

Now in Focus: All you need to make your lab even better.

Find out how we can help streamline your lab's workflow and improve patient management.

Call 1-562-240-6500 today or visit www.focusdx.com for more information.

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Simplexa™ Group A Strep Direct Assay

YOUR ANSWER TO GROUP A STREP TESTING.

Direct *in vitro* qualitative detection of group A strep DNA.



www.focusdx.com

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REFERENCES: 1. C. Choby BA (March 2009). "Diagnosis and treatment of streptococcal pharyngitis." *Am Fam Physician*. 79(5):383-90. 2. MOL2850, Simplexa Group A Strep Direct Kit, Package Insert Rev.



Simplexa™ Group A Strep Direct Assay

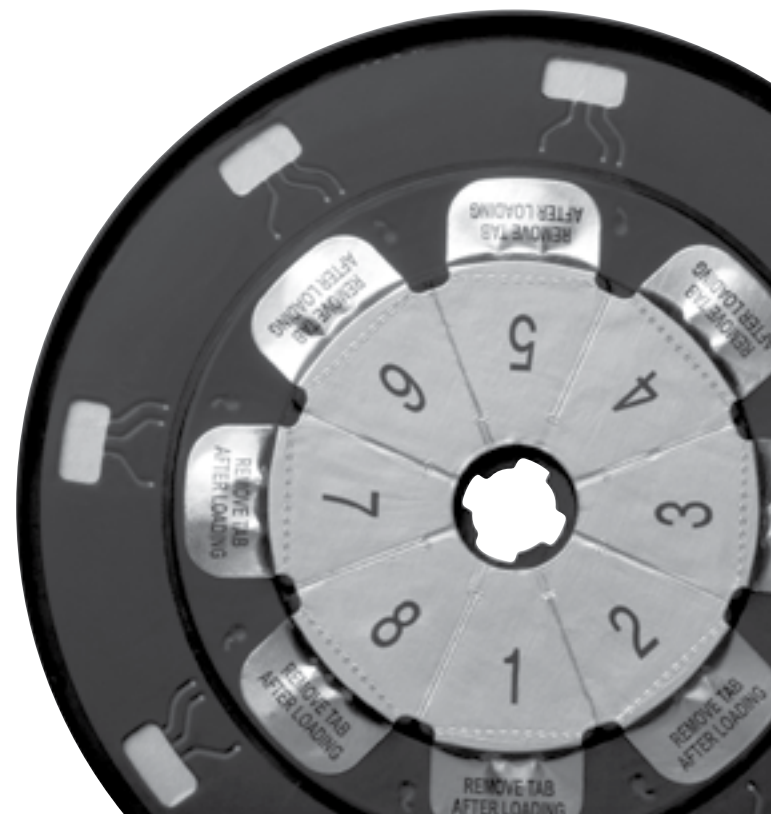


Group A streptococcus is responsible for common infections, such as strep throat, and accounts for 30% of acute pharyngitis in children and 20% in adults. Patients may present symptoms that overlap with other infectious diseases, which can be difficult to diagnose solely on clinical observation.¹

The benefits of quality molecular testing continue to gain momentum as an alternative to culture and point-of-care testing. Focus Diagnostics is leading the way by developing high-performing assays with seamless workflow and reduced turnaround time. Simplexa Direct Chemistry can achieve reliable results without the need for sample extraction and will free your laboratory from costly and time-consuming constraints of extraction. This simplified workflow allows your laboratory to perform molecular testing with up to eight samples per run. Our Simplexa Group A Strep Direct assay employs the benefits of our proprietary Direct Chemistry including an all-in-one reaction mix that does not require any mixing or precision pipetting.

Eliminate the constraints of costly extraction instrumentation with the Direct Amplification Disc.

- Directly detects group A streptococcus from throat swabs
- No extraction required
- Easy to perform – up to 8 samples per run
- Results are available in about an hour
- Only 50 µL of sample required
- CLIA moderate complexity



Performance Summary.

Our Simplexa Group A Strep Direct assay features the high performance your laboratory is seeking.

You can have confidence in your results, without the time constraints of culture and cost of sample extraction.

Performance – Simplexa Group A Strep Direct ²		
	SENSITIVITY	SPECIFICITY
Prospective Samples	97.4%(152/156) 95% CI: 93.6% to 99.0%	95.2%(1139/1196) 95% CI: 93.9% to 96.3%

Your solution for Group A Strep testing.

Simplexa Group A Strep Direct ²		
CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2850	Simplexa Group A Strep Direct Assay*	24
MOL2860	Simplexa Group A Strep Positive Control Pack	10 x 100µL

*Direct Amplification Discs are provided with kit.

