

RCPAQAP Pilot Program for Strongyloides Detection

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Background

Strongyloidiasis is an infectious disease caused by the parasitic roundworm *Strongyloides stercoralis*. In immunocompromised individuals, *Strongyloides* infection can be fatal. Strongyloidiasis is endemic in tropical and subtropical regions, however there is a worldwide distribution with an estimated 370 million people affected due to global migration patterns¹. High seroprevalence levels have been shown in disadvantaged communities including some remote communities in Australia². Following requests from RCPAQAP participants, in 2018 RCPAQAP Serology issued a Strongyloides Pilot Program to assess the suitability of introducing an external quality assurance (EQA) program.

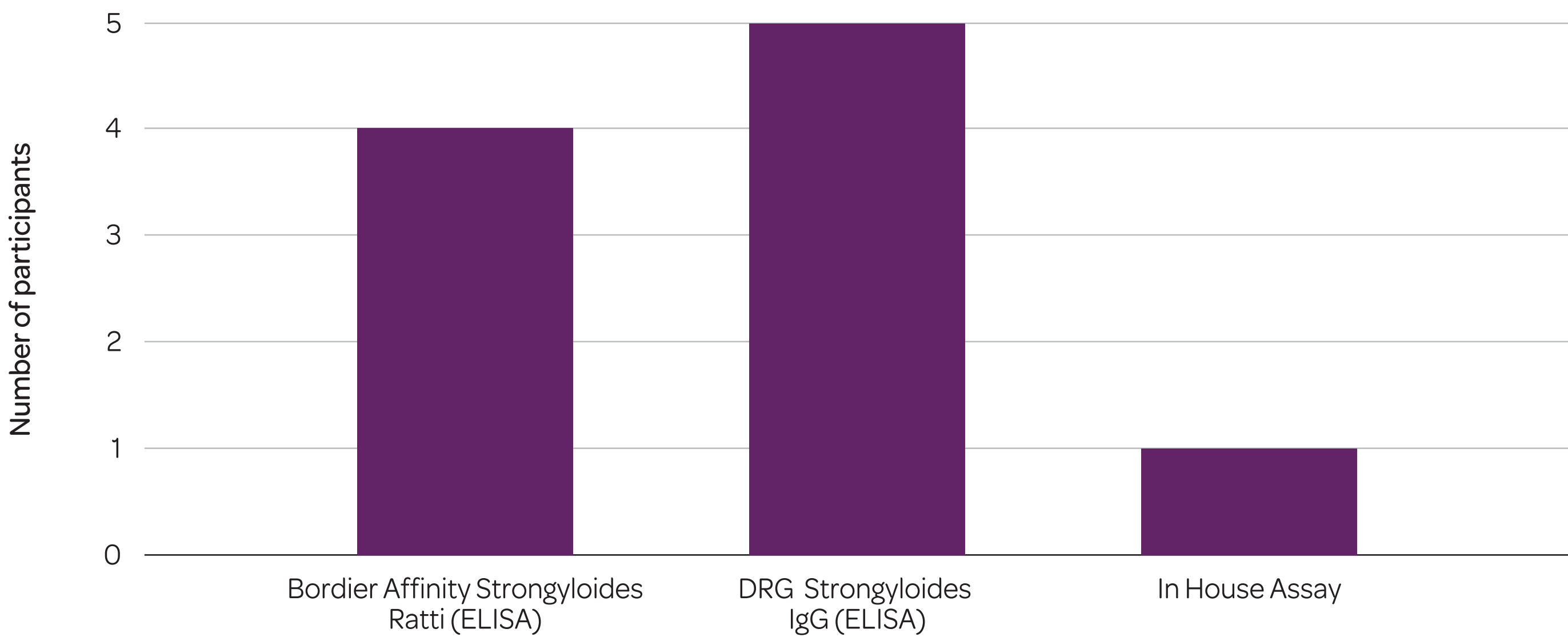
Methods

The 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 1 was a positive neat sample; Specimens 2 and 4 were positive pooled samples and Specimen 3 was a negative neat sample. Qualitative (positive/negative) and quantitative (OD, Index and S/CO) data was analysed. Assigned results were determined by a consensus of ≥ 80% for qualitative data. Quantitative data analysis was performed by converting all result values to the same unit (S/CO) and robust statistics performed for the positive samples using in-house RCPAQAP statistical software.

Results

1. All 10 participants returned results for the 4 specimens. Participants tested for Strongyloides IgG using a commercial enzyme-linked immunosorbent assay (ELISA) or an In-house assay. Two commercial assays and one In-house assay were used for testing in this survey (Figure 1).

Figure 1. Strongyloides IgG Kits.



2. Discrepancies were identified in the reporting of cut-off values and units. Some participants reported units and cut-off values inconsistent with the values recommended by the kit manufacturer (Figure 2).

Figure 2. Comparison of units and cut-off values reported

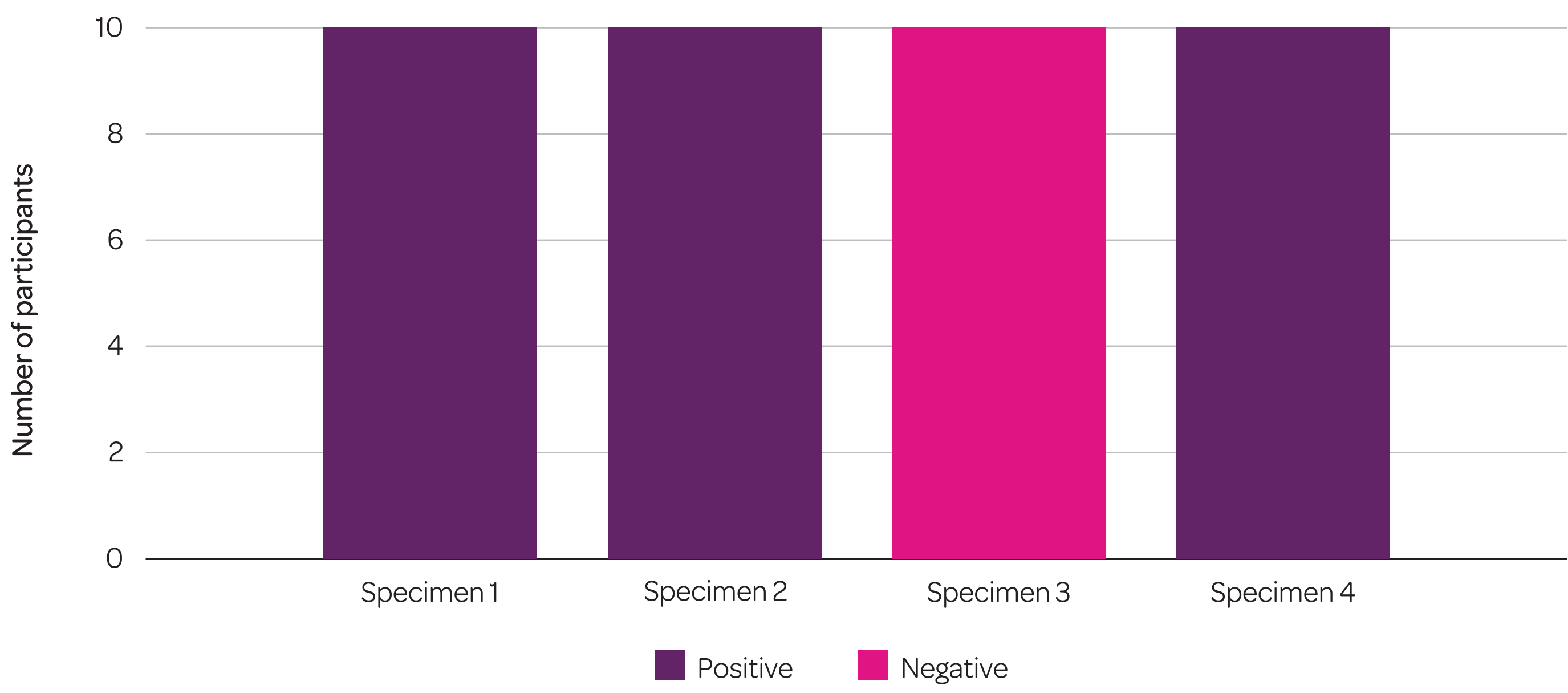
Participant	Manufacturer	Manufacturer's recommendation		Values reported	
		Units	Cut off	Units	Cut off
1	Bordier	Index	>1.0	S/CO	1
2	Bordier			S/CO	>1.1
3	Bordier			Index	>1.1
4	Bordier Affinity			Index	1.2
5	DRG	OD	0.2	OD	0.2
6	DRG			OD	0.2
7	DRG			OD	0.2
8	DRG			OD	0.2
9	DRG			OD	>0.4
10	In House	N/A	N/A	S/CO	>1.2

References

1. Page W, et al. The unique life cycle of *Strongyloides stercoralis* and implications for public health action. *Tropical medicine and infectious disease* 2018; 3,2: 53.
2. Einsiedel L, and Fernandes L. *Strongyloides stercoralis*: a cause of morbidity and mortality for indigenous people in Central Australia. *Internal Medicine Journal* 2008; 38,9: 697-703.

3. Qualitative results showed 100% consensus for the 3 positive and 1 negative Strongyloides IgG specimens (Figure 3).

Figure 3. Strongyloides IgG results.

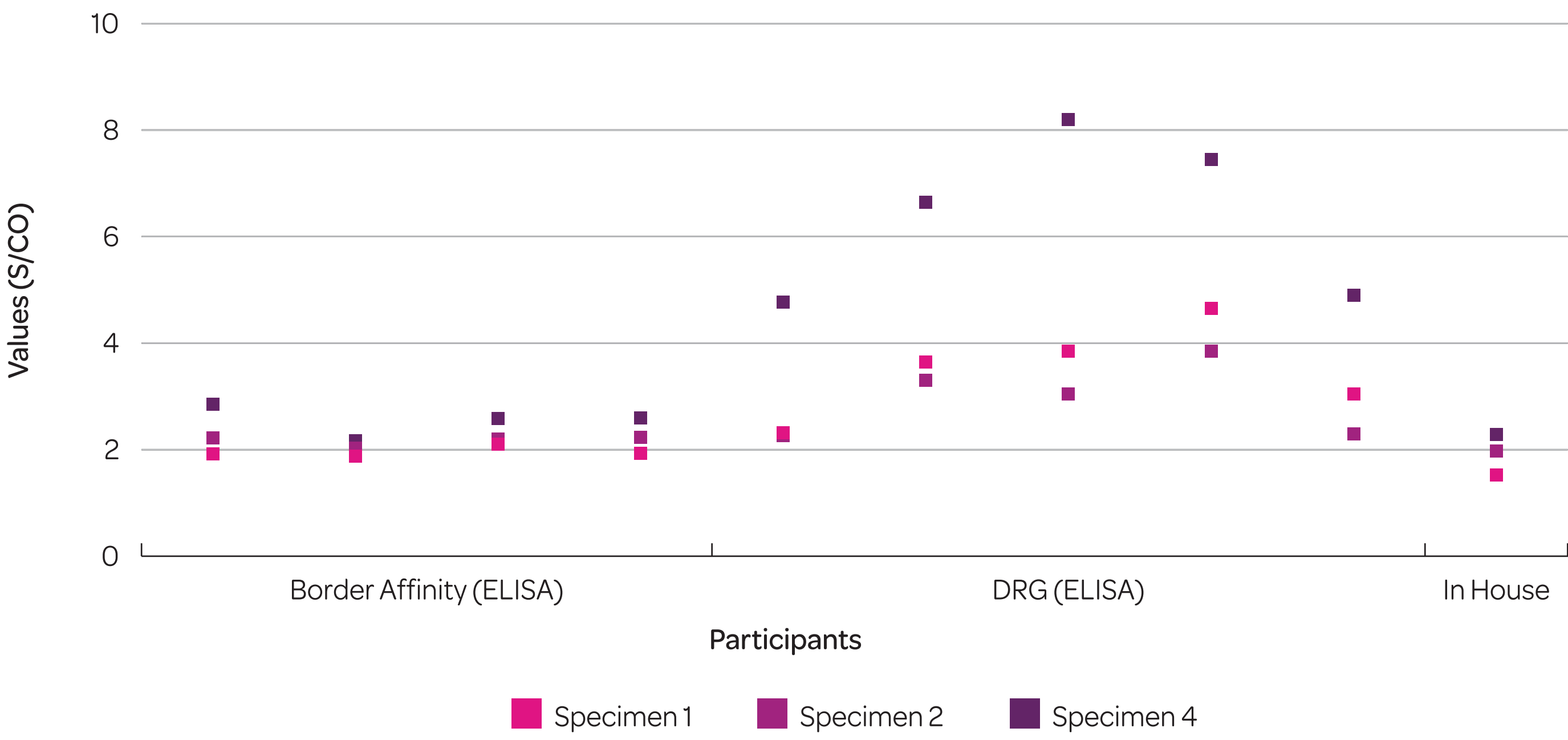


4. The robust CV is a coefficient of variation (CV%) which allows for the variability in different samples to be compared. The high CV values (Figure 4) and scatter pattern (Figure 5) highlight the level of variation between and within the method groups used. Specimen 4 and Specimen 1 showed high variation with the values reported ranging from 2.17–8.20 and 1.53–4.65 S/CO respectively. The high robust CV% for the positive specimens demonstrate increased variability for the highly positive samples.

Figure 4. Robust Statistics

	No. of results	Median	Minimum	Maximum	Range	Robust CV
Specimen 1	10	2.21	1.53	4.65	3.12	60%
Specimen 2	10	2.25	1.97	3.85	1.88	31%
Specimen 4	10	3.81	2.17	8.20	6.03	84%

Figure 5. Quantitative values for the positive specimens n=10.



Discussion

The results reflect a high concordance in qualitative reporting of Strongyloides IgG. However, analysis of the quantitative data showed a high variation in the reporting of Strongyloides IgG quantitative results. The introduction of an EQA program can assist laboratories in assessing the validity of the testing method, assay performance and quality of results by providing the opportunity to compare their results with their peers.

Further pilot studies with increased participant numbers, including international participants, will allow for more detailed data analysis of results and a requirement to report test interpretation would be of additional value as an educational tool for laboratories for the diagnosis of Strongyloidiasis.

Conclusion

Introduction of a Strongyloides EQA would enable ongoing review and improvement in the quality of results, particularly when reporting low level positive specimens with result values close to the clinical cut-off value for Strongyloidiasis.