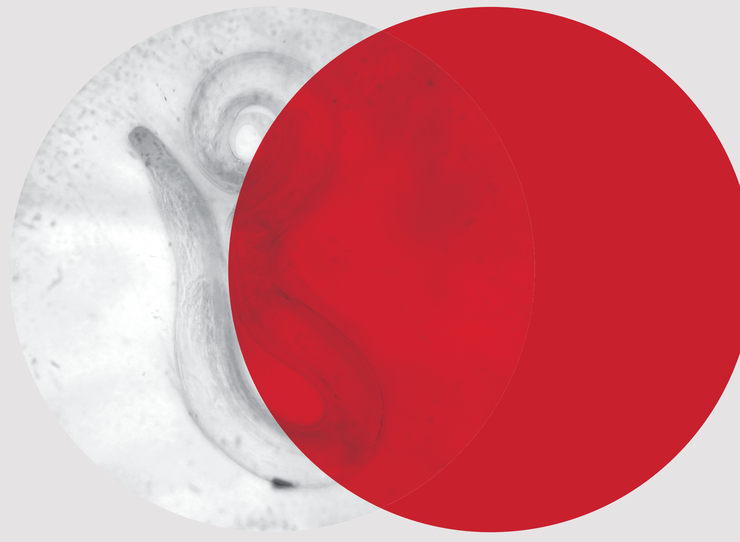
Evaluating a Strongyloides EQA Program: Outcomes of a two-year pilot study



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Introduction

In 2018, RCPAQAP Serology issued a Strongyloides pilot Program to Australian and New Zealand laboratories to assess the feasibility of introducing an external quality assurance (EQA) program. The results reflected a high concordance in qualitative reporting of Strongyloides IgG, however, a high variation was observed in the reporting of quantitative results.

A further study with increased participant numbers, including international participants, was conducted in 2019 with a view to further investigate assay performance and reporting for low-level positive specimens where result values are close to the clinical cut-off value for Strongyloides antibodies.

Method

The 2018 Strongyloides pilot survey was distributed to 10 Australian and New Zealand laboratories for Strongyloides IgG testing as per routine laboratory protocols. Four serum specimens of human origin were distributed in one survey. Specimen 18-01 was a positive neat sample; Specimens 18-02 and 18-04 were positive pooled samples and Specimen 18-03 was a negative neat sample.

The 2019 pilot survey was distributed to 12 Australian and five international laboratories for Strongyloides IgG and total antibody testing. Four serum specimens of human origin were distributed in one survey. Specimen 19-01 was a positive neat sample; Specimens 19-02 and 19-04 were duplicate negative neat samples; Specimen 19-03 was a 1-in-2 dilution of the positive sample with the negative sample used in this survey.

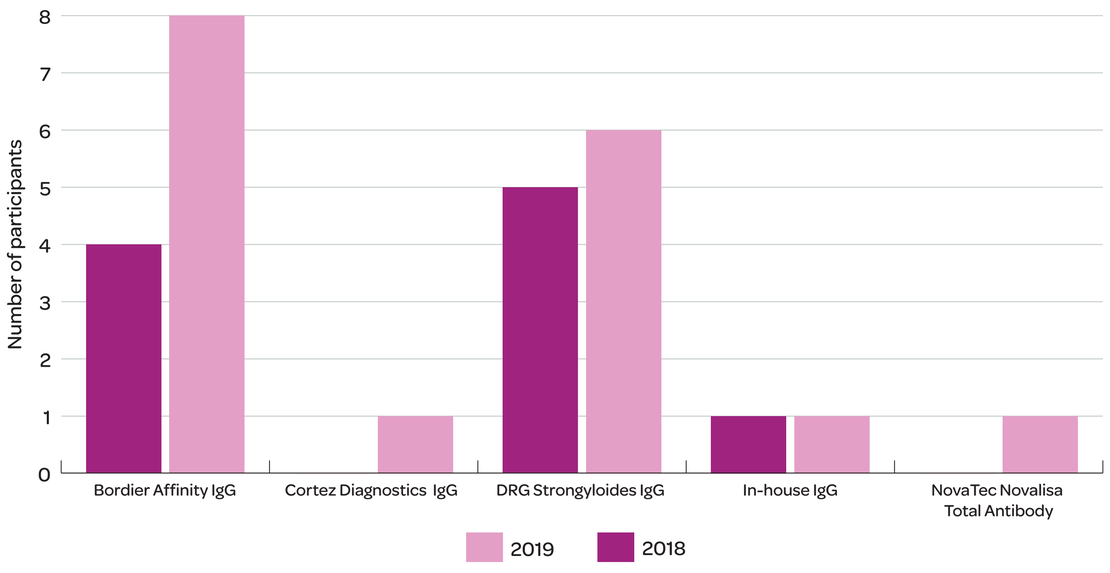
Qualitative (positive/negative) and quantitative (OD, Index and S/CO) data were submitted by participating laboratories. Quantitative data was converted to a common unit (S/CO) and robust statistics performed for the positive samples using in-house RCPAQAP statistical software.

For both pilot studies, participants tested for Strongyloides IgG and total antibody using a commercial enzyme-linked immunosorbent assay (ELISA) or an in-house assay.

Results

Four commercial assays and one in-house assay were used for testing (Figure 1).

Figure 1. Strongyloides kits in use by participating laboratories.



All users of the In-house Strongyloides IgG kit (1), Bordier Affinity Strongyloides ratti IgG kit (8) and Cortez Diagnostics AccuDiag Strongyloides IgG kit (1) returned positive results for the characterised positive samples (SE-SG-19-01 and SE-SG-19-03). 5/6 of participants using DRG Strongyloides IgG kits returned negative results for the diluted positive sample (SE-SG-19-03), the other user returned a positive result.

The 2018 pilot study showed 100% consensus for qualitative results. The 2019 pilot study showed 81% consensus (positive) for Specimen 19-01; 100% consensus (negative) for duplicate Specimens 19-02 and 19-04 and 69% consensus (positive) for Specimen 19-03 for Strongyloides IgG. One participant performed Strongyloides total antibody testing and reported positive results for both Specimens 19-01 and 19-03 and negative results for Specimens 19-02 and 19-04 (Figure 2).

Figures 3 and 4 demonstrate the degree of variation of the quantitative data between and within the method groups for Strongyloides IgG positive samples for both pilots.

Figure 2. Qualitative Results for Strongyloides IgG

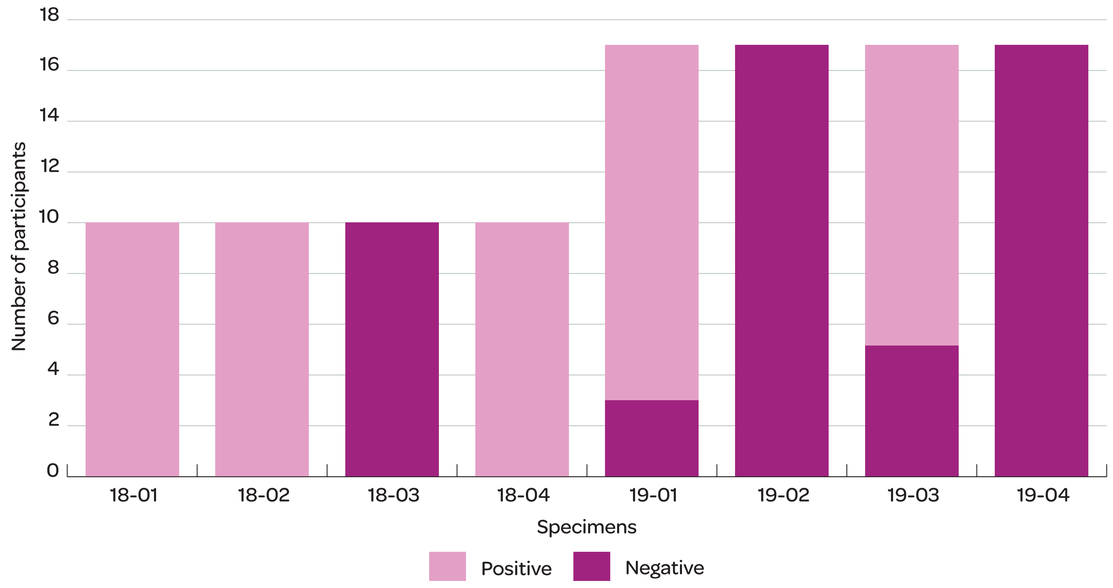


Figure 3. 2018 Quantitative Values for IgG Positive Specimens n=10

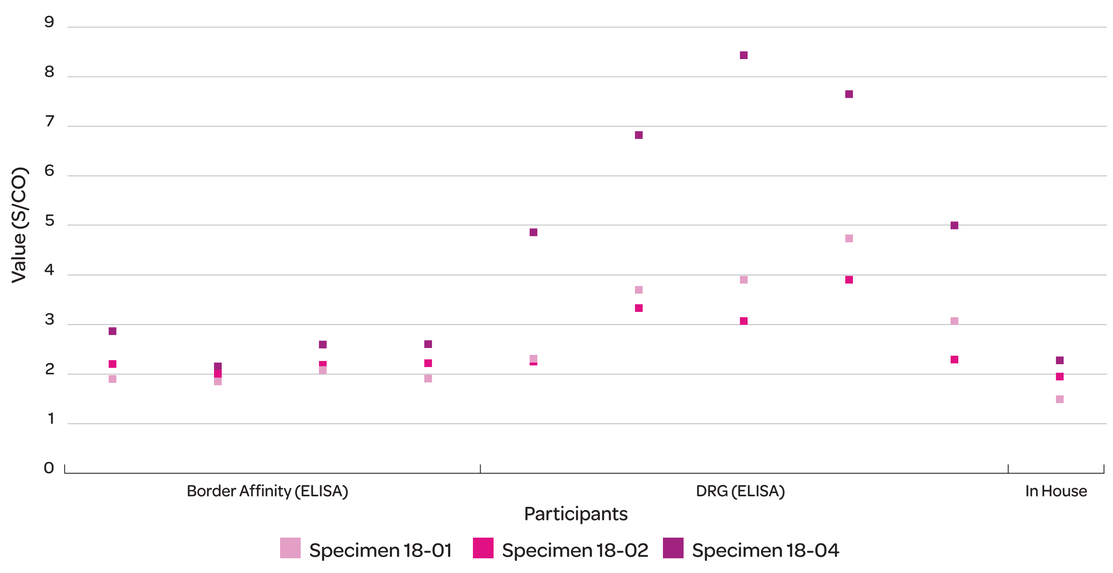
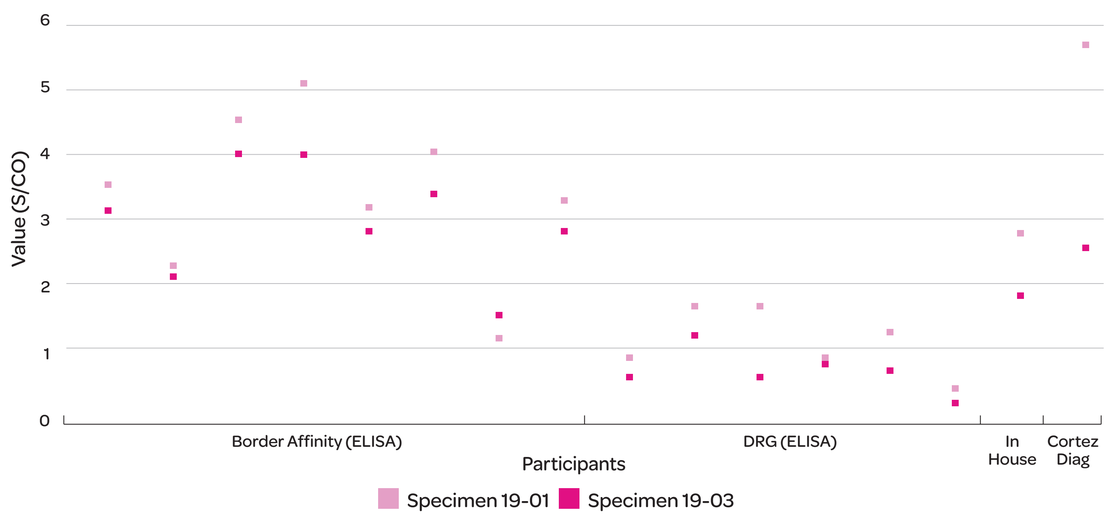


Figure 4. 2019 Quantitative Values for IgG Positive Specimens n=16



Discussion

The results reflect a high concordance in qualitative reporting of characterised positive and negative Strongyloides IgG samples. However, analysis of the quantitative data showed a high variation in the reporting of Strongyloides IgG quantitative results. The distribution of results appear to be kit related. The variation of results may be due to differences in assay sensitivity and specificity in the presence of low-level antibody in the sample.

Conclusion

Overall, the two pilot studies demonstrated inconsistencies in the detection of low-level antibodies for Strongyloides IgG and a high variation in the reporting of quantitative values between and within method groups highlighting the need for an EQA. RCPAQAP plans to introduce an ongoing Strongyloides program to assist laboratories when assessing the validity of their testing method, assay performance and quality of results compared with their peers. Addition of a qualitative result interpretation to the program will also give an indication as to whether the variation in the quantitative results could be contributing to over or underdiagnosis of Strongylodiasis.

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