



Recommendations for MSMS method for newborn screening

Extract and translation of the French document

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III-1/ Fidelity verification

Intra-series

The acceptable coefficient of variation (CV) must be less than 15%, as indicated by previous method validation results.

Inter-series :

The acceptable CV must be less than 20%, based on prior method verification.

These results align with international recommendations: a 15% threshold is specified for chromatographic methods (for both repeatability and intermediate precision), and a 20% threshold is acceptable when the expected value is near the limit of quantification.

For further details, refer to the *Bioanalytical Method Validation – Guidance for Industry – May 2018*.