Instructions for Use

RealLine Chlamydia trachomatis / Ureaplasma urealyticum Str-Format

AN ASSAY KIT FOR THE DETECTION OF *CHLAMYDIA TRACHOMATIS* AND *UREAPLASMA UREALYTICUM* DNA BY REAL-TIME PCR

In vitro Diagnostics

CE 0123

RealLine Chlamydia trachomatis / Ureaplasma urealyticum (Str-Format)	**VBD0492**	**96 Tests**
valid from	**September 2019**	

BIORON Diagnostics GmbH
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RealLine Chlamydia trachomatis / Ureaplasma urealyticum Str-Format

Explanation of symbols used in labeling

IVD	*In vitro* diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Contains sufficient for <n> tests
	Use-by-date
	Temperature limit
	Consult instructions for use
	Keep away from sunlight
	Manufacturer

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1. INTRODUCTION AND INTENDED USE

1.1. Pathogen information

Chlamydia trachomatis is a Gram-negative, ovoid, non-motile bacterium from the genus *Chlamydia*. It is an obligate intracellular parasite, for which humans are the only host [1]. Chlamydia is one of the most common sexually transmitted diseases worldwide. Infections are most common among those between the ages of 15 and 25 and are more common in women than men. The young women have the highest prevalence of genitourinary *C. trachomatis* infections. Most infected women (more than 70%) and about 50% of infected men are asymptomatic [2]. Women infected with Chlamydia are up to three times more likely to become infected with HIV, if exposed [3]. In men, the most common manifestation of *C. trachomatis* infection is inflammation of the urethra (about 50% of cases) [4]. The untreated infection may result in epididymitis, which in some cases can lead to fertility problems. Neonates born of infected mothers can develop inclusion conjunctivitis, nasopharyngeal infections and pneumonia due to *C. trachomatis* [5].
Definitive diagnosis is very important for infected person and his/her partner(s). As many people in the population are infected and the significant proportion of infection is asymptomatic, the diagnosis is often established by screening, which is recommended to perform regularly in sexually active young women, in other people from higher risk groups, and at the first prenatal visit [6]. Most *C. trachomatis* strains have a multicopy extrachromosomal cryptic plasmid, which is widely used as the target for PCR testing. As some *C. trachomatis* isolates are reported not to carry cryptic plasmid or have deletion(s) in it [7], “RealLine Chlamydia trachomatis/ Ureaplasma urealyticum” assay kit detects two DNA fragments from gyrA gene and cryptic plasmid, specific to *C. trachomatis* species.

Ureaplasma species are bacteria belonging to *Mycoplasmatacea* family that lack a cell wall and therefore cannot be seen on Gram stain. Species are subdivided into *U. parvum* (serotypes 1, 3, 6, and 14) and *U. urealyticum* (serotypes 2, 4, 5, and 7 through 13). These subtypes cannot be distinguished from each other with routine microbiological method. Differentiation might be important because nongonococcal urethritis and adverse pregnancy outcome with respect to birth weight, gestational age, and preterm delivery are suggested to be implicated with the presence of *U. urealyticum* and not with *U. parvum*.
Ureaplasma spp. are detected in the vaginal flora of 40-80% of sexually active women and may cause urethritis and cystitis. Horizontal transmission is by sexual contact and genital infection is usually asymptomatic. The vertical transmission rate varies from 18 to 88% in different studies. Babies can be infected by intrauterine infection or intrapartum transmission. Newborns infected with *U. urealyticum* were subject to more frequent and longer therapeutic procedures supporting respiration, needed more frequent surfactant and antibiotic administration. *U. urealyticum* and *U. parvum* may also cause neonatal infections, including meningoencephalitis and pneumonia.
In men, although genital tract infection is usually asymptomatic, *U. urealyticum* is one of the most common pathogens associated with male infertility and is isolated in 76% of infertile men compared with 19% of fertile men. In addition, *Ureaplasma spp.* have been reported to cause unusual infections, such as prosthetic joint infection and infections in transplant recipients. Although rare,

invasive *Ureaplasma* infection (meningitis, renal abscess, mediastinitis and arthritis) has also been reported in both adults and children [8-17]. “RealLine Chlamydia trachomatis / Ureaplasma urealyticum” assay kit detects the fragment of the urease enzyme gene, which is highly conserved in all *Ureaplasma* species. Primers and probe in the kit are designed for better discrimination between *species U. urealyticum* and *U. parvum,* none of cross-specific reactions has been observed.

1.2. Intended use

RealLine Chlamydia trachomatis / **Ureaplasma urealyticum** is intended for the detection of *Chlamydia trachomatis* and *Ureaplasma urealyticum* DNA in clinical specimens:
urine, swabs of the epithelial cells, semen, prostate fluid.
The assay is based on real-time polymerase chain reaction (PCR) method with fluorescent detection of amplified product

The extraction of DNA from clinical materials can be performed using the extraction kits:

- **RealLine DNA-Express (REF VBC8899)**
- **RealLine DNA-Extraction 3 (REF VBC8889)**
- **RealLine Extraction 100 (REF VBC8896)**

When using DNA extraction kits of other manufacturers it is highly recommended to use Internal Control sample (IC) (VBC8881, BIORON Diagnostics)

The results of PCR analysis are taken into account in complex diagnostics of disease.

The **Str-format Kit** is intended for use with block-type PCR cyclers: iQ5 iCycler, CFX96 (Bio-Rad, USA), DT-96 (DNA-Technology, Russia) and RealLine Cyclers 96 and 48 (BIORON Diagnostics GmbH).

The **Str-Format Kit** contains 96 tubes (0.2 ml) in strips with lyophilized Mastermix. 50 µl of extracted DNA have to be pipetted into the tube and the ready mastermix is diluted. The kit contains reagents required for 96 tests, including control samples.

The use of:

- ! **Extraction Kits for nucleic acids from clinical specimen from other supplier**
- ! **other real-time PCR devices**
- ! **appropriate reaction volumes, other than 50 µl**

has to be validated in the lab by the user. The special notes regarding the internal control IC have to be strongly followed.

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2. KIT CONTENTS

Universal Positive Control Sample (PC)	1 vial, 1 ml
Ready Master Mix (RMM), lyophilized	96 test-tubes -
The kit is additionally supplied with optical-quality PCR-film)	

3. PRINCIPLE OF THE METHOD

Real-time PCR is based on the detection of the fluorescence, produced by a reporter molecule, which increases as the reaction proceeds. Reporter molecule is dual-labeled DNA-probe, which specifically binds to the target region of pathogen DNA. Fluorescent signal increases due to the fluorescent dye and quencher separating by Taq DNA-polymerase exonuclease activity during amplification. PCR process consists of repeated cycles: temperature denaturation of DNA, primer annealing and complementary chain synthesis.

Threshold cycle value - Ct – is the cycle number at which the fluorescence generated within a reaction crosses the fluorescence threshold, a fluorescent signal rises significantly above the background fluorescence. Increased fluorescence signal is due to the use of a specific for given DNA sequence DNA hybridization probe that in the course of reaction binds with one of the DNA strands, also providing additional specificity of the method. DNA probe comprises of a fluorescent dye at the 5’ end and of fluorescence quencher at the 3’ end which significantly reduces the fluorescence intensity. During the polymerase synthesis of the complementary strand, due to the 5’-3’ nuclease activity of Taq DNA polymerase the probe is cleaved from the 5’-terminus and separation of the quencher and the dye occurs, resulting in the increase the fluorescence signal due to accumulation of the reaction product. Fluorescence intensity detected depends on initial quantity of pathogen DNA template in the sample.

The use of **Internal Control (IC)** prevents generation of false negative results associated with possible loss of DNA template during specimen preparation. IC indicates if PCR inhibitors occur in the reaction mixture. IC template should be added in each single sample (including control samples) prior to DNA extraction procedure. The amplification and detection of IC does not influence the sensitivity or specificity of the target DNA PCR.

Note: IC is a component of the DNA extraction kits of RealLine series. Internal Control is added to the specimen during DNA isolation step and is used throughout the whole process of DNA extraction, amplification, detection.

4. SPECIFICATIONS

4.1. Analytical Specificity:

The analytical specificity of "RealLine Chlamydia trachomatis / Ureaplasma urealyticum" assay kit is ensured by specific primers and probes. The primers and probes were checked for possible homologies to all sequences published in gene banks by sequence comparison analysis.

The analytical specificity of *Chlamydia trachomatis* DNA detection is determined on five samples containing 100 copies of *Ureaplasma urealyticum* DNA, as a percentage of the samples determined by the kit as negative.

The analytical specificity of *Ureaplasma urealyticum* DNA detection is determined on five samples containing 100 copies of *Chlamydia trachomatis* DNA, as a percentage of the samples determined by the kit as negative. Specificity of *Chlamydia trachomatis* and *Ureaplasma urealyticum* DNA detection equals 100%.

4.2. Analytical Sensitivity:

The analytical sensitivity of *Chlamydia trachomatis* DNA detection is determined on 5 samples, containing 100 copies of *Chlamydia trachomatis* DNA per sample prepared from *Chlamydia trachomatis* DNA Standard Reference Sample (SRS), as percentage of samples detected by the kit as positive. Sensitivity equals 100 %.

The analytical sensitivity of *Ureaplasma urealyticum* DNA detection is determined on five samples, containing 100 copies of *Ureaplasma urealyticum* DNA per sample prepared from *Ureaplasma urealyticum* DNA Standard Reference Sample (SRS), as percentage of samples detected by the kit as positive. Sensitivity equals 100 %.

4.3. Diagnostic Evaluation:

Diagnostic sensitivity of *Chlamydia trachomatis* DNA detection: clinical tests conducted on 55 positive samples (29 epithelial cells swabs from the patients infected with *Chlamydia trachomatis*; 26 epithelial cells swabs from the patients infected with *Chlamydia trachomatis* and *Ureaplasma urealyticum*) showed 100 % sensitivity (interval 94.7 % - 100 %, with a confidence level of 90 %).

Diagnostic sensitivity of *Ureaplasma urealyticum* DNA detection: clinical tests conducted on 63 positive samples (37 epithelial cells swabs from the patients infected with *Ureaplasma urealyticum*; 26 epithelial cells swabs from the patients infected with *Chlamydia trachomatis* and *Ureaplasma urealyticum*) showed 100 % sensitivity (interval 95.4 % - 100 %, with a confidence level of 90 %).

Diagnostic specificity of *Chlamydia trachomatis* DNA detection: clinical tests conducted on 133 negative samples (50 epithelial cells swabs from healthy donors; 46 epithelial cells swabs from patients infected with *Mycoplasma genitalium*, *Mycoplasma hominis*, *Trichomonas vaginalis*; 37 epithelial cells swabs from the patients infected with *Ureaplasma urealyticum)* showed 100 % specificity (interval 97.8 % - 100 %, confidence level of 90 %).

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Diagnostic specificity of *Ureaplasma urealyticum* DNA detection: clinical tests conducted on 125 negative samples (50 epithelial cells swabs from healthy donors; 46 epithelial cells swabs from patients infected with *Mycoplasma genitalium*, *Mycoplasma hominis*, *Trichomonas vaginalis*; 29 epithelial cells swabs from the patients infected with *Chlamydia trachomatis*) showed 100 % specificity (interval 97.6 % - 100 %, confidence level of 90 %).

Analysis by the CE-marked reference kit showed full match of results.

5. PRODUCT USE LIMITATIONS

- This assay must not be used on the clinical specimen directly. Appropriate nucleic acids extraction methods have to be conducted prior to using this assay.
- The presence of PCR inhibitors (e.g. heparin) may cause false negative or invalid results.
- When monitoring a patient the same extraction method must be used in all determinations. Otherwise, results may not be relative.
- The kit is intended to be used for supporting the diagnosis of *C. trachomatis / U. urealyticum* infection and should be interpreted with consideration of clinical and laboratory findings.
- Diagnostic sensitivity of the kit may vary depending on the pathogen prevalence and characteristics of the enrolled cohort.
- Reliable results depend on adequate specimen sampling.
- Positive results indicate active or asymptomatic infection; results should be interpreted with consideration of clinical and laboratory findings.
- Negative results indicate lack of detectable DNA but do not exclude the infection or disease.
- Potential mutations within the target regions of the *C. trachomatis* and *U. urealyticum* genome covered by the primers and/or probes used in the kit may result in failure to detect the presence of the pathogens.
- The kit is not intended to replace culture and other methods (e.g., cervical exam) for diagnosis of urogenital infection.

6. WARNING AND PRECAUTIONS

- For in vitro use only.
- The kits must be used by skilled personnel only.
- When handling the kit, follow the national safety requirements for working with pathogens.
- To prevent contamination, the stages of DNA isolation and PCR test run must be spatially separated.
- Avoid microbial and ribonuclease contamination of reagents when removing aliquots from reagent vials.
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents.
- Every workplace must be provided with its own set of variable-volume pipettes, necessary auxiliary materials and equipment. It is prohibited to relocate them to other workplaces.
- The use of sterile disposable pipette tips is recommended.
- Never use the same tips for different samples.
- Do not pool reagents from different lots or from different vials of the same lot.
- Dispose unused reagents and waste in accordance with country, federal, state and local regulations.
- Do not use the kit after the total expiration date at the side label of the box.

7. ADDITIONAL MATERIALS AND DEVICES REQUIRED BUT NOT SUPPLIED

- Real time PCR system, like described in p.1
- DNA-Extraction Kit: **RealLine DNA-Express, , RealLine DNA-Extraction 3** or **RealLine Extraction 100**
- Internal Control reagent (VBC8881) and Negative Control Sample, if the kit is used with the extraction kits of other supplier.
- Laminar safety box;
- Refrigerator;
- Microcentrifuge;
- Half-automatic variable-volume single-channel pipettes;
- Disposable medical non-sterile powder-free gloves;
- Disposable pipette tips with aerosol filter;
- Biohazard waste container;
- Scalpel or razor
- Racks for 2 ml and 0.2 ml tubes

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8. PREPARATION OF THE SPECIMEN

The assay is performed on extracted DNA samples obtained from the clinical material using one of the DNA extraction kits listed in p.1.2, according to the Instruction Manual to the kit. If an extraction kit with magnetic particles is used, keep the tubes with extracted DNA in the magnetic rack.

Each group of samples undergoing the procedure of DNA isolation must include a **Positive Control sample (PC)** from this kit and a **Negative Control sample (NC)** which is a component of the DNA extraction kit.

We strongly recommend the implementation of the Internal Control IC, the Negative Control NC and Positive Control PC samples to the extraction procedure.
When using kits of another supplier for the extraction of nucleic acids as recommended in chapter 1: add **20 µl** of **IC (VBC8881)** to each tube.

- For the NC use **100 µl** of the Negative Control Sample
- For the PC use **70 µl** of Negative Control Sample and **30 µl** of Positive Control to the tube marked PC.

If samples of isolated DNA were stored frozen prior the assay, thaw them and keep at least 30 minutes at a temperature of (18 – 25) °C.

Store the extracted DNA at (2–8) °C for no more than 24 hours.
After initial opening, store Positive Control sample at (2 – 8) °C for no more than 1 month or in 50 µl aliquots 3 month at (-18 … -24) °C for no more than 3 month.

9. PROCEDURE

9.1 Preparation of the Kit Components.

Prior to the test take the kit out of the refrigerator and keep the **Ready Master Mix (RMM)** closed in the package at (18 – 25) °C for at least 30 minutes. Then open the package and cut the necessary number of tubes in strips with RMM (*including prepared samples and controls: 1 NC and 1 PC*) with the razor or scalpel. Cut the tubes together with the covering film.
Put the remaining strips immediately back into the foil pouch, squeeze the air out and tightly close with the clip.
After initial opening store RMM at (2 – 8) °C for no more than 3 months.

9.2 **Label** the tubes with RMM for each specimen and control.
Attention! *Labels should be placed on the lateral side of the tubes.*

9.3 Add **50 µl** of corresponding isolated DNA solution to each tube using a separate pipette tip with filter. Tightly close the tubes with caps or seal with the PCR transparent film.

9.4 Place the tubes into the real-time PCR system.

9.5 Program real time PCR system as follows:

Step 1:	50°C	2min	
Step 2:	95°C	2min	
Step 3:	94°C	10 sec	50 cycles
	60°C*	20 sec	

* Measure the fluorescence at 60°C

9.6 Select the amplification detection channels:

- Collect real-time PCR data through the **FAM** channel for detection of amplification of IC DNA.
- Collect real-time PCR data through the **HEX** channel for detection of amplification of ***Chlamydia trachomatis*** DNA.
- Collect real-time PCR data through the **ROX** channel for detection of amplification of ***Ureaplasma urealyticum*** DNA.

9.7 Program the positions of test tubes with samples, positive and negative controls according to the instruction manual for the real time PCR system in use.

9.8 Run the program.

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10. DATA ANALYSIS AND INTERPRETATION

10.1 For **Positive Control** the program should detect:

- Increase of the IC DNA amplification signal (channel **FAM**) and determine the threshold cycle, IC **Ct**;
- Increase of the ***Chlamydia trachomatis*** DNA amplification signal (channel **HEX**) and determine the PC **Ct** value;
- Increase of the ***Ureaplasma urealyticum*** DNA amplification signal (channel **ROX**) and determine the PC **Ct** value.

10.2 For **Negative Control NC** the program should detect the increase of the amplification signal of IC DNA (channel **FAM**) and determine the threshold cycle, IC **Ct**. No **ROX** or **HEX** fluorescent increase should appear (*no **Chlamydia trachomatis** or **Ureaplasma urealyticum** DNA amplification*).

10.3 For each sample the program should detect the increase of the amplification signal of IC DNA (channel **FAM**) and determine IC **Ct**.

10.4 Calculate (IC **Ct**)$_{av}$ as an average IC **Ct** of all analysed samples (including PC and NC). IC **Ct** values that differ by more than 2 from the (IC **Ct**)$_{av}$ should be ignored. Recalculate the (IC **Ct**)$_{av}$ for the remaining values after the screening.

10.5 The specimen is considered **positive**, i.e. containing *Ureaplasma urealyticum* DNA, if **Ct** value through **ROX** channel for this specimen is **less than or equals to 40.**

The specimen is considered **positive**, i.e. containing *Chlamydia trachomatis* DNA, if **Ct** value through **HEX** channel for this specimen is **less than or equals to 40.**

10.6 The specimen is considered negative, if Ct value through **ROX** and **HEX** channels for this specimen is **above 40 or is not determined**. If IC Ct value for such specimen differs from the (IC Ct)$_{av}$ value by more than 2, the result is regarded as **equivocal**. A repeated analysis of the specimen, starting from the DNA extraction step is required.

10.7 If Ct value for NC through **ROX** or **HEX** channel **is less than or equal to 40,** it indicates the presence of contamination. In this case, all positive results of this individual PCR run are considered **equivocal**. Actions are required to identify and eliminate the source of contamination. Repeat the analysis of all specimens of this run that were identified as positive. Specimens that showed negative results in this run should be considered negative.

11. STORAGE AND TRANSPORTATION

- Store the assay kit at (2 - 8) °C in the manufacturer's packing.
- Transport at (2 - 8) °C. Transportation for up to 25 °C for up to 10 days is allowed.
- Do not freeze the kit!
- Do not pool reagents from different lots or from different vials of the same lot.
- Strictly follow the Instruction manual for reliable results.
- Do not use kits with damaged inner packages and get in contact with BIORON Diagnostics GmbH.

- **Storage and shelf life of solutions and components of the kit after initial opening:**
  Positive Control sample: 1 month at (2 - 8) °C *or in 50 µl aliquots at minus (18 - 60) °C for up to 3 months*.
  Ready Master Mix (RMM): 3 months at (2 – 8) °C

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Technical Support: techsupport@bioron.de

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ANNEX I: Settings for RealLine Cycler and DT96:

for these cyclers the measurement exposure must be adjusted. Choose the **Operation with the device** mode in the **Settings** menu, select the item **Measurement exposition:**

- **FAM** to **250**
- **HEX** and **ROX** to **1000**

Confirm that the current exposure value is saved by pressing **YES**

Attention! The specified exposure values are applicable only for RealLine kits and, if necessary, must be changed for other purposes.

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