Performance of the IDEXX Cancer Dx Panel for detection of mast cell tumors in dogs

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Introduction

Mast cell tumors (MCTs) are among the most common cancers in dogs, accounting for up to 11% of all diagnosed canine cancers and up to 24% of canine skin tumors.[1] MCTs are common in middle-aged to older dogs, with a median age of 7.8 years at first diagnosis.[2] Breed predisposition to higher risk has been reported for the Labrador retriever, Boston terrier, Weimaraner, and others.[3]

MCTs are typically cutaneous or subcutaneous, with variable behavior ranging from benign acting to highly aggressive. Cytology is a mainstay of initial diagnosis; biopsy and histopathology remain the gold standard of diagnosis and are recommended in cases of MCT to provide additional information, such as margin evaluation and grade.[1] Histopathologic grade is one of the most reliable predictors of biological behavior of MCTs in dogs. Low-grade cutaneous tumors and subcutaneous tumors without high-risk features (high mitotic index (MI), multinucleated cells, and/or infiltrative growth pattern) are more likely to be slow growing and cured with surgical excision alone. About 15% of these tumors may not exhibit aggressive features on biopsy but clinically go on to metastasize to other locations.[4] High-grade cutaneous tumors and subcutaneous tumors with high-risk features may metastasize to lymph nodes, spleen, liver, or bone marrow and have an increased risk of recurrence.[1] Certain locations on the body have been associated with more aggressive behavior, including MCTs arising in the oral cavity, on the muzzle, and on genitalia.[5,6] MCTs arising in the viscera, or organs, are rare and most commonly highly aggressive.[7]

Most dogs with mast cell disease develop low-grade cutaneous tumors or less aggressive subcutaneous tumors. These patients may have singular or multiple masses on or under their skin. Less aggressive tumors are most often not terminal and cured with surgical excision alone, though de novo tumors can occur in the future.[1] Approximately 25% of patients present with high-grade or aggressive tumors that grow rapidly and may cause systemic signs.[4,8]

Dogs with these more aggressive tumors may be treated with a combination of surgery, radiation therapy, and/or systemic medications, such as chemotherapy or small molecule inhibitors. The prognosis for dogs with aggressive disease is dependent upon treatment undertaken and extent of disease (stage) with higher stage disease carrying a worse prognosis.

The IDEXX Cancer Dx™ Panel is a blood-based panel using immunoassay and PCR to detect circulating biomarkers for canine lymphoma and MCT. The IDEXX Cancer Dx Panel can be used in apparently healthy dogs at increased risk for cancer (senior dogs aged 7 and above as well as dogs categorized as an at-risk breed aged 4 and above) as part of a routine wellness care visit with no additional specimen collection necessary.

Breeds at increased risk of cancer

Increased risk of cancer (overall), including mast cell tumors:

+ Golden retriever[2]
+ French bulldog[2]
+ Beagle[9]
+ Boxer[9]
+ Miniature schnauzer[9]
+ Bernese mountain dog[10]
+ Flat-coated retriever[10]
+ Scottish terrier[10]
+ Bullmastiff[10]

Increased risk of mast cell tumors:[3]

+ Labrador retriever
+ Boston terrier
+ Weimaraner
+ Shar-pei
+ Chinese pug

Methods and results

Each specimen was measured in duplicate across combinations of reagent lots. Assay sensitivity detecting clinically aggressive MCTs and specificity detecting non-MCTs were estimated separately by logistic regression.[11] Relevant model coefficient standard errors were used to construct 95% logit confidence intervals for each statistic.

The effects of interfering substances on assay performance were evaluated by comparing the distributions of assay concentrations between groups of specimens with various

levels of interferent. Field specimens for 2,225 canines with paired IDEXX Cancer Dx™ Panel results and interfering substance results were used for this analysis. Comparison groups were defined as N, 1+, 2+, 3-4+ for hemolysis and N, 1+, 2-4+ for lipemia and bilirubin. For each interferent, each group was compared to the lowest group (N) by comparing the proportions of IDEXX Cancer Dx concentrations exceeding the critical assay threshold. 95% Newcombe confidence intervals were calculated for this difference.[12]

Patient population

Specimens were collected from 2 private specialty groups, IDEXX Reference Laboratories, additional private collections, a nonprofit research initiative, and 1 university for evaluation of the IDEXX Cancer Dx Panel in dogs with confirmed MCTs; dogs with non-MCT cutaneous masses, inflammatory dermatologic disease, or other cancers; and healthy dogs. Dogs with confirmed MCTs were diagnosed via histology with Patnaik and Kiupel grading systems,[13,14] when applicable, or cytology with additional staging to provide clinical behavior. Upon confirmation of inclusion, subjects were categorized as having clinically aggressive disease or nonaggressive disease, as shown in table 1.

Group	Basis for classification	Dogs (n)
Clinically aggressive disease		
Cutaneous, high grade	Kiupel high grade/Patnaik grade III	40
Cutaneous, no grade assigned or low grade + metastasis	No grade assigned or low grade with confirmed nodal or distant metastasis	9
Cutaneous, low grade at high-risk site	Low grade at a site on the high-risk list*	4
Subcutaneous, high-risk features	Infiltrative growth, MI ≥ 4, and/or metastasis	17
Nongraded sites (oral, visceral)	No validated grading scheme applies; aggressive by site	5
Subtotal—clinically aggressive		75
Clinically nonaggressive disease		
Cutaneous, low grade, localized	Low grade, low-risk site, no metastasis	82
Subcutaneous, low-risk features	Well-circumscribed, low MI, no metastasis	17
Subtotal—clinically nonaggressive		99
All dogs with MCT		174

Table 1. Categorization of MCTs as clinically aggressive vs. clinically nonaggressive.

* Locations considered of high risk: on the muzzle, near mucocutaneous junction, on the genitalia.

Dogs were excluded from analysis if chemotherapy or steroid treatment was reported within one month prior to specimen collection. Seventy-five dogs with clinically aggressive MCTs, 99 dogs with clinically nonaggressive MCTs, 179 dogs with other active disease processes, and 117 apparently healthy dogs were included. Apparently healthy dogs had a normal physical examination and no significant findings on a CBC and comprehensive biochemistry profile.

Sensitivity for detecting mast cell disease

The IDEXX Cancer Dx Panel demonstrated increased sensitivity for high-grade and clinically aggressive tumors, particularly high-grade cutaneous, biologically aggressive subcutaneous, and visceral/oral tumors compared to histologically low-grade tumors (see table 2). The IDEXX Cancer Dx Panel has limited detection of low-grade and clinically nonaggressive tumors, meaning that positive results are more common in patients with clinically aggressive disease.

Group	Dogs (n)	Target detected (n)	Sensitivity
Clinically aggressive disease			
Classified aggressive by histology and visceral/oral MCT			
Cutaneous, high grade	40	14	35.0%
Subcutaneous, biologically aggressive features	17	7	41.2%
Aggressive nongraded sites (oral, visceral)	5	2	40.0%
Low grade/no grade reclassified as aggressive due to prognostic factors			
Cutaneous, no grade assigned or low grade + HN2 metastasis	9	2	22.0%
Cutaneous, low grade at high-risk site	4	0	0.0%
Clinically nonaggressive disease			
Cutaneous, low grade, localized	82	3	3.6%
Subcutaneous, low-risk features	17	0	0.0%

Table 2. Sensitivity of target detection by disease group, stratified by aggressiveness classification.

Specificity against other diseases and healthy controls

Control cohorts included patients with active disease processes other than MCTs (see table 3) and healthy patients. The IDEXX Cancer Dx Panel demonstrated high specificity

against other diseases, both malignant and benign, and healthy control patients with a specificity of 99.0% (293/296 control patients with negative results).

Controls with other diseases	Dogs (n)
Malignant non-MCT neoplasia	105
Non-MCT mass—benign neoplasm, hamartoma, cyst, inflammatory mass	55
Inflammatory skin disease, no discrete mass	14
Systemic/nondermatologic disease, no mass	5
Total nonhealthy controls	179

Table 3. Diagnoses of dogs with other active disease processes. Malignant non-MCT neoplasia diagnoses include lymphoma (44), soft tissue sarcoma (20), carcinoma (15), mammary tumor (6), other sarcoma (6), melanoma (5), hemangiosarcoma (5), and osteosarcoma (4).

Intrinsic specimen interference

A significant change in false-positive result rate was not observed for specimens with mild/moderate lipemia, icterus, or hemolysis. Changes in the biomarker distributions of MCT-negative specimens that were associated with interferents were primarily observed well below critical decision thresholds.

Discussion

Results on the IDEXX Cancer Dx™ Panel for MCT are highly specific with a higher detection rate for aggressive or clinically significant tumors than nonaggressive tumors that tend to have more benign behavior clinically. Sensitivity was increased for high-grade cutaneous, biologically aggressive subcutaneous and visceral/oral MCTs. Within the initially identified clinically aggressive group, four masses were identified as low grade by histopathology but placed within the clinically aggressive category due to arising on a location that has been previously associated with poor outcomes. Additional literature that has been published after design of this study has indicated that these tumors may not carry a higher risk of recurrence or metastasis and, therefore, may act less aggressively.[15] Lack of presence of the biomarkers used in the IDEXX Cancer Dx Panel is in alignment with that novel information. Additionally, those patients within the clinically aggressive group identified by histopathology as low grade with metastatic disease all had HN2 metastatic disease to the draining lymph node (HN2 metastatic disease is defined as early metastasis to the lymph node).[16] Since publication of this grading scheme, additional investigation concluded that low-grade/low-risk MCTs with HN2 metastatic disease in that study showed good clinical outcomes without chemotherapy or other systemic therapy.[17] Lack of presence of the biomarkers used in the IDEXX Cancer Dx Panel is also in alignment with this information.

The IDEXX Cancer Dx Panel has limited detection of low-grade MCTs. It is built to detect aggressive tumors in which outcomes can be improved by earlier investigation and intervention.[18] A positive result should be approached as an aggressive disease until proven otherwise with additional testing, such as biopsy with histopathologic grading. A negative result does not rule out one or more MCTs in a patient, and additional testing that includes cytology and/or histopathology should be considered in patients with palpable masses or abnormal tissue noted on physical examination.

The IDEXX Cancer Dx Panel is recommended for screening for lymphoma and MCTs in apparently healthy patients identified due to risk profiles, including senior dogs ages 7 and older and at-risk breeds ages 4 and older. Due to the low prevalence of subclinical cancer in apparently healthy dogs, false-positive results can occur in healthy patients screened for cancer despite a very high specificity. A positive result on a screening test is not a definitive diagnosis, and with a high specificity, the result indicates additional workup is recommended. A negative result in screening is highly likely to be reflective of true absence of disease due to the low prevalence in this population of dogs.

Conclusion

The IDEXX Cancer Dx Panel expansion to include mast cell tumor screening offers a simple, affordable option for broader blood-based screening that fits in the workflow of a routine wellness visit using commonly obtained specimens. It is highly specific, offering disease-specific results and designed with increased sensitivity for clinically aggressive mast cell tumors compared to low grade or nonaggressive tumors.

Acknowledgements

We would like to thank Ethos Veterinary Health, MedVet, Kado Consulting, Transcend Animal Research Management, Moore Veterinary Hospital, Morris Animal Foundation's Golden Retriever Lifetime Study, University of Guelph–Ontario Veterinary College, and the IDEXX Biobank for their invaluable contribution to the specimen sets used in this study. Their support and collaboration were essential to the successful completion of this research.

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