Simplify mRNA Analytics

Speed Development of mRNA Vaccines

With InDevR's easy-to-use VaxArray® Platform you can bring mRNA analytics to your laboratory for essential CQA measurements, like mRNA intactness and 5' capping efficiency with 5'Cap***Q***, as well as identity and quantity testing of multivalent naked and LNP-encapsulated mRNA mixtures.

5'Cap*Q* Assay: Simplify Measurement of mRNA Attributes

Current vaccine manufacturers measure mRNA intactness and 5' capping efficiency using complex chromatographic methods that can take up to 2 days plus additional queue and analysis time. Reduce analytical wait times during mRNA vaccine development with the 5'Cap***Q*** Assay.

- **Develop Vaccines Faster:** Consolidate your mRNA capping and intactness testing into 1 assay that can be completed in less than two hours.
- **Analyze at Your Benchtop:** Reduce testing bottlenecks by bringing mRNA analytics to your facility.
- **Standardize mRNA Characterization:** Easy-to-use microarray-based platform that requires no unique expertise to operate.

mRNA Molecules Detected During Testing

mRNA Molecule Description	Current 5' Capping Test (LC/MS or HPLC)	Current PolyA Tail Test (LC/MS, HPLC)	Current Integrity Test (CE, CGE, or Gel)	InDevR's Assay Capped and Intact mRNA
Capped mRNA with no polyA tail	⊖	⊗	⊗	⊗
AAAAA Uncapped mRNA with a polyA tail	⊗	⊖	⊖	⊗
AAAAA Fully Intact and Capped mRNA	✓	✓	✓	✓

⊖ = overstated measurement as the sample is not a complete intact capped mRNA

Desired mRNA

Rapidly Measure Intact mRNA and 5' Capping Efficiency

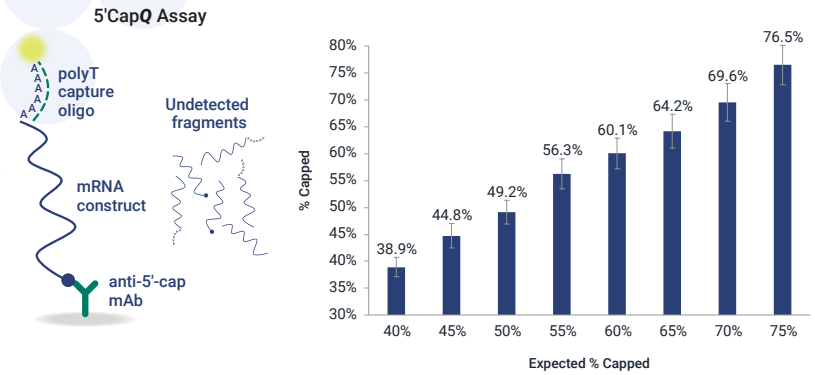
The 5' cap and poly(A) tail elements of mRNA are essential for protein expression and mRNA stability. Waiting for the mRNA analysis of concentration, intactness, and purity from a central laboratory or outsourced partner slows down mRNA vaccine development.

In just 90 minutes, the 5'CapQ Assay is a simple, direct measurement of capped and tailed mRNA. This assay works by capturing the mRNA molecules via the 5' cap and labeling the molecules on the poly(A) tail, enabling quantification of only the complete intact mRNA molecules. RNA molecules that lack a 5' cap or poly(A) tail are not measured in the 5'CapQ Assay, leading to a single test for quantifying your mRNA.

Trial Sample Submission Form for 5'Cap*Q* Assay

Use the QR code to learn more about the 5'Cap***Q*** Assay and to submit samples to verify how this 5' capping test will work in your analytics process.

Case Study: Differentiation of 5% Capping Ratios



Expected Value	Measured Capping Efficiency (95% CI)	Difference from Expected
40%	38.9 (38.4 – 39.4)%	-1.1%
45%	44.8 (44.1 – 45.3)%	-0.2%
50%	49.2 (48.5 – 49.8)%	-0.8%
55%	56.3 (55.5 – 57.0)%	+1.3%
60%	60.1 (59.3 – 60.8)%	+0.1%
65%	64.2 (63.3 – 65.0)%	-0.8%
70%	69.6 (68.7 - 70.5%	-0.4%
75%	76.5 (75.5% - 77.5)%	+1.5%

Figure 1. 5'Cap***Q*** measurement of contrived samples with known % capping efficiency.

Case Study: Custom Assay Development for Multivalent mRNA

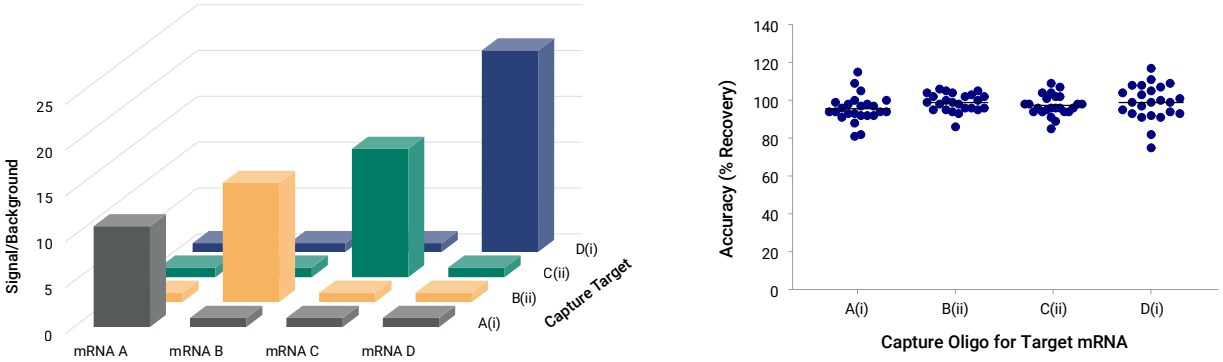
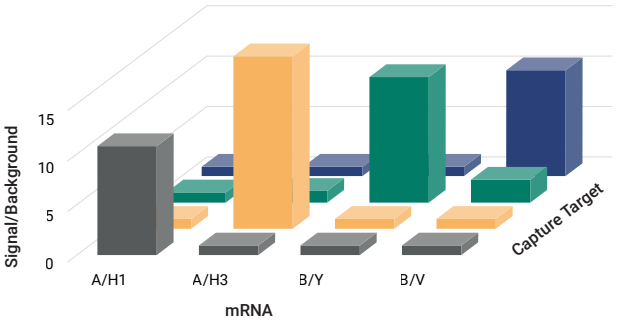


Figure 2. In collaboration with Pfizer, a custom assay for mRNA identity and quantity was developed with captures highly specific to each of 4 mRNAs, mRNA A, B, C, and D. The assay was shown to accurately quantify a quadrivalent LNP-encapsulated mixture of mRNA with precision of ≤10% CV in under 2 hours without additional processing steps.[1]

mRNA flu*IQ*: Universal Identity and Quantity of Quadrivalent Influenza HA mRNA



The mRNA flu***IQ*** Assay was strategically designed to provide universal reactivity for HA from A/H1, A/H3, B/Yamagata, and B/Victoria mRNA sequences. This assay contains multiple capture oligos per vaccine component for robustness to different codon optimization schemes and the assay has shown broad reactivity to strains from over a decade of influenza seasons.

Figure 3. Specificity of quadrivalent influenza HA mRNA for mRNA flu***IQ*** Assay.

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1. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4849255

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