

# PCR-/NAT *C. trachomatis* & GO (RV 530) Mai 2021



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

*Sample composition and expected results.*

|         | <i>Erwartet / expected</i> | <i>Probenzusammensetzung / Sample composition</i>  |
|---------|----------------------------|--|
| 2115301 | ++ / ++                    | <i>Chlamydia trachomatis</i> (~ 5x10 <sup>4</sup> IFU/mL)<br><i>Neisseria gonorrhoeae</i> (~ 5x10 <sup>4</sup> CFU/mL) |
| 2115302 | ++ / +                     | <i>Chlamydia trachomatis</i> (~ 5x10 <sup>4</sup> IFU/mL)<br><i>Neisseria gonorrhoeae</i> (~ 1x10 <sup>3</sup> CFU/mL) |
| 2115303 | +++ / +                    | <i>Chlamydia trachomatis</i> (~ 1x10 <sup>5</sup> IFU/mL)<br><i>Neisseria gonorrhoeae</i> (~ 5x10 <sup>3</sup> CFU/mL) |
| 2115304 | ∅ / ∅                      | <i>Escherichia coli</i> K12  |

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

*Absolute numbers of reported individual results. Note: only the C. trachomatis-specific results are depicted in this table.*

| <i>n</i> = 277                         | Probennummer (Sample no.) |         |         |         | Inhibition   |         |         |         |     |
|--|---------------------------|---------|---------|---------|--------------|---------|---------|---------|-----|
|  | 2115301                   | 2115302 | 2115303 | 2115304 | 2115301      | 2115302 | 2115303 | 2115304 |     |
| <b>Befund</b><br><i>Result</i>         |                           |         |         |         |              |         |         |         |     |
| <b>Positiv</b>                         | 276                       | 277     | 277     | 4       | n.d.         | 3       | 3       | 3       | 3   |
| <b>Negativ</b>                         | 0                         | 0       | 0       | 273     | nein /<br>no | 273     | 274     | 274     | 274 |
| <b>Fraglich</b><br><i>Questionable</i> | 1                         | 0       | 0       | 0       | ja /<br>yes  | 1       | 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 *Chlamydia trachomatis* dargestellt.**

*Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods. Note: only the C. trachomatis-specific results are depicted.*

| NAT-Methode<br>[Code] (total number *)  | NAT richtig positiv<br><i>True positive results</i> |     |                            |     |                            |     | NAT richtig negativ        |     |
|---|---|-----|----------------------------|-----|----------------------------|-----|----------------------------|-----|
|   | 2115301   |     | 2115302                    |     | 2115303                    |     | 2115304                    |     |
|   | Absolut<br><i>Absolute</i>                          | %   | Absolut<br><i>Absolute</i> | %   | Absolut<br><i>Absolute</i> | %   | Absolut<br><i>Absolute</i> | %   |
| Abbott RealTime CT (n = 28)             | 28  | 100 | 28                         | 100 | 28                         | 100 | 27                         | 96  |
| BD MAX CT (n = 17)                      | 16  | 94  | 17                         | 100 | 17                         | 100 | 17                         | 100 |
| HAIN FluoroType CT (n = 22)             | 22  | 100 | 22                         | 100 | 22                         | 100 | 22                         | 100 |
| Cepheid Xpert CT (n = 32)               | 32  | 100 | 32                         | 100 | 32                         | 100 | 32                         | 100 |
| GeneProof <i>C. trachomatis</i> (n = 5) | 5   | 100 | 5                          | 100 | 5                          | 100 | 5                          | 100 |

|  |    |     |    |     |    |     |    |     |
|--|----|-----|----|-----|----|-----|----|-----|
| Hologic Aptima Combo 2 assay (n =15)   | 15 | 100 | 15 | 100 | 15 | 100 | 15 | 100 |
| Mikrogen ampliCube STD (n = 10)        | 10 | 100 | 10 | 100 | 10 | 100 | 10 | 100 |
| Roche COBAS 4800 CT (n = 37)           | 37 | 100 | 37 | 100 | 37 | 100 | 35 | 95  |
| Roche COBAS 6800 CT (n = 26)           | 26 | 100 | 26 | 100 | 26 | 100 | 26 | 100 |
| Sacace C. trachomatis Real TM (n = 5)  | 5  | 100 | 5  | 100 | 5  | 100 | 5  | 100 |
| Seegene Allplex STI Essential (n = 21) | 21 | 100 | 21 | 100 | 21 | 100 | 21 | 100 |
| LightMix CT (n = 6)                    | 6  | 100 | 6  | 100 | 6  | 100 | 6  | 100 |
| Other commercial tests (n = 41)        | 41 | 100 | 41 | 100 | 41 | 100 | 41 | 100 |
| In house PCR assay (n = 12)            | 12 | 100 | 12 | 100 | 12 | 100 | 11 | 92  |

**Tabelle 4:** Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Neisseria gonorrhoeae* dargestellt. Absolute numbers of reported individual results. Note: only the *N. gonorrhoeae*-specific results are depicted in this table

| n = 275                  | Probennummer (Sample no.) |                  |                  |         |              | Inhibition |         |         |         |
|--------------------------|---------------------------|------------------|------------------|---------|--------------|------------|---------|---------|---------|
|                          | 2115301                   | 2115302          | 2115303          | 2115304 |              | 2115301    | 2115302 | 2115303 | 2115304 |
| Befund<br>Result         |                           |                  |                  |         |              |            |         |         |         |
| Positiv                  | 274                       | 261              | 262              | 3       | n.d.         | 3          | 3       | 3       | 3       |
| Negativ                  | 0                         | 14 <sup>1)</sup> | 13 <sup>1)</sup> | 271     | nein /<br>no | 271        | 272     | 272     | 272     |
| Fraglich<br>Questionable | 1                         | 0                | 0                | 1       | ja /<br>yes  | 1          | 0       | 0       | 0       |

**Tabelle 5:** Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Neisseria gonorrhoeae* dargestellt. Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods. Note: only the *N. gonorrhoeae*-specific results are depicted.

| NAT-Methode<br>[Code] (total number *) | NAT richtig positiv<br>True positive results |     |                     |     |                     |     | NAT richtig negativ |     |
|--|--|-----|---------------------|-----|---------------------|-----|---------------------|-----|
|  | 2115301                                      |     | 2115302             |     | 2115303             |     | 2115304             |     |
|  | Absolut<br>Absolute                          | %   | Absolut<br>Absolute | %   | Absolut<br>Absolute | %   | Absolut<br>Absolute | %   |
| Abbott RealTime NG (n = 28)            | 28   | 100 | 28                  | 100 | 28                  | 100 | 28                  | 100 |
| BD MAX NG (n = 17)                     | 16   | 94  | 17                  | 100 | 17                  | 100 | 17                  | 100 |
| HAIN FluoroType NG (n = 21)            | 21   | 100 | 21                  | 100 | 21                  | 100 | 20                  | 95  |
| Cepheid Xpert NG (n = 33)              | 33   | 100 | 33                  | 100 | 33                  | 100 | 33                  | 100 |
| EUROArray STI (n = 5)                  | 5  | 100 | 5                   | 100 | 5                   | 100 | 5                   | 100 |
| GeneProof N. gonorrhoeae (n = 5)       | 5  | 100 | 5                   | 100 | 5                   | 100 | 5                   | 100 |

|  |    |     |    |     |    |     |    |     |
|--|----|-----|----|-----|----|-----|----|-----|
| Hologic Aptima Combo 2 assay (n= 14)   | 14 | 100 | 2  | 14  | 2  | 14  | 14 | 100 |
| Mikrogen ampliCube STD (n = 9)         | 9  | 100 | 9  | 100 | 9  | 100 | 8  | 89  |
| Roche COBAS 4800 NG (n = 35)           | 35 | 100 | 35 | 100 | 35 | 100 | 34 | 97  |
| Roche COBAS 6800 NG (n = 25)           | 25 | 100 | 25 | 100 | 25 | 100 | 24 | 96  |
| Sacace N. gonorrhoeae Real TM (n = 5)  | 5  | 100 | 5  | 100 | 5  | 100 | 5  | 100 |
| Seegene Allplex STI Essential (n = 21) | 21 | 100 | 21 | 100 | 21 | 100 | 21 | 100 |
| Seegene Anyplex II STI-7 (n = 5)       | 5  | 100 | 5  | 100 | 5  | 100 | 5  | 100 |
| LightMix NG (n = 6)                    | 6  | 100 | 6  | 100 | 6  | 100 | 6  | 100 |
| Other commercial tests (n = 34)        | 34 | 100 | 32 | 94  | 33 | 97  | 34 | 100 |
| In house PCR assay (n = 12)            | 12 | 100 | 12 | 100 | 12 | 100 | 12 | 100 |

**Comments:** <sup>1)</sup> As samples #2115302 contained a low number of *Neisseria gonorrhoeae* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.