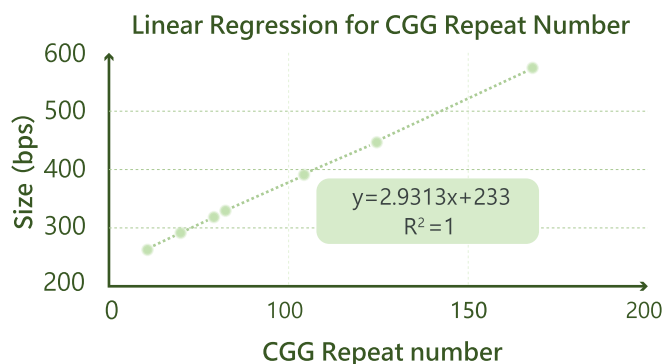
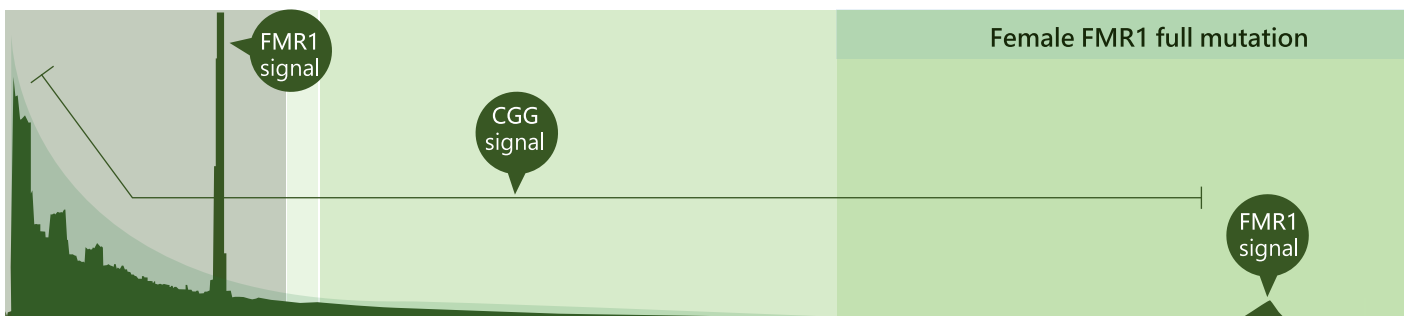


## Accurate Repeat Number

Using linear regression with eight standard samples covering different repeat numbers, including the positive threshold, ensures accurate CGG repeat number calculation and differentiation of various types.

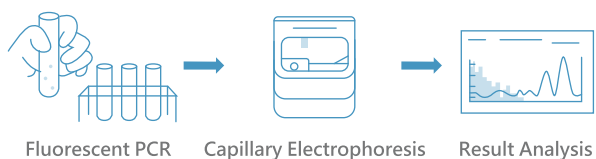


## Experimental Results



## Experimental Procedure

After amplification, capillary electrophoresis is conducted, followed by automated analysis to generate reports.



## Product Advantages

- High Sensitivity**  
Accurate detection with as low as 5ng DNA input
- High Accuracy**  
Linear regression with 8 repeat numbers, including positive threshold
- Ultra-High Repeat Numbers**  
Can detect > 1300 CGG repeats
- Prevention of False Negatives**  
CGG repeat number and FMR1 biallelic review
- Low Proportion Mosaic**  
Detects low proportion mosaic
- Fast Operation**  
Results obtained within 5 hours



# PCR-CE FMR1 Kit



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Answers for better life

# Fragile X Syndrome (FXS)

Fragile X Syndrome is the most common inherited intellectual disability disorder, which is an X-linked genetic condition with a carrier rate of 1/250.

Characterized by an abnormal increase in CGG repeats in the non-coding region of the FMR1 gene on the X chromosome, results in a deficiency of the FMRP protein, crucial for brain neuroconduction. Symptoms include intellectual disability, autism, developmental delay, seizures, and behavioral disorders.

## International guidelines



The American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics and Genomics (ACMG) recommend screening for fragile X syndrome in women of childbearing age to prevent the birth of affected children.

## Clinical Classification

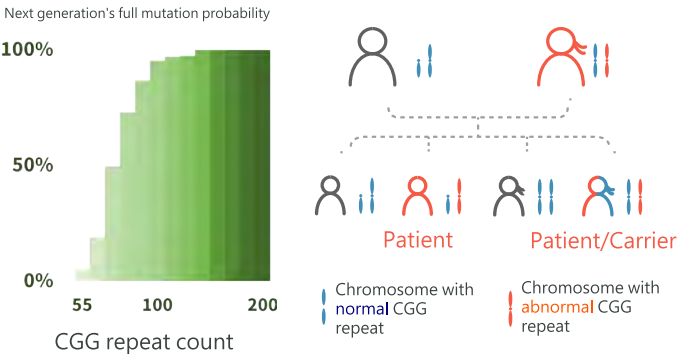
Based on the number of CGG repeats, FMR1 genotypes can be classified into normal, intermediate, premutation, and full mutation types. Premutation carriers of fragile X syndrome can cause tremor/ataxia syndrome in males and premature ovarian insufficiency in females.

## Genetic Types and Clinical Manifestations

| CGG Repeats | Genotypes                                 |
|-------------|-------------------------------------------|
| >200        | Prevalence 1/3600~1/5000<br>Full mutation |
| 55-200      | 1/250<br>Premutation                      |
| 45-54       | Intermediate                              |
| <45         | Normal                                    |

## Inheritance Pattern

The prevalence of affected males is 1/3600, higher than females. FMR1 gene shows dynamic mutation. Higher CGG repeats in premutation females increase the chance of full mutation in offspring, with a 50% chance of having an affected child.



## Population for Use

- Children with unexplained intellectual disabilities, autism, or behavioral or language disorders
- Fetuses of Fragile X Syndrome carriers
- The following family history:
  - Fragile X Syndrome
  - Unexplained Intellectual Disabilities
  - Premature Ovarian Insufficiency
  - Tremor/Ataxia Syndrome
- Women with infertility, recurrent miscarriages
- Families preparing for conception and in need of fertility assistance

| Male                 | Female                      | Recommendations    |
|----------------------|-----------------------------|--------------------|
| Typical FXS Symptoms | 50% Intellectual Disability | Prenatal Diagnosis |
| 40% FXTAS            | 20% FXPOI                   | Prenatal Diagnosis |
| Asymptomatic         |                             | Newborn screening  |
| Asymptomatic         |                             | -                  |



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