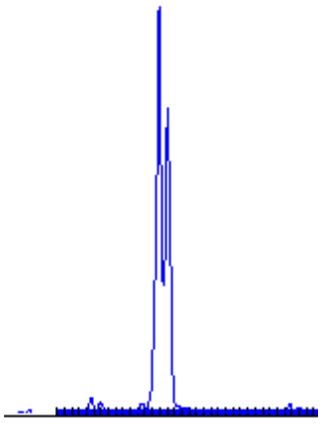
SpotLight™ ePARR Report

Summary: Likely B-Cell Malignancy

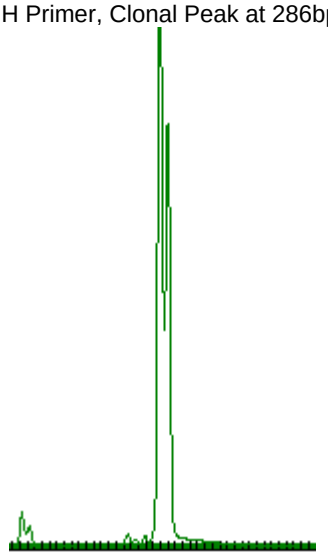
Pet Name: Spot Davis

Sample ID:	VDM-21001265	Prior Diagnostics:	Cytology
Breed:	Mixed	Sample Collection Date:	2020-12-01
Gender:	M/N	Differential Diagnosis:	
Date of Birth:	2011-06-15	Report Date:	2021-07-22
Owner:	Tim Davis	Specimen Location:	
Veterinarian:	Esther Chon	Specimen Type:	FNA
Veterinary Clinic:	Vidium Animal Health	Client Accession #:	N/A

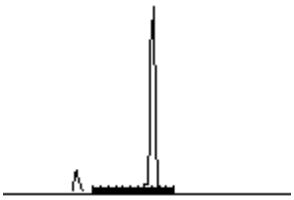
IGH Primer, Clonal Peak at 99bp



IGH Primer, Clonal Peak at 286bp



Control Primer



Interpretation:

Clonal immunoglobulin gene (IgH) rearrangement was detected. No clonal T-cell receptor (TCR) gene rearrangement was detected. These clonality results support a diagnosis of B-cell lymphoma. The final clinical interpretation must also take into account cytologic, histopathologic, and immunophenotypic findings. The phenotype of the identified clonal population can be further supported with flow cytometry and/or immunocytochemistry. This sample passed DNA quality control and control primer requirements.

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Assay Description

PARR (PCR for Antigen Receptor Rearrangement) is a molecular test for lymphocyte clonality that enables discrimination of lymphoid malignancies from benign, reactive hyperplasia, and inflammatory processes in dogs. During maturation, normal lymphocytes acquire unique antigen receptors through rearrangements of the V(D)J regions of T-cell and B-cell receptor genes and are thus polyclonal at these genetic loci (wide peaks in electropherograms). However, lymphoma arises from clonal expansion of a single progenitor cell and therefore is characterized by monoclonal receptor loci (sharp narrow peaks in electropherograms). A positive control peak confirms amplification of DNA.

In a benchmarking study (see References) evaluating the performance of ePARR in discrimination of lymphoma versus non-lymphoma for cytologically or histologically confirmed lymphoid malignancies, ePARR exhibited 100% sensitivity, specificity, and accuracy on FNA samples; 100% sensitivity, specificity, and accuracy on FFPE samples; and 85% sensitivity and accuracy on flow cytometry pellets when utilizing stringent input DNA quantity and quality cutoffs.

References

1. Ehrhart, EJ., Wong, S., Richter, K. et al (2019). Polymerase chain reaction for antigen receptor rearrangement: Benchmarking performance of a lymphoid clonality assay in diverse canine sample types. *J Vet Intern Med*, 33(3):1392-1402. doi: 10.1111/jvim.15485. PMID 30939225 (https://pubmed.ncbi.nlm.nih.gov/30939225/)

Limitations

Samples with few malignant cells or lymphocytes may contain rearrangements below our limit of detection which can lead to reduced sensitivity and false negative results. Mutations at primer binding sites may also lead to false negative results. In rare cases, neoplastic lymphocytes may undergo clonal rearrangement of IgH and/or TCR genes regardless of phenotype. Background noise inherent in DNA from FFPE samples may affect sensitivity of reporting from FFPE. Rarely, inflammatory clones can proliferate disproportionately and appear as distinct peaks over a polyclonal background causing false positive results, and have been described in ehrlichiosis, leishmaniasis, and cutaneous histiocytomas.

Disclaimers

This test has not been approved by the U.S. FDA. The FDA has determined that such clearance or approval for veterinary diagnostics is not necessary. This test is used for clinical purposes for veterinary patients. It should also be noted that the data interpretations are based on our current understanding of IGH and TCR rearrangements as of the report date. Antigen receptor rearrangements should be considered in the context of the patient's history, risk factors, and any previous genomic testing. Vidium Animal Health's services, including but not limited to the results contained in this report, are governed by Vidium's Terms & Conditions, which are available at vidiumah.com.

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Electronically signed by:

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