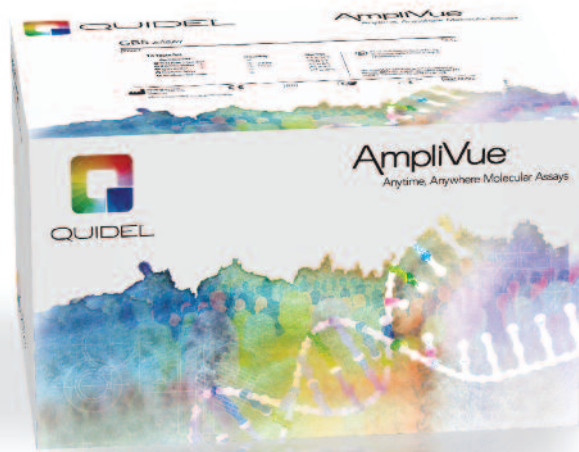




AmpliVue®

Anytime, Anywhere Molecular Assays

GBS

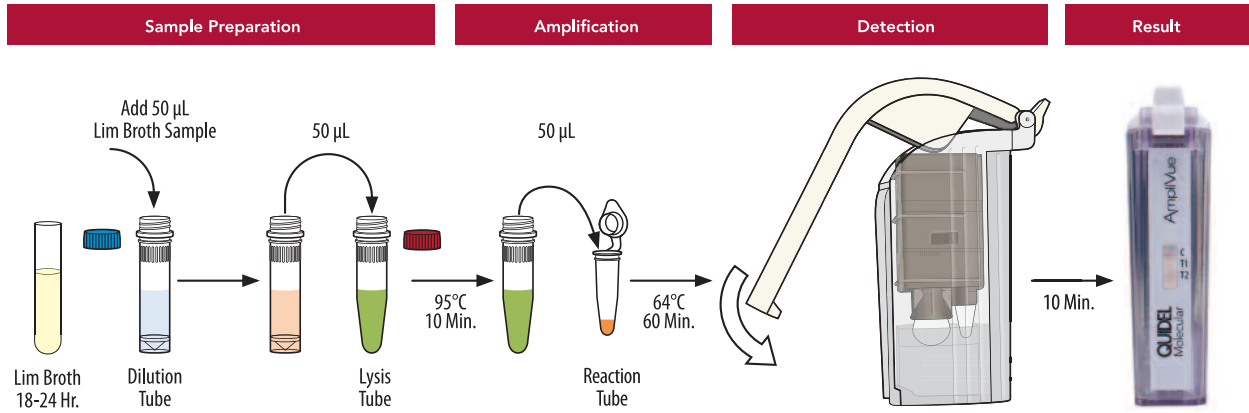


Molecular testing in the palm of your hand!

- Proprietary Helicase Dependent Amplification for sensitivity and accuracy
 - Isothermal – no need for thermocyclers
 - DNA probes and primers for better specificity
 - Multiplex in a single reaction tube
- Easy to interpret disposable cassette
- No capital investment
- Simple, intuitive workflow minimizes hands-on time
- CLIA moderate complexity offers easy training
- Assay results in approximately 80 minutes after overnight enrichment
- Lyophilized reagents provide long shelf life
- Uniform pipetting volumes



Procedure

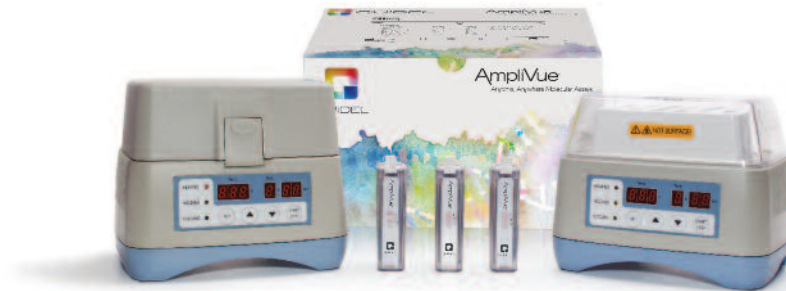


Clinical performance

Group B Streptococcus			
Vaginal/Rectal Swabs (N=908)	Bacterial Culture		
	Positive	Negative	Total
AmpliVue GBS Assay			
Positive	196	52*	248
Negative	1**	659	660
Total	197	711	908
		95% CI	
Sensitivity	99.5%	96.9%	100%
Specificity	92.7%	90.5%	94.3%

*Fifty-two (52) discordant specimens (AmpliVue Positive/Bacterial Culture Negative) reported above were tested with an FDA-cleared molecular device for the detection of GBS, thirty-nine (39) of these specimens were positive for GBS, and thirteen (13) were negative.

**The one (1) discordant specimen (AmpliVue Negative/Bacterial Culture Positive) reported above were tested with an FDA-cleared molecular device for the detection of GBS, and was negative.



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AmpliVue GBS Assay – 16 Test Kit: Catalog #M202
 Quidel Molecular GBS Control Set – 20-Reaction Kit: Catalog #M116
 AmpliVue 95°C Lysis Block – Cat. #M203
 AmpliVue 64°C Amplification Block – Cat. #M205

