

**PCR-/NAT Urogenital Panel  
 (RV 547) November 2022**



**Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.**

*Sample composition and expected results.*

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
2225471	<b>+ / +++</b>	<b><i>Ureaplasma urealyticum</i> (~ 5x10<sup>3</sup> CFU/mL)</b> <b><i>Mycoplasma hominis</i> (~ 5x10<sup>5</sup> CFU/mL)</b>
2225472	<b>++</b>	<b><i>Trichomonas vaginalis</i> (~ 1x10<sup>4</sup> CFU/mL)</b>
2225473	<b>∅</b>	<b><i>Escherichia coli</i> K12</b>
2225474	<b>+++</b>	<b><i>Gardnerella vaginalis</i> (~ 1x10<sup>6</sup> CFU/mL)</b>

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

*Absolute numbers of reported individual results.*

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

<i>n = 108</i>	<b>Probennummer (Sample no.)</b>					<b>Inhibition</b>			
	<b>2225471</b>	<b>2225472</b>	<b>2225473</b>	<b>2225474</b>		<b>2225471</b>	<b>2225472</b>	<b>2225473</b>	<b>2225474</b>
<b>Befund Result</b>									
<b>Positiv</b>	<b>108</b>	<b>1</b>	<b>2</b>	<b>1</b>	n.d.	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Negativ</b>	<b>0</b>	<b>107</b>	<b>106</b>	<b>107</b>	nein no	<b>108</b>	<b>108</b>	<b>108</b>	<b>108</b>
<b>Fraglich Questionable</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	ja yes	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

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

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

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

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b>		<b>NAT richtig negativ</b> <i>True negative results</i>					
	<b>2225471</b>		<b>2225472</b>		<b>2225473</b>		<b>2225474</b>	
	<b>Absolut Absolute</b>	<b>%</b>	<b>Absolut Absolute</b>	<b>%</b>	<b>Absolut Absolute</b>	<b>%</b>	<b>Absolut Absolute</b>	<b>%</b>
<b>AID GenID STI (n = 1)</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>
<b>Amplex eazyplex STD complete (n = 2)</b>	<b>2</b>	<b>100</b>	<b>2</b>	<b>100</b>	<b>2</b>	<b>100</b>	<b>2</b>	<b>100</b>
<b>AmpliGnost M.hominis (n = 1)</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>
<b>BIORON RealLine M.hom/M.gen (n = 2)</b>	<b>2</b>	<b>100</b>	<b>2</b>	<b>100</b>	<b>2</b>	<b>100</b>	<b>2</b>	<b>100</b>

BioGX Mycopl. / Ureapl. (n = 5)	5	100	5	100	5	100	5	100
HAIN FluoroType STI (n = 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI-11 (n = 5)	5	100	5	100	5	100	5	100
ampliCube STD Panel 2 (n = 7)	7	100	7	100	6	86	7	100
Seegene Allplex STI Essential (n = 39)	39	100	39	100	39	100	39	100
Seegene Anyplex II STI-7 (n = 4)	4	100	4	100	4	100	4	100
Seegene Anyplex STI-5 Detection (n= 2)	2	100	2	100	2	100	2	100
LightMix modular M.hominis (n = 5)	5	100	5	100	5	100	5	100
Aprimeo Vivalytic STI (n = 1)	1	100	1	100	1	100	1	100
RIDAGENE STI Myc. Panel (n = 7)	7	100	7	100	7	100	7	100
In house PCR assay [28] (n = 7)	7	100	7	100	7	100	7	100
Other commercial tests (n = 18)	18	100	17	94	17	94	17	94

**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 = 26	Probennummer (Sample no.)					Inhibition			
	2225471	2225472	2225473	2225474		2225471	2225472	2225473	2225474
<b>Befund</b> Result									
<b>Positiv</b>	1	0	1	26	n.d.	0	0	0	0
<b>Negativ</b>	25	26	25	0	nein no	26	26	26	26
<b>Fraglich</b> 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					
	2225474		2225471		2225472		2225473	
	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
GeneProof G.vaginalis PCR Kit (n = 2)	2	100	2	100	2	100	1	50

Allplex Bact. Vaginosis plus (n = 11)	11	100	10	91	11	100	11	100
In house PCR assay [28] (n = 7)	7	100	7	100	7	100	7	100
Other commercial tests (n = 4)	4	100	4	100	4	100	4	100

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

Absolute numbers of reported individual results.

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

n = 96	Probennummer (Sample no.)					Inhibition			
	2225471	2225472	2225473	2225474		2225471	2225472	2225473	2225474
Befund Result									
Positiv	84	0	1	0	n.d.	0	0	0	0
Negativ	12	96	95	96	nein no	96	96	96	96
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 urealyticum* dargestellt.

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ True negative results					
	2225471		2225472		2225473		2225474	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
Amplex eazyplex STD complete (n = 1)	0	0	1	100	1	100	1	100
AmpliGnost U.ureal/ U.parv. (n = 1)	1	100	1	100	1	100	1	100
BIORON RealLine U.ur./ U. pa. (n = 2)	2	100	2	100	1	100	1	100
BioGX Mycopl. / Ureapl. (n = 5)	4	80	5	100	5	100	5	100
HAIN FluoroType STI (n = 2)	1	50	2	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n = 5)	5	100	5	100	6	100	6	100
Seegene Allplex STI Essential (n = 40)	37	93	40	100	38	100	38	100
Seegene Anyplex II STI-7 (n = 4)	4	100	4	100	4	100	4	100
Seegene Anyplex STI-5 Detection (n = 2)	2	100	2	100	4	100	4	100
LightMix modular U. ur / U. pa. (n = 4)	3	75	4	100	5	100	5	100
Aprimeo Vivalytic STI (n = 1)	1	100	1	100	7	100	7	100

<i>In house</i> PCR assay [28] (n = 6)	5	83	6	100	7	100	7	100
Other commercial tests (n = 23)	19	83	23	100	22	96	14	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 = 100	Probennummer (Sample no.)					Inhibition			
	2225471	2225472	2225473	2225474		2225471	2225472	2225473	2225474
Befund Result									
Positiv	0	97	0	1	n.d.	0	0	0	0
Negativ	100	3	100	99	nein no	100	100	100	100
Fraglich Questionable	0	0	0	0	ja yes	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 True negative results					
	2225472		2225471		2225473		2225474	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
BIORON RealLine T. vaginalis (n = 3)	3	100	3	100	3	100	3	100
HAIN FluoroType STI (n = 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI-11 (n = 5)	5	100	5	100	5	100	5	100
ampliCube STD Panel 2 (n = 7)	7	100	7	100	7	100	7	100
Roche COBAS TV / MG (n = 4)	4	100	4	100	4	100	4	100
Seegene Allplex STI Essential (n = 40)	40	100	40	100	40	100	40	100
Seegene Anyplex STI-7 (n = 3)	3	100	3	100	3	100	3	100
Seegene Anyplex STI-5 Detection (n = 2)	2	100	2	100	2	100	2	100
LightMix modular T. vaginalis (n = 3)	3	100	3	100	3	100	2	67
Aprimeo Vivalytic STI (n = 1)	0	0	1	100	1	100	1	100
<i>In house</i> PCR assay [28] (n = 8)	8	100	8	100	8	100	8	100
Other commercial tests (n = 22)	20	91	22	100	22	100	22	100

**Comments:**

1. *Mycoplasma genitalium*-detection was performed by 113 laboratories. All reported results were correct.
2. *Ureaplasma parvum*-detection was performed by 90 laboratories. With the exception of 2 laboratories, all reported results were correct.
3. Only *Ureaplasma* spp. detection was performed by 13 laboratories. With the exception of 2 laboratories, all reported results were correct.
4. *Treponema pallidum*-detection was performed by 50 laboratories. All reported results were correct.
5. Unter "Andere kommerzielle Testsysteme" sind folgende Testsysteme aufgeführt: Abbott Alinity m STI Assay (3x), AID GenID STI (1x), AmpliSens Ureaplasma spp. FRT PCR kit (1x), AmpliGnost STI Urethritis (2x), AusDiagnostics Urinogenital and Resistance 12-well (1x), BD Max CT/GC/TV Panel (2x), BD Max (1x), CerTest VIASURE STD Real Time PCR Detection Kit (3x), Immundiagnostik MutaPLEX STI-2 (2x), Immundiagnostik MutaPLEX STI-1 (2x), Immundiagnostik MutaPLEX BV-1 (1x), Immundiagnostik MutaPLEX U. urealyticum / U. parvum (2x), Immundiagnostik MutaPLEX T. pallidum (2x), MIKROGEN ampliCube STD Panel 2.1 (7x), MIKROGEN ampliCube STD Panel 2.1 LC (2x), GeneProof M. genitalium/hominis PCR Kit (3x), GeneProof Ureaplasma (UUP) PCR Kit (4x), GeneProof T. vaginalis (1x), GeneProof T. pallidum PCR Kit (3x), Gerbion diarellaSTI-1 (1x), Gerbion diarellaSTI-2 (1x), Gerbion diarellaBV-1 (1x), Sacace Biotechnologies U. parvum / U. urealyticum Real TM (1x), Sacace Biotechnologies M. hominis Real TM (1x), Seegene Allplex CT/NG/MG/TV Assay (1x) und PANAGENE PANA RealTyper (1x).