

**PCR-/NAT *Borrelia burgdorferi*
 (RV 535) November 2011**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1125351	∅	62	<i>Leptospira interrogans</i> (~ 1x10 ⁵ organisms/mL)
1125352	++	61	<i>Borrelia garinii</i> , OspA Typ3, PBr (~1x10 ⁴ organisms/mL)
1125353	++	61	<i>Borrelia valaisiana</i> (~ 1x10 ⁴ organisms/mL)
1125354	+++	61	<i>Borrelia lusitaniae</i> (~ 1x10 ⁵ organisms/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n = 107</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1125351	1125352	1125353	1125354		1125351	1125352	1125353	1125354
Befund <i>Result</i>									
Positiv	1	102	100	84	n.d.	3	3	3	3
Negativ	106	5	5	19 ¹⁾	nein <i>no</i>	104	104	104	102
Fraglich <i>Questionable</i>	0	0	2	4	ja <i>yes</i>	0	0	0	2

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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
artus <i>Borrelia</i> LC kit [20] (n = 19)	57	57 / 57	100	19	19 / 19	100
Demeditec GenFlow [21] (n = 10)	28	28 / 30	93	10	10 / 10	100
Other/commercial tests [27] (n = 19)	50	50 / 57	88	19	19 / 19	100
<i>In house</i> PCR assay [28] (n = 58)	151	151 / 168 [§]	90	57	57 / 58	98
Andere / k.A. / other [29] (n = 2)	2	2 / 6	33	2	2 / 2	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

§ Due to reporting questionable results, the number of true results (denominator in the "relative" column) have been reduced.

Comments: ¹⁾ Negative PCR results with sample # 1125354 were not rated as false-negative in the course of issuing the corresponding QC certificates.