

## PCR-/NAT Urogenital Panel (RV 547) Mai 2020



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

*Sample composition and expected results.*

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
2015471	+++	<i>Gardnerella vaginalis</i> (~ 1x10 <sup>5</sup> CFU/mL)
2015472	++	<i>Ureaplasma parvum</i> (~ 5x10 <sup>3</sup> CFU/mL)
2015473	++	<i>Trichomonas vaginalis</i> (~ 5x10 <sup>4</sup> CFU/mL)
2015474	+++	<i>Mycoplasma genitalium</i> (~ 1x10 <sup>5</sup> 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 = 88</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	<i>2015471</i>	<i>2015472</i>	<i>2015473</i>	<i>2015474</i>	<i>2015471</i>	<i>2015472</i>	<i>2015473</i>	<i>2015474</i>	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	0	0	0	87	n.d.	0	0	0	0
<b>Negativ</b>	88	88	88	1	nein <i>no</i>	88	88	88	88
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b>		<b>NAT richtig negativ</b> <i>True negative results</i>					
	<b>2015474</b>		<b>2015471</b>		<b>2015472</b>		<b>2015473</b>	
	<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>
AmpliGnost <i>M. genitalium</i> (n = 2)	2	100	2	100	2	100	2	100
BIORON RealLine <i>M.hom/genitai.</i> (n= 2)	2	100	2	100	2	100	2	100
BioGX <i>Mycopl. / Ureapl.</i> (n = 4)	4	100	4	100	4	100	4	100
EUROIMMUN EUROArray STI-11 (n = 3)	3	100	3	100	3	100	3	100
Seegene Allplex STI Essential (n = 16)	16	100	16	100	16	100	16	100
Seegene Anyplex STI-5 Detection (n= 3)	3	100	3	100	3	100	3	100

LightMix modular M.genitalium (n =4)	4	100	4	100	4	100	4	100
RIDAGENE STI Myc. Panel (n = 10)	10	100	10	100	10	100	10	100
Other commercial tests (n = 33)	32	97	33	100	33	100	33	100
In house PCR assay [28] (n = 11)	11	100	11	100	11	100	11	100

**Tabelle 4:** 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 = 71	Probennummer (Sample no.)				Inhibition			
	2015471	2015472	2015473	2015474	2015471	2015472	2015473	2015474
Befund Result								
Positiv	0	1	69	1	n.d.	0	0	0
Negativ	71	70	2	70	nein no	71	71	71
Fraglich Questionable	0	0	0	0	ja yes	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 *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					
	2015473		2015471		2015472		2015474	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
BIORON RealLine T.vaginalis (n = 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI-11 (n =3)	3	100	3	100	3	100	3	100
Seegene Allplex STI Essential (n = 16)	16	100	16	100	16	100	16	100
Seegene Anyplex STI-5 Detection (n= 2)	2	100	2	100	2	100	2	100
LightMix modular M.vaginalis (n = 2)	1	50	2	100	2	100	1	50
RIDAGENE T.vaginalis (n = 2)	2	100	2	100	2	100	2	100
Other commercial tests (n = 31)	30	97	31	100	30	97	31	100
In house PCR assay [28] (n = 13)	13	100	13	100	13	100	13	100

**Tabelle 6:** 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 = 19	Probennummer (Sample no.)					Inhibition			
	2015471	2015472	2015473	2015474		2015471	2015472	2015473	2015474
Befund Result									
Positiv	16	0	1	1	n.d.	0	0	0	0
Negativ	3	19	19	19	nein no	19	19	19	19
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 *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					
	2015471		2015472		2015473		2015474	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
BIORON RealLine G.vaginalis (n = 1)	1	100	1	100	1	100	1	100
GenID STI (n = 1)	1	100	1	100	1	100	1	100
Seegene Allplex Bact. Vaginosis plus (n = 5)	3	60	5	100	5	100	5	100
Other commercial tests (n = 4)	4	100	4	100	4	100	4	100
In house PCR assay [28] (n = 8)	7	88	8	100	8	100	8	100

**Tabelle 8:** 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 = 74	Probennummer (Sample no.)					Inhibition			
	2015471	2015472	2015473	2015474		2015471	2015472	2015473	2015474
Befund Result									
Positiv	1	71	1	1	n.d.	0	0	0	0
Negativ	73	1	73	73	nein no	74	74	74	74

<b>Fraglich</b> <i>Questionable</i>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>ja</b> <i>yes</i>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
--	----------	----------	----------	----------	-------------------------	----------	----------	----------	----------

**Tabelle 9:** 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>					
	1925472		1925471		1925473		1925474	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AmpliGnost U.urealyt./U.parvum (n = 2)	2	100	2	100	2	100	2	100
BioGX Mycopl. / Ureapl. (n = 4)	4	100	4	100	4	100	4	100
EUROIMMUN EUROArray STI-11 (n = 3)	3	100	3	100	3	100	3	100
Seegene Allplex STI Essential (n = 16)	16	100	16	100	16	100	15	94
Seegene Anyplex STI-5 Detection (n= 2)	2	100	2	100	2	100	2	100
LightMix modular UU/UP (n=3)	3	100	3	100	3	100	3	100
RIDAGENE STI Mycop. Panel (n = 8)	8	100	8	100	8	100	8	100
AmpliGnost U.urealyt./U.parvum (n =2)	2	100	2	100	2	100	2	100
Other commercial tests (n = 28)	26	93	27	96	27	96	28	100
<i>In house</i> PCR assay [28] (n = 8)	7	88	8	100	8	100	8	100

- Comments:**
- <sup>1)</sup> *Mycoplasma hominis*-detection was performed by 84 laboratories. With the exception of 4 laboratories, with false positive results, all reported results were correct.
  - <sup>2)</sup> *Ureaplasma urealyticum*-detection was performed by 82 laboratories. With the exception of 1 laboratory, with 1 false positive result, all reported results were correct. 21 of them reported a positive result for sample # 2015472, containing *U. parvum*. This shows that the applied tests can not differentiate between the two different species.
  - <sup>4)</sup> *Treponema pallidum*-detection was performed by 39 laboratories. All reported results were correct.