referred back to the primary laboratory). This could allow management to consider consolidation of some services, or drop some services from some of the labs that are currently struggling to recruit personnel into vacancies.

Another advantage is that once fully accredited, the auditors arrive once every 5 years and audit the entire system at one time; a comprehensive holistic audit, but very efficient for the laboratory. That is compared to an every-other-year audit of every test when using the test-by-test accreditation method.

The one disadvantage of the 'Primary lab with branch lab model' for AAVLD accreditation of the RAHLS is that one problematic lab in the system could place the RAHLS on accreditation probation until resolved.

Another way of achieving accreditation via AAVLD would be for each laboratory to independently pursue accreditation. This would be less efficient and more expensive. However, each laboratory's status is independently determined, and one problematic lab does not impact the status of the entire system. Historically, once a laboratory or system has achieved AAVLD accreditation, due to the inherent advantages offered by membership as previously discussed, it has been unusual to lose accreditation in well managed laboratories. However, there are no guarantees and compliance to the standard is the determining factor.

## **Staffing**

*Recommendation: **Improve staff recruitment and retention.*** Several areas that should be addressed include:

- Staffing levels should be set to accommodate not just routine testing demands, but must also allow for time necessary for QA, continuing education and reasonably expected staffing shortages (sickness, vacations...). Diagnostic testing by its nature is often episodic with most submissions not predetermined. Where submissions for certain types of testing are predictably cyclical (e.g. EIA serology, Dairy Microbiology...) opportunities for use of wage positions, students or other seasonal help could be explored to augment regular staffing.
- In general, expectations for technical competency and proficiency of analysts should encompass no more than one primary discipline and one backup discipline.
- Creation of career ladders consisting of multiple possible grades or steps for each type of position. The current situation of a single classification (Scientist 1) for most analysts, with no possible progression is a disincentive. Typically, at least two and often three possible steps or grades of advancement are used (e.g., Technician 1, Technician 2...). Alternatively, or even additionally, levels within a grade can be used (e.g., Scientist 1/Junior, Scientist 1/Senior...). In either scenario, reasonable salary incentives should be included in promotions, which typically include acceptance of more responsibilities.
- A formal, written policy of supporting continuing education should be established with designated funding identified in the annual budget to support this activity.
- Processes for recognizing and rewarding outstanding efforts should be fully employed (e.g. SPOT awards) without limits on the number of times a year such efforts can be acknowledged.
- Salary increases should be merit-based, not across the board.
- Salary increases should be possible for lateral moves, based on any significant differences in complexity or scope of the before and after positions.
- When possible, start the recruitment process well in advance of announced departure. Consider allowing some degree of overlap of the new hire with the outgoing person.

*Recommendation: **All Laboratories need adequate administrative support staff to perform the following duties that will allow analysts to remain at their primary analytical testing tasks:***

- Receiving clients and completing appropriate registration paperwork
- Initiating test order paperwork and getting specimens to the appropriate laboratory

- Setting up test orders in the LIMS
- Receive client phone calls and emails and where appropriate directly disperse information to the clients and their veterinarians
- Coordinate and order supplies for the testing sections
- Coordinate the filing of case paperwork
- Coordinate billing

***Recommendation: Develop a training program for new employees with proper steps performed and documented before any new analyst is released to perform tests for clients without supervision.***

- Establish formal, standardized training curricula, processes and expectations for each position. This is critical to ensure new staff or staff transitioning to a new area are properly and fully trained and formally approved to conduct test procedures for clients. This includes supervisory, management and leadership training as appropriate.
- This would be easier to accomplish if there were a critical mass of analysts in each testing section. However, under the current circumstances it can be accomplished by:
  - Attempt to hire new staff before retiring staff leave so that adequate training and mentoring can occur; this would be ideal. The timeframe required to pass on these complex skills are typically months or years, not days or weeks.
  - For unexpected sudden vacancies, a new analyst employee should be initially assigned to work at another lab on site with a mentor at one of the other laboratories with the appropriate discipline.

***Recommendation: Establish positions for Subject Matter Experts (SMEs), both to provide required expert oversight of routine diagnostics as well as explore and advance diagnostic capabilities. This requires staff with suitable formal training and credentials, generally at the PhD and/or DVM level.***

***Recommendation: Implement reasonable levels of cross-discipline training, utilization and rotation.***

Typically, an analyst can be expected to be proficient in only about two disciplines at a time, one primary and one secondary as a backup for other staff. Rotations among disciplines must be frequent enough and of long enough duration to maintain proficiency and not so frequent or of such short duration as to reduce consistency and quality.

## **Operations**

***Recommendation: Establish an External Advisory Committee (EAC).*** The composition of the EAC should reflect the various commodity groups, veterinary practice types and public agencies or institutions relevant to RAHLS services. The EAC should:

- Provide insight on issues of interest to and needs of the stakeholders relative to RAHLS services
- Provide feedback on performance of and satisfaction with RAHLS services
- Provide strategic direction on the continued growth and development of the RAHLS
- Provide a communications conduit for the RAHLS to stakeholders, legislators and other relevant parties.

**Recommendation: Change workflows to improve testing turnaround times.**

- Histopathology/Necropsy – In general, the best person to trim tissues from a necropsy is the person who performed the necropsy. If that isn't feasible, all fixed tissues should be forwarded to a single location, probably the College of Veterinary Medicine at Virginia Tech, for trimming as well as slide processing. All other fixed tissues (biopsies, field necropsies) received at the labs should be forwarded to the CVM for trimming and processing.
  - Concentration of the trimming and processing at the CVM may require additional support for .5 to 1 FTE of staffing. The CVM may be able to leverage students to keep costs low.
  - VDACS should strongly support and encourage the implementation of digital slide scanning as quickly as possible. This will greatly improve the efficiency of the available histopathologists via remote access as well as any other VDACS or remote resources to ensure reasonable workflow and turnaround times.
  - Explore ways to encourage clients to submit biopsies (fixed tissues) directly to the CVM for trimming and slide preparation. Incentives could include providing shipping labels, discounted pricing for appropriate submissions, prioritization of cases with decreased turnaround times or other means.
  - Pulling histopathologists away to cover necropsies in other labs is counterproductive and an inefficient use of this limited resource. We recommend that any lab without a Lab Director (Diagnostician) on site, not offer necropsy services.
  - The RAHLS should have a minimum of 2.0 FTE devoted to histopathology
- Serology – explore opportunities to further consolidate serology testing based on technology, not species or location. Take full advantage of state-of-the-art, automated sample processing and testing instrumentation and software (e.g. ELISA). It may be feasible to maintain “satellite” serology capabilities for STAT requests, but those should incur additional STAT fees.
- Molecular Diagnostics (PCR) – similar to Serology, explore opportunities to further consolidate testing based on technology, not species or location. Take full advantage of state-of-the-art, automated sample processing and testing instrumentation and software.
- Dairy Microbiology – have samples submitted directly to fully capable testing locations, get away from interlaboratory shipping which results in sample loss and additional delay.

**Recommendation: Develop and implement an annual formal fee review process.** This includes determination of reasonable periodicity for review. Fee review should include a quantitative cost accounting for each test, including personnel time, as well as a comparison to other appropriate state laboratory fee schedules. In some states, the laboratory system advisory committee is involved with this process.

**Recommendation: Maximize application of General Funds to salaries and benefits.** This will reduce the amount of benefits having to be paid out of Non General Funds.

*Recommendation: **Consolidate testing to take advantage of sample processing and testing automation.*** Serology testing is a prime example, where changing from AGID to ELISA methods for EIA and perhaps other tests would facilitate implementation of this increased efficiency.

*Recommendation: **Upgrade the existing Laboratory Information Management System (LIMS).*** The existing LIMS is based on outdated technology, reports are suboptimal and there is no internet portal for clients to access results or pay bills. An up-to-date LIMS is critical, both for clients and the laboratory, allowing you to take advantage of increased efficiency of testing using automated equipment, better cybersecurity, improved hardware management, system failover/redundancy, scalability for growth or emergency response and continuity of business. There should be at least .5-1.0 FTE of laboratory staff devoted to being a LIMS Superuser resource to provide necessary laboratory side support to users, in addition to vendor support or technical IT support.

*Recommendation: **Increase support and resources for QA.*** Meeting industry-recognized QA standards is an absolute must for all diagnostic laboratories today. Testing results from any laboratory that does not meet such standards cannot and must not be relied upon for making clinical or regulatory decisions. It is not unusual for adequate QA to consume an additional 15-20% of time, personnel and funding resources. For a system of the size, geographic distribution and complexity of the RAHLS, staffing of one Quality Manager and two Regional Quality Control assistants is reasonable. This level of staffing will ensure adequate QA oversight and resource expertise for all staff and testing processes to ensure consistency across the system. It will also reduce the amount of time currently lost to travel, time that needs to be spent on addressing QA needs. The QA team should have access to at least annual continuing education and it would be beneficial to put them through the AAVLD Auditor Training.

*Recommendation: **Streamline the Quality Management System.*** Implement system-wide SOPs to ensure consistency across the system. All SOPs should be reviewed with a goal of consolidating where possible to achieve documentation that adequately documents processes without being overly detailed, redundant or cumbersome. SOP document reviews and internal audits should be staggered temporally to reduce overburdening staff.

*Recommendation: **Seek reimbursement for regulatory Dairy testing.*** Regulatory testing performed by the RAHLS for both the Office of Dairy Services in VDACS and the Virginia Department of Health costs the program in excess of \$150,000 annually in lost revenue because they are done at no charge. To accurately and efficiently manage the RAHLS budget and program, these costs should be billed to the submitting programs to accurately reflect work performed and expenses incurred by the laboratories.

*Recommendation: **Further leverage collaboration opportunities with the Virginia-Maryland College of Veterinary Medicine (VMCVM).*** Opportunities may include: research and development or validation of new tests, access to cutting edge diagnostics (e.g. genome sequencing), laboratory safety, shared SMEs, part-time student employees, and diagnostic educational opportunities for DVM students utilizing RAHLS case submissions.

*Recommendation: **Explore additional outreach and communication efforts.*** Possible avenues include giving one or more CE presentations annually at the VVMA convention and regional VMA meetings, implementing a RAHLS booth at the VVMA convention, promotion of unique capabilities (e.g., food safety testing, forensics, fish testing...), call submitting practitioner prior to performing necropsy to discuss case, adopt a policy of always requesting submitter to identify a practitioner to be involved in every case.

**Recommendation: Improve Laboratory Safety Program.** It is standard practice to have, similar to QA, a designated Laboratory Safety Officer (LSO) for the entire system. This position typically answers directly to the Program Manager and has the authority to immediately stop any activities deemed a safety hazard. In addition to the LSO, each facility should have a designated lead Safety Officer and adherence to safety procedures should be included in every staff member's position expectations. Facility safety reviews should be conducted at least annually. Safety orientation and training should be part of the initial onboarding training of all new staff. All staff that work in the necropsy room should be fit tested for an N95 respirator or else PAPRs (Powered Air Purifying Respirators) should be provided for use. We also recommend RAHLS implements a Chemical Safety Management program.

### **Possible paths to achieve major recommendations**

Immediately:

- Form a **RAHLS External Advisory Committee**: Ideally this group should be composed of representatives from each animal agriculture commodity group, the Virginia-Maryland College of Veterinary Medicine, equine, companion animal, wildlife, and fish sectors. Meetings are coordinated by the Program Manager and State Veterinarian.
- Contact **AAVLD Accreditation** Committee Cochairs, Dr. Amy Swinford [amy.swinford@tvmidl.tamu.edu](mailto:amy.swinford@tvmidl.tamu.edu) and Pat Lukens [plukens@wsu.edu](mailto:plukens@wsu.edu) and start the process for application to become an AAVLD accredited veterinary medical diagnostic laboratory system.
- Designate a significant **continuing education and training budget** for key laboratory personnel including all members of the Quality System team, microbiology supervisors, analytical scientists (with special emphasis on new employees), and laboratory directors.
- Establish a **new employee training and mentoring program**, which shall include steps for authorization to perform tests independently.
- **Stop offering necropsy services at any laboratory that does not have a full time on-site DVM Director/Diagnostician.**
  - Consider allowing any such laboratory the option of allowing licensed DVM practitioners full-use of the necropsy room with the assistance of a state-employee necropsy technician during normal laboratory operating hours
  - Encourage the use of necropsy kits and field necropsy submissions from all areas of the state but especially those that may be impacted by the above change.
- **Fill full-time receptionists and front office personnel vacancies** to manage client receiving, specimen receiving and shipping, client communications including phone calls and test result information, billing, and report communications to referring veterinarians and animal owners.

Long Range:

- **Form a RAHLS Modernization Task Force** sanctioned and tasked by VDACS to study the current situation and make recommendations to modernize the RAHLS system. We recommend this task force be composed of selected key RAHLS External Advisory Committee members, VDACS leaders, and other appropriate state decision makers.



- Their **primary charge should be to explore the feasibility of transitioning from the current four-laboratory system to a system of two modern laboratories**, one at Harrisonburg and a new, full-service laboratory on the campus of the VMCVM.

## Additional Recommendations

Addressing the additional recommendations listed below is also important. Some of them may be accomplished as part of the implementation of one or more of the major recommendations listed above.

### Staffing

Work cooperatively with other state agencies that employ analytical scientists (such as the state public health laboratory and universities) to **request a review of the state pay system to address the current shortfalls in the pay scale that contributes significantly to recruitment and retention issues**, relative to analyst and diagnostician vacancies within the state.

### Operations

**Referral testing, orders and results, should be captured in LIMS and be an integral part of reports.**

Currently there is no ability to track or analyze the types and amounts of referral tests, blinding management to the impact of this testing on budget or enabling granular analysis of whether certain referral tests should be implemented in-house.

**Evaluate test offerings.** Review of test and services catalog should be done at least annually to evaluate if there is testing that is not cost efficient or practical for the system to maintain. Any testing or services deemed important to keep should have sufficient resources to support both the quality and timeliness of the service. One example is small animal forensic pathology services, which is extremely time consuming, frequently pulling the diagnostician involved away from management of the laboratory. Continuation, much less growth, of this service may require additional dedicated diagnostician resources. There will be services deemed necessary to maintain even when not cost efficient, in order to meet the disease detection and surveillance goals of the OLS.

**Review current test discounting.** Establish a firm basis for supporting such discounting and determine if discounting can be simplified, reduced or eliminated to reduce complications and losses.

**Review Out of State charge differential.** Reconsider justification for such a differential, taking into consideration the multi-state nature of many clients, the chilling effect of such an additional charge and comparative practices of other state labs.

**Develop and implement full Business Intelligence (BI) tools.** Informed decisions based on up to date, reliable data requires a BI or data analytics capability that allows for the collation and analysis of workload, financial and client information. Consider training existing staff to more fully utilize LIMS and financial data ([https://www.youtube.com/watch?v=K74\\_FNnIIF8](https://www.youtube.com/watch?v=K74_FNnIIF8)) to support management decisions.



**Implement credit card processing at each laboratory.** Not being able to accept and process credit cards at the regional laboratories is a significant impediment to business. Consider eliminating cash or check transactions and implement credit card processing instead.

**Track ancillary testing for necropsies.** Revenue lost due to the application of a cap on ancillary testing associated with necropsies should be tracked and evaluated on a regular basis. It may be justifiable to exclude specific types of testing (e.g. toxicology, virus isolation...) from the necropsy cap due to the high cost of this testing.

**Molecular testing (PCR) requires physical separation of clean room, extraction and amplification.** Cross contamination with nucleic acid is a significant threat and it is standard practice to have both physical and operational barriers and processes in place to prevent this. A newly constructed diagnostic laboratory today would have rooms specifically designed for this purpose.

**Implement WiFi at each laboratory facility.** The widespread availability of high-bandwidth WiFi in each laboratory will allow establishment or expansion of telemedicine outreach with clients on cases.

**Address facility issues.** – while the overall age and condition of the facilities is good, there are specific areas that should be addressed including:

- Current laboratory space is insufficient for the workload in some locations or disciplines. All locations except Harrisonburg have one or more areas with this problem. To a degree some space could be freed up from use for filing cabinets by implementing digital scanning of paperwork as well as careful review of equipment needs and efficient space utilization.
- While most locations appeared to be maintained in good shape, the Warrenton laboratory was notably deficient in cleanliness and upkeep of the floors and other parts of the building, especially the necropsy room.
- Lack of suitable drainage at the loading dock/incinerator area of the Wytheville laboratory presents a real threat to good biocontainment of pathogens and wastes in general.

### **Miscellaneous**

**Develop Lab/Section specific goals and strategies tied to implementation of the Strategic Plan.** These goals and strategies should be customized to the specific situation of each laboratory's role, clients and future plans. These plans should be reviewed quarterly to determine progress and obstacles.

**Develop a formal agreement (Memorandum of Understanding, MOU) with the Department of Wildlife Resources, Virginia Department of Health, Virginia-Maryland College of Veterinary Medicine or other significant state agency partners.** The MOU should spell out the expectations and commitments of the parties. Serving all animal sectors in Virginia is key to maximizing the usage of these complex public service facilities. Serving them all diversifies stakeholder support and justification.

**Implement a client data mapping capability (Geographic Information System, GIS) as a management tool.** The ability to visualize the geographic distribution of client veterinary practices and even producers provide critical actionable intelligence for business and surveillance considerations.

**Establish either an internal or linkage to an external Research and Development capability.** Staying at the forefront of diagnostics requires engagement with R&D. At the least, establishing a framework or

mechanism for routinely engaging with public, institutional or private R&D partners will have many benefits.