

**Volition** 

**Capital Markets  
Event**

October 2020

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**Welcome**



# Agenda



- **Introduction & Business Update - Cameron Reynolds**
- **Introducing the Nu.Q™ Vet Cancer Screening Test**
  - **Heather Wilson-Robles, Chief Medical Officer VVDD**
  - **Gaetan Michel, CEO VVDD**
- **Blood Cancer in Humans – Jason Terrell, Chief Medical Officer**
- **Summary – Cameron Reynolds**
- **Q&A session**
- **Concluding Remarks**

# Our Pandemic Focus

- Safety of team
- Maintaining operations
- Strengthening our balance sheet
- Securing our supply
- Focusing on simplicity - Nu.Q™ H3.1 assay
- Ongoing programs    will be updated at the Q

# COVID-19 Pandemic Operational Update



## Current status

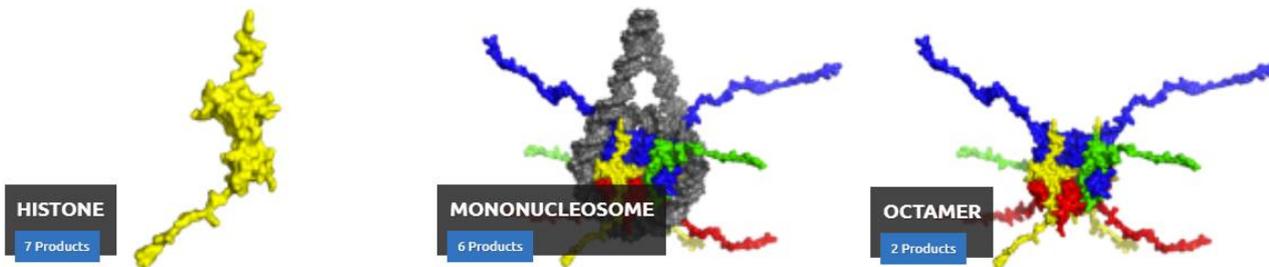
- ✓ Non-Laboratory staff working from home
- ✓ Lab remains open and is operating near capacity (TAMU lab two-week closure)
- ✓ Small and medium size studies already collected and samples available in our biobank.
- ✓ On-going sample collection (CRC and Lung) in Taiwan still on track
- ✓ Work commenced on developing a COVID-19 Triage product utilizing Nu.Q™ technology
- ✓ Strengthened balance sheet
- ✓ Increased the flexibility of our supply chain of key components and are moving towards producing our key components in house

## Currently identified risks

- Consumables and antibody supply chain has slowed, so additional suppliers sought and plans to bring production in-house in hand.
- Service contractors affected by the crisis
- U.S. EDRN study recruitment has been put on hold so potentially delayed. Timing impact currently unknown
- Lab would need to close if any lab techs contract the disease.

# Securing supply & developing internal expertise

- Currently fitting out a NEW 10,000 square ft neighboring facility in Belgium, known as “Silver One” – due to open by the end of October
- This facility will:
  - Be the production hub for all of our products and components
  - Be a service lab so that we can run samples for other companies
  - Secure supplier at a lower cost
  - Enable us to drive reagent revenue, building on the acquisition of Octamer GmbH Jan 2020



# COVID-19 Product Development



- Our goal is to develop a clinically useful prognostic product
- The preliminary study results demonstrated the Area Under the Curve (AUC) for a single Nu.Q™ assay was 98.7% PCR positive versus control subjects, with 100% sensitivity at 94% specificity. A second Nu.Q™ assay also showed promising results with an AUC of 86.2%.
- To date we have now tested two independent cohorts of COVID-19 positive patients with quantitative nucleosome immunoassays and found that
  - nucleosomes were *highly elevated* in plasma of severe COVID-19 patients relative to healthy control subjects
  - importantly, that both histone 3.1 variant and citrullinated nucleosomes *increased with disease severity*.
- Given that the highest levels of nucleosomes were found in patients requiring artificial ventilation or extracorporeal oxygenation, these data imply that Nu.Q could serve as a guiding biomarker for disease severity in COVID-19 positive patients.
- We are now focused on the completion of larger longitudinal studies that would be needed to support a potential COVID-19 product launch.
- We have filed a novel patent for the utilization of our Nu.Q™ epigenetic platform in this area

# Keeping things Simple – Nu.Q™ H3.1 assay

**Continue to develop other assays to form panels for more complex cancers (colorectal, lung etc)**

- CE Mark achieved
- Highest ever single assay results in many studies
- Will utilize for;
  - Nu.Q™ Vet Cancer Screening Test
  - Blood Cancer Studies
  - COVID-19 and NETosis Studies



**Heather Wilson-Robles,  
Chief Medical Officer**

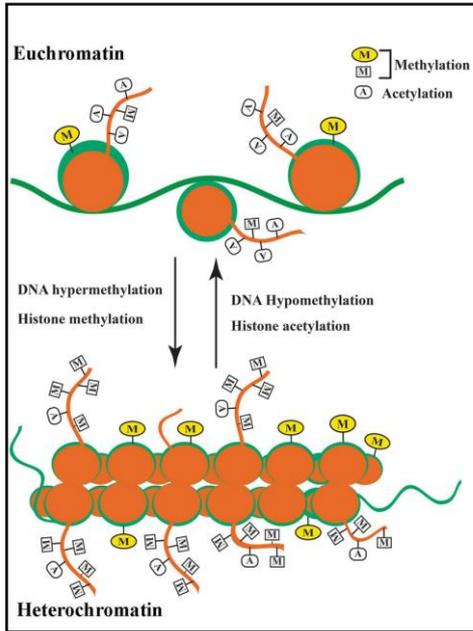
# High Unmet Needs

- Similar to the human diagnostic market there are no simple, easy to use, blood tests to help diagnose or monitor cancer
- Consequently, cancer in dogs is diagnosed late and through costly and/or potentially painful procedures such as scans and/or biopsies
- Human proteins such as PSA are not found in dogs and so human tests historically have not been transferrable however this is not the case for Nucleosomes

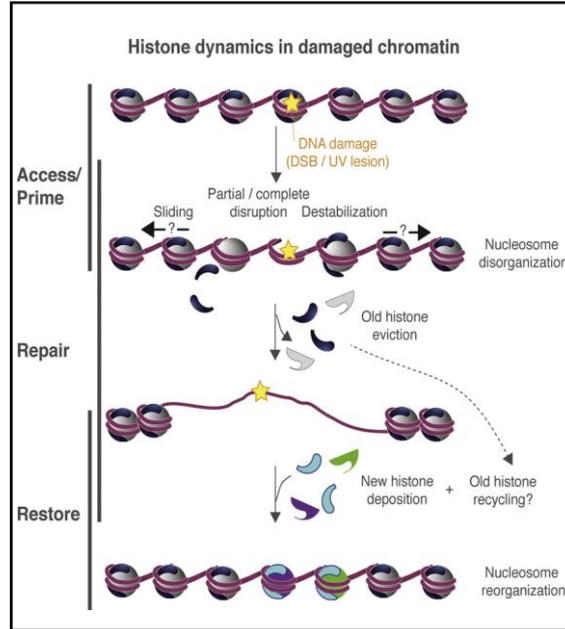


# Key Functions of Epigenetic Regulation

## Gene Expression

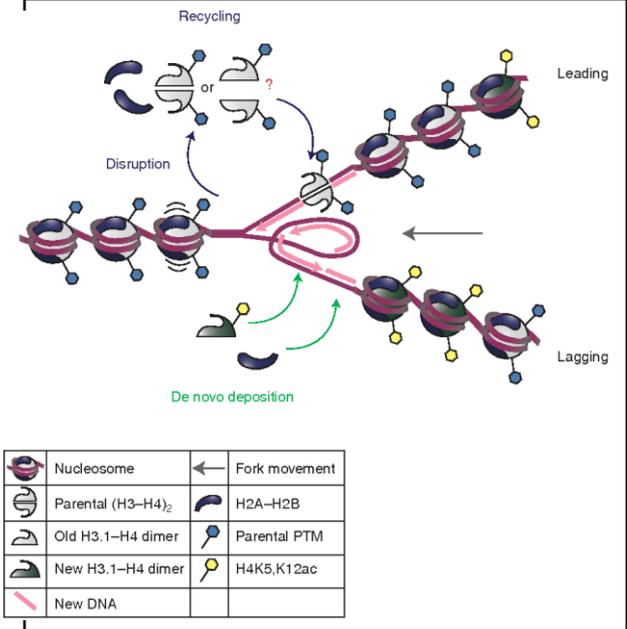


## DNA Damage



<https://www.sciencedirect.com/science/article/abs/pii/S0022283614002757>

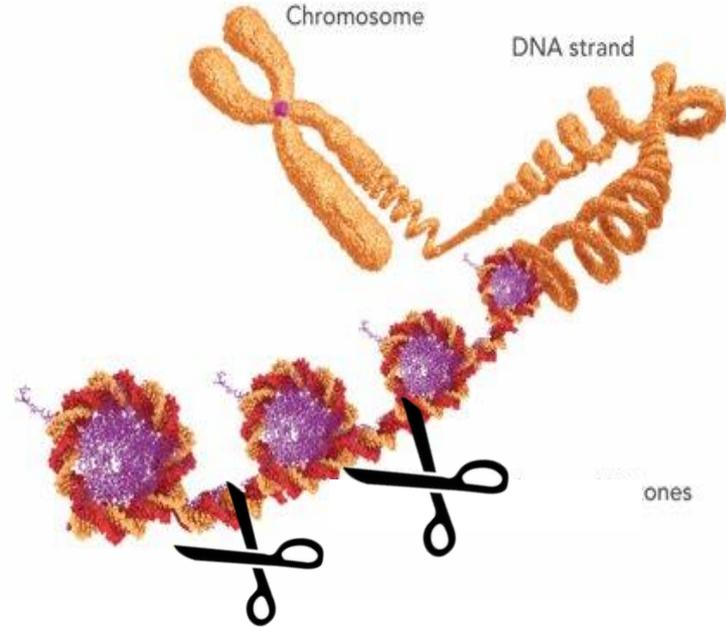
## DNA Replication



<https://pubmed.ncbi.nlm.nih.gov/23751185/>

# Nu.Q™ - The Basic Concept

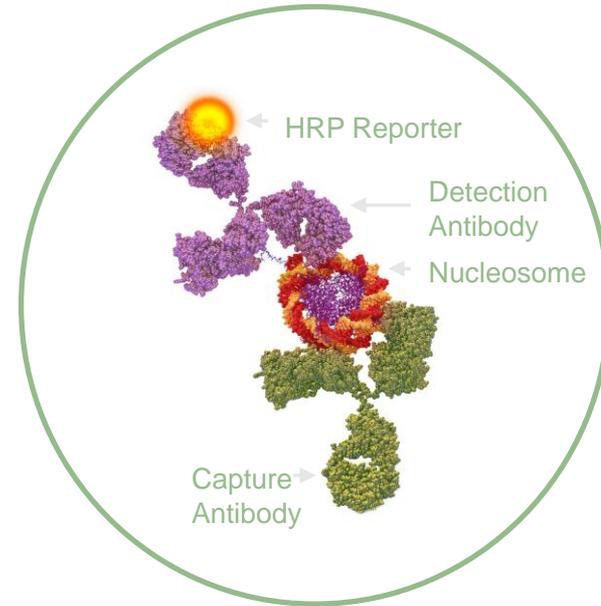
- Cancer & cell death results in chromatin fragmentation and release of nucleosomes into the blood.
- Nucleosomes contain >200 possible modifications that regulate every fundamental cellular process.
- Measuring nucleosome levels and modifications in circulation have the potential to be both prognostic and diagnostic markers for disease.



**VETERINARY MEDICINE  
& BIOMEDICAL SCIENCES**  
TEXAS A & M UNIVERSITY

# Nu.Q™ Technology

- Proprietary epigenetic immunoassay platform
- Determine levels of circulating nucleosomes
- Profiles nucleosome epitopes
  - Histone post translation modifications
  - Histone variants
  - DNA modifications
- Flexibility of platform and diversity of modifications enables the development of disease specific panels.

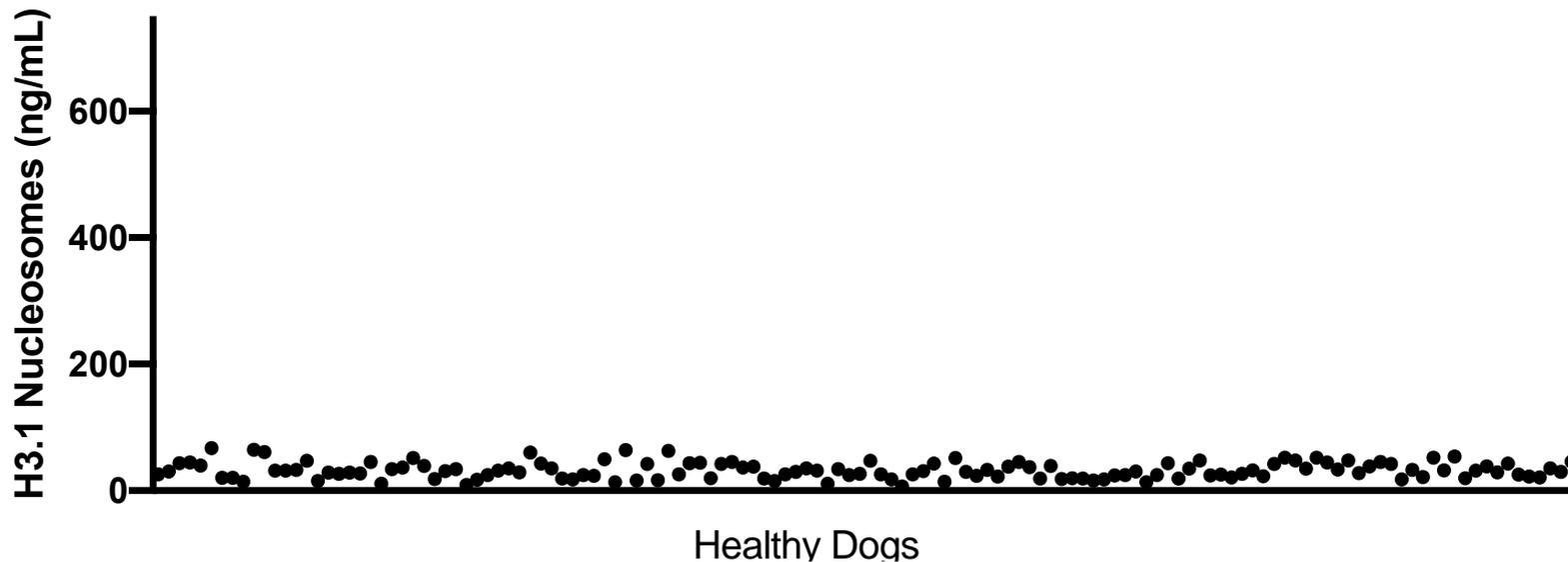


# Methods – data presented at VCS 2020

- Samples collected internally from Texas A&M Veterinary clinic and NIH's DCTC Biobank
- Samples were collected from **134** normal healthy dogs, **127** dog with Lymphoma and **73** dogs with hemangiosarcoma
- A variety of breeds, weights and cancer stages were represented in the dataset
- Samples collected according to pre-analytics previously described to maintain stable nucleosome levels (Wilson-Robles et al., Plos One 2020)

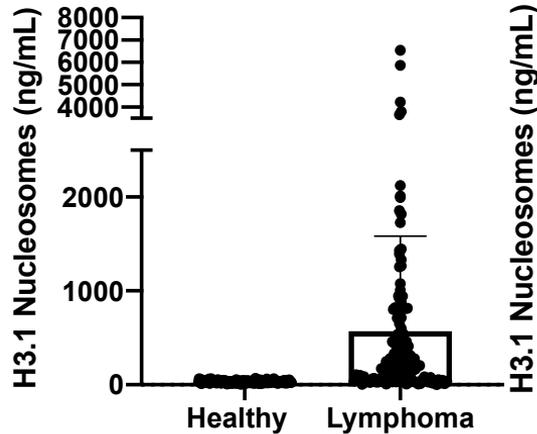
# Nucleosome Levels are Consistently Low Across Normal Canines

## Variability in Nucleosome Levels Across Normal Samples

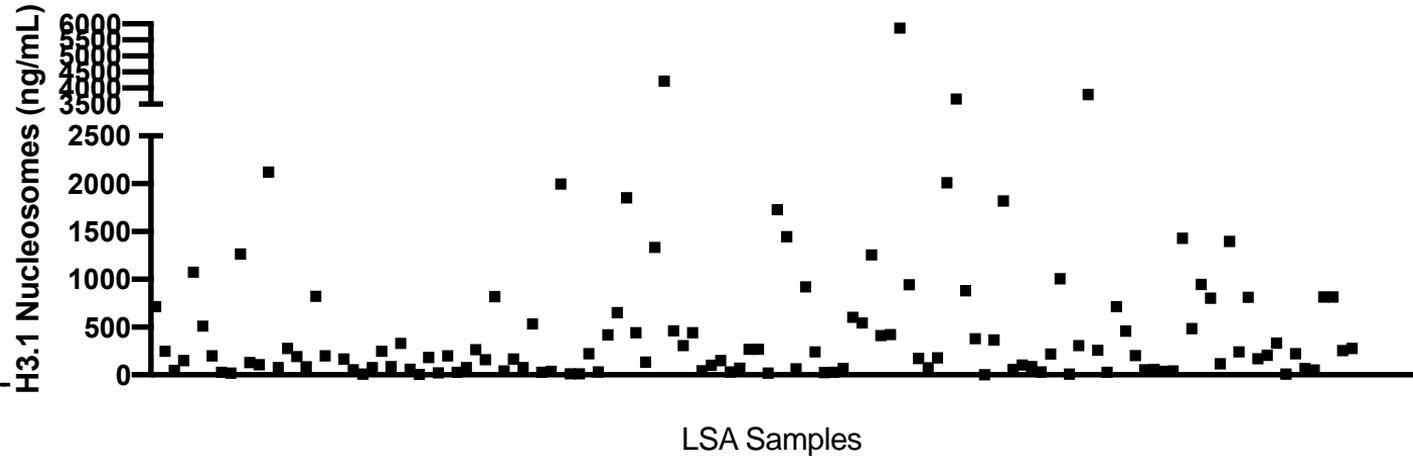


# Nucleosome Levels are Elevated in Lymphoma and Variable across Patients

## Elevated Nucleosome Levels in Lymphoma (LSA)

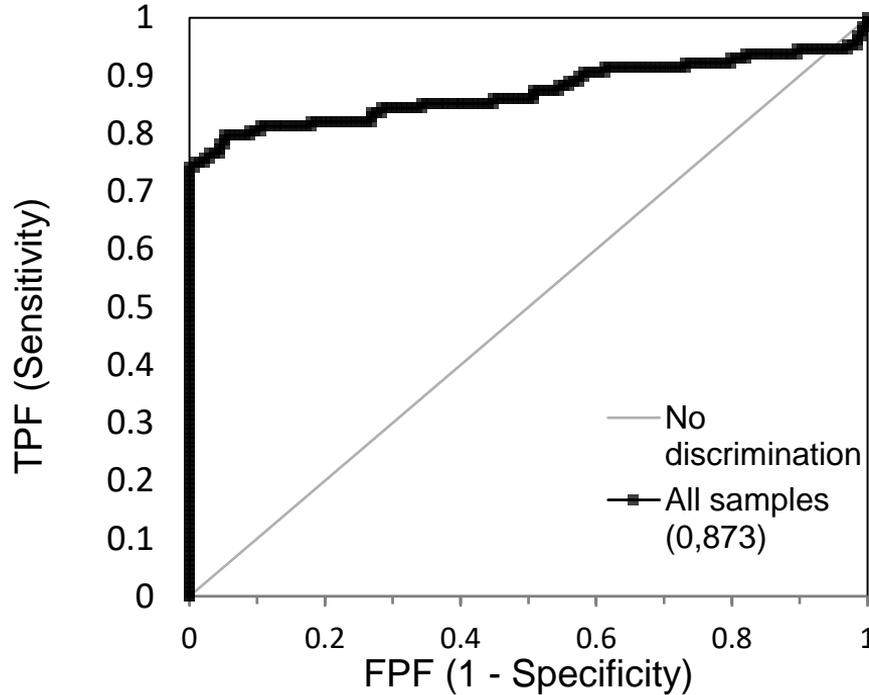


## Variability in Nucleosome Levels Across Lymphoma Samples



# Nu.Q™ Vet Cancer Screening Test has High Specificity and Sensitivity in Detecting Lymphoma

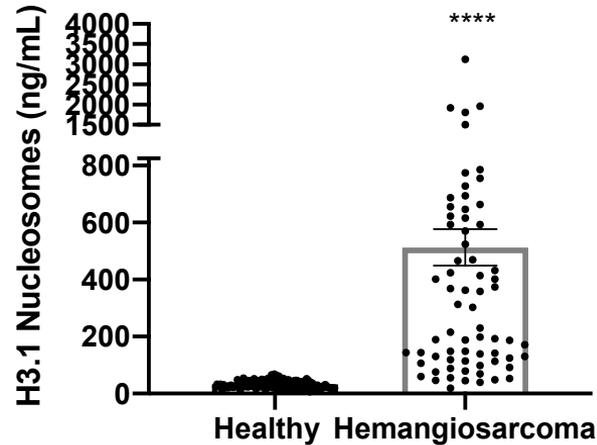
AUC=87.3%



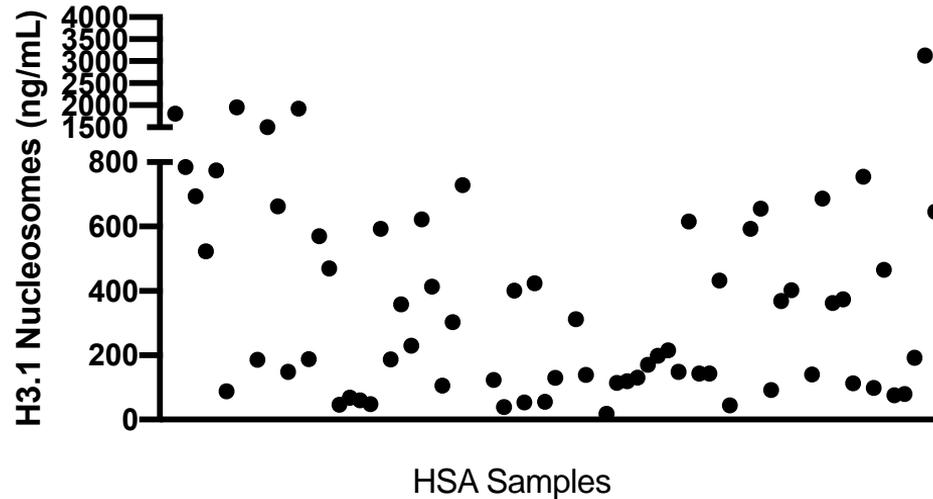
Cutoff	Sensitivity	Specificity
67.41 ng/ml	74%	100%
48.12 ng/ml	81%	90%

# Nucleosome Levels are Elevated in Hemangiosarcoma and Variable across Patients

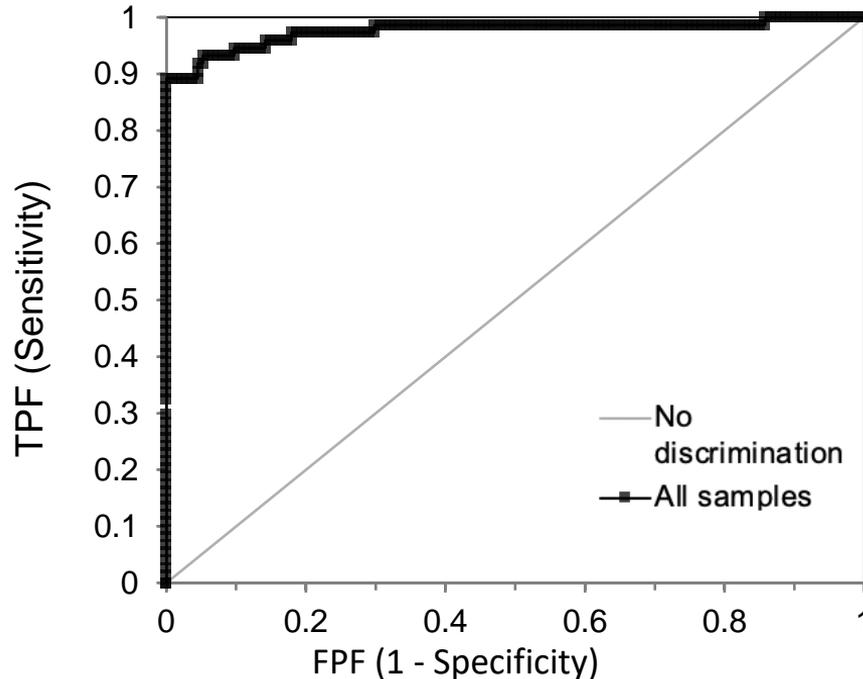
Elevated Nucleosome Levels in Hemangiosarcoma (HSA)



Variability in Nucleosome Levels Across Hemangiosarcoma Samples



# Nu.Q™ Vet Cancer Screening Tests also has High Specificity and Sensitivity in Detecting Hemangiosarcoma



**AUC=97.6%**

Cutoff	Sensitivity	Specificity
67.4 ng/ml	89%	100%
48.1 ng/ml	95%	90%

# Conclusions

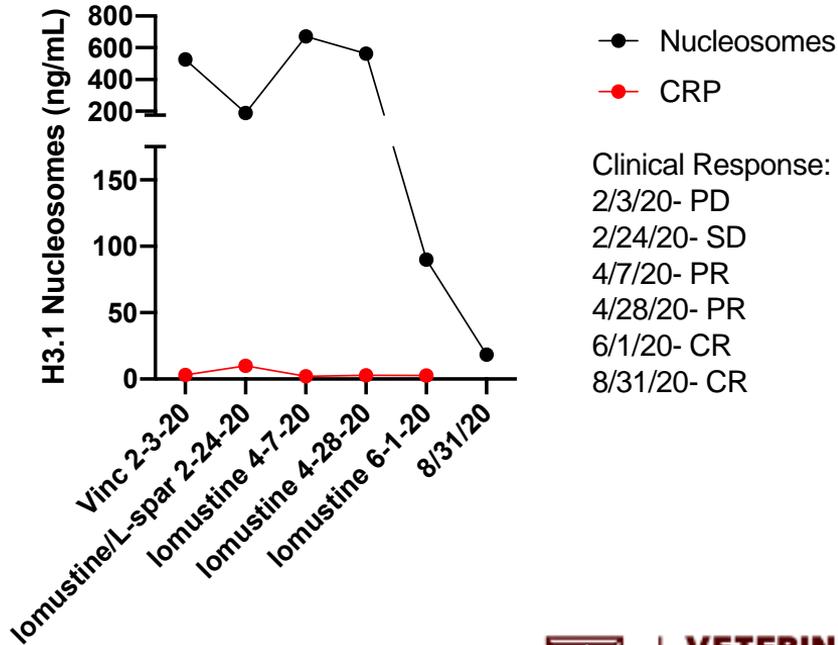
- The Nu.Q™ Vet Cancer Screening Test can be used to measure nucleosome levels in canines
- Nucleosome levels are consistently low in healthy dogs and elevated in both lymphoma and hemangiosarcoma
- The Nu.Q™ Vet Cancer Screening Test gives good clinical discrimination with an AUC of 87.3% for lymphoma and 97.6% for hemangiosarcoma
- Using the H3.1Nu.Q™ assay we recommend a cut off of 67.4 ng/mL to reliably detect LSA and HSA

# Ongoing and Possible Future Studies

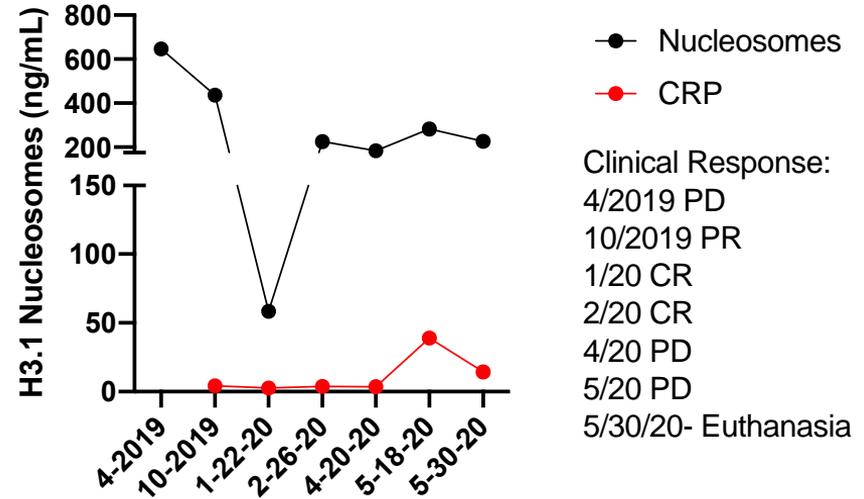
- Longitudinal study ongoing
  - The H3.1Nu.Q™ assay also shows promise as a marker for treatment efficacy and remission monitoring

# Nucleosome Levels Vary across Course of Disease and Treatment

**Cujo: Trends in Nucleosome Concentrations During Treatment for LSA**



**Otis: Trends in Nucleosome Concentrations During Treatment for HSA**



# Ongoing and Possible Future Studies

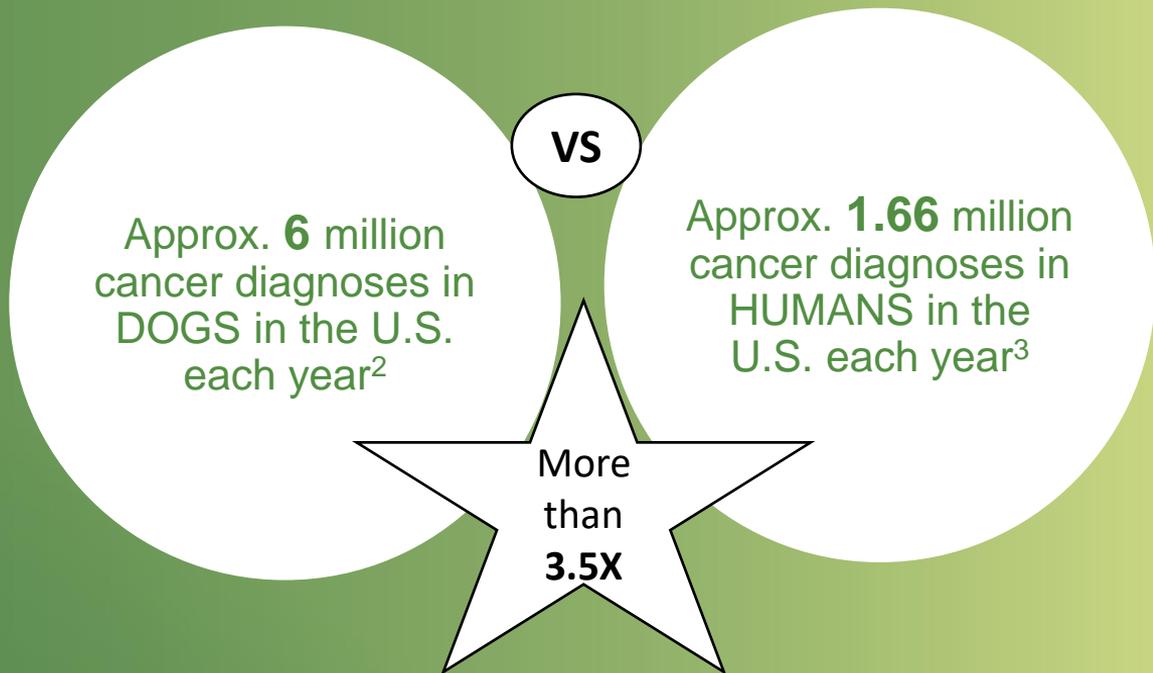
- Longitudinal study ongoing
  - The H3.1Nu.Q™ assay also shows promise as a marker for treatment efficacy and remission monitoring
- Other Cancers – Histiocytic sarcoma next.
- Other hematopoietic cancers.
- Other species.



**Gaetan Michel**  
**Chief Executive Officer**

# Significant Market Opportunity

- 38% of U.S. Households have a dog – the highest rate since measuring began in 1982
- Approx. 77 million dogs
- 85% of owners consider their dogs to be family members<sup>1</sup>



1. 2017-1018 AVMA Pet Ownership and Demographics SourceBook
2. <https://fetchacure.org/resource-library/facts//>
3. <https://www.cancer.gov/about-cancer/understanding/statistics>

# Our Product Proposition

- Currently, dogs suspected of having cancer are required to undergo a variety of diagnostic tests that may be expensive, time consuming and/or painful for the animal.
- We hope to change this with the introduction of the Nu.Q™ Vet Cancer Screening Test – a **simple, low-cost, easy to use** ELISA based screening blood test which will help streamline the diagnostic process for up to 1/3<sup>rd</sup> of malignancies in dogs: Lymphoma and Hemangiosarcoma.

# Our Product Proposition – Reason to Believe



- In a study of over 330 dogs, at **100%** specificity, the Nu.Q™ Vet Cancer Screening Test identified **74%** of lymphomas and **89%** of hemangiosarcoma versus control<sup>1</sup>.  
(Control dogs= 134, Lymphoma=127 client owned dogs, Hemangiosarcoma= 73 client owned dogs).
- The benefit for the Vet, the owner and the dog is a streamlined diagnostic process: **simpler, quicker and less painful** with the aim to detect cancer earlier, aid decision making and ultimately help improve the quality of life.

1. <http://vetcancersociety.org/conference/wp-content/uploads/sites/2/2020/09/FINAL-proceedings.pdf>

# Nu.Q™ Vet Cancer Screening Test Launch Plan



- ✓ Establish lab facility – test will be processed at TAMU GI Lab
- Create Awareness
- Develop Credibility
- Generate Trial
- Cultivate Advocacy

# Key Customers

- Key Opinion Leaders
- Veterinary Oncology Specialists
- GP Veterinarians
- Pet Owners

# Key Opinion Leaders

- Hosted a Roundtable
- Generated Expert-Led Report for distribution to Specialists at VCS
- Collaborating further with participating KOLs and expanding our network

# Veterinary Oncology Specialists

- Presented abstracts at VCS Conference and hosted busy virtual exhibition stand
- Targeting Top ten U.S. University Hospitals and Texas Hospitals for “Lunch & Learn” sessions throughout November / December
- Marketing Campaign items include the Expert Led Report and Product Flyer

# GP Veterinarians

- Focusing initially on TEXAS
- 4770 GP Veterinarians
- 7.5 million dog population ~ 10% of the U.S. market
  
- Marketing Campaign items include;
- Expert Led Report
- Product Flyer
- Paid social media advertising
- GP Veterinary focused Webinar
- CE Program

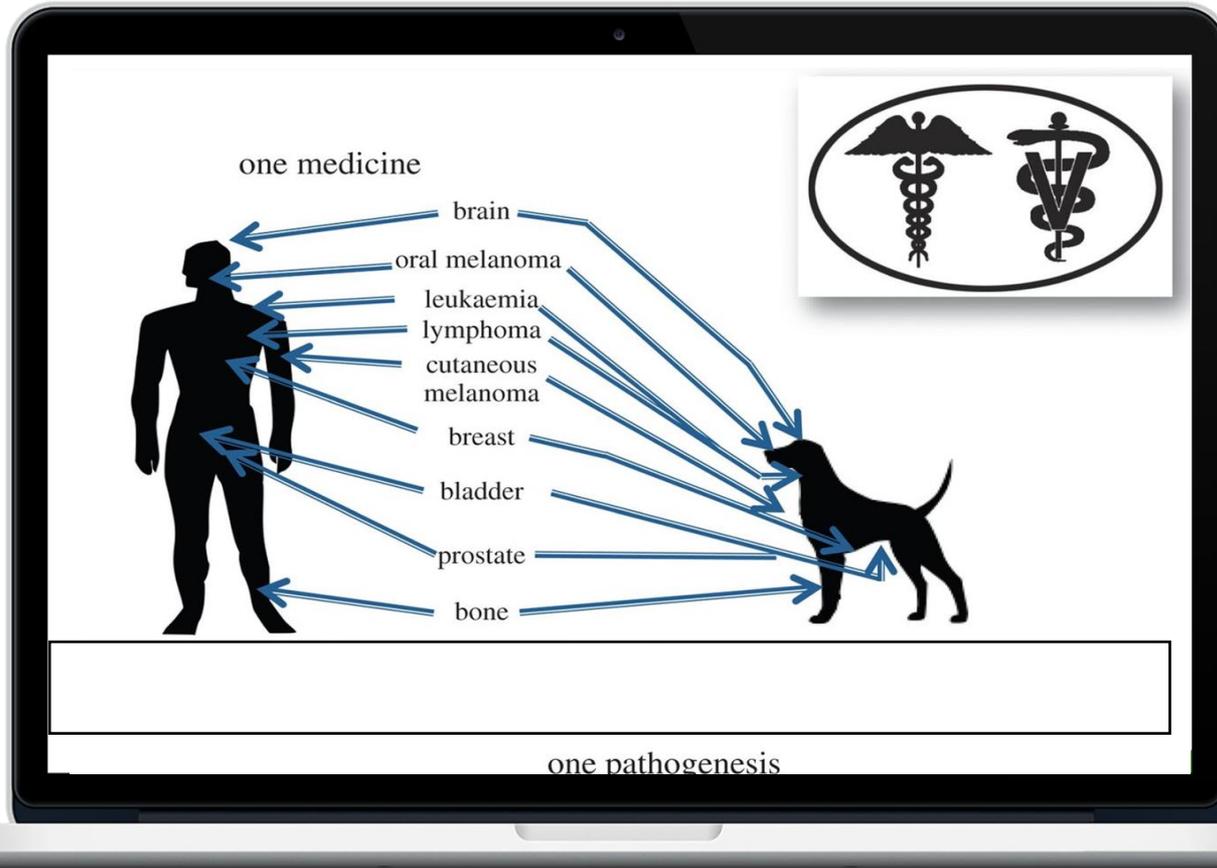
# Pet Owners

- Simple leaflet for the Veterinarian to share with Pet Owners
- Direct campaign 2021 once the product is established with Veterinarians.

**Exciting Times...**  
**..launch is almost here!**

# Research findings often transferrable between humans & dogs AND.....dogs & humans

Nucleosomes found in humans & dogs



**Volition** 

**Jason Terrell,  
Chief Medical Officer**

# Setting the Scene – Blood Cancer

**700,000**  
new cases of  
NHL, AML and  
ALL globally each  
year.....

...and  
approximately  
**415,000**  
deaths each  
year

Non-specific  
symptoms  
often delays  
diagnosis.

# Study Results to date

- **Cohort Size:** Total Healthy = 144, Cancer = 280 (however split into multiple smaller studies)
- **Cancer:** NHL / ALL/ AML
- **Clinical Question:** Cancer vs Healthy
- **Study Results:**
  - **Single** Nu.Q™H3.1 assay produces excellent AUCs ranging from **85%** to **88%** for both newly diagnosed and total patients on both the manual plates and the i10 automated platform.
  - Largest and most recent cohort (Healthy =82, NHL new diagnosis = 74) Nu.Q™ H3.1 assay detects 61% of cancers at 95% specificity and 72% of cancers at 90% specificity for BOTH formats.
- **Clinical Relevance:**
  - NHL particularly challenging to diagnose
  - Adjunct test to provide additional information to physician

# NHL Pre-Treatment Original Diagnosis U.S. Regulatory Trial

- U.S. CRO Selected
- 1,000 patients including cohorts for all 8 most common aggressive subtypes
- Total trial duration is 22 months including set-up (IRB approvals, site training, etc) and wrap-up (data analysis, follow-up, etc)
- Plan to utilize higher prevalence of DLBCL to file 510k at 10-12 months
  - Petition FDA for subsequent 510ks of rare subtypes as accrual permits

## U.S. Treatment Response Study

- DLBCL is most common aggressive subtype (35% of all NHL) and responds rapidly to treatment
- U.S. CRO selected to prospectively collect 30 subjects
  - 6-month collection of 6 serial samples corresponding to rounds of chemo
- Benefits of study include:
  - Treatment regimen is similar for most leukemias and lymphomas and so this could unlock potential for additional 510ks
  - DLBCL is essentially same pathology as dog lymphoma



# Summary

Cameron Reynolds



# Our Pandemic Focus

- Safety of team
- Maintaining operations
- Strengthening our balance sheet
- Securing our supply
- Ongoing programs    will be updated at the Q
- Focusing on simplicity - Nu.Q™ H3.1 assay



# Questions & Answers



# Thank you for your interest in Volition

For more information email  
[mediarelations@volition.com](mailto:mediarelations@volition.com)