

Evaluation of a commercial IgG monotest assay: a new automated chemiluminescent immunoassay for the serodiagnosis of cystic echinococcosis

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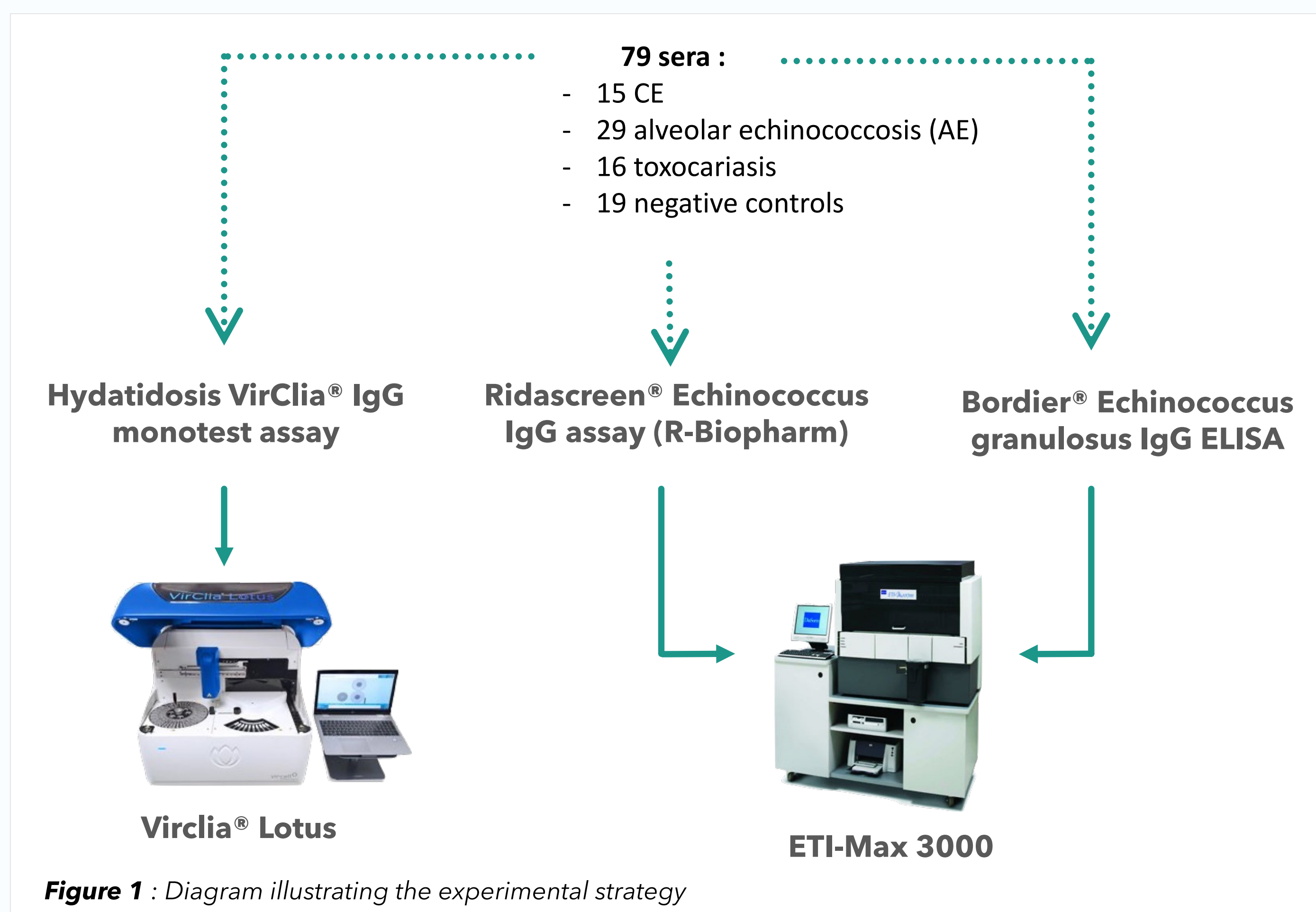
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1 Introduction

Cystic echinococcosis (CE) is a zoonotic disease caused by the tapeworm *Echinococcus granulosus complex*. The geographical distribution is worldwide with variable incidences. In Belgium, only few imported cases are reported each year (<10 cases). The diagnosis is based on a combination of several methods such as medical imaging, serology, histology and PCR. Serodiagnosis of CE is usually performed by using a combination of immunoassays which are mainly based on crude hydatid antigens. Any positive reaction should be confirmed by immunoblot which is more specific. The Belgian National Reference Laboratory, has evaluated the CE-IVD Hydatidosis VirClia® IgG chemiluminescent immunoassay and compared it with two other immunoassays for the serodiagnosis of CE.

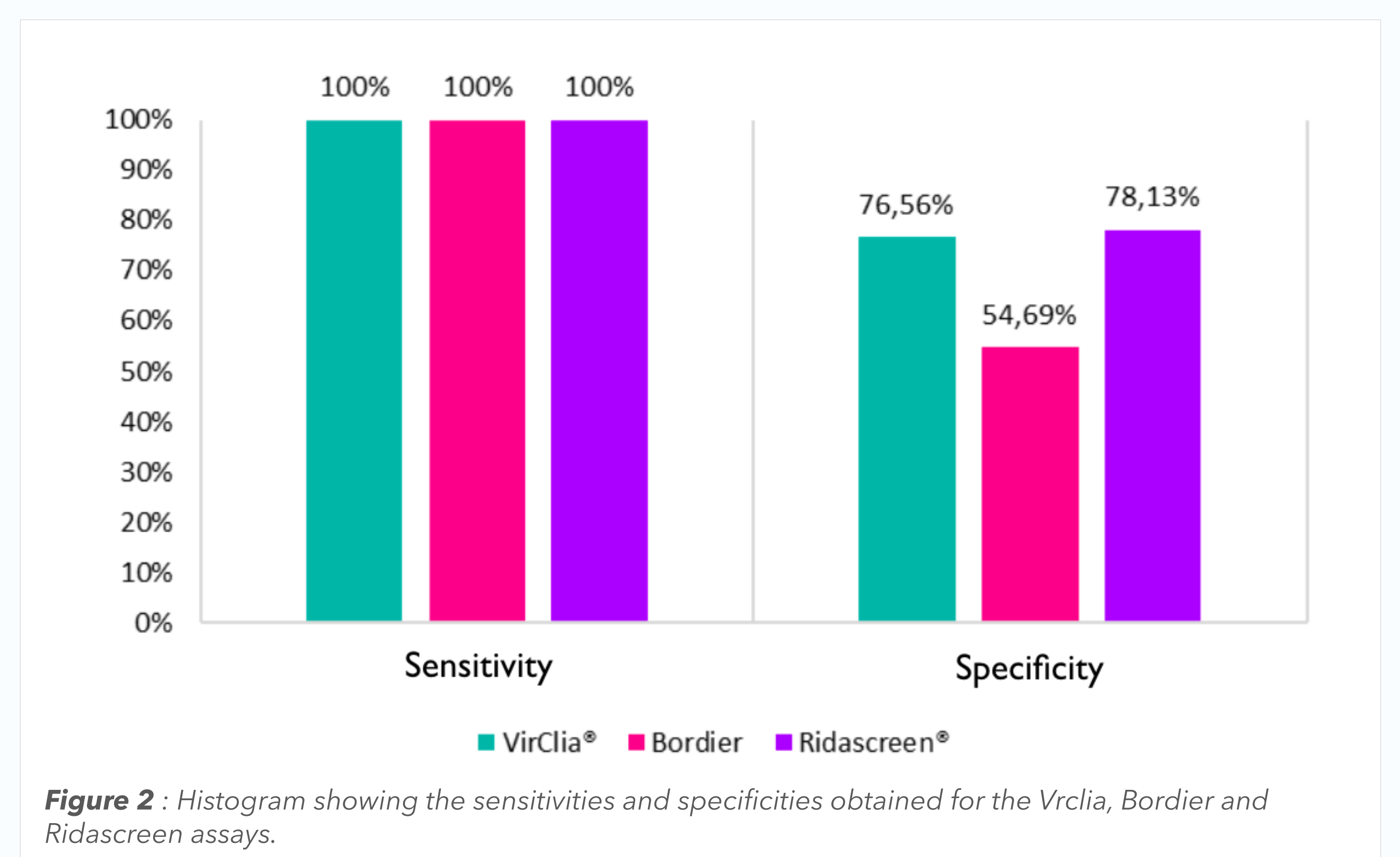
2 Methods

A total of **79 sera** were retrospectively included from 15 patients with CE, 29 with alveolar echinococcosis (caused by *Echinococcus multilocularis*), 16 with toxocarasis and 19 negative controls. Three immunoassays were compared: the **Hydatidosis VirClia® IgG monotest assay** which was run on the **Virclia® Lotus** (Vircell, Spain); the **Ridascreen® Echinococcus IgG assay** (R-Biopharm, Germany) and the **Bordier® Echinococcus granulosus IgG ELISA** (Bordier, Switzerland), which were tested on the **ETI-Max 3000 immunoassay analyzer** (DiaSorin, Italy). For each method tested, the sensitivity and specificity were determined and compared. The McNemar test is used for statistical analysis.



3 Results

All three methods showed **100% sensitivity**. Regarding specificity, the Ridascreen® (**78.1%**) and VirClia® (**76.6%**) assays showed comparable performance (p-value: 1), while the Bordier® assay had poor results (**54.7%**) (p-value: 0,0007). The Bordier® assay showed 76% cross-reactions with *E. multilocularis* (22/29) and 31% with *Toxocara sp.* (5/16), while the VirClia® assay showed 51,7% (15/29) and no cross-reaction with *Toxocara* antigens. For Ridascreen® assay, 34% and 19% cross-reactions were observed for *E. multilocularis* (10/29) and *Toxocara sp.* (3/16), respectively. Non-specific reactions in negative controls were only observed with the Ridascreen® (1/19) and Bordier® assays (2/19). The shortest turnaround time was observed with Virclia® Lotus: 1 hour versus 3 hours for two other assays.



4 Conclusions

- ❖ All assays showed 100% sensitivity.
- ❖ Regarding specificity, the VirClia® performs better than the Bordier® assay and similarly to the Ridascreen® assay.
- ❖ The ready-to-use monotest format of the Virclia assay offers many advantages such as a faster procedure and a reduced workflow.
- ❖ The VirClia® assay is an efficient screening method for the detection of CE but should always be combined with an immunoblot to confirm the specificity.

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