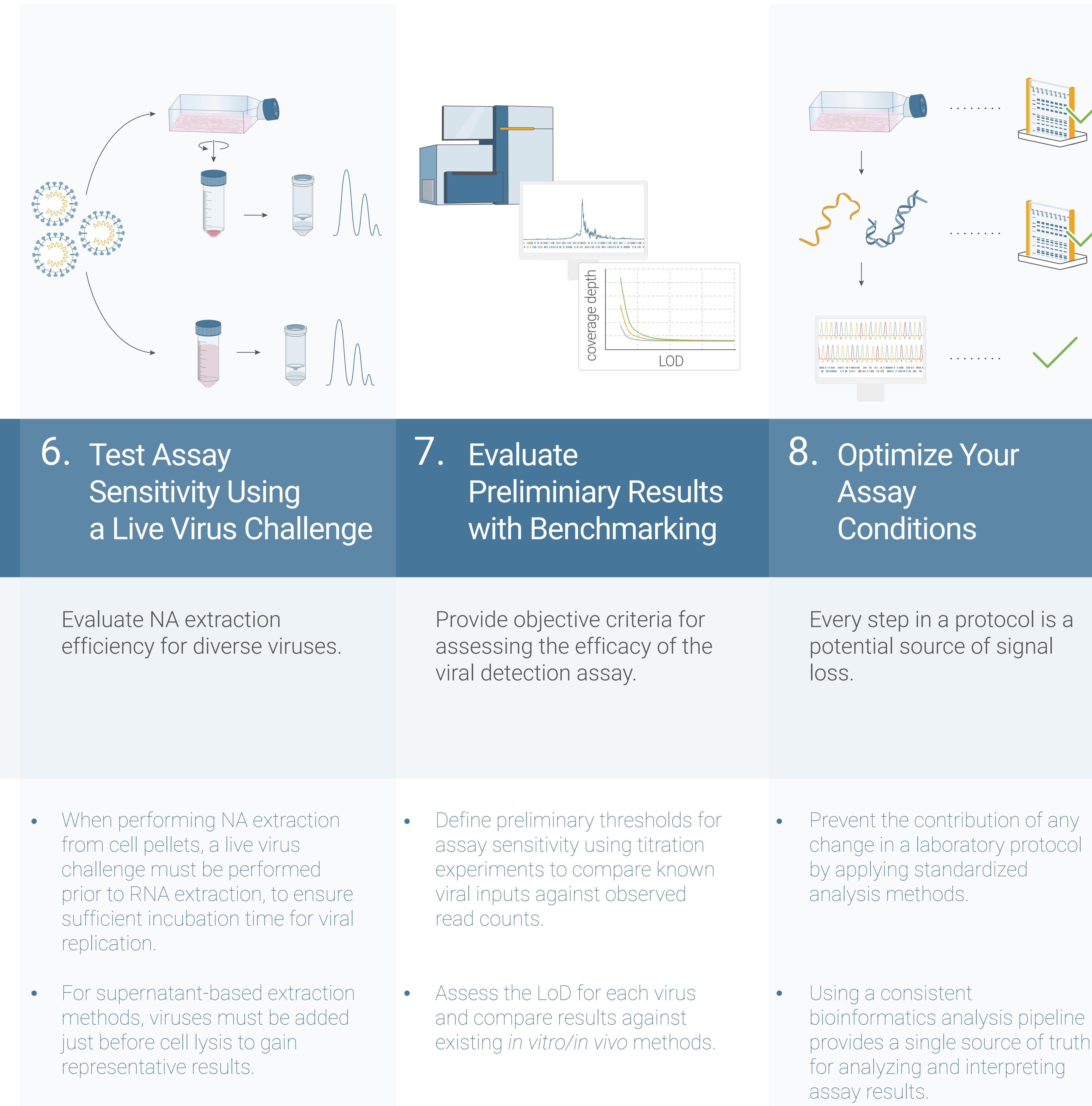
10 Steps to Implement an NGS-Based Biosafety Assay

	<image/>	<image/>		
 Define Your Success Criteria 	2. Define the Assay Purpose	3. Ensure Detection of All Virus Types	4. Evaluate Preliminary Workflows in silico	5. Test the Sensitivity with NA Spike-In
Provide actionable targets for assay development.	Select the optimal protocols and starting material required.	Adventitious Agent Detection (AAD) assay performance is impacted by the extensive variability in viral genome composition (RNA vs. DNA), genome size, and resistance to lysis.	<i>In silico</i> testing is gold standard for assessing true-positive and false-positive detection rates for any assay.	Use of nucleic acid (NA) spike-in to estimate the Limit of Detection (LoD) provides quatifiable evaluation of post-lysis extraction efficiency and library preparation without live virus use.
 Document assay objectives, benchmarking standards, and success criteria in direct collaboration with internal stakeholders. 	• For internal quality control (QC) assays, RNA extraction from the cell pellet is a simple method to detect viral contamination.	• Identify facilities where live virus work can be performed.	 Implement preliminary bioinformatic workflow (such as those provided by Genedata Selector[®]). 	 Perform initial tests by spiking-in NAs to the cell lysate at defined concentrations (with the use of e.g., ddPCR), to determine the sensitivity of the assay.
	• Validation of lot release or assessment of cell bank material requires both DNA and RNA extraction from the supernatant to achieve the required sensivity.	• Generate a representative panel of viruses with different lysis susceptibilities, containing ssRNA, dsRNA, DNA, and genomes of varying sizes.	• Optimize bioinformatic parameters in combination with your reference databases to establish a baseline for assessing <i>in vitro</i> results.	 Spike-in tests serve as an excellent starting point when designing and calibrating bioinformatic pipelines.



Your	9. Finalize the Validation of Your Assay	10. Automate Your Data Workflows
protocol is a ce of signal	Ensure consistent reproducibility of adventitious agent detection.	Automated analysis of large, complex data sets reduces bottlenecks for faster, more confident decision making.
ribution of any pratory protocol dardized ds.	• Repeat experiments to validate initial results and confirm the reproducibility of your assay.	 Adopt Genedata Selector for automated, easy to use analysis workflows, operable by laboratory personnel without the need for extensive bioinformatics trainings.
ent nalysis pipeline e source of truth d interpreting	 Confirm the target sensitivity and specificity of your assay. 	 Genedata Selector[®] integrates your data, tracks your samples, generates reports, and can be implemented in a GMP compliant environment.