

# CERTIFICATE

Survey of 16 June 2023

You have fulfilled the requirements of the External Quality Assessment with the following analysis

## Bacterial Genome Detection - Urogenital Panel (547):

Validity 12 months:

**Mycoplasma hominis**  
**Mycoplasma genitalium**  
**Ureaplasma parvum**  
**Ureaplasma urealyticum**  
**Trichomonas vaginalis**  
**Gardnerella vaginalis**  
**Treponema pallidum**

(R) analysis is subject to the RiliBÄK

**Participant:**  
**29506**  
**GeneProof a.s.**  
**GeneProof a.s.**  
**Videnska 101/119**  
**61900 Brno**

Düsseldorf, 06 July 2023



Prof. Dr. med. Michael Spannagl  
(Head of Reference Institution)



Prof. Dr. rer. nat. Udo Reischl  
(Adviser)

# CERTIFICATE OF PARTICIPATION

Survey of 16 June 2023

You have participated in the External Quality Assessment with the following analysis

## Bacterial Genome Detection - Urogenital Panel (547):

Mycoplasma spp.  
Mycoplasma hominis  
Mycoplasma genitalium  
Ureaplasma spp.  
Ureaplasma parvum  
Ureaplasma urealyticum  
Trichomonas vaginalis  
Gardnerella vaginalis  
Treponema pallidum

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(Adviser)

## Listing and evaluation of the results

29506: GeneProof a.s.  
GeneProof a.s.

Survey of 16 June 2023

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### Bacterial Genome Detection - Urogenital Panel

#### Mycoplasma spp.

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1,2)	547-230523-01	negative (62)	negative (62)	SV		+
(1,2)	547-230523-02	positive (61)	positive (61)	SV		+
(1,2)	547-230523-03	positive (61)	positive (61)	SV		+
(1,2)	547-230523-04	negative (62)	negative (62)	SV		+

#### Mycoplasma hominis

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	547-230523-01	negative (62)	negative (62)	SV		+
(1)	547-230523-02	negative (62)	negative (62)	SV		+
(1)	547-230523-03	positive (61)	positive (61)	SV		+
(1)	547-230523-04	negative (62)	negative (62)	SV		+

#### Mycoplasma genitalium

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	547-230523-01	negative (62)	negative (62)	SV		+
(1)	547-230523-02	positive (61)	positive (61)	SV		+
(1)	547-230523-03	negative (62)	negative (62)	SV		+
(1)	547-230523-04	negative (62)	negative (62)	SV		+

#### Ureaplasma spp.

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1,2)	547-230523-01	positive (61)	positive (61)	SV		+
(1,2)	547-230523-02	negative (62)	negative (62)	SV		+
(1,2)	547-230523-03	negative (62)	negative (62)	SV		+
(1,2)	547-230523-04	negative (62)	negative (62)	SV		+

#### Ureaplasma parvum

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	547-230523-01	positive (61)	positive (61)	SV		+
(1)	547-230523-02	negative (62)	negative (62)	SV		+
(1)	547-230523-03	negative (62)	negative (62)	SV		+
(1)	547-230523-04	negative (62)	negative (62)	SV		+

#### Ureaplasma urealyticum

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	547-230523-01	negative (62)	negative (62)	SV		+
(1)	547-230523-02	negative (62)	negative (62)	SV		+
(1)	547-230523-03	negative (62)	negative (62)	SV		+
(1)	547-230523-04	negative (62)	negative (62)	SV		+

## Listing and evaluation of the results

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### Trichomonas vaginalis

+

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	547-230523-01	negative (62)	negative (62)	SV		+
(1)	547-230523-02	negative (62)	negative (62)	SV		+
(1)	547-230523-03	negative (62)	negative (62)	SV		+
(1)	547-230523-04	positive (61)	positive (61)	SV		+

### Gardnerella vaginalis

+

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	547-230523-01	negative (62)	negative (62)	SV		+
(1)	547-230523-02	positive (61)	positive (61)	SV		+
(1)	547-230523-03	negative (62)	negative (62)	SV		+
(1)	547-230523-04	negative (62)	negative (62)	SV		+

### Treponema pallidum

+

Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	547-230523-01	negative (62)	negative (62)	SV		+
(1)	547-230523-02	negative (62)	negative (62)	SV		+
(1)	547-230523-03	negative (62)	negative (62)	SV		+
(1)	547-230523-04	negative (62)	negative (62)	SV		+

- (1) To obtain a certificate, at least 3 of the 4 samples must be correctly determined (samples classified as educative were not considered).  
 (2) No certificate is issued for this parameter, because you have already specified the bacteria on species level.

## Individual summary of results

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Survey of 16 June 2023

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### Bacterial Genome Detection - Urogenital Panel

**Mycoplasma spp.** (N = 11, Rate of success: 81,8%)

**Sample 547-230523-01**

Collective	negative (62)	total
with Species differentiation	11 ●	11

**Sample 547-230523-02**

Collective	positive (61)	negative (62)	total
with Species differentiation	9 ●	2	11

**Sample 547-230523-03**

Collective	positive (61)	total
with Species differentiation	11 ●	11

**Sample 547-230523-04**

Collective	negative (62)	total
with Species differentiation	11 ●	11

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

**Mycoplasma hominis** (N = 134, Rate of success: 96,3%)

**Sample 547-230523-01**

Collective	negative (62)	total
all participant	134 ●	134

**Sample 547-230523-02**

Collective	positive (61)	negative (62)	total
all participant	1	133 ●	134

**Sample 547-230523-03**

Collective	positive (61)	negative (62)	total
all participant	131 ●	3	134

**Sample 547-230523-04**

Collective	positive (61)	negative (62)	total
all participant	1	133 ●	134

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

**Mycoplasma genitalium** (N = 147, Rate of success: 96,6%)

**Sample 547-230523-01**

Collective	negative (62)	total
all participant	147 ●	147

**Sample 547-230523-02**

Collective	positive (61)	negative (62)	total
all participant	143 ●	4	147

**Sample 547-230523-03**

Collective	negative (62)	total
all participant	147 ●	147

**Sample 547-230523-04**

Collective	positive (61)	negative (62)	total
all participant	1	146 ●	147

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

**Ureaplasma spp.** (N = 25, Rate of success: 100%)

**Sample 547-230523-01**

Collective	positive (61)	total
with Species differentiation	13 ●	13
only Ureaplasma spp.	12 ●	12

**Sample 547-230523-02**

Collective	negative (62)	total
with Species differentiation	13 ●	13
only Ureaplasma spp.	12 ●	12

**Sample 547-230523-03**

Collective	negative (62)	total
with Species differentiation	13 ●	13
only Ureaplasma spp.	12 ●	12

**Sample 547-230523-04**

Collective	negative (62)	total
with Species differentiation	13 ●	13
only Ureaplasma spp.	12 ●	12

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

**Ureaplasma parvum (N = 114, Rate of success: 99,1%)**
**Sample 547-230523-01**

Collective	positive (61)	total
all participant	114 ●	114

**Sample 547-230523-02**

Collective	negative (62)	total
all participant	114 ●	114

**Sample 547-230523-03**

Collective	negative (62)	total
all participant	114 ●	114

**Sample 547-230523-04**

Collective	positive (61)	negative (62)	total
all participant	1	113 ●	114

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

**Ureaplasma urealyticum (N = 124, Rate of success: 93,5%)**
**Sample 547-230523-01**

Collective	positive (61)	negative (62)	total
all participant	6	118 ●	124

**Sample 547-230523-02**

Collective	positive (61)	negative (62)	total
all participant	1	123 ●	124

**Sample 547-230523-03**

Collective	positive (61)	negative (62)	total
all participant	1	123 ●	124

**Sample 547-230523-04**

Collective	negative (62)	total
all participant	124 ●	124

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

**Trichomonas vaginalis (N = 133, Rate of success: 96,2%)**
**Sample 547-230523-01**

Collective	negative (62)	total
all participant	133 ●	133

**Sample 547-230523-02**

Collective	negative (62)	total
all participant	133 ●	133

**Sample 547-230523-03**

Collective	positive (61)	negative (62)	total
all participant	1	132 ●	133

**Sample 547-230523-04**

Collective	positive (61)	negative (62)	total
all participant	129 ●	4	133

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

**Gardnerella vaginalis (N = 31, Rate of success: 96,8%)**
**Sample 547-230523-01**

Collective	positive (61)	negative (62)	total
all participant	1	30 ●	31

**Sample 547-230523-02**

Collective	positive (61)	total
all participant	31 ●	31

**Sample 547-230523-03**

Collective	negative (62)	total
all participant	31 ●	31

**Sample 547-230523-04**

Collective	negative (62)	total
all participant	31 ●	31

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective



## Treponema pallidum (N = 72, Rate of success: 100%)

### Sample 547-230523-01

Collective	negative (62)	total
all participant	72 •	72

### Sample 547-230523-03

Collective	negative (62)	total
all participant	72 •	72

### Sample 547-230523-02

Collective	negative (62)	total
all participant	72 •	72

### Sample 547-230523-04

Collective	negative (62)	total
all participant	72 •	72

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective