



EPI2ME end-to-end workflows for biopharma quality control of plasmids and mRNA

Sample preparation, bespoke basecalling and medaka models, the Q-Line GridION™ device, and EPI2ME™ analysis workflows are revolutionising quality control in biopharma

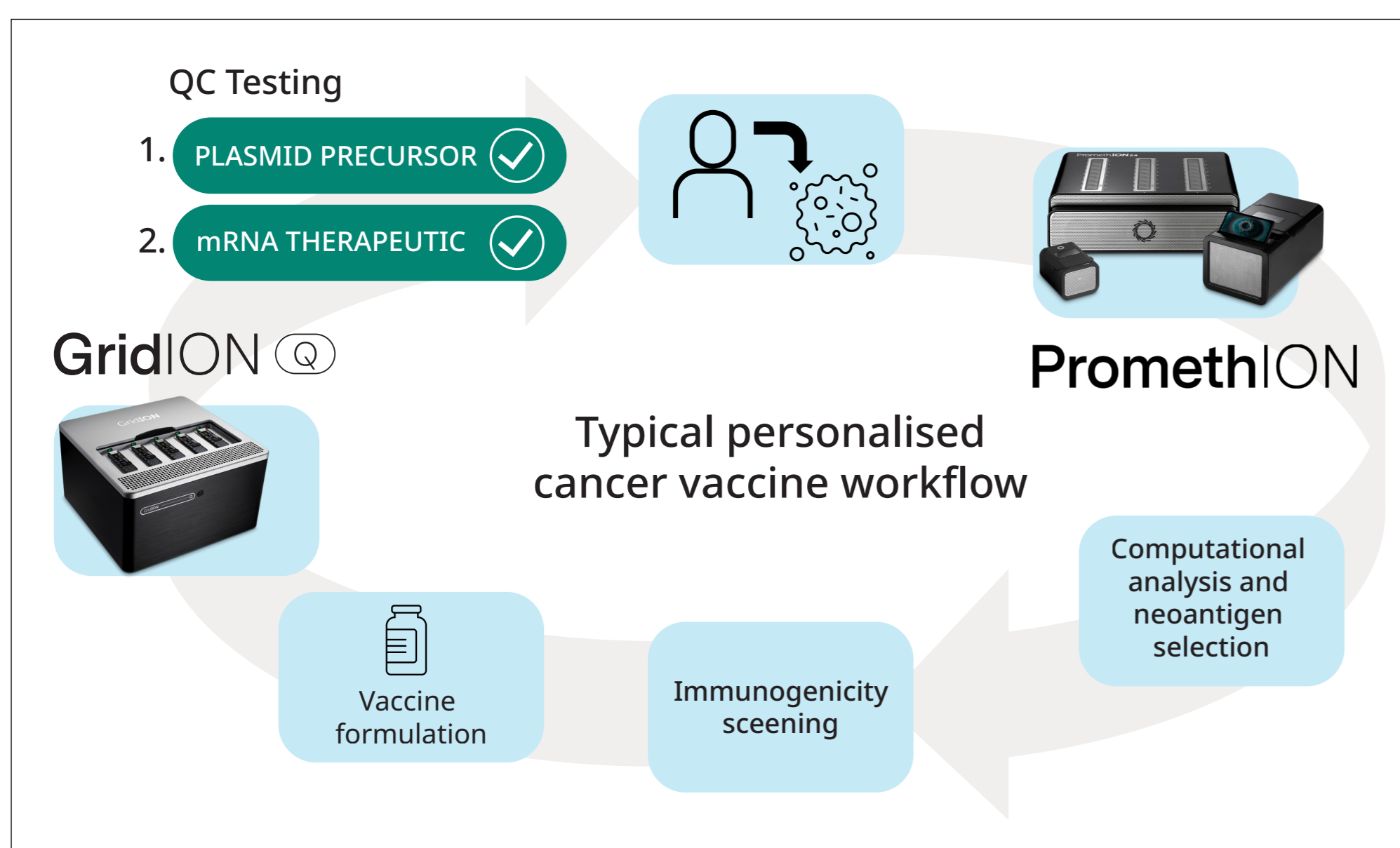


Fig. 1 A typical personalised cancer vaccine/therapeutic workflow.

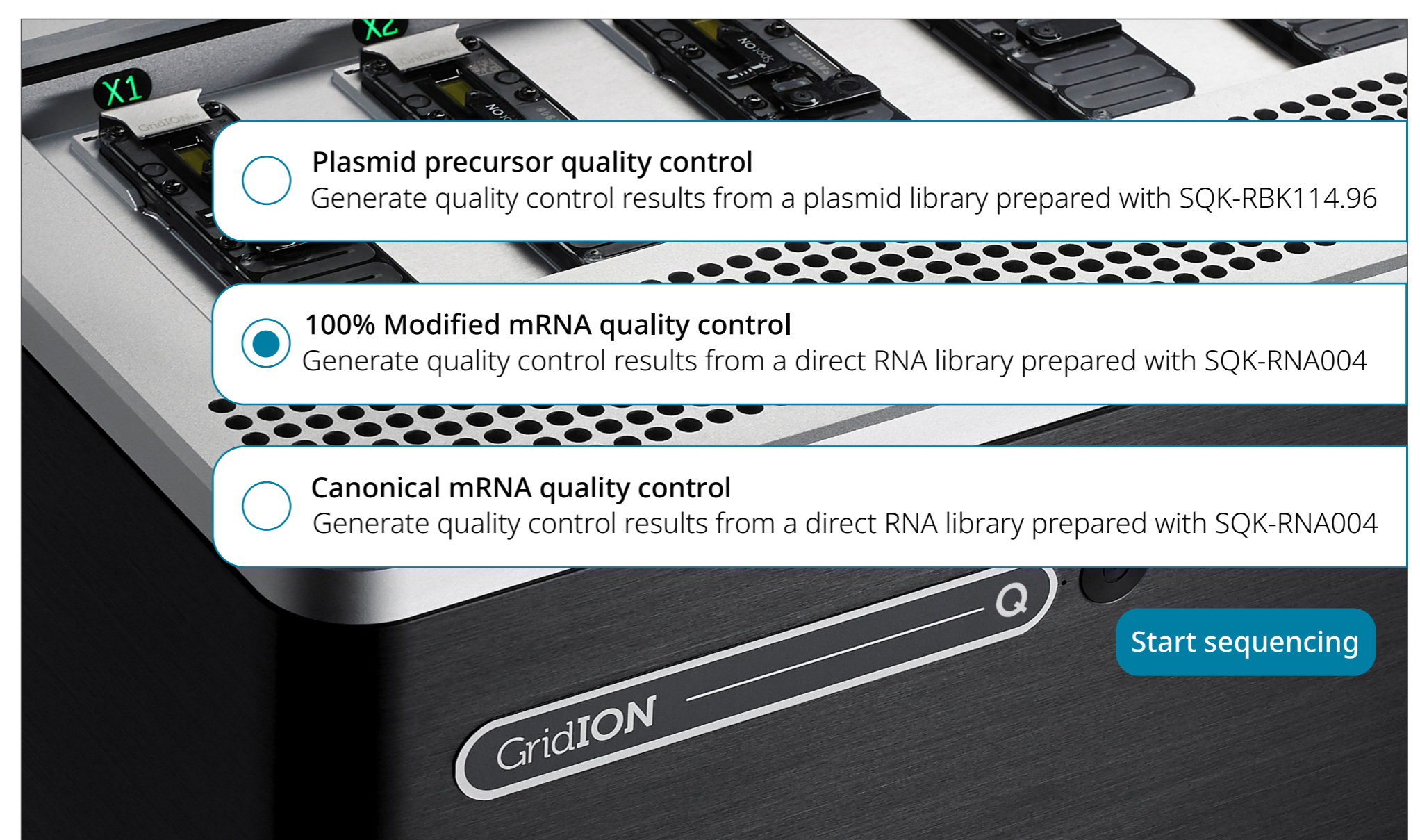


Fig. 2 Optional plasmid and mRNA vaccine quality control workflows available on the Q-Line GridION.

Personalised mRNA therapeutics hold promise in the treatment of cancer

Oxford Nanopore sequencing can now help in the discovery and production of mRNA therapeutics*. This new class of treatment was successful during the SARS-CoV-2 pandemic, where mRNA vaccines provided much-needed immunity to the virus. Attention has turned to other uses of this technology, one of which is personalised cancer treatments. Tissue is taken from a person with cancer and sequenced to discover changes in the tumour that could be used to help prime the immune system to target and destroy cancer cells. These 'neoantigens' are screened for immunogenicity and promising candidates are manufactured from plasmid precursors into final mRNA formulations. Our new biopharma end-to-end workflows can replace traditional quality control methods, which will be required once these technologies are scaled.

Quality control assays are available on the Oxford Nanopore Technologies Q-Line GridION

Q-Line GridION is a cost-effective and compact benchtop system offering on-demand sequencing with integrated real-time data processing. With the capacity to run five flow cells either concurrently or individually, Q-Line GridION provides busy labs and service providers with cost-efficient access to the advantages of long-read, real-time nanopore sequencing. For biopharma, the devices are pre-loaded with assays, including plasmid and mRNA quality control. These assays comprise optimal sequencing settings, analysis configuration, and the analysis itself. Users are presented with a simple interface allowing assay selection, sample sheet selection, and sequencing start. Analysis is started automatically after sequencing completion and requires no additional user input.



Fig. 3 Plasmid quality control EPI2ME workflow report examples.

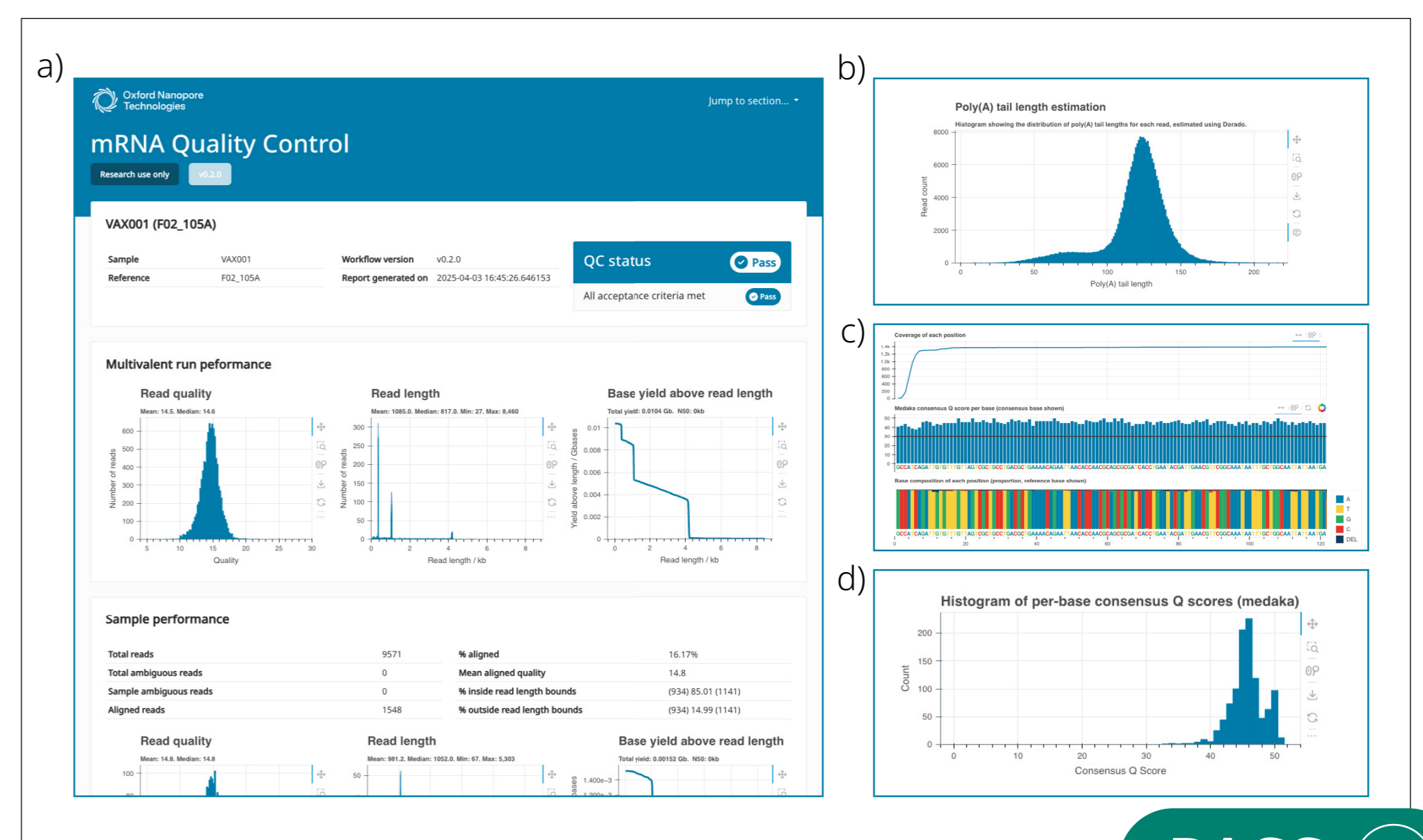


Fig. 4 mRNA vaccine quality control EPI2ME workflow report examples.

Plasmid precursor quality control workflow assesses critical quality attributes

Plasmids are manufactured containing the sequence of the mRNA therapeutic of interest. Oxford Nanopore sequencing of these precursors produces full-length reads, which allow the full sequence of the precursors to be interrogated. The analysis allows users to customise several acceptance criteria (Fig. 3a), and these critical quality attributes are then compared to the analysed data. A clear pass or fail result is displayed. Detailed analysis of coverage (Fig. 3b), an interactive plasmid map (Fig. 3c), and any contaminating sequences (Fig. 3d) are also shown in reports alongside the usual basic run statistics, such as read length and quality.

mRNA quality control workflow assesses critical quality attributes of the final mRNA product

Recent advances in direct RNA sequencing (dRNA), basecalling models, and poly(A) length prediction mean we can now offer an assay for mRNA quality control. This assay includes models for 100% N1-methylpseudouridine modified mRNA, a modification commonly used in mRNA therapeutic production, and a dRNA medaka model. The analysis can deconvolute up to 16 dissimilar vaccines in one mixture and provides an intuitive report (Fig. 4a) containing poly(A) length predictions from Dorado (Fig. 4b), coverage, per-base quality scores from medaka (Fig. 4c), and a summary for those scores (Fig. 4d). The analysis compares critical quality attributes to user-provided thresholds to give an overall quality control status.

*Oxford Nanopore Technologies products are currently for research use only (RUO). Information correct at time of publication. May be subject to change.

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