

Statement from IgeneX in Response to LDA's Comments in LDUK/LDA Q&As

We have had talks and are still talking with Public Health England. In fact we caught up at the LDA (Lyme Disease Association) meeting in Rhode Island in November and have also communicated since then. Originally we had planned to do a study between IGeneX and Public Health England. Now the study is going to even larger involving labs in US, including IGeneX, UK, Australia and Germany. The study organized is organized by the Australian government.

Regarding false positive results - our test specificity is about 92% for IgM Western Blot and about 95% for IgG Western Blot. Some patients with viral infections, autoimmune diseases, or other Borrelia infections can give false positive results. Also people living in endemic areas can have antibodies but may not have active disease. As part of quality control, we perform proficiency testing 5 times a year. for Lyme Western blots. We have not failed any proficiencies. The quality of our testing has held up to any challenges to-date.

Hope this helps.

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