Indiana University Health Molecular Pathology Laboratory

Trichomonas vaginalis Qualitative Assay For in vitro diagnostic use

CERNER ORDERABLE

Trichomonas PCR QL, TRICHPCR, 3127

CPT CODE

87661

CLINICAL UTILITY

This *Trichomonas vaginalis* Assay is an in vitro qualitative nucleic acid amplification test for the detection of Trichomonas vaginalis in female endocervical, cervical, or vaginal specimens collected with the cobas PCR Dual Swab Sample Kit and female and male urine specimens tested with the cobas PCR Urine Sample Kit. This *Trichomonas vaginalis* Assay utilizes the cobas4800 system for testing and is not FDA approved. The specimen types listed above have been validated for testing with this assay by the Molecular Pathology Lab at Indiana University Health. For indeterminate results, a repeat specimen is recommended.

METHODOLOGY

This *Trichomonas vaginalis* Assay utilizes PCR amplification of target DNA sequences using specific primer pairs and real-time detection of cleaved fluorescent-labeled oligonucleotide detection probes.

SPECIMENS

Cobas PCR Swab Sample Kit (endocervical swab, vaginal swab, cervical swab) Urines in preservative free sterile container (must be received with 24 hours of collection)

SPECIMEN STABILITY

Store the swab in the swab specimen transport tube at 2°C to 30°C Urine samples in the collection container must be transported to the lab at 2°C to 30°C

SHIPPING

Transport and store the swab in the swab specimen transport tube at 2°C to 30°C Urine samples in the collection container must be transported to the lab at 2°C to 30°C

CAUSES FOR REJECTION

Probetek tubes, 2 swabs in Cobas tube, no swab in Cobas tube, urine specimen >24 hours since collection, grey urine Cx tubes, male urethral and penile specimens in Cobas tubes.

ASSAY RANGE

Qualitative Results (*Trich* positive or negative)

TURNAROUND TIME

1-3 days

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.