

Test Name:	Aptima Combo® Assay
Test Methodology:	Qualitative detection and differentiation of rRNA from <i>Neisseria gonorrhoeae</i> through target amplification
Test to be Performed:	Gonorrhea NAAT
CPT:	87491, 87591
Reflex Testing Criteria:	N/A
Pre-Approval Required:	N/A
Accepted Specimens:	• Endocervical and male urethral swab specimens collected to transport tube (white label) from Aptima Unisex Swab Specimen Collection Kit • Anal/ rectal, Oral/throat, Vaginal swabs specimens collected to transport tube (orange label) from Aptima Multitest Swab Specimen Collection Kit • Male and female urine specimens collected in primary collection container and transferred to transport tube (yellow label) from Aptima Urine Collection Kit. Liquid level MUST fall between the two black indicator lines on the tube label. Otherwise, specimen will be rejected.
Specimen Stability:	• Swab specimens: transport and store in the swab specimen transport tube at 2-30°C until tested. Specimens must be tested within 60 days of collection. • Urine samples that are still in the primary collection container must be transferred into the Aptima urine specimen transport tube within 24 hours of collection. Store at 2-30°C and test within 30 days of collection.
Storage/Transport Conditions:	Specimens should be stored and transported at 2-8°C. Sufficient frozen cold packs in an insulated cooler can be used to maintain this temperature. Specimens may be transported at room temperature (15-25°C).
Turnaround Time:	7 business day
Reference Range:	Gonorrhea rRNA Not Detected.