

**PCR-/NAT *Borrelia burgdorferi*
 (RV 535) Mai 2022**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

| | <i>Erwartet / expected</i> | | <i>Probenzusammensetzung / Sample composition</i> |
|---------|----------------------------|----|--|
| 2215351 | +++ | 61 | <i>Borrelia bavariensis</i> (~ 5x10 ⁵ organisms/mL) |
| 2215352 | ∅ | 62 | <i>Escherichia coli</i> K12 |
| 2215353 | +++ | 61 | <i>Borrelia afzelii</i> (~ 1x10 ⁵ organisms/mL) |
| 2215354 | ∅ | 62 | <i>Borrelia hispanica</i> (~ 5x10 ⁵ organisms/mL) |

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

| <i>n = 118</i> | Probennummer (Sample no.) | | | | | Inhibition | | | |
|--|----------------------------------|---------|---------|---------|-------------------|-------------------|---------|---------|---------|
| | 2215351 | 2215352 | 2215353 | 2215354 | | 2215351 | 2215352 | 2215353 | 2215354 |
| Befund <i>Result</i> | | | | | | | | | |
| Positiv | 116 | 3 | 117 | 19 | n.d. | 2 | 2 | 2 | 2 |
| Negativ | 2 | 115 | 1 | 97 | nein <i>no</i> | 116 | 116 | 116 | 115 |
| Fraglich <i>Questionable</i> | 0 | 0 | 0 | 2 | ja <i>yes</i> | 0 | 0 | 0 | 1 |

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

| NAT-Methode [Code] (total number *) | NAT richtig positiv <i>True positive results</i> | | | | NAT richtig negativ <i>True negative results</i> | | | |
|---|--|-----|----------------------------|-----|--|-----|----------------------------|-----|
| | 2215351 | | 2215353 | | 2215352 | | 2215354 | |
| | Absolut <i>Absolute</i> | % | Absolut <i>Absolute</i> | % | Absolut <i>Absolute</i> | % | Absolut <i>Absolute</i> | % |
| AID RDB 2225 Zecken-Screening (n = 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| Attomol B burgdorferi Realtime LT (n = 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| BIORON RealLine B.burgdorferi (n = 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| HAIN FluoroType Borrelia (n = 7) | 7 | 100 | 7 | 100 | 7 | 100 | 0 | 0 |
| EliGene Borrelia RT (n = 3) | 3 | 100 | 3 | 100 | 3 | 100 | 0 | 0 |

| | | | | | | | | |
|--|-----------|------------|-----------|------------|-----------|------------|------------|------------|
| GeneProof B. burgdorferi (n = 27) | 25 | 93 | 26 | 96 | 26 | 96 | 25* | 93 |
| Gerbion diarella Borrelia (n = 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| Immundiagnostik MutaPLEX (n = 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| Ingenetix BactoReal B.burgdorferi (n = 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| Mikrogen alphaCube Borrelia (n = 16) | 16 | 100 | 16 | 100 | 16 | 100 | 16 | 100 |
| Sacace TBEV, B.burg,... Real-TM (n = 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| LightMix Borrelia (n = 6) | 6 | 100 | 6 | 100 | 6 | 100 | 5 | 83 |
| In house PCR assay (n = 35) | 35 | 100 | 35 | 100 | 33 | 94 | 31 | 89 |
| Other commercial tests (n = 7) | 7 | 100 | 7 | 100 | 7 | 100 | 3 | 43 |

* Inhibition

Comments:

1. Unter "Andere kommerzielle Testsysteme" sind folgende Testsysteme aufgeführt: Master diagnostica Tick-borne bacterial flow chip (1x), Sacace Biotechnologies Borrelia burgdorferi Real-TM (1x), RealBest DNA Borrelia burgdorferi s.l. (Set 1) (1x), Novaplex Tick-borne (EU) Assay (RUO) (1x), CerTest VIASURE C. pneumonia, M. pneumonia and L. pneumophila Real Time PCR Detection Kit -CML172- (1x), DNA-TECHNOLOGY B. burgdorferi Real Time PCR Kit (1x) und AMPLICON AmpliTect B. burgdorferi (Real Time PCR) (1x).