

**PCR-/NAT Urogenital Panel
 (RV 547) November 2021**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
2125471	++ / ++	<i>Ureaplasma parvum</i> (~ 5x10 ³ CFU/mL) <i>Mycoplasma genitalium</i> (~ 1x10 ⁴ CFU/mL)
2125472	∅	<i>Escherichia coli</i> K12
2125473	++	<i>Gardnerella vaginalis</i> (~ 1x10 ⁴ CFU/mL)
2125474	++	<i>Trichomonas vaginalis</i> (~ 1x10 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*

n = 93	Probennummer (Sample no.)				Inhibition				
Befund Result	2125471	2125472	2125473	2125474		2125471	2125472	2125473	2125474
Positiv	90	0	0	0	n.d.	0	0	0	0
Negativ	3	93	93	93	nein no	93	93	93	93
Fraglich Questionable	0	0	0	0	ja yes	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden 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 True negative results					
	2125471		2125472		2125473		2125474	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID GenID STI (n = 1)	1	100	1	100	1	100	1	100
Amplex eazyplex STD complete (n = 2)	2	100	2	100	2	100	2	100
AmpliGnost M. genitalium (n = 1)	1	100	1	100	1	100	1	100

BIORON RealLine M.hom/M.gen (n = 1)	1	100	1	100	1	100	1	100
BioGX Mycopl. / Ureapl. (n = 5)	5	100	5	100	5	100	5	100
HAIN FluoroType STI (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n = 3)	3	100	3	100	3	100	3	100
ampliCube STD Panel 1 (n = 10)	10	100	10	100	10	100	10	100
Roche COBAS TV / MG (n = 4)	4	100	4	100	4	100	4	100
Seegene Allplex STI Essential (n = 25)	25	100	25	100	25	100	25	100
Seegene Anyplex II STI-7 (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 M.genitalium (n =6)	6	100	6	100	6	100	6	100
RIDAGENE STI Myc. Panel (n = 8)	5	63	8	100	8	100	8	100
In house PCR assay [28] (n = 8)	8	100	8	100	8	100	8	100
Other commercial tests (n = 13)	13	100	13	100	13	100	13	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			
	2125471	2125472	2125473	2125474		2125471	2125472	2125473	2125474
Befund Result									
Positiv	0	1	20	0	n.d.	0	0	0	0
Negativ	21	20	1	21	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					
	2125473		2125471		2125472		2125474	
	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

Allplex Bact. Vaginosis plus (n = 8)	8	100	8	100	8	100	8	100
In house PCR assay [28] (n = 8)	8	100	8	100	8	100	8	100
Other commercial tests (n = 3)	2	67	3	100	2	67	3	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

n = 62	Probennummer (Sample no.)					Inhibition			
	2125471	2125472	2125473	2125474		2125471	2125472	2125473	2125474
Befund Result									
Positiv	61	0	0	0	n.d.	1	1	1	1
Negativ	1	62	62	62	nein no	61	61	61	61
Fraglich Questionable	0	0	0	0	ja yes	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 True negative results					
	2125471		2125472		2125473		2125474	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AmpliGnost U.ureal/ U.parv. (n = 1)	1	100	1	100	1	100	1	100
BioGX Mycopl. / Ureapl. (n = 5)	5	100	5	100	5	100	5	100
HAIN FluoroType STI (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n = 3)	3	100	3	100	3	100	3	100
Seegene Allplex STI Essential (n = 25)	25	100	25	100	25	100	25	100
Seegene Anyplex II STI-7 (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 U. parvum (n =2)	2	100	2	100	2	100	2	100
RIDAGENE STI Myc. Panel (n = 1)	1	100	1	100	1	100	1	100
In house PCR assay [28] (n = 7)	7	100	7	100	7	100	7	100
Other commercial tests (n = 12)	11	92	12	100	12	100	12	100

Tabelle 8: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Trichomonas vaginalis* dargestellt.

Absolute numbers of reported individual results.

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

n = 76	Probennummer (Sample no.)					Inhibition			
	2125471	2125472	2125473	2125474		2125471	2125472	2125473	2125474
Befund <i>Result</i>									
Positiv	0	0	0	76	n.d.	0	0	0	0
Negativ	76	76	76	0	nein <i>no</i>	76	76	76	76
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 9: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Trichomonas vaginalis* dargestellt.

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	2125474		2125471		2125472		2125473	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
BIORON RealLine T. vaginalis (n = 2)	2	100	2	100	2	100	2	100
HAIN FluoroType STI (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n = 3)	3	100	3	100	3	100	3	100
ampliCube STD Panel 2 (n = 9)	9	100	9	100	9	100	9	100
Roche COBAS TV / MG (n = 4)	4	100	4	100	4	100	4	100
Seegene Allplex STI Essential (n = 25)	25	100	25	100	25	100	25	100
Seegene Anyplex STI-7 (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 T. vaginalis (n = 3)	3	100	3	100	3	100	3	100
RIDAGENE T. vaginalis (n = 2)	2	100	2	100	2	100	2	100
In house PCR assay [28] (n = 8)	8	100	8	100	8	100	8	100
Other commercial tests (n = 14)	14	100	14	100	14	100	14	100

Comments: ¹⁾ *Mycoplasma hominis* detection was performed by 83 laboratories. With the exception of 1 laboratory, with a false positive result, all reported results were correct.

²⁾ *Ureaplasma urealyticum* detection was performed by 62 laboratories. With the exception of 3 laboratories, all reported results were correct. One of them reported a positive result for sample #

2125471, containing *U. parvum*. This shows that the applied tests can not differentiate between the two different species.

⁴⁾ *Treponema pallidum* detection was performed by 36 laboratories. With the exception of one laboratory with one false positive result, all reported results were correct.

Unter "**Andere kommerzielle Testsysteme**" wurden diesmal folgende Testsysteme aufgeführt: Abbott Alinity m STI Assay (3x), VIASURE STD Kit (2x), AmpliSens *U. parvum*/*U. urealyticum* FRT PCR kit (1x), AB Analytica Realquality *U. parvum* (1x), AID GenID STI (1x), AID RDW 2110 STD (1x), AmpliGnost STI Urethritis (1x), AusDiagnostics Urinogenital 8-well (1x), DNA-TECHNOLOGY *M. genitalium* Real Time PCR Kit (1x), BD Max CT/GV/TV Panel (3x), BD Max Vaginal Panel (1x), GeneProof *M. genitalium/hominis* PCR Kit (2x), GeneProof Ureaplasma (2x), GeneProof MH/UU/UP Multiplex (1x), GeneProof *T. vaginalis* (1x), Seegene Allplex Genital ulcer (1x), Mikrogen ampliCube STD Panel 3 (1x), TIB Molbiol LightMix modular *T. pallidum* (1x) und PANAGENE PANA RealTyper (1x).