Well-defined analytical test-criteria of serology of Borrelia burgdorferi sensu lato are indispensable for routine laboratory testing. They are also significant in the evaluation of the seropositivity of Borrelia burgdorferi antibodies and in upcoming efforts of standardization.

Analytical test-criteria can be subdivided into technical criteria such as precision and accuracy, linearity, detection limit, analytical sensitivity and selectivity criteria such as specificity, interference, cut and hierarchy of reference-methods.

### Technical Criteria

**Detection limit**
- The analytical sensitivity determines the resolution capability of a system.
- The detection limit defines the lowest detectable amount of an analyte.
- Two methods are used: 3-fold standard-deviation of the blank value or the 5% overlay of blank value and the standard value. The blank value contains matrix or buffer.
- **Recrystallized, Lazio**
  - 35 clinically characterized sera and 204 unselected sera

**Reference-method: Diagnostic sensitivity**
- Sensitivity-defined 0.05% (95/100) without underlying analytical evaluation. According to the German standard (SN 4715-1:2000), the name of the selected reference-method is marked as “IEEE-ELISA (GriB)”. Relative sensitivity: ELISA + biot-comparison 0.05/46% Relative specificity: ELISA + biot-comparison 0.35/48%.

### Methodical Criteria

**Selectivity (analytical specificity)**
- Allows to detect only the designated analyte.
- Interferences are interactions, e.g. cross-reactivity or matrix effects.

**Evaluation by a diagnostic method:**
- The cut is the determining analytical criterion and the indicator for reactivity or non-reactivity of the sample. There is no rule for its preparation. In most cases it is estimated by the clinical picture or the approximated seropositivity of post-tested sera.
- When post-tested sera belong to the cut, the result will provide information on antibody levels in the sample in comparison with antibody levels in averaged post-tested sera.

### Diagnostic Criteria

**Clinical study German NRC:**
- Data acquisition and comparison with PCR- and culture-positive samples are performed. The clinical study is performed at the Institute of Clinical Microbiology, University of Würzburg.
- **Borrelia burgdorferi ELISA**
  - Borrelia burgdorferi ELISA
  - 105 sera

### Summary: Specifications of the manufacturers to analytical criteria

**Diagnostic sensitivity and diagnostic specificity**

- **Diagnostic specificity:**
  - Probability to get positive reaction of sick persons’ sera.

- **Diagnostic sensitivity:**
  - Probability to get a negative reaction of healthy persons’ sera.

- **Positive predictive value:**
  - Probability, that a reactive test-result detects a sick person.

- **Negative predictive value:**
  - Probability, that a negative test-result is obtained from a healthy person.

**Specifications of the manufacturers:**
- **Diagnostic sensitivity:**
  - E-manufacturers prove their tests on clinical defined sera, 8 manufacturers take “comparison samples”, 2 x sero logical controls, 3 x percentage data, 2 x raw data.

### Conclusions

**A well defined detection limit is necessary for detection of Borrelia burgdorferi antibodies as well as the disclosure of reference / comparative methods with their restrictions. Subsequently conclusions can be made about clinical aspects such as sensitivity, specificity and predictive value.**

Data acquisition and comparison with PCR and culture-positive samples are indispensable for this purpose. Making the cut by estimation of the seronegativity of blood donors or other comparative methods is not evidence-based. Analytical test-criteria should rank before diagnostic conclusions.

It does not surprise, that there are so few data about sensitivity and specificity of ... of tests. Tests for gaining them are high in comparison to the benefit. Despite of this there should be certain as much data as possible in order to judge about evidence-based measures.

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