

# Oncology in the real world

## When and how to use novel cancer diagnostics

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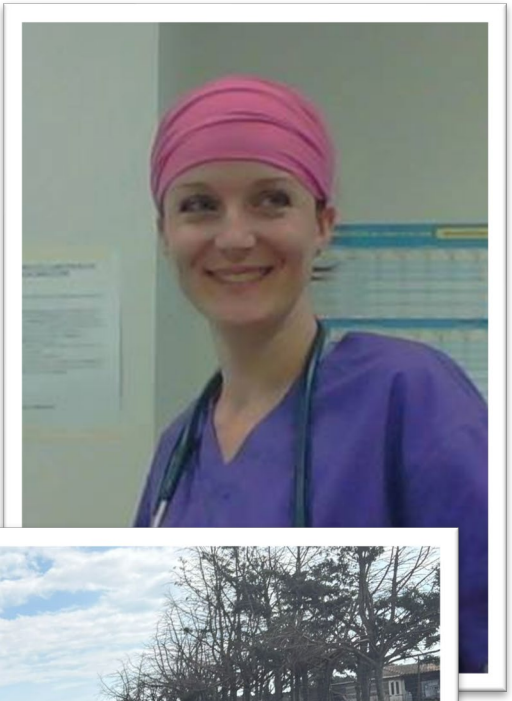
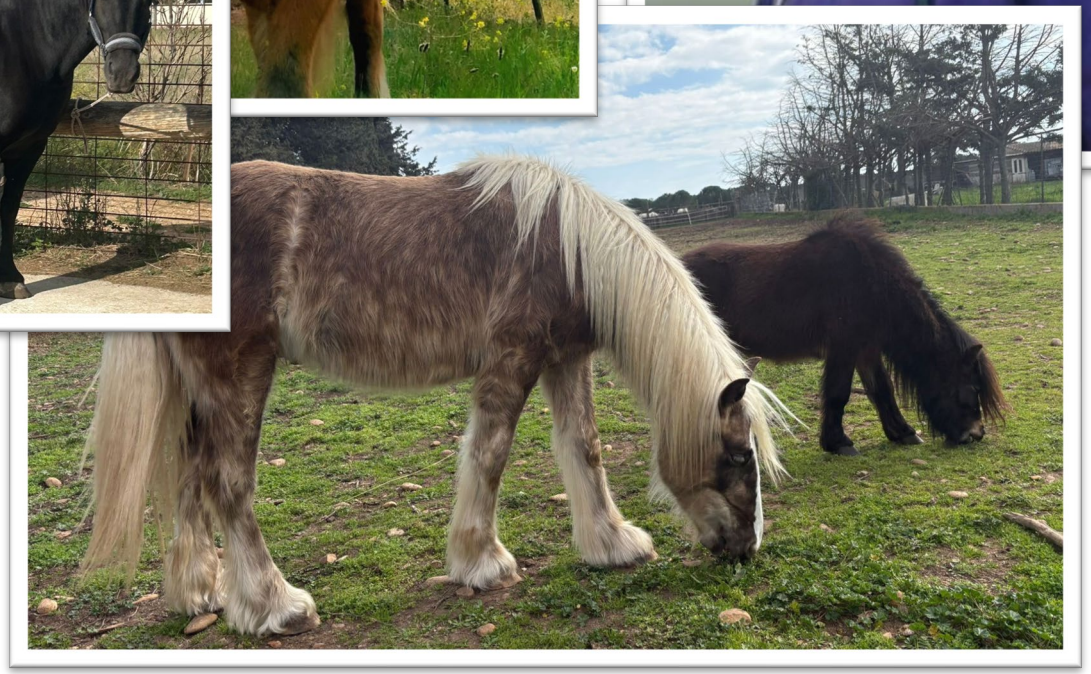
**Disclosure:**
Full-time Employee of IDEXX



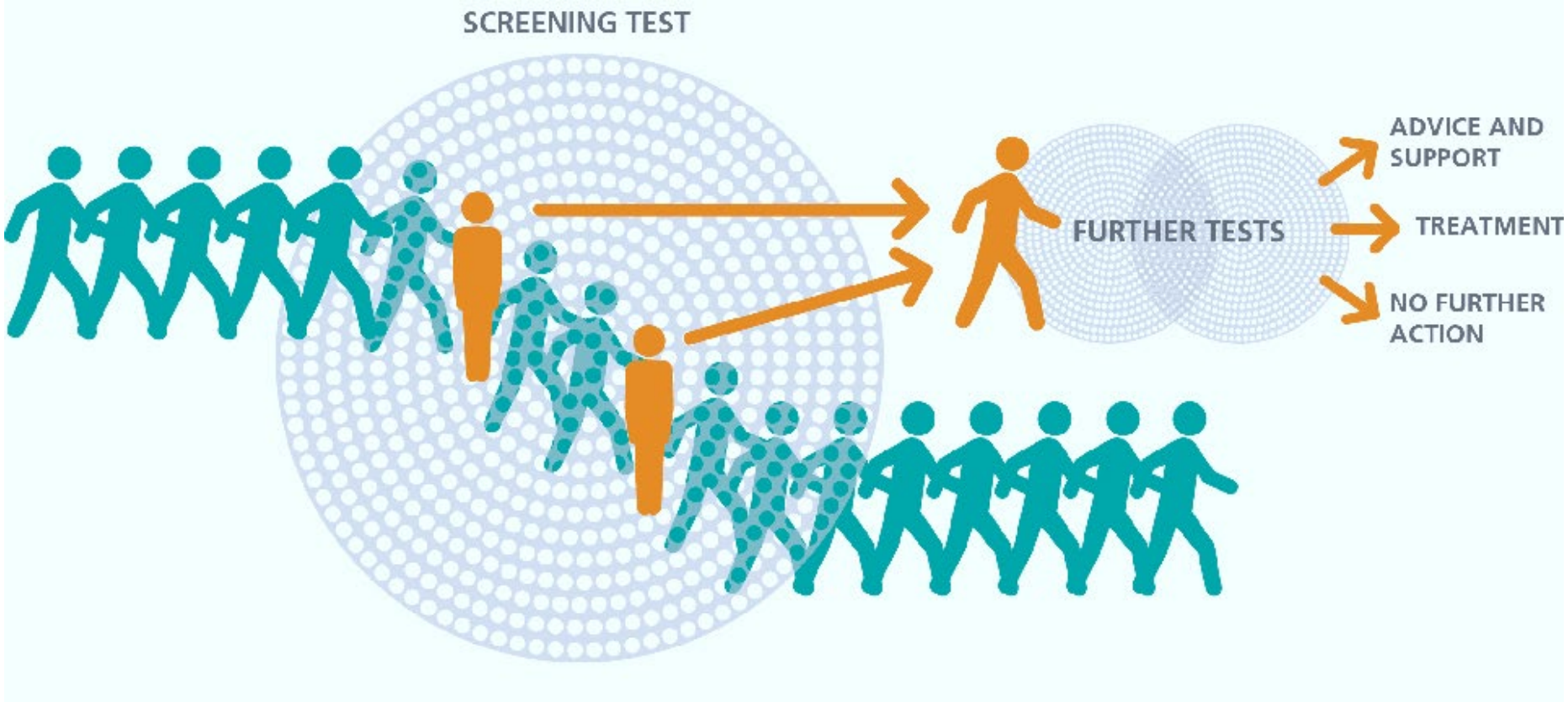


# Cancer screening and Multi Cancer Early Detection tests (MCED)

# Principles of Screening

+ Screening → apparently healthy population

  Systematic application of a test or inquiry to identify individuals at sufficient risk of a specific disorder to benefit from further investigation or direct preventive action.



# Principles of Effective CANCER Screening

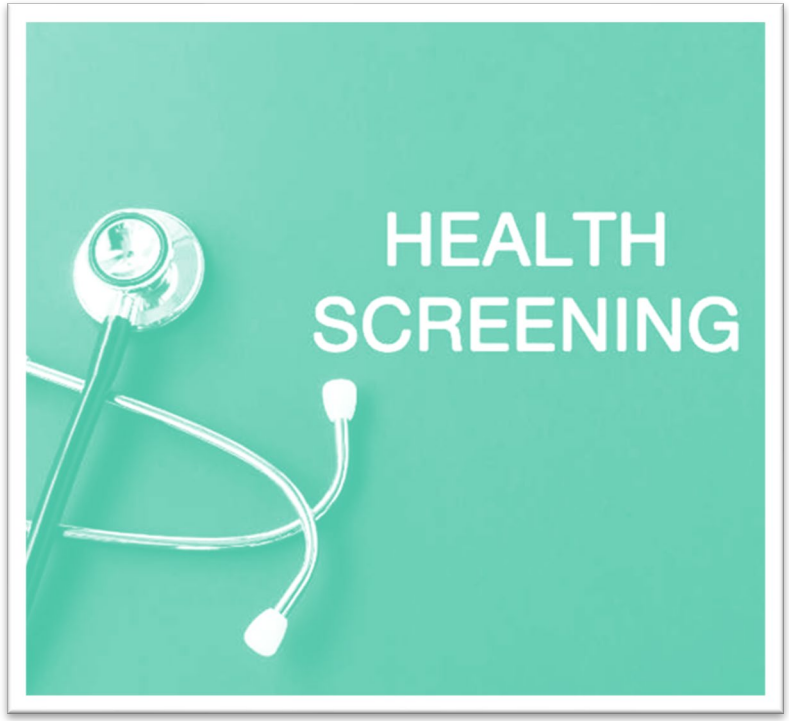
Detect cancer early

Prevent cancer through precursor detection

Reduce morbidity & mortality

Improve population health impact

# Principles of Effective Cancer Screening




- **Target Population & Prevalence**
  - Ex: Mammography: aimed at women over 40 or 50
  - Ex: colonoscopy: adults over 45 or earlier with risk factors
- **High prevalence = more true positives.**
- **Low prevalence = risk of false positives.**
  - Ex: Mammography not performed on men as a screening tool → low prevalence → too many false positive

# Principles of Effective Cancer Screening

## Benefits

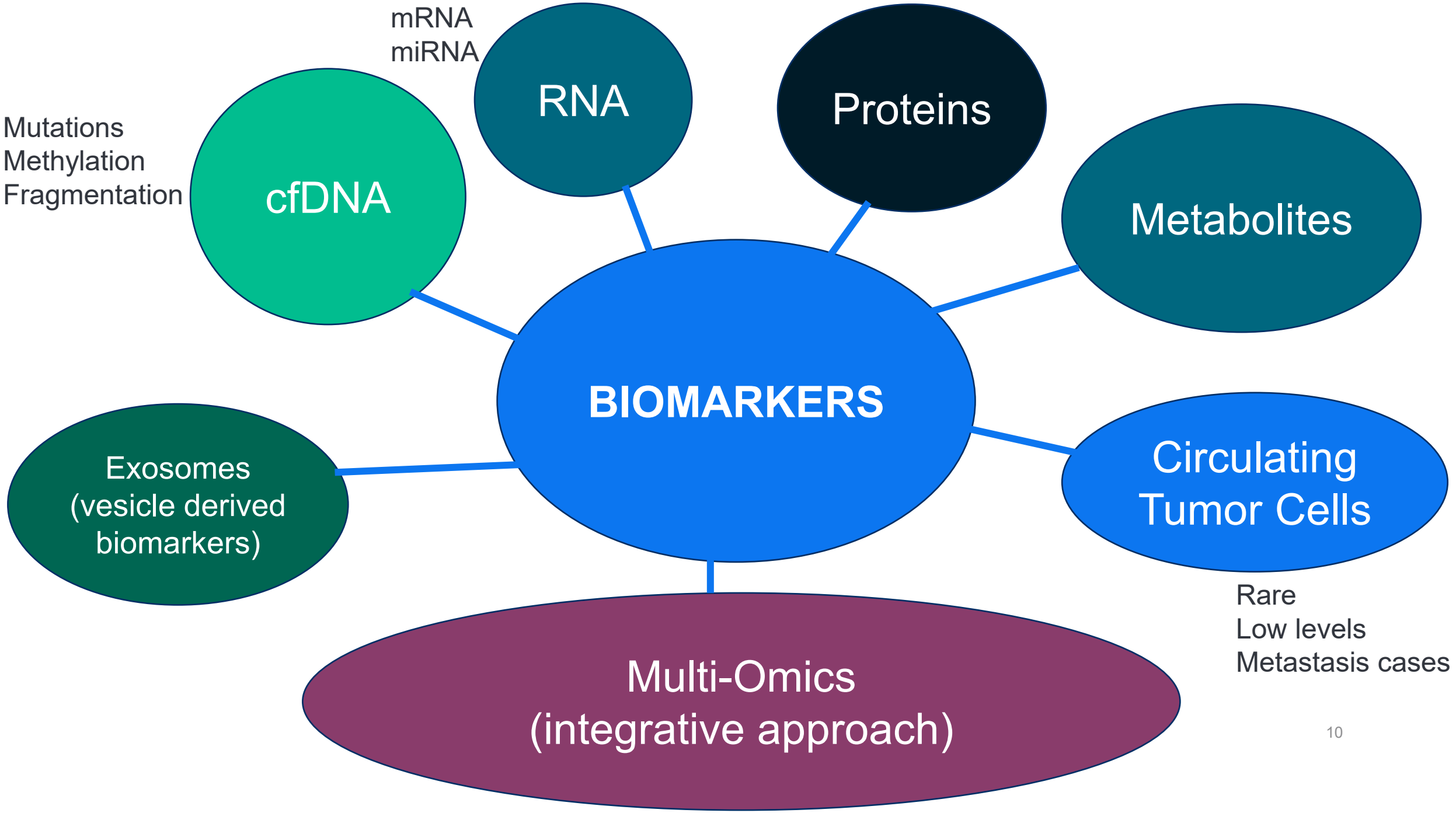
+ Early detection.
+ Better survival.
+ Reassurance of negative results.

## Harms

+ False positives → anxiety, unnecessary biopsies.
+ False negatives → missed cancers.
+ Overdiagnosis → unnecessary treatment.

# What is liquid biopsy?

- Non-invasive
- Performed most often on blood
- Other body fluid
  - Urine, CSF, pleural fluid
- Detects signs of disease
  - Here, cancer
- Alternative to tissue biopsies
- Multi Cancer Early Detection tests (MCED)


mRNA
miRNA
RNA
Proteins
Mutations
Methylation
Fragmentation
cfDNA
Metabolites
BIOMARKERS
Exosomes
(vesicle derived
biomarkers)
Circulating
Tumor Cells
Rare
Low levels
Metastasis cases
Multi-Omics
(integrative approach)

# Human oncology and Multi Cancer Early Detection (MCED) tests

| | QuantGene Inc DEEPGEN™ | Cancer SEEK | Cancer SEEK + PET-CT = DETECT A | IvyGeneCORE® Test | PanSEER |
|---|---|---|---|---|---|
| ***What is it?*** | Mutation based, tumor-derived cfDNA, ML algorithms | Mutation based, NGS Multiplex PCR and immunoassay | Mutation based, NGS Multiplex PCR and immunoassay +PET-CT | DNA methylation + AI ML | DNA methylation, Semi-targeted PCR libraries + seq for 477 methylated regions |

| | DELFI | DELFI + Mutation analysis | Cancer Radar | GRAIL - Galleri® Genome Atlas Study | GRAIL - Galleri® PATHFINDER |
|---|---|---|---|---|---|
| ***What is it?*** | Fragmentation cfDNA | Fragmentation + mutational analysis | cfDNA fragmentation, methylation, copy # variants, microbial composition | 3 Sequencing assays LR model – targeted cfDNA methylation assay + AI ML | Prospective evaluation of Galleri as a screening test |

# Human oncology and MCED tests

+ **Mutation based tests**: great capacity for cancer detection but TOO identification difficult

→additional exams

+ **Sensitivity 27-87%**
+ **Specificity 90-99%**

# Human oncology and MCED tests

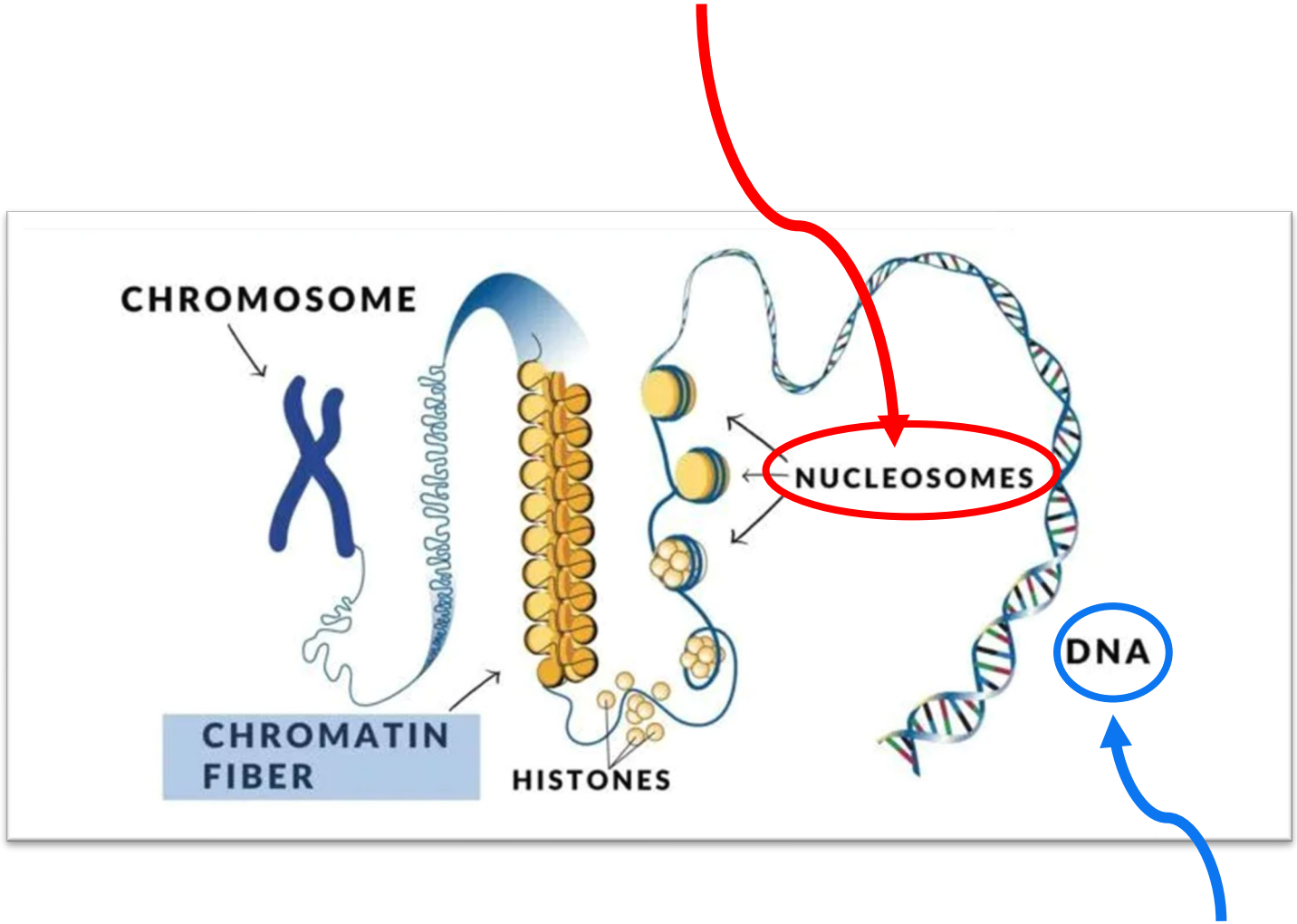
+ **Fragmentation based tests**
+ Cell death → variable DNA shedding patterns
+ Variable fragmentation patterns (cell and tissue dependent mechanism)
+ Reflects nucleosome positioning in the nucleus

→**Allow for TOO identification**

+ **Sensitivity 51-91%**
+ **Specificity 98-99.5%**

# Veterinary Oncology – where do MCED tests stand?

+ cfDNA/nucleosomes
+ Organic compounds (urine)
+ Volatile compounds (saliva)
+ Onconeural antibodies - serology
+ microRNA

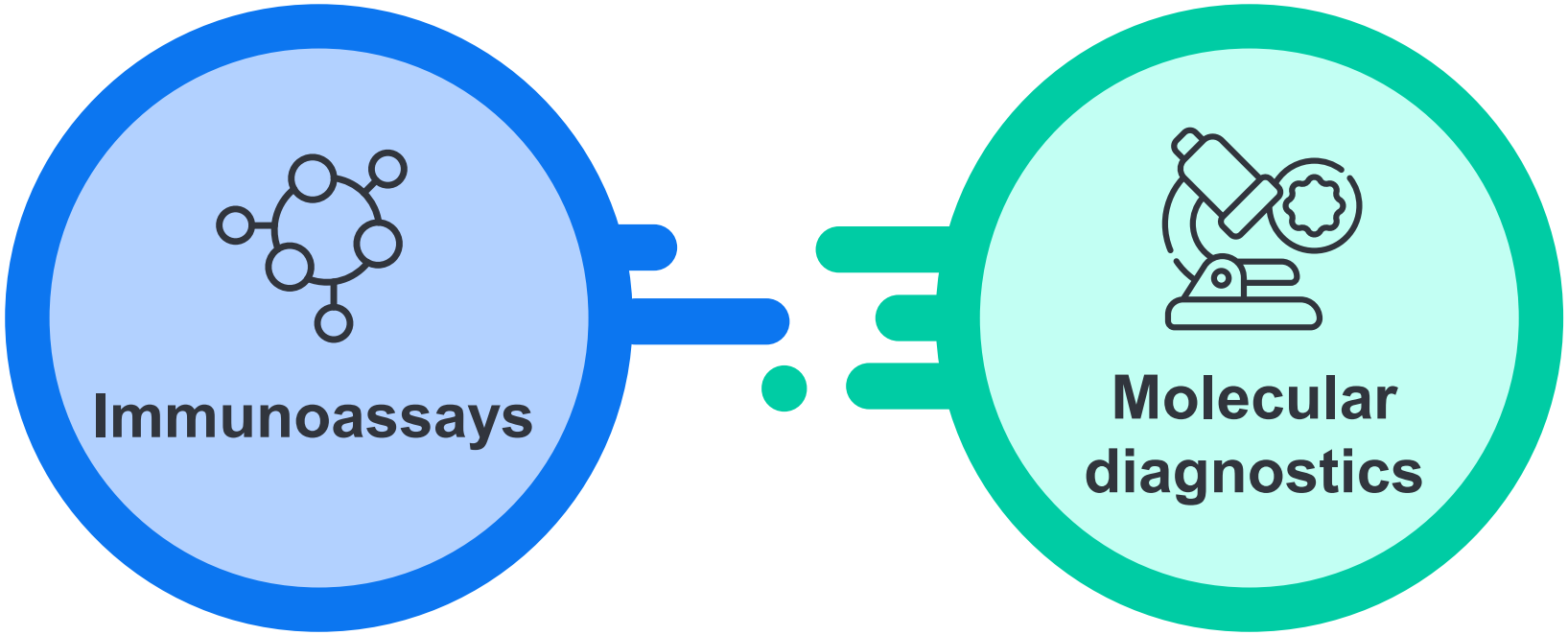


# Veterinary Oncology – where do MCED tests stand?

+ Sensitivity 49,8-98%
+ Specificity 90-99%
+ **TOO: no**
+ Risk index
+ False positive for cfDNA: inflammatory diseases, trauma, activated or dying white blood cells, high cellular turn-over

# Cancer Dx

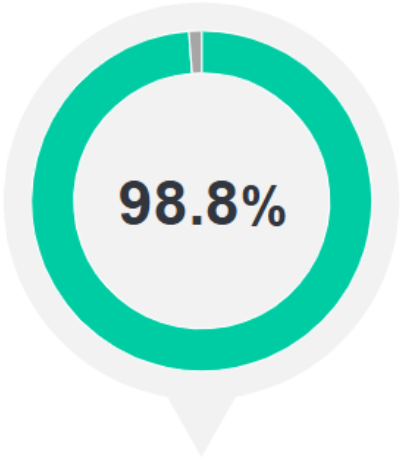
# IDEXX Cancer Dx™



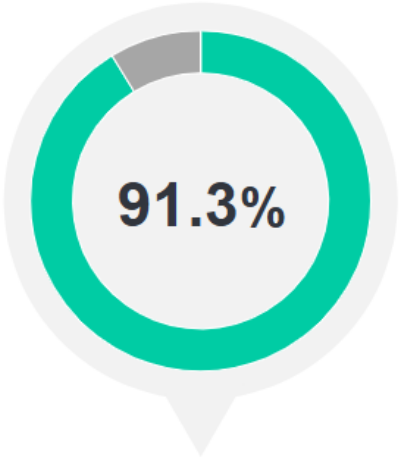

+ Multi-omics approach
+ Immunoassays + molecular tests
+ New circulating biomarkers, specific to canine lymphoma

# IDEXX Cancer Dx™

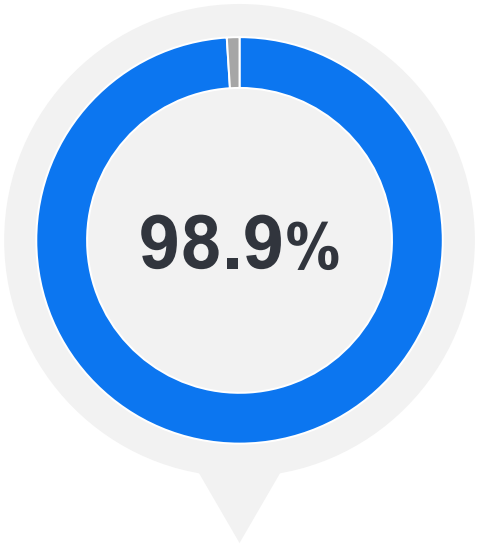
+ Blood test
+ Dog
+ 1 ml EDTA blood + 2 ml serum
+ First-line testing - GP



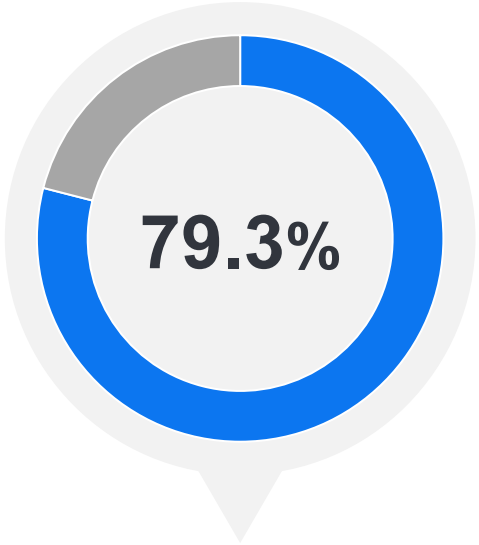

T-cell Specificity




B-cell Specificity




Lymphoma Specificity




Lymphoma Sensitivity

**If test positive, phenotype included in 56% of cases, at no additional cost to the customer**

# Populations used to assess lymphoma detection performance

# Populations used to assess lymphoma detection performance

**105**

## Confirmed lymphoma

- Cytology + PARR
- Cytology + Flow Cytometry
- Cytology + IHC
- Histology+ IHC
- No prior treatment, no steroids or immunosuppressants > 1 month

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**Confirmed lymphoma**

+ Cytology + PARR
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Types of lymphoma:
Multicentric (Stages 1-5)
T-Zone
Cutaneous
Mediastinal
Splenics
Renal

# Populations used to assess lymphoma detection performance

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- Cytology + PARR
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**Sensitivity and specificity for detecting lymphoma**

| | | |
|---|---|---|
| **Distribution** | Multicentric | 98 (93.3%) (94 aggressive, 4 indolent) |
| | Cutaneous/ mucocutaneous | 3 (2.9%) |
| | Mediastinal | 3 (2.9%) |
| | Other extranodal | 1 (0.9%) |
| Phenotype | B | 77 (73.3%) |
| | T | 28 (26.7%) |
| Stage | I | 2 (3.6%) |
| | II | 1 (1.8%) |
| | III | 40 (71.4%) |
| | IV | 9 (16.1%) |
| | V | 4 (7.1%) |
| Method of phenotyping | PARR | 25 |
| | Flow cytometry | 45 |
| | Unknown flow cytometry or PARR | 28 |
| | Immunocytochemistry | 5 |
| | Immunohistochemistry | 2 |

Table 1. Characterization of 105 lymphoma dogs included in the sensitivity and specificity analysis

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**73**

## Other diseases

+ Inflammatory diseases
+ Other cancers excluding lymphoma

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**73**

## Other diseases

+ Inflammatory diseases
+ Other cancers excluding lymphoma

Other cancers (MCT, OSA, anal sack ADK)
Inflammation (EPI, atopic dermatitis, IBD, polyarthritis)

# Populations used to assess lymphoma detection performance

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- Cytology + IHC
- Histology+ IHC
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**73**

## Other diseases

- Inflammatory diseases
- Other cancers excluding lymphoma

**156**

## Apparently healthy

- Normal clinical examination
- Normal CBC and normal complete biochemistry
- Range of ages and races to reflect the population observed in clinic

# Populations used to assess lymphoma detection performance

**105**

## Confirmed lymphoma

+ Cytology + PARR
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**156**

## Apparently healthy

+ Normal clinical examination
+ Normal CBC and normal complete biochemistry
+ Range of ages and races to reflect the population observed in clinic

Age 1-13 years
Wide range of breeds

# Populations used to assess lymphoma detection performance

**105**

## Confirmed lymphoma

- Cytology + PARR
- Cytology + Flow Cytometry
- Cytology + IHC
- Histology+ IHC
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**156**

## Apparently healthy

- Normal clinical examination
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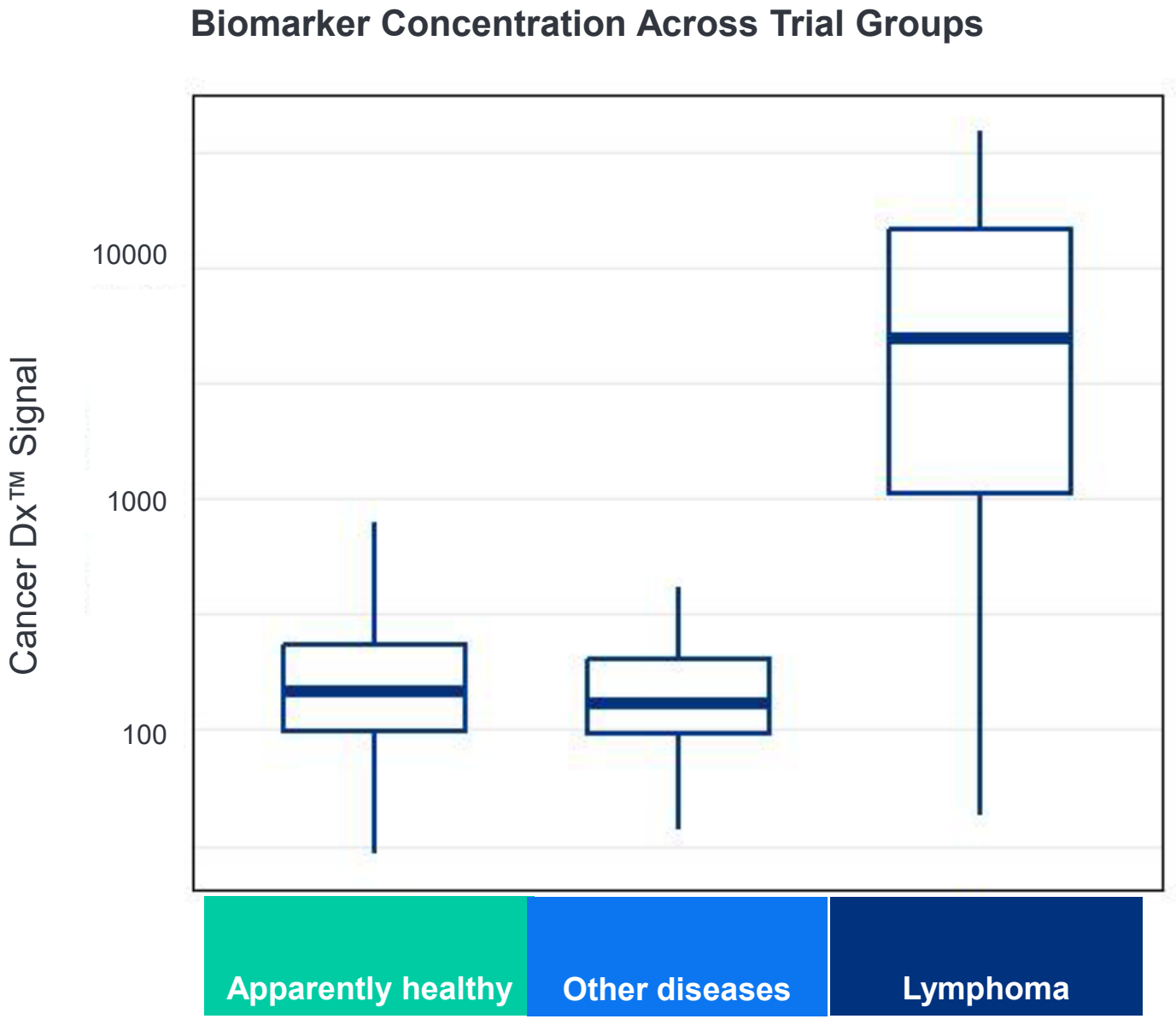
- Range of ages and races to reflect the population observed in clinic

# Verification and validation data



# Comparison to existing diagnostics

| Metric | IDEXX Cancer Dx™ | Cytology | Lymphoma PCR (PARR)( |
|---|---|---|---|
| Sensitivity | 79% | 92.6% | 75% - 92% |
| Specificity | 99% | 89.4% | 94% - 98.7% |
| Turnaround Time | 2-5 days | 1-5 days | 10-14 days |
| Specimen | Serum/ Blood | Cells from lesion | Cells from lesion |
| Cost | $ | $$ | $$$ |

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| Cost | $ | $$ | $$$ |

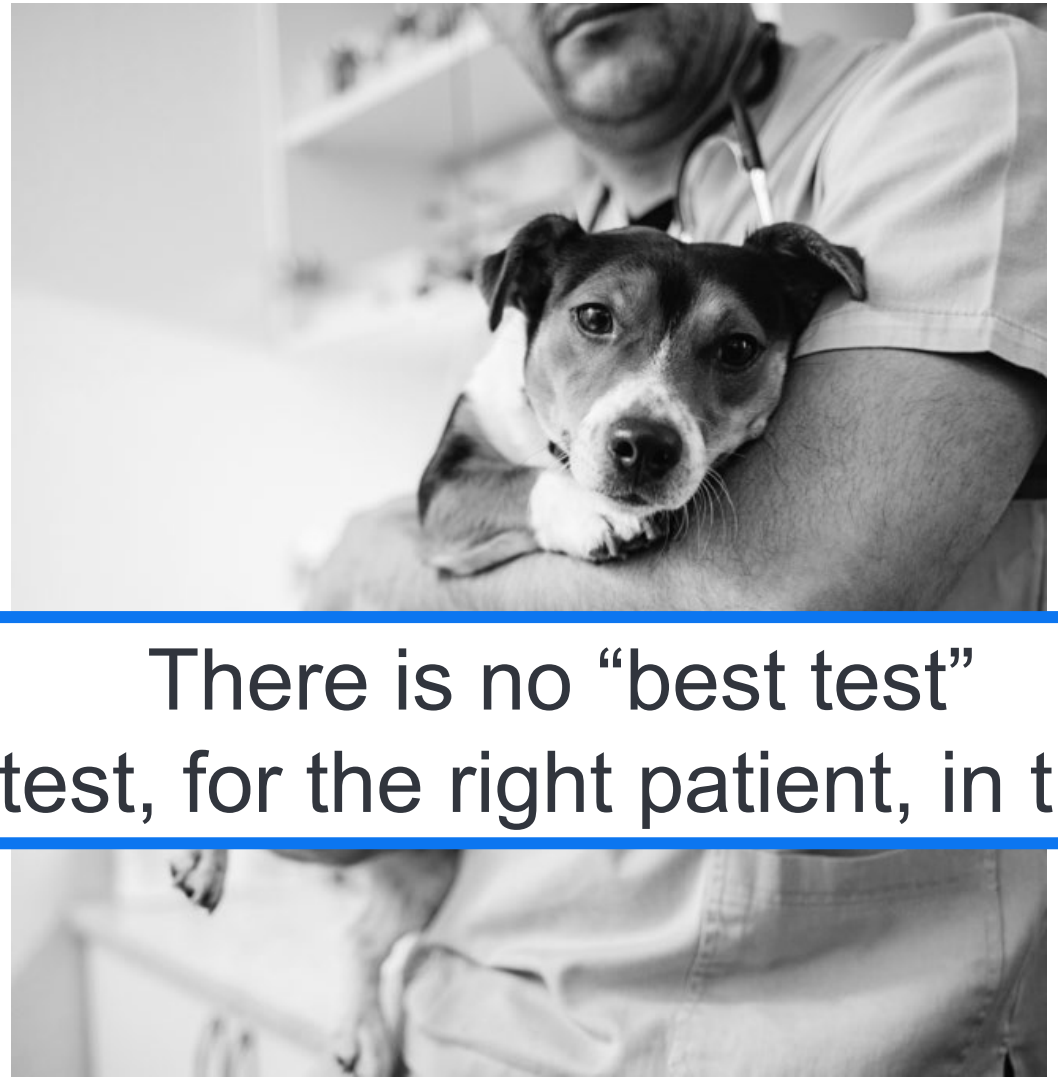
| Metric | IDEXX Cancer Dx™ | Lymphoma PCR (PARR) | Flow cytometry |
|---|---|---|---|
| B-cell specificity | 91.3% | 67% - 89% | 100% |
| T-cell specificity | 98.8% | 64% - 100% | 98% |
| Specimen | Serum/ Blood | Cells from lesion | Cells from lesion |
| Special handling? | No | No | Yes |
| Cost | $ | $$$ | $$$ |

# IDEXX Cancer Dx™/Cytology

- **IDEXX Cancer Dx**
  - more specific
  - same TAT
  - less expensive
  - sample easier to collect
  - phenotype in 56% of positive cases
  - screening or aid-in-diagnosis context

- **Cytology:** cell description, more sensitive

# IDEXX Cancer Dx™/Cytology



There is no “best test”
Just the right test, for the right patient, in the right context

# Target populations

+ **Screening** (apparently healthy)

dogs >7

at-risk breeds >4

Cf EU White paper:
Dobermann, Golden Retriever, Labrador, French/English bulldog, Boxer, Beagle, Bernese Mountain dog…

+ **Aid-in-diagnosis**: any sick dog with compatible clinical signs

# Screening vs diagnosing

+ Different target populations

+ **High prevalence = more true positives = higher PPV** but lower NPV (clinically ill dogs)

+ **Low prevalence = more true negative = higher NPV** but lower PPV (screening context)

2 populations

2 situations

2 algorithms

# The sick dog

# Translating results into clinical decisions: Clinically **ill** dogs

**Consistent with Lymphoma**

**Supports a clinical diagnosis of lymphoma**

+ Consider further diagnostics including cytology or biopsy of tissue potentially containing abnormal lymphocytes (lymph nodes, organs, masses) and staging (imaging such as chest radiographs and abdominal ultrasound) to guide treatment/monitoring

+ Consultation with a veterinary oncologist could be considered to determine next steps before referral

# Translating results into clinical decisions: Clinically **ill** dogs

**Not Consistent with Lymphoma**

**High concern for lymphoma?**

No

Continue diagnostic workup for other causes of clinical signs

Yes

Negative result makes lymphoma less likely but does not rule it out
If suspicion persists, consider lymph node cytology, biopsy with histology, and diagnostic imaging (chest radiographs, abdominal ultrasound)

**Consistent with Lymphoma**

**Supports a clinical diagnosis of lymphoma**

+ Consider further diagnostics including cytology or biopsy of tissue potentially containing abnormal lymphocytes (lymph nodes, organs, masses) and staging (imaging such as chest radiographs and abdominal ultrasound) to guide treatment/monitoring

+ Consultation with a veterinary oncologist could be considered to determine next steps before referral

# The “apparently healthy dog”

# Target populations: dogs >7 years old, at-risk breeds >4 years old, sick dogs

## Breeds at increased risk for lymphoma

### Increased risk of cancer (overall), including lymphoma

+ Golden retriever[14]
+ French bulldog[2]
+ Beagle[15]
+ Boxer[15]
+ Miniature schnauzer[15]
+ Bernese mountain dog[16]
+ Flat-coated retriever[16]
+ Scottish terrier[16]
+ Bullmastiff[16]

### Increased risk of lymphoma

+ Labrador retriever[17]
+ Rottweiler[18]
+ Doberman pinscher[19]
+ English bulldog[1]
+ Boxer[19]
+ German shepherd[19]
+ Bernese mountain dog[19]
+ Beagle[19]
+ English cocker spaniel[19]

**Reference**

1. Data on file at IDEXX Laboratories, Inc. Westbrook, Maine USA: Data based on testing performed at IDEXX Reference Laboratories in North America between November 1, 2024, and December 6, 2024. *Analysis Report: IDEXX Cancer Dx Validation, 100282* [008_CancerDx-Validation-Report-2.Rmd].

# Translating results into clinical decisions: Clinically **well** dogs

## Not Consistent with Lymphoma

Result supports absence of detectable lymphoma;
evaluate patient at next planned wellness examination*

*American Animal Hospital Association (AAHA) recommends wellness examinations every 6 months in senior dogs and yearly in all other dogs.1

Reference 1. Creevy KE, Grady J, Little SE, et al. 2019 AAHA Canine Life Stage Guidelines. J Am Anim Hosp Assoc. 2019;55(6):267–290. doi:10.5326/JAAHA-MS-6999

# Translating results into clinical decisions: Clinically **well** dogs

## Not Consistent with Lymphoma

Result supports absence of detectable lymphoma; evaluate patient at next planned wellness examination*

## Consistent with Lymphoma

**Evaluate full history, physical examination, and blood work**

Further evaluation may be considered to confirm presence of disease, including the following:

+ Aspirates or biopsy of lymph nodes/organs
+ Diagnostic imaging (chest radiographs and abdominal ultrasound)
+ Flow cytometry of blood in cases of lymphocytosis

**If lymphoma is not detected, perform recheck physical examination in 8-12 weeks (sooner if new symptoms arise)**

*American Animal Hospital Association (AAHA) recommends wellness examinations every 6 months in senior dogs and yearly in all other dogs.1

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# Summary

+ Apparently healthy dog, screening (>7 years, at-risk breed>4 years)

→**Consistent with lymphoma**: lymphoma possible, further examination/monitoring indicated

→**Not consistent with lymphoma**: lymphoma ruled out with confidence at this time

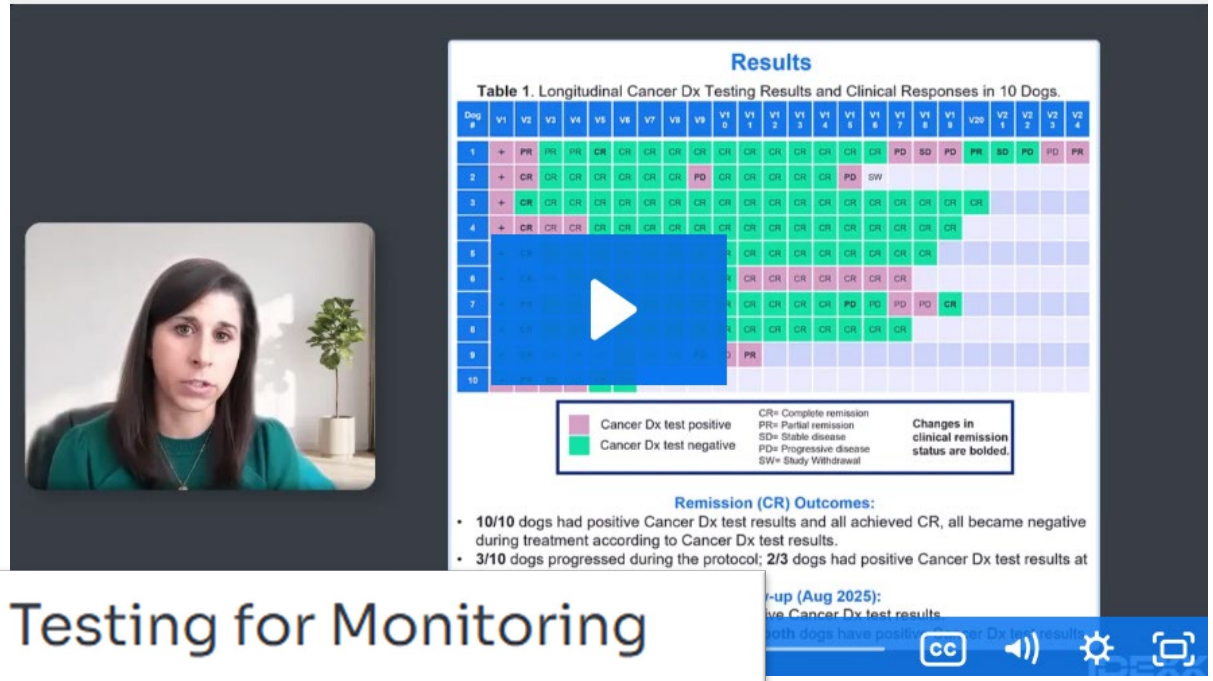
Sick dog, suspected lymphoma, aid-in-diagnosis

→ **Consistent with lymphoma**: lymphoma very likely, can go for next steps

→ **Not consistent with lymphoma**: if still highly suspicious for lymphoma, further investigations warranted

# What about monitoring?

+ Preliminary data
+ VCS 2025 poster
+ More to come in 2026: stay connected!




## Pilot Evaluation of IDEXX Cancer Dx Testing for Monitoring CHOP Treatment Response in Canine Lymphoma

Ten treatment-naïve dogs with confirmed lymphoma were prospectively enrolled to assess the utility of IDEXX Cancer Dx testing as a monitoring tool during a 25-week CHOP protocol. IDEXX Cancer Dx results correlated with clinical remission, indicating this liquid biopsy test may aid remission monitoring and warrants validation in larger cohorts.

# A few cases

# Meet **Evie, a 15 y/o FS Maltese**

**Day 1**
Initial visit: enlarged lymph nodes → Cytology

**Day 5**
Cytology: inconclusive due to lysis

**Day 7**
Revisit: recheck lymph nodes → Cytology

**Day 12**
Cytology: inconclusive due to low cellularity

**Day 14**
Revisit: recheck lymph nodes → IDEXX Cancer Dx™ and biopsy

**Day 16**
**IDEXX Cancer Dx "consistent with lymphoma," indeterminate phenotype**

**Day 25**
Biopsy: high grade lymphoma

**Day 28**
IHC: Pax5 positive, consistent with B-cell

# Why does time matters?

+ Time to take a decision
+ Time to explain
+ Time for the dog
+ Time to take actions
+ In human medicine, early detection = longer survival
+ In veterinary medicine, no studies, late detection
+ Substage a > b

Annie

# Annie

- 10-year-old, spayed female golden retriever
- Presented in August for wellness visit with senior panel with IDEXX Cancer Dx™ testing at IDEXX Reference Laboratories
- **IDEXX Cancer Dx**: consistent with lymphoma
- **Phenotype:** indeterminate

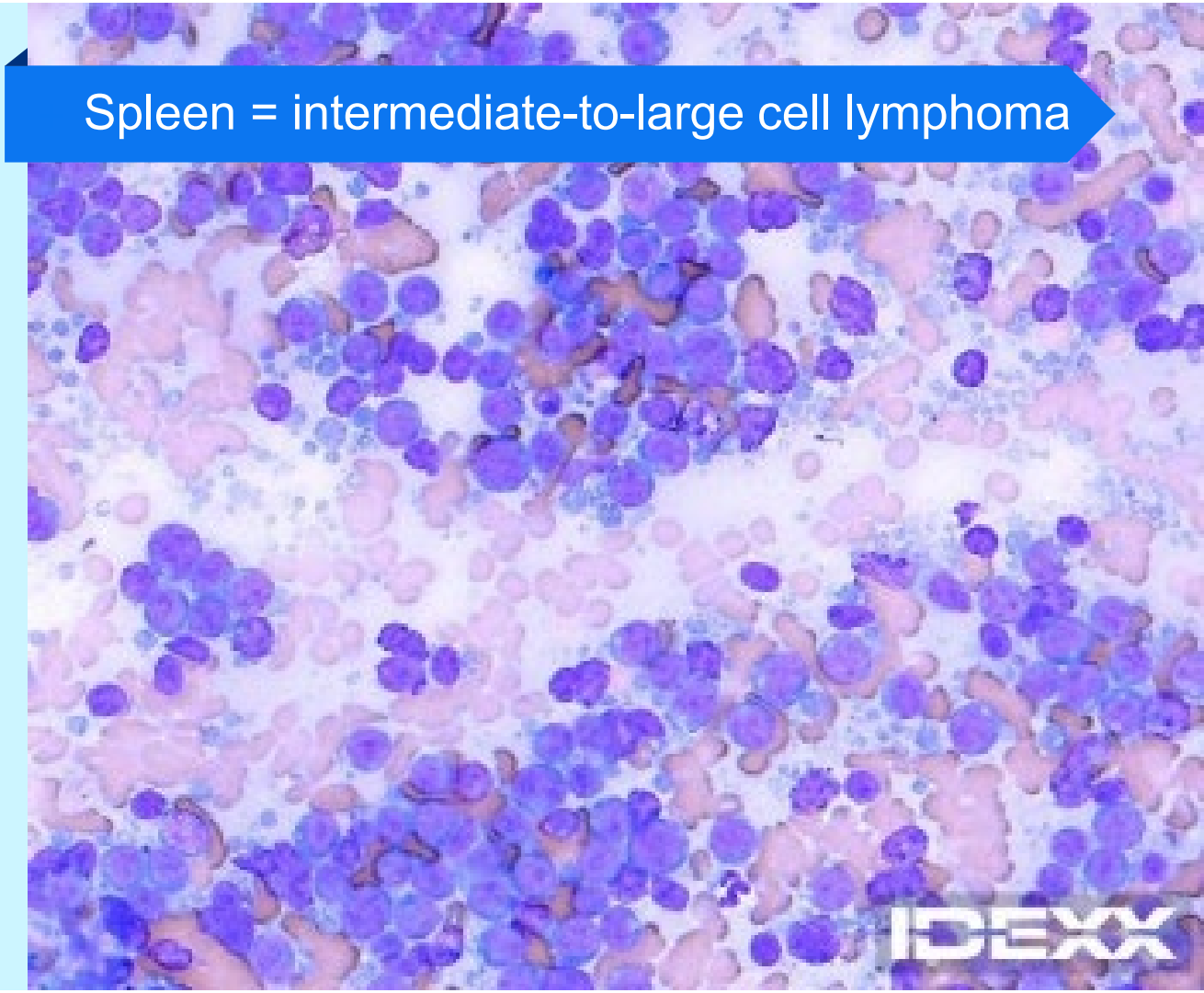
| | | |
|---|---|---|
| **Cancer Dx Lymphoma** | a | **Consistent with lymphoma** |
| Phenotype: | b | Phenotype indeterminate |

a A positive result indicates the presence of lymphoma-associated biomarkers and should be interpreted alongside clinical findings. In dogs showing signs of lymphoma, this result supports a clinical diagnosis of lymphoma. Additional diagnostics may be indicated to further characterize and stage the disease. Consultation with a veterinary oncologist to determine appropriate next steps before referral is recommended.
In dogs without clinical signs being screened due to risk profiles, further evaluation may be considered to confirm presence of disease. This may include complete blood count and chemistry panel (if not already pursued), diagnostic imaging , and aspirates of lymph nodes and/or organs. If lymphoma is not identified, monitoring and re-evaluation of peripheral lymph nodes in 8-12 weeks is advised (sooner if new symptoms arise).
Test results do not differentiate clinical aggressiveness. Indolent lymphomas and chronic lymphoid leukemia cases may also be identified. Further testing, including histopathology or flow cytometry, especially if lymphocytosis is present, may help differentiate aggressive from indolent lymphoma.
In rare cases, positive results may reflect other lymphoproliferative cancers such as myeloma-related conditions due to shared cell origin. Interpretation should be guided by clinical context and additional testing.

b In certain cases, the phenotype cannot be confidently determined due to limitations in sample quality, quantity, or marker expression. To further characterize the lymphoid population, consider additional diagnostic modalities such as Lymphoma PCR (PARR) for clonality assessment, flow cytometry for immunophenotyping, or biopsy with immunohistochemistry on tissue containing abnormal lymphocytes.

# Annie

- **Owners pursued imaging workup**
- **Thoracic radiographs**
  - Mild chronic bronchial pattern (asthma), no evidence of pulmonary metastasis or mediastinal lymphadenopathy
- **Abdominal ultrasound**
  - **Spleen:** mild splenomegaly, mixed echogenic pattern
    - Aspirate: lymphoma
  - **Liver:** normal sonographically
    - Aspirate: suspicious but not definitive of lymphoma



# Annie

01

**Stage IV:** Multicentric lymphoma with confirmed splenic involvement and suspicion of hepatic involvement.

02

**Substage a:** Patient is clinically well without systemic illness at time of diagnosis.

03

Referred to oncology for options. Owners grateful for early diagnosis to learn about options while still clinically well.

Ruger

# Ruger

- 10-year-old, neutered male Australian shepherd
- Presented in July for wellness visit with senior panel with IDEXX Cancer Dx™ testing at IDEXX Reference Laboratories
- **IDEXX Cancer Dx:** consistent with lymphoma
- **Phenotype:** indeterminate

| | | |
|---|---|---|
| **Cancer Dx Lymphoma** | a | **Consistent with lymphoma** |
| Phenotype: | b | Phenotype indeterminate |

a A positive result indicates the presence of lymphoma-associated biomarkers and should be interpreted alongside clinical findings. In dogs showing signs of lymphoma, this result supports a clinical diagnosis of lymphoma. Additional diagnostics may be indicated to further characterize and stage the disease. Consultation with a veterinary oncologist to determine appropriate next steps before referral is recommended.
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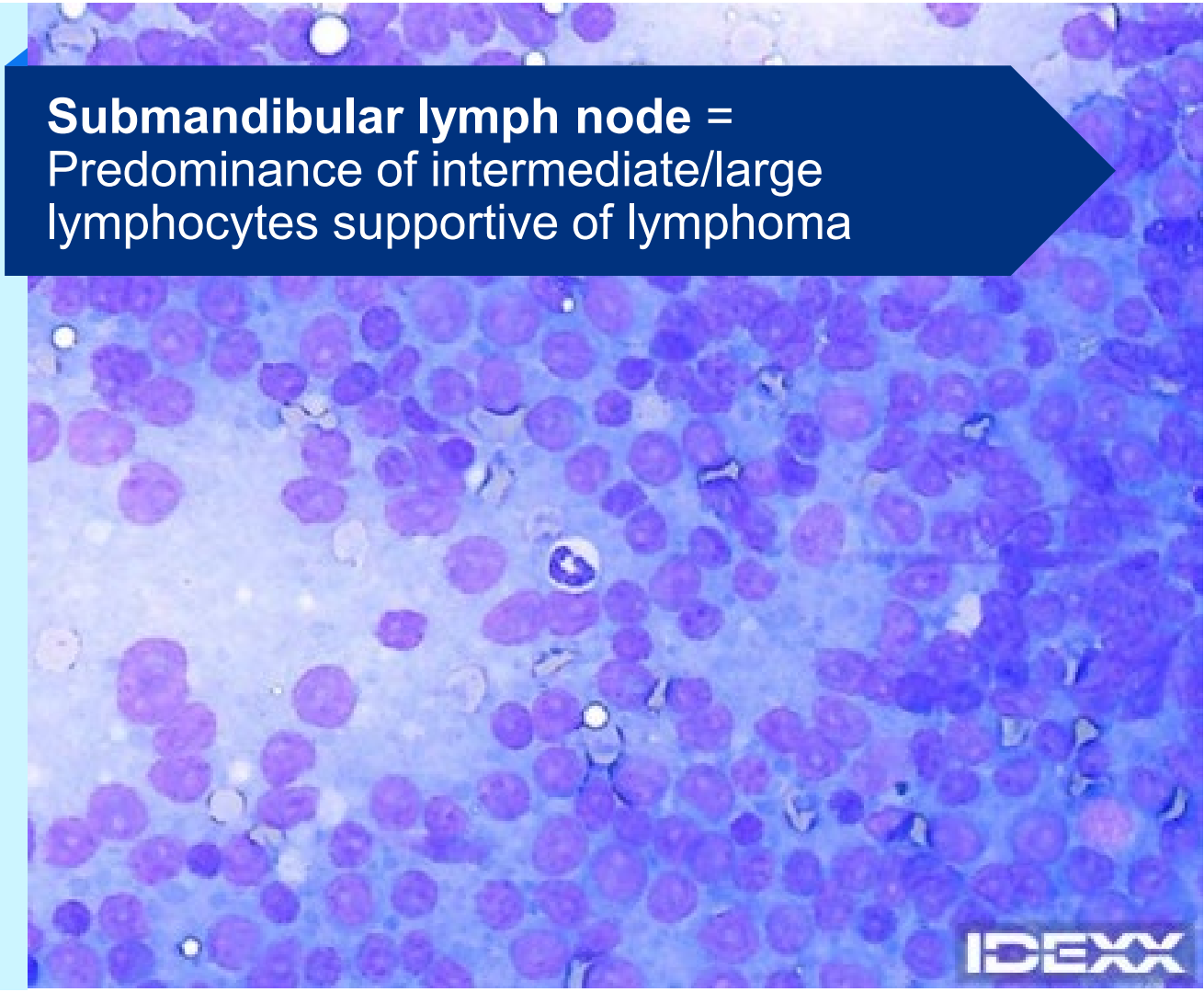
# Ruger

- Owners pursued imaging workup and cytology
- FNA submandibular LN
- Thoracic radiographs
  - Within normal limits
- Abdominal ultrasound
  - Mesenteric lymphadenopathy
- PARR testing
  - Immunoglobulin gene: clonal
  - T-cell receptor: polyclonal
  - Consistent with B-cell



# Ruger

01

**Stage III:** Multicentric lymphoma with confirmed on both sides of diaphragm.

02

**Substage a:** Patient is clinically well without systemic illness at time of diagnosis.

03

Referred to oncology for options.

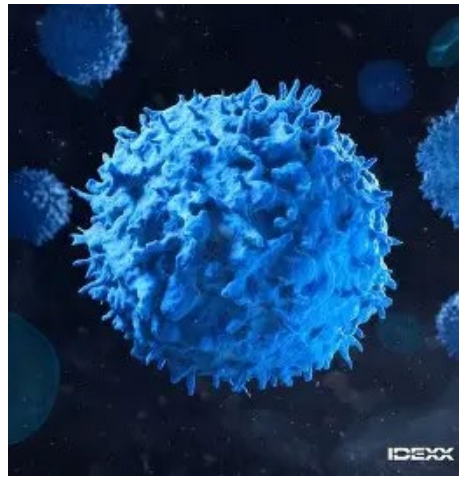
# 1st EU cases

# **From Suspicion to Confirmation**: How Reliable Lymphoma Testing **Saved Time**, **Reduced Costs**, and Enabled **Earlier Treatment.**

**Posh**

## Background

- 12y old Labrador
- Female Neutered
- Enlarged LN
- FNA inconclusive




### Why Test?

+ Large subcutaneous lump on neck
+ Multiple lymph nodes enlarged.
+ Fine needle aspirate was inconclusive

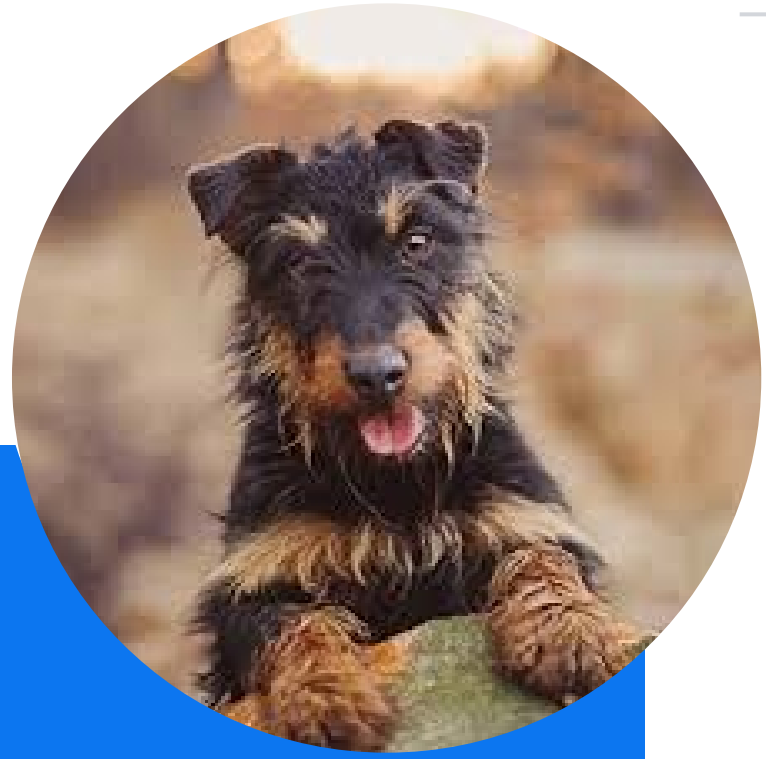
### The Test

+ 6 day turn around time
+ Consistent with lymphoma
+ B-cell lymphoma confirmed.

### Feedback

+ Clarified suspicions without the need for invasive diagnostics or a general anaesthetic.
+ Finances channelled towards treatment.
+ To start oral chemotherapy.

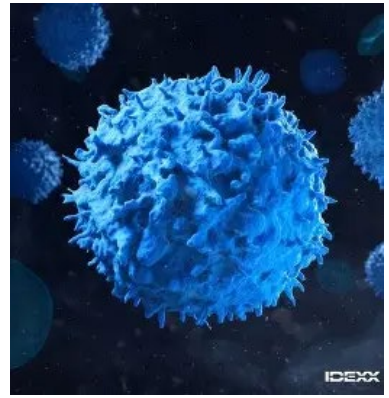
# Offering clarity and ease of use when owners need an answer before taking decisions

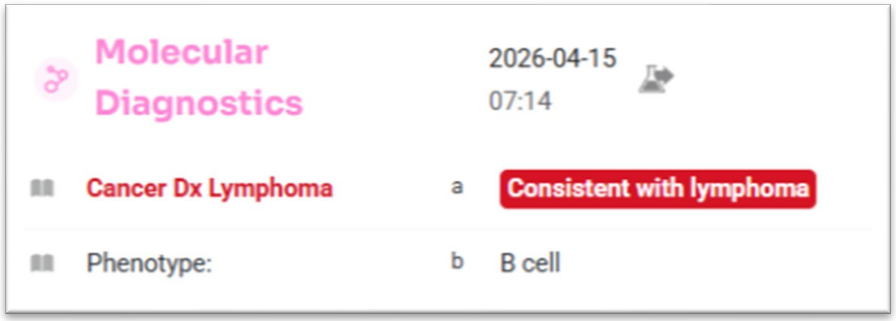


**Marley**

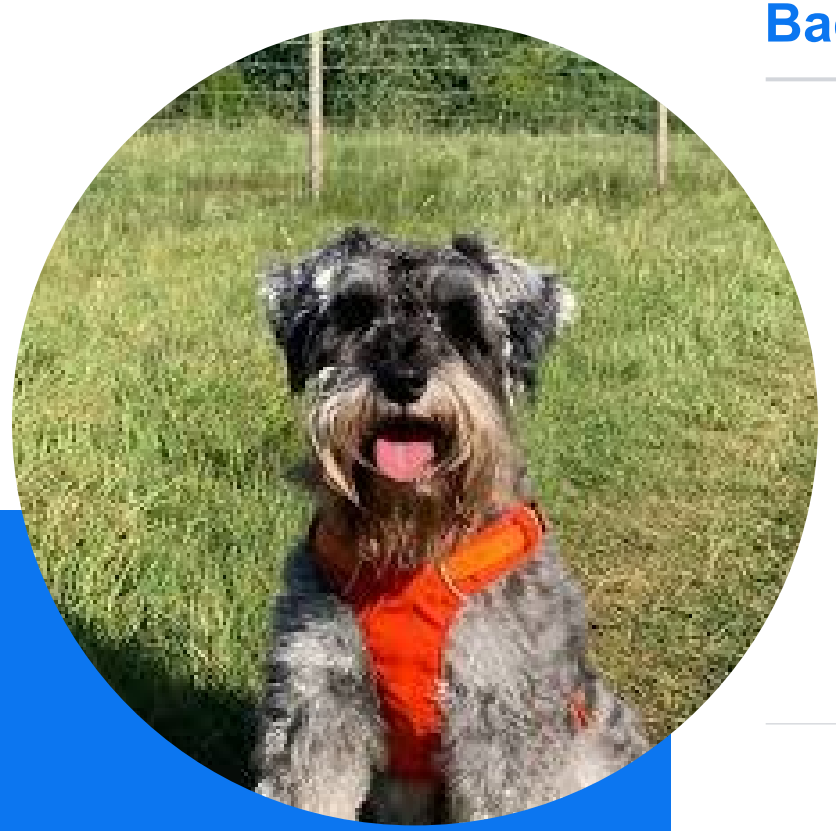
## Background

- 8-year-old intact Male German Hunt terrier
- Swelling around the neck.
- Lymphadenopathy – mild hyperthermia
- Drooling – swollen tonsils – infectious process?
- FNA of the LN → Cytology: lymphoma
- The owner wished for an even more certain diagnosis
- IDEXX Cancer Dx™ chosen because of specificity, less invasive than a biopsy and result faster than a biopsy as well



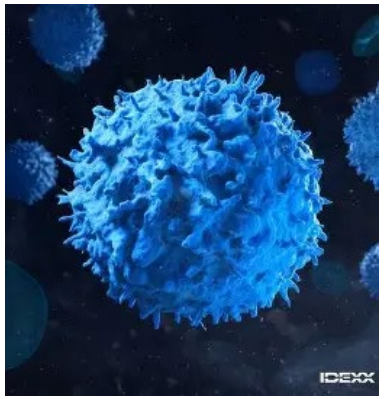



# Take actions earlier



**Oggy**

## Background



- Old male miniature Schnauzer
- Doing well but enlarged LN
- FNA + IDEXX Cancer Dx™ → IDEXX
- FNA: inconclusive although cellularity OK - indolent form or early aggressive form
- Cancer Dx: consistent with lymphoma, T phenotype
- LN excised → histology → high grade T cell lymphoma

*→ "Cancer Dx allowed earlier detection, LN removal and earlier diagnosis instead of monitoring and repeating FNA" (email from the vet)*

# Presentations at the VCS congress 2025:

→ 1 abstract
→ 3 posters

→ Validation, IDEXX Cancer Dx™ vs Cytology, Early Detection, Monitoring

# Current studies US/EU:

→ Screening, longitudinal, prospective trial for early detection 5000 dogs >7 years old and/or at-risk breeds

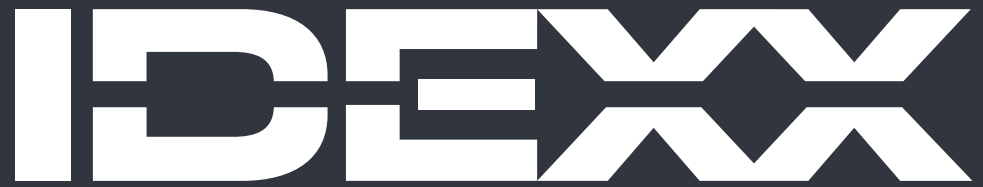
→ Monitoring

→ ACVIM, ECVIM, VCS, VSSO collaborative conference 2026

# IDEXX Cancer Dx™: Lymphoma is just the beginning

*Expansion of the panel over ~36 months to cover >50% of canine cancers by 2028, providing detection by cancer type*

Merci!


IDEXX