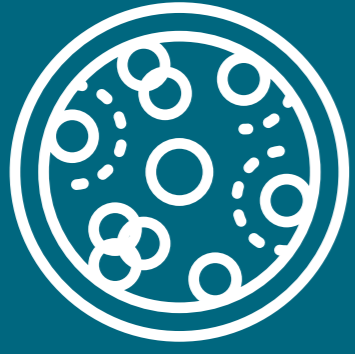
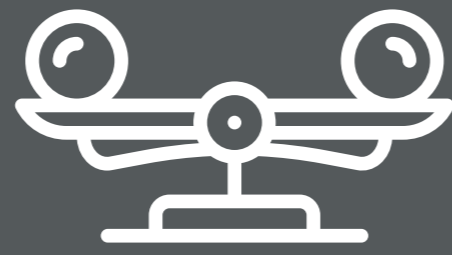


Reducing regulatory risks in PCR assays for bioanalytical validation



Polymerase chain reaction (PCR) based bioanalytical testing is critical for the proper delivery, safety, and efficacy of cell and gene therapies (CGTs)



PCR assays resemble immunoassay based pharmacokinetic (PK) assays in overall concept and desired outcome

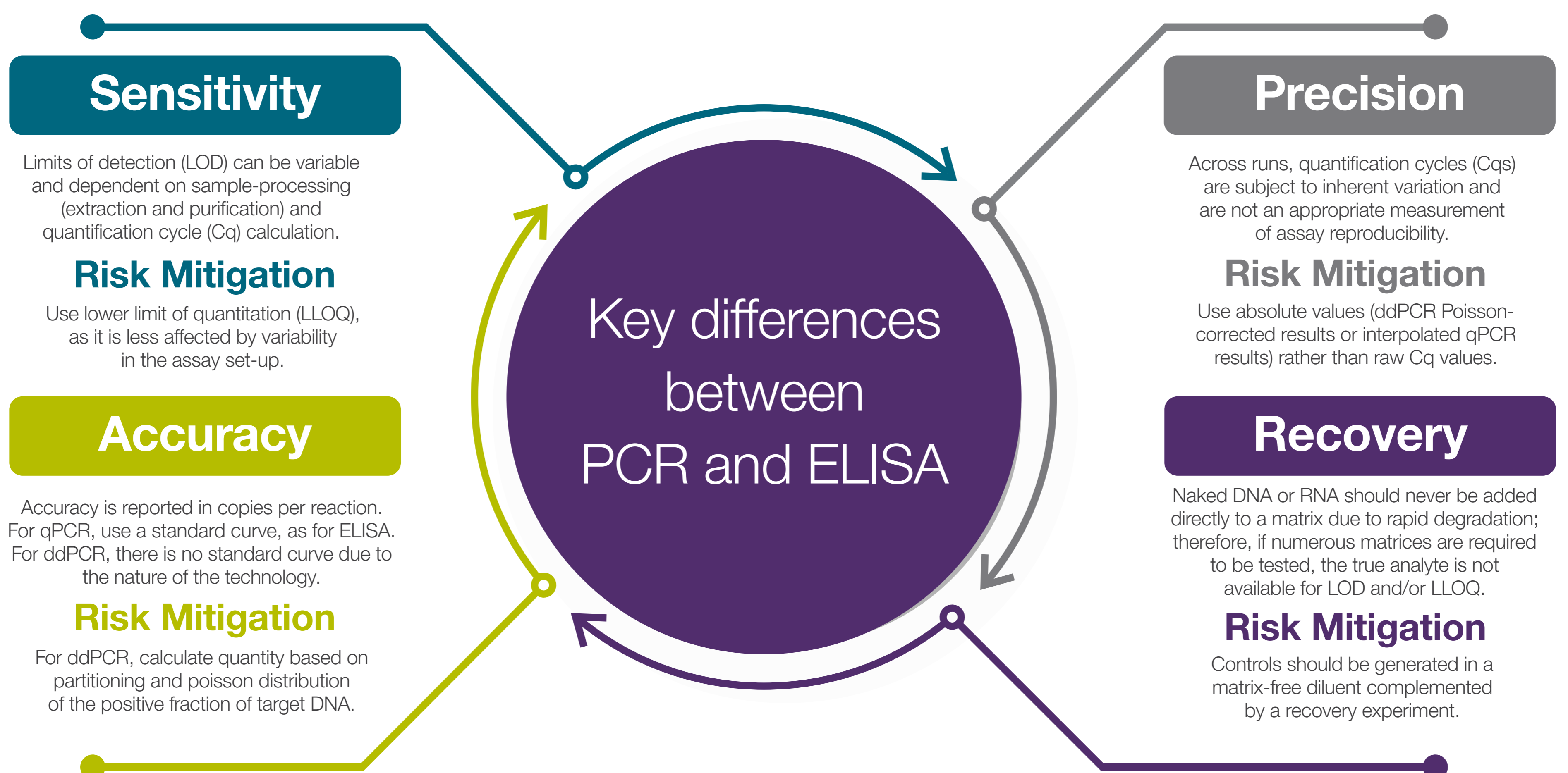


Using a similar assay framework can be beneficial; however, the technologies differ in sample preparation requirements and detection methods, which can affect the validation parameters of the PCR assay



When developing a quantitative nucleic acid method for PK analysis, key differences from standard ELISA assays must be considered

Current guidance for validation testing parameters of immunoassay PKs is clear. However, there is no regulatory guidance for validation of nucleic acid PK assays.



The validation parameters outlined reflect the need to understand current regulatory recommendations in the context of use and applicability for PCR-based PK assays, to best mitigate risks resulting from lack of clear regulatory guidelines.

Working with a partner that continually evaluates trends, guidance, and industry recommendations on building a model-validated PCR assay for PK can enable you to navigate adoption of new methods, understand regulatory considerations, and provide an agile response to your study's needs.

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