

**PCR-/NAT Urogenital Panel
 (RV 547) November 2023**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

| Proben Nr. | Erwartet / expected | Probenzusammensetzung / Sample composition |
|---------------|---------------------|---|
| 547 231024 01 | ++ | <i>Trichomonas vaginalis</i> (~ 1x10 ⁴ CFU/mL) |
| 547 231024 02 | +++ / +++ | <i>Gardnerella vaginalis</i> (~ 5x10 ⁵ CFU/mL) <i>Ureaplasma parvum</i> (~ 5x10 ⁵ CFU/mL) |
| 547 231024 03 | +++ / +++ | <i>Mycoplasma genitalium</i> (~ 5x10 ⁴ CFU/mL) <i>Mycoplasma hominis</i> (~ 1x10 ⁵ CFU/mL) |
| 547 231024 04 | +++ | <i>Gardnerella vaginalis</i> (~ 2x10 ⁵ CFU/mL) |

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*

| n = 138 | Proben Nr. (Sample no.) | | | | | Inhibition | | | |
|--|-------------------------|-----|-----|-----|-------------------|------------|-----|-----|-----|
| | 01 | 02 | 03 | 04 | | 01 | 02 | 03 | 04 |
| Befund <i>Result</i> | | | | | | | | | |
| Positiv | 0 | 0 | 138 | 0 | n.d. | 1 | 1 | 1 | 1 |
| Negativ | 138 | 138 | 0 | 138 | nein <i>no</i> | 137 | 137 | 137 | 137 |
| 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 Anwenden 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.*

| NAT-Methode [Code] (total number *) | NAT richtig positiv | | NAT richtig negativ <i>True negative results</i> | | | | | |
|--|----------------------------|-----|---|-----|----------------------------|-----|----------------------------|-----|
| | 03 | | 01 | | 02 | | 04 | |
| | Absolut <i>Absolute</i> | % | Absolut <i>Absolute</i> | % | Absolut <i>Absolute</i> | % | Absolut <i>Absolute</i> | % |
| AID RDB 2335 STI (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Amplex eazyplex STD complete (n= 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| AmpliGnost M. hominis (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| AmpliGnost STI Urethritis (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |

| | | | | | | | | |
|--|----|-----|----|-----|----|-----|----|-----|
| BIORON RealLine M.hom./ gen. (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| BioGX Mycoplasma / Ureaplasma (n= 7) | 7 | 100 | 7 | 100 | 7 | 100 | 7 | 100 |
| Bruker-Hain FluoroType STI (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| CerTest VIASURE STD (n= 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| EUROIMMUN EUROArray STI-11 (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| GeneProof M.gen./ hom. PCR Kit (n= 5) | 5 | 100 | 5 | 100 | 5 | 100 | 5 | 100 |
| Immundiagnostik MutaPLEX STI-2 (n= 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| ampliCube STD Panel 2.1/2.1 LC (n= 12) | 12 | 100 | 12 | 100 | 12 | 100 | 12 | 100 |
| Seegene Allplex STI Essential (n= 54) | 54 | 100 | 54 | 100 | 54 | 100 | 54 | 100 |
| Seegene Anyplex II STI-5 (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Seegene Anyplex II STI-7 (n= 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| LightMix modular M.hominis (n= 5) | 5 | 100 | 5 | 100 | 5 | 100 | 5 | 100 |
| aprimeo/ BOSCH Vivalytic STI (n=1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| RIDAGENE STI Mycopl. Panel (n= 7) | 7 | 100 | 7 | 100 | 7 | 100 | 7 | 100 |
| In house PCR assay (n = 8) | 8 | 100 | 8 | 100 | 8 | 100 | 8 | 100 |
| Other commercial tests (n = 14) | 14 | 100 | 14 | 100 | 14 | 100 | 14 | 100 |

Tabelle 4: 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 = 158 | Proben Nr. (Sample no.) | | | | | Inhibition | | | |
|---------------------------------|-------------------------|-----|-----|-----|------------|------------|-----|-----|-----|
| | 01 | 02 | 03 | 04 | | 01 | 02 | 03 | 04 |
| Befund Result | | | | | | | | | |
| Positiv | 0 | 0 | 156 | 0 | n.d. | 1 | 1 | 1 | 1 |
| Negativ | 158 | 158 | 2 | 158 | nein no | 157 | 157 | 157 | 157 |
| 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 *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 | | | | | |
|--|---------------------|---|--|---|---------------------|---|---------------------|---|
| | 03 | | 01 | | 02 | | 04 | |
| | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % |
| | | | | | | | | |

| | | | | | | | | |
|--|----|-----|----|-----|----|-----|----|-----|
| AID RDB 2335 STI (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Abbott Alinity m STI assay (n= 9) | 9 | 100 | 9 | 100 | 9 | 100 | 9 | 100 |
| Amplex eazyplex STD complete (n=3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| AmpliGnost M. genitalium (n=1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| AmpliGnost STI Urethritis (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| BIORON RealLine M.hom./ gen. (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| BioGX Mycoplasma / Ureaplasma (n= 7) | 7 | 100 | 7 | 100 | 7 | 100 | 7 | 100 |
| Bruker-Hain FluoroType STI (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| CerTest VIASURE STD (n= 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| EUROIMMUN EUROArray STI-11 (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| GeneProof M.gen. / hom. PCR Kit (n= 5) | 5 | 100 | 5 | 100 | 5 | 100 | 5 | 100 |
| Immundiagnostik MutaPLEX STI-1 (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= 56) | 56 | 100 | 56 | 100 | 56 | 100 | 56 | 100 |
| Seegene Anyplex II STI-5 (n=1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Seegene Anyplex II STI-7 (n=2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| LightMix modular M. genitalium (n=6) | 6 | 100 | 6 | 100 | 6 | 100 | 6 | 100 |
| aprimeo/ BOSCH Vivalytic STI (n=1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| RIDAGENE STI Mycopl. Panel (n=7) | 6 | 86 | 7 | 100 | 7 | 100 | 7 | 100 |
| In house PCR assay (n= 7) | 7 | 100 | 7 | 100 | 7 | 100 | 7 | 100 |
| Other commercial tests (n= 22) | 21 | 95 | 22 | 100 | 22 | 100 | 22 | 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 = 33 | Proben Nr. (Sample no.) | | | | | Inhibition | | | |
|--|-------------------------|----|----|----|-------------------|------------|----|----|----|
| | 01 | 02 | 03 | 04 | | 01 | 02 | 03 | 04 |
| Befund <i>Result</i> | | | | | | | | | |
| Positiv | 0 | 31 | 0 | 31 | n.d. | 1 | 1 | 1 | 1 |
| Negativ | 33 | 2 | 33 | 2 | nein <i>no</i> | 32 | 32 | 32 | 32 |
| 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 *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 depicted.**

| NAT-Methode [Code] (total number *) | NAT richtig positiv True positive results | | | | NAT richtig negativ True negative results | | | |
|--|--|-----|---------------------|-----|--|-----|---------------------|-----|
| | 02 | | 04 | | 01 | | 03 | |
| | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % |
| AID RDB 2335 STI (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| AmpliGnost STI Urethritis (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Bruker-Hain FluoroType STI (n= 1) | 0 | 0 | 0 | 0 | 1 | 100 | 1 | 100 |
| GeneProof G. vaginalis PCR Kit (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Allplex Bacterial Vaginosis plus (n= 10) | 9 | 90 | 9 | 90 | 10 | 100 | 10 | 100 |
| In house PCR assay (n= 7) | 7 | 100 | 7 | 100 | 7 | 100 | 7 | 100 |
| Other commercial tests (n= 12) | 12 | 100 | 12 | 100 | 12 | 100 | 12 | 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 = 119 | Proben Nr. (Sample no.) | | | | | Inhibition | | | |
|--------------------------|-------------------------|-----|-----|-----|------------|------------|-----|-----|-----|
| | 01 | 02 | 03 | 04 | | 01 | 02 | 03 | 04 |
| Befund Result | | | | | | | | | |
| Positiv | 0 | 119 | 0 | 0 | n.d. | 1 | 1 | 1 | 1 |
| Negativ | 119 | 0 | 119 | 119 | nein no | 118 | 118 | 118 | 118 |
| 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 *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 | | | | | |
|---|---------------------|-----|--|-----|---------------------|-----|---------------------|-----|
| | 02 | | 01 | | 03 | | 04 | |
| | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % |
| AID RDB 2335 STI (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| BIORON RealLine U. ureal. / U. parv. (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| BioGX Mycoplasma / Ureaplasma (n= 7) | 7 | 100 | 7 | 100 | 7 | 100 | 7 | 100 |

| | | | | | | | | |
|--|----|-----|----|-----|----|-----|----|-----|
| Bruker-Hain FluoroType STI (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| CerTest VIASURE STD (n= 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| EUROIMMUN EUROArray STI-11 (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| GeneProof Ureaplasma (JUP) PCR Kit (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| Immundiagnostik MutaPLEX U.ur. /U.pa. (n= 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| ampliCube STD Panel 2.1/2.1 LC (n= 12) | 12 | 100 | 12 | 100 | 12 | 100 | 12 | 100 |
| Seegene Allplex STI Essential (n= 55) | 55 | 100 | 55 | 100 | 55 | 100 | 55 | 100 |
| Seegene Anyplex II STI-5 (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Seegene Anyplex II STI-7 (n= 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| LightMix modular U. ureal./U.parv. (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| In house PCR assay (n= 5) | 5 | 100 | 5 | 100 | 5 | 100 | 5 | 100 |
| Other commercial tests (n= 14) | 14 | 100 | 14 | 100 | 14 | 100 | 14 | 100 |

Tabelle 10: 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 = 143 | Proben Nr. (Sample no.) | | | | | Inhibition | | | |
|---------------------------------|-------------------------|-----|-----|-----|------------|------------|-----|-----|-----|
| | 01 | 02 | 03 | 04 | | 01 | 02 | 03 | 04 |
| Befund Result | | | | | | | | | |
| Positiv | 141 | 0 | 0 | 1 | n.d. | 1 | 1 | 1 | 1 |
| Negativ | 2 | 143 | 143 | 142 | nein no | 142 | 142 | 142 | 142 |
| Fraglich Questionable | 0 | 0 | 0 | 0 | ja yes | 0 | 0 | 0 | 0 |

Tabelle 11: 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 | | | | | |
|--|---------------------|-----|--|-----|---------------------|-----|---------------------|-----|
| | 01 | | 02 | | 03 | | 04 | |
| | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % | Absolut Absolute | % |
| AID RDB 2335 STI (n= 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| Abbott Alinity m STI assay (n= 10) | 10 | 100 | 10 | 100 | 10 | 100 | 10 | 100 |
| AmpliGnost STI Urethritis (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| BD MAX CT/GC/TV (n= 6) | 6 | 100 | 6 | 100 | 6 | 100 | 6 | 100 |
| BIORON RealLine T.vaginalis (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |

| | | | | | | | | |
|--|-----------|------------|-----------|------------|-----------|------------|-----------|------------|
| Bruker-Hain FluoroType STI (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| CerTest VIASURE STD (n= 3) | 3 | 100 | 3 | 100 | 3 | 100 | 3 | 100 |
| EUROIMMUN EUROArray STI-11 (n= 4) | 4 | 100 | 4 | 100 | 4 | 100 | 4 | 100 |
| ampliCube STD Panel 2.1/2.1 LC (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= 55) | 53 | 96 | 55 | 100 | 55 | 100 | 54 | 98 |
| Seegene Anyplex II STI-5 (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| Seegene Anyplex II STI-7 (n= 2) | 2 | 100 | 2 | 100 | 2 | 100 | 2 | 100 |
| LightMix modular T.vaginalis (n= 6) | 6 | 100 | 6 | 100 | 6 | 100 | 6 | 100 |
| aprimeo/ BOSCH Vivalytic STI (n= 1) | 1 | 100 | 1 | 100 | 1 | 100 | 1 | 100 |
| In house PCR assay (n= 7) | 7 | 100 | 7 | 100 | 7 | 100 | 7 | 100 |
| Other commercial tests (n= 27) | 27 | 100 | 27 | 100 | 27 | 100 | 27 | 100 |

Comments:

1. *Ureaplasma urealyticum*-detection was performed by 124 laboratories. With the exception of 5 laboratories, all reported results were correct.
2. *Treponema pallidum*-detection was performed by 67 laboratories. All reported results were correct.
3. Only *Ureaplasma* spp. detection was performed by 13 laboratories. All reported results were correct
4. The following tests are listed under "Other commercial tests": AB Analitica REALQUALITY RQ-SevenSTI (1x), Amplex eazyplex UrogenCheck (1x), AmpliSens U. parvum/U. urealyticum FRT PCR kit (1x), AmpliGnost Trichomonas vaginalis (1x), BD Max (1x), Bioeksen Bio-Speedy (1x), CerTest VIASURE STD Kit für Gardnerella und Treponema pallidum (1x), DNA-TECHNOLOGY M. hominis Real Time PCR Kit (1x), DNA-TECHNOLOGY M. genitalium Real Time PCR Kit (1x), DNA-TECHNOLOGY T. vaginalis Real Time PCR Kit (1x), DNA-TECHNOLOGY Ureaplasma complex Real Time PCR Kit (1x), DNA-TECHNOLOGY Urogenital Microbiome (1x), Immundiagnostik MutaPLEX STI-2 (2x), Immundiagnostik MutaPLEX BV-1 (1x), GeneProof *T. vaginalis* (3x), GeneProof CT/NG/MG Multiplex PCR Kit (1x), GeneProof MH/UU/UP Multiplex PCR Kit (2x), Gerbion diarellaSTI-1 (1x), Gerbion diarellaSTI-2 (1x), Gerbion diarellaBV-1 (1x), Hologic Panther *M. genitalium* (1x), Hologic Aptima *T. vaginalis* (1x), KOGENE BIOTECH PowerChek STI Multiplex Real-time PCR Kit I (1x), KOGENE BIOTECH PowerChek STI Multiplex Real-time PCR Kit II (2x), Vitro master diagnostica STD direct flow Chip Kit (2x), PANAGENE PANA RealTyper (1x), Seegene Allplex CT/NG/MG/TV Assay (7x), TIB Molbiol LightMix Gardnerella and Qiagen NeuMoDx (1x).