Prevalence of Ocular Inflammation in the General Population
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Introduction
Dry eye is a multifactorial disease. Factors that adversely affect tear film stability and osmolarity can initiate inflammatory mediators that lead to ocular surface damage, including corneal barrier disruption and apoptosis. One of these mediators is matrix metalloproteinase 9 (MMP-9), The Dry Eye Workshop (DEWS) Report defined levels of MMP-9 ≥ 40 ng/mL corresponding to moderate-to-severe dry eye disease (1). RPS’s InflammaDry yields positive results when levels of MMP-9 of 40 ng/mL or more are detected in a tear fluid sample taken from the palpebral conjunctiva.

Methods & Materials
Twenty-seven subjects between the ages of 16 and 68 years old participated in this study. The average age of the participants was 40 years old, with almost equal male and female involvement (14:13). Of the 27 encounters, the majority were annual eye examinations, 16/27 (59.3%); the remaining encounters were medical office visits at 11/27 (40.7%). The right eye of subjects was tested and all test results were read by the primary investigator to maintain consistency of interpretation. Testing was interpreted on a scale ranging from Strong Positive to Weak Positive to Trace to Negative.

Results
63% of subjects in the general patient population tested positive for MMP-9 ≥ 40 ng/mL
Of the 27 subjects, 63% tested positive and 37% tested negative. Of the positive results, 3/17 (17.6%) were strong positive, 8/17 (47.1%) were weak positive, and 6/17 (35.3%) were trace (see graph below).

In comparing the results by gender, female and male participants tested about equally positive. Females tested 61.5% positive. Males tested 64.3% positive.
In comparing the results by age, subjects 40 years and older tested 72.7% positive compared to those under 40 testing 56.3% positive.

Discussion
InflammaDry is a rapid point-of-care test commonly incorporated into dry eye clinics due to its strong sensitivity to detect inflammation on the ocular surface. A previous study, 2013 Sambursky et al, concluded that InflammaDry showed sensitivity of 85% (in 121 of 143 dry eye patients) and specificity of 94% (59 of 63 healthy controls) (2). This study sought to detect the prevalence of MMP-9-related inflammation in a general patient population to determine the utility of InflammaDry as a dry eye screening tool. Sixty-three percent of subjects tested positive for MMP-9 levels above 40 ng/mL, much higher than expected in an population without dry eye diagnoses.
Prevalence of higher positive results was found in the medical office visit encounters, which ranged from cataract post-operative appointments to blepharitis follow-ups. These diagnoses are typically associated with some degree of ocular inflammation, so this result was not surprising.
Males and female tested equally positive for MMP-9 above 40 ng/mL, unlike most reports exhibiting an increased prevalence of dry eye in females (3). This may be due to the small sample size of the study.

Annual eye examination encounters yielded 56.3% positive InflammaDry results
Even more relevant for primary care practitioners, annual eye examination encounters yielded 56.3% positive InflammaDry results, reflecting the often subclinical nature of inflammatory dry eye, as many of these patients were either asymptomatic or without strong signs of inflammation.

Conclusion
MMP-9 inflammation ≥ 40 ng/mL in the tears has a prevalence of 63% in a general patient population without prior dry eye diagnosis. Implementing MMP-9 testing in a primary care setting can be a useful objective tool to educate patients about the implications of inflammation on the ocular surface and provide clinicians with another screening test to capture non-obvious dry eye patients. Most importantly, clinical exam alone may not be appropriate to guide therapeutic decision-making to start an anti-inflammatory treatment or to monitor the impact of treatment.

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References

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