Test Definition: URBRP

Ureaplasma PCR, B

Overview

Useful For

Rapid, sensitive, and specific identification of *Ureaplasma urealyticum* and *U parvum* from whole blood

Method Name

Real-Time Polymerase Chain Reaction (PCR) Using LightCycler and Fluorescent Resonance Energy Transfer (FRET)

NY State Available

Yes

Specimen

Specimen Type

Whole Blood EDTA

Specimen Required

Container/Tube:

Preferred: Lavender top (EDTA)

Acceptable: Royal blue top (EDTA), pink top (EDTA), or sterile vial containing EDTA-derived aliquot

Specimen Volume: 1 mL

Collection Instructions: Send specimen in original tube (preferred).

Additional Information: The high sensitivity of amplification by PCR requires the specimen to be processed in an environment in which contamination of the specimen by *Ureaplasma* DNA is not likely.

Specimen Minimum Volume

0.5 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Whole Blood EDTA	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical and Interpretive

Clinical Information

Ureaplasma urealyticum and *U parvum* have been associated with a number of clinically significant infections, although their clinical significance may not always be clear as they are part of the normal genital flora. *U urealyticum* and *U parvum*have been associated with urethritis and epididymitis. They may cause upper urinary tract infection and they have been associated with infected renal stones. *U urealyticum* and *U parvum*may be isolated from amniotic fluid of women with preterm labor, premature rupture of membranes, spontaneous term labor, or chorioamnionitis. They may also cause neonatal infections, including meningoencephalitis and pneumonia. In addition, *U urealyticum* and *U parvum* have been reported to cause unusual infections, such as prosthetic joint infection and infections in transplant recipients.

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Recently, *U urealyticum* and *U parvum*have been found to cause hyperammonemia in lung transplant recipients.(1) In lung transplant recipients with hyperammonemia, the ideal diagnostic specimen is a lower respiratory specimen (eg, bronchoalveolar lavage fluid), although *U urealyticum* and *U parvum*may also be detected in blood. Treatment directed against these organisms has resulted in resolution of hyperammonemia.

Culture of *Ureaplasma* species is laborious, requiring a high degree of technical skill and taking several days. PCR detection is sensitive, specific, and provides same-day results. In addition, PCR allows the differentiation of *U urealyticum* and *U parvum*, which is not easily accomplished with culture. PCR assay has replaced conventional culture for *U urealyticum* and *U parvum* at Mayo Clinic Laboratories due to its speed and equivalent performance to culture.

Reference Values

Not applicable

Interpretation

A positive PCR result for the presence of a specific sequence found within the *Ureaplasma urealyticum* and *U parvum ureC* gene indicates the presence of *U urealyticum* or *U parvum* DNA in the specimen.

A negative PCR result indicates the absence of detectable *U urealyticum* and *U parvum* DNA in the specimen, but does not rule-out infection as false-negative results may occur due to inhibition of PCR, sequence variability underlying the primers and probes, or the presence of *U urealyticum* or *U parvum* in quantities less than the limit of detection of the assay.

Cautions

Interfering substances may affect the accuracy of this assay; results should always be interpreted in conjunction with clinical and epidemiological findings.

Since *Ureaplasma* species may be part of the normal flora, results should be interpreted accordingly.

This test does not detect other mycoplasmas or ureaplasmas (including *Mycoplasma pneumoniae*, a common cause of community acquired pneumonia).

This test is not intended for medicolegal use.

Supportive Data

Validation included spiking studies for each *Ureaplasma* species.Spiking studies were carried out using 30 EDTA whole blood and plasma samples spiked with genomic DNA for *Ureaplasma urealyticum* and *U parvum* (as well as 10 naive specimens). Sensitivity and specificity was 100% for both targets.

Clinical Reference

1. Bharat A, Cunningham SA, Scott Budinger GR, Kreisel D, et al: Disseminated Ureaplasma infection as a cause of fatal hyperammonemia in humans. Sci Transl Med 2015;7(284):284re3

2. Stellrecht KA, Woron AM, Mishrik NG, Venezia RA: Comparison of multiplex PCR assay with culture detection of genital mycoplasmas. J Clin Microbiol 2004;42:1528-1533

3. Farrell JJ, Larson JA, Akeson JW, et al: *Ureaplasma parvum* prosthetic joint infection detected by PCR. J Clin Microbiol 2014;52:2248-2250

4. Waites KB, Taylor-Robinson D: *Mycoplasma* and *Ureaplasma*. In Manual of Clinical Microbiology. 11th edition. Edited by JH Jorgensen. ASM Press, Washington, DC, 2015, pp 1088-1105

5. Kenny GE: Genital mycoplasmas: *Mycoplasma genitalium*, *Mycoplasma hominis*, and *Ureaplasma* species. In Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. Edited by GL Mandell, et al. Churchill Livingstone, New York, 2008

Performance

Method Description

This PCR method employs a target-specific detection system including primers, as well as fluorescent resonance energy transfer (FRET) hybridization probes designed for the *ureC* gene of *Ureaplasma urealyticum* and *U parvum*. The LightCycler instrument amplifies and monitors target nucleic acid sequences by fluorescence during PCR cycling. This is an automated PCR system that can rapidly detect amplified product development. The detection of amplified products is based on the FRET principle. For FRET product detection, a hybridization probe with a donor fluorophore, fluorescein, on the 3' end is excited by an external light source, which emits light that is absorbed by a second hybridization probe with an acceptor fluorophore, LC-Red 640, on the 5' end. The acceptor fluorophore then emits light of a different wavelength that is measured with a signal that is proportional to the amount of specific PCR product. The process is completed in a closed tube system and the melting temperature of the probes allows differentiation of *U urealyticum* from *U parvum*.(Cunningham SA, Mandrekar JN, Rosenblatt JE, Patel R: Rapid PCR Detection of *Mycoplasma hominis*, *Ureaplasma urealyticum*, and *Ureaplasma parvum*. Int J Bacteriol 2013 Jan 30, doi: 10.1155/2013/168742)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday

Analytic Time

3 days

Maximum Laboratory Time

4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

87798 x 2

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
URBRP	Ureaplasma PCR, B	69934-8

Result ID	Test Result Name	Result LOINC Value
UBSRC	Specimen Source	31208-2
44132	Ureaplasma urealyticum PCR, B	51988-4
44133	Ureaplasma parvum PCR, B	69933-0