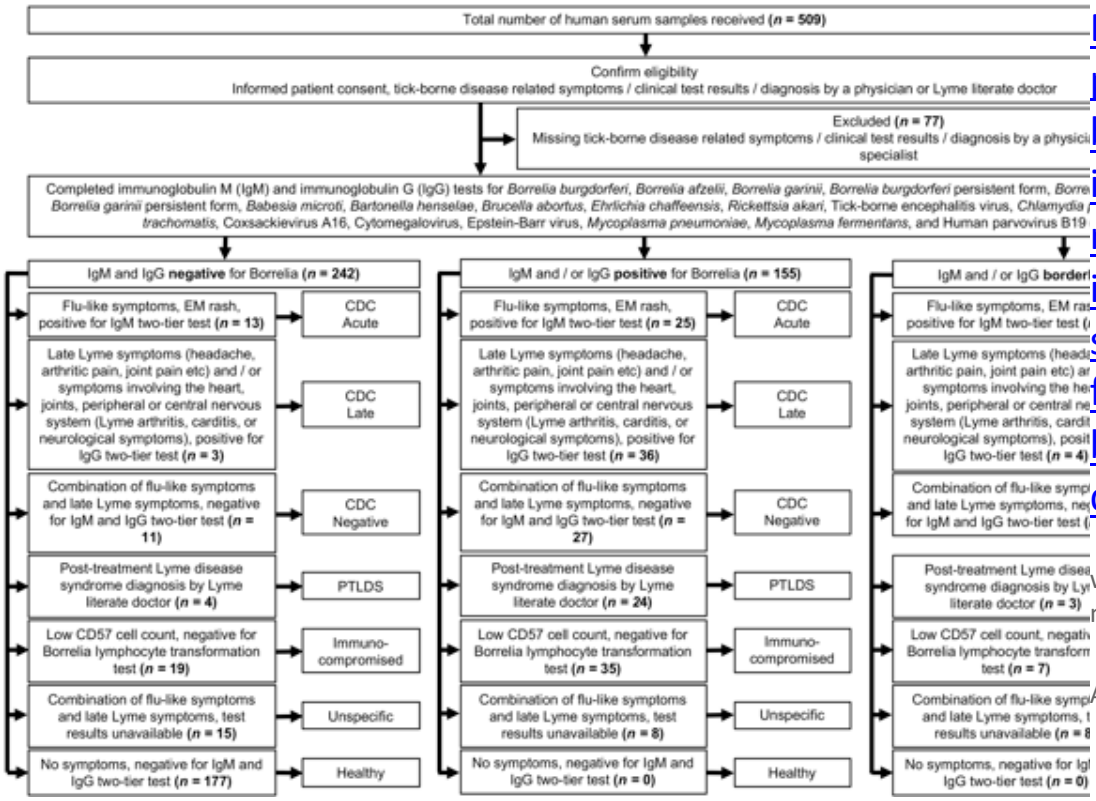
Tickplex Validation Process

Te?ted Oy is a university spin off company from research work conducted under Dr. Leona Gilbert, and Te?ted Oy is now manufacturing and selling to clinical laboratories TICKPLEX Products. Tickplex in itself was a research project at under Dr. Leona Gilbert's research team from July 2015 to Sept 2016 funded by the Finnish Funding Agency for Innovation, (Finnish Government) now called Business Finland. Within this project we have scientifically validated the test kit as reported in the peer reviewed in Nature's Scientific Reports paper found at this site https://www.nature.com/articles/s41598-018-34393-9



Evaluating polymicrobial immune responses in patients suffering from tick-borne diseases

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As soon as Te?ted Oy was established, TICKPLEX Products, (Basic and Plus test kits) underwent an additional scientific and clinical validation according to all appropriate laws; EU IVD Directive (In vitro diagnostic medical devices directive) 98/79/EC and the Finnish Medical Device Law Regarding Healthcare, Devices and Supplies 2010/629 that lead to its IVD CE conformity declaration. Our test kits also conformed as declared to the following relevant harmonized standards used of references to the other technical specifications in relation to which conformity is declared:

- SFS-EN ISO 14971 Medical devices. Application of risk management to medical devices.
- SFS-EN 13612n + AC Performance evaluation of in vitro diagnostic medical devices.
- SFS-EN ISO 23640 In vitro diagnostic medical devices. Evaluation of stability of in vitro medical reagents.
- SFS-EN ISO 18113-1 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: terms, definitions and general requirements.
- SFS-EN-ISO 18113-2. Part 1: terms, definitions and general requirements.
- SFS-EN 15223-1:2016 Medical devices. Symbols to be used with medical device label, labelling and information supplied. Part 1: General requirements.

These products are registered with the national regulatory authorities here in Finland as ascribed by the law. In addition, the national regulatory authority, Valvira, conducted a routine inspection and found that we are conducting business and manufacturing according to the laws. Te?ted Oy company even went further to provide credibility with its processes and manufacturing and was accredited ISO 13485:2016

qualification through an external auditor, Lloyd's Register LRQA. In order for any clinical lab to start selling our test kits, they have to independently validate the test kit as directed by the law, EU IVD Directive 98/79/EC. It is the law which means that this test kit has been independently validated. At the moment TICKPLEX Products have been validated independently in clinical laboratories that have expertise in diagnosing tick-borne diseases, in Germany, Poland, Netherlands, USA, Latvia, Spain, and Finland. All the best Te?ted Oy Team