

PCR-/NAT Urogenital Panel (RV 547) Mai 2021



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
2115471	+++	<i>Gardnerella vaginalis</i> (~ 1x10 ⁵ CFU/mL)
2115472	++	<i>Ureaplasma parvum</i> (~ 5x10 ³ CFU/mL)
2115473	∅	<i>Chlamydia trachomatis</i> (~ 1x10 ⁴ IFU/mL)
2115474	+++	<i>Mycoplasma genitalium</i> (~ 5x10 ⁴ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Mycoplasma genitalium* dargestellt.

Absolute numbers of reported individual results.

*Note: only the **M.genitalium-specific results** are depicted in this table*

<i>n = 97</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>2115471</i>	<i>2115472</i>	<i>2115473</i>	<i>2115474</i>		<i>2115471</i>	<i>2115472</i>	<i>2115473</i>	<i>2115474</i>
Befund <i>Result</i>									
Positiv	1	0	1	92	n.d.	0	0	0	0
Negativ	96	97	96	5	nein <i>no</i>	97	97	97	97
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Mycoplasma genitalium* dargestellt.

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

*Note: only the **M.genitalium -specific results** are depicted in this table.*

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	2115474		2115471		2115472		2115473	
	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>
BioGX Mycopl. / Ureapl. (n = 5)	4	80	5	100	5	100	5	100
EUROIMMUN EUROArray STI-11 (n = 4)	4	100	4	100	4	100	4	100
Mikrogen ampliCube STD Panel1(n=10)	10	100	10	100	10	100	10	100
Roche COBAS TV / MG (n = 3)	3	100	3	100	3	100	3	100

Seegene Allplex STI Essential (n = 26)	26	100	25	96	26	100	26	100
Seegene Anyplex STI-5 Detection (n= 3)	3	100	3	100	3	100	3	100
LightMix modular M.genitalium (n =5)	5	100	5	100	5	100	5	100
RIDAGENE STI Myc. Panel (n = 9)	8	89	9	100	9	100	9	100
Other commercial tests (n = 20)	17	85	20	100	20	100	19	95
In house PCR assay [28] (n = 12)	12	100	12	100	12	100	12	100

Tabelle 4: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Gardnerella vaginalis* dargestellt.

Absolute numbers of reported individual results.

Note: only the *G.vaginalis*-specific results are depicted in this table

n = 21	Probennummer (Sample no.)					Inhibition			
	2115471	2115472	2115473	2115474		2115471	2115472	2115473	2115474
Befund Result									
Positiv	20	0	0	1	n.d.	0	0	0	0
Negativ	1	21	21	20	nein no	21	21	21	21
Fraglich Questionable	0	0	0	0	ja yes	0	0	0	0

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Gardnerella vaginalis* dargestellt.

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

Note: only the *G.vaginalis* -specific results are depicted in this table.

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ True negative results					
	2115471		2115472		2115473		2115474	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID GenID STI (n = 1)	1	100	1	100	1	100	1	100
BIORON RealLine G.vaginalis (n = 1)	1	100	1	100	1	100	1	100
Seegene Allplex Bact. Vaginosis plus (n = 6)	6	100	6	100	6	100	6	100
Other commercial tests (n = 5)	4	80	5	100	5	100	4	80
In house PCR assay [28] (n = 8)	8	100	8	100	8	100	8	100

Tabelle 6: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Ureaplasma parvum* dargestellt.

Absolute numbers of reported individual results.

Note: only the *U.parvum* -specific results are depicted in this table

<i>n</i> = 61	Probennummer (Sample no.)					Inhibition			
	2115471	2115472	2115473	2115474		2115471	2115472	2115473	2115474
Befund <i>Result</i>									
Positiv	1	60	0	0	n.d.	0	0	0	0
Negativ	60	1	61	61	nein <i>no</i>	61	61	61	61
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 7: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Ureaplasma parvum* dargestellt.

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

Note: only the *U.parvum* -specific results are depicted in this table.

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	2125472		2125471		2125473		2125474	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
BioGX Mycopl. / Ureapl. (n = 5)	5	100	5	100	5	100	5	100
EUROIMMUN EUROArray STI-11 (n = 4)	4	100	4	100	4	100	4	100
Seegene Allplex STI Essential (n = 26)	26	100	26	100	26	100	26	100
Seegene Anyplex STI-7 Detection (n= 2)	2	100	2	100	2	100	2	100
Seegene Anyplex STI-5 Detection (n= 3)	3	100	3	100	3	100	3	100
LightMix modular UU/UP (n =2)	2	100	2	100	2	100	2	100
Other commercial tests (n = 11)	10	91	10	91	11	100	11	100
<i>In house</i> PCR assay [28] (n = 8)	8	100	8	100	8	100	8	100

- Comments:**
- ¹⁾ *Mycoplasma hominis*-detection was performed by 89 laboratories. With the exception of 3 laboratories, with false positive results, all reported results were correct.
 - ²⁾ *Ureaplasma urealyticum*-detection was performed by 70 laboratories. With the exception of 1 laboratory, with 1 false positive result, all reported results were correct. 6 of them reported a positive result for sample # 2115472, containing *U. parvum*. This shows that the applied tests can not differentiate between the two different species.
 - ³⁾ *Trichomonas vaginalis*-detection was performed by 80 laboratories. With the exception of 2 laboratories, with false positive results, all reported results were correct.
 - ⁴⁾ *Treponema pallidum*-detection was performed by 41 laboratories. With the exception of 1 laboratory, with one false positive result, all reported results were correct.