

AmplideX[®]

DM1 Dx Kit^{*}

Simply and Reliably Size *DMPK* Repeat Expansions within a Single Day

Myotonic Dystrophy Type I (DM1, Steinert's Disease) is an inherited form of muscular dystrophy and is characterized by the presence of 50 or more CTG repeats within the *DMPK* gene. The AmplideX[®] DM1 Dx Kit introduces a groundbreaking alternative for the detection and sizing of CTG repeats within the *DMPK* gene, reducing testing turnaround to just one day. By introducing a simple, streamlined, PCR-only workflow, the AmplideX DM1 Dx Kit offers an alternative to Southern blot and puts *DMPK* analysis within the reach of laboratories everywhere.

REDUCED COMPLEXITY

- Proprietary PCR solutions for GC-rich amplification and detection
- May eliminate need for Southern blot
- Resolves zygosity and detects mosaicism

OPTIMIZED WORKFLOW

- Direct injection of PCR products into CE instruments
- Fully kitted, end-to-end solutions that significantly reduce hands-on-time
- Sample-to-result possible within a single shift

QUALITY PERFORMANCE

- Accurate sizing of alleles ≤ 200 CTG repeats and detection of all alleles >200 repeats using CE
- Optional AGE protocol allows sizing of alleles up to 1000 repeats
- Analysis tool converts raw base pair data into repeat number



Figure 1. AmplideX PCR/CE DM1 Dx Workflow, including optional AGE workflow for larger expansions.

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Sample Name	External Lab PCR + Southern	Asuragen PCR/CE	Asuragen PCR/AGE (allele 2)
S1	10, 300-500	11, >200	Smear, High Mosaic 300-500
S2	4, 1200-1350	5, >200	~1100
S3	4, 1100-1500	5, >200	Smear, High Mosaic >500
S4	11, 200-300	12, >200	~260-350
S5	4, 800-900	5, >200	~650-700
S6	25, 1050	26, >200	~1000
S7	12, 100-150	13, 71, 129	70, 130
S8	11, 1900-2220	12, >200	700, 1900
S9	21, 300	22, >200	Mosaic, 261
S10	4, 50-250	5, >200	150, Smear >200

*AmplideX detects mosaicism down to 5%

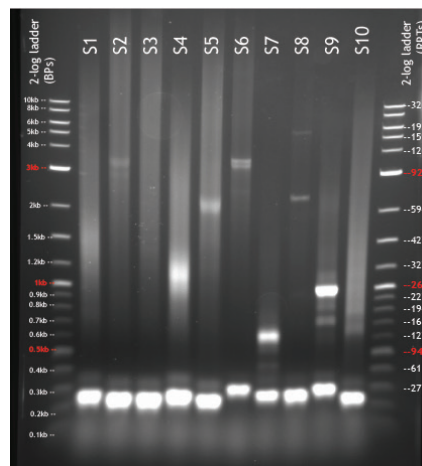


Figure 2. Comparison of residual clinical sample results between Asuragen (AmplideX Kit) and partner lab (PCR + Southern blot).

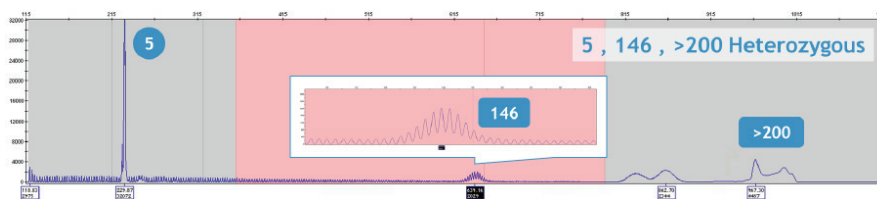


Figure 3. Sensitive and accurate sizing of *DMPK* expansions up to 200 repeats.

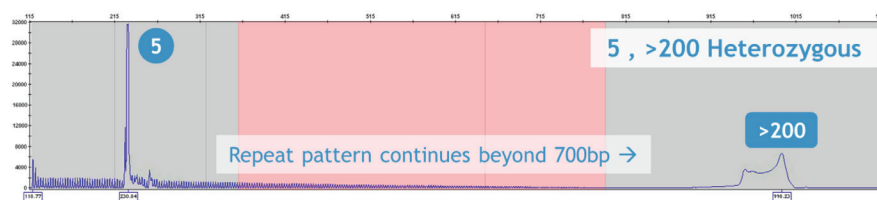
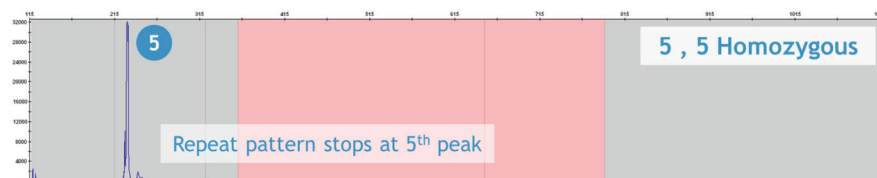


Figure 4. Clear resolution of zygosity.

KIT ORDERING INFORMATION

AmplideX DM1 Dx Kit*

[P/N: 76048] 32 REACTIONS

*CE-IVD for US export only.



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