



SMN1 and SMN2 Copy Number, Silent Carrier, and Disease Modifier Genotyping in Less Than Four Hours

The AmplideX® SMA Plus Kit delivers comprehensive results for *SMN1* and *SMN2*, including accurate quantification of exon 7 copy number plus detection of relevant variants and gene hybrids, from a single reaction in less than four hours. Copy number variations in *SMN1* and *SMN2* are associated with the onset and severity of spinal muscular atrophy (SMA), but recent studies have demonstrated that carrier risk and disease severity may also be impacted by the presence of *SMN1* gene duplication variants and a disease modifier variant in *SMN2*, respectively.

Reduced Complexity

- Detection of relevant alterations in a single trace
- AmplideX Reporter Software automates calling and analysis
- Complete kit includes all calibrators, controls and reagents

Optimized Workflow

- <4 hours from DNA to data
- Flexible use on widely installed CE equipment
- Common workflow with AmplideX PCR/CE *FMR1* assay eases implementation and training

Quality Results

- High concordance with multiple reference methods
- Differentiates between 0, 1, 2, 3, and ≥ 4 copies for both *SMN1* and *SMN2*
- Robust performance across extraction methods



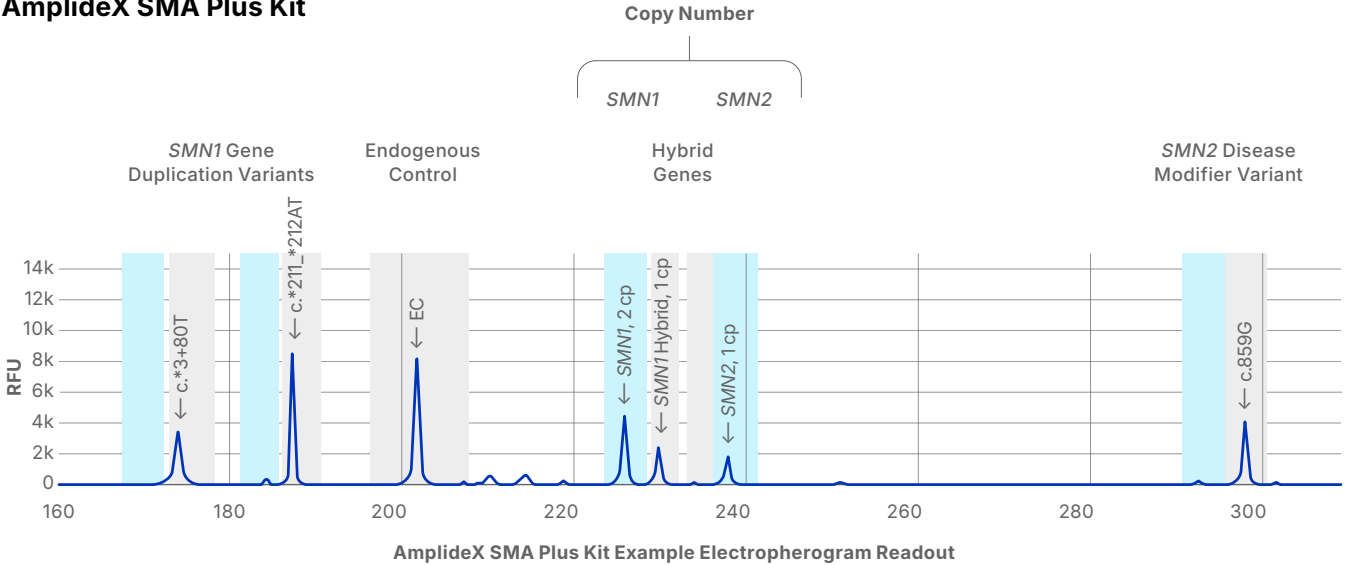
FIGURE 1

AmplideX SMA Plus Kit Workflow— <4 Hours from DNA to Data

	PCR	CE	Data Analysis	Total
Hands-On Time	25 min	30 min	5 min	60 min
Instrument Time	65 min	70 min		< 3 hrs

A Complete Picture from a Single Trace

FIGURE 2
AmplideX SMA Plus Kit



Reliable Performance

Excellent Concordance in Independent, Multisite Testing for >460 Samples

>98%

Copy number, variant, and gene hybrid detection concordance with multiple reference methods (MLPA, ddPCR, Sanger Seq)

100%

Agreement for all 3 variants

100%

Concordance of gene conversions with Sanger sequencing

High Intralaboratory Precision

>99%

Agreement across multiple operators and runs

Robust Performance Across Extraction Methods

>98%

Copy number agreement with reference methods, regardless of purification methods

Ordering Information

Part No.	Product Description	Number of Reactions
A00055	AmplideX® SMA Plus Kit	50
A00056	AmplideX® SMA Plus Kit	100



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*Milligan JN, et al. *J Mol Diagn.* 2021.

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