

TESTING

- Viral safety testing for cell banks and in-process samples
- · Cell bank characterization
- Shallow NGS (alternative to karyology) for characterization and genetic stability of cell lines
- Integration site analysis (for genetically modified calls) for clone selection and genetic stability of cell lines

BENEFITS OF NGS FOR CULTURED MEAT

- ✓ Single test covers all viruses → reduced complexity and cost
- Ethical alternative to traditional animal based testing
- ✓ Precise selection of clones for banking
- NGS is well accepted by regulatory authorities

VIRUS TESTING AND GENETIC CHARACTERIZATION ACROSS THE CULTURED MEAT PROCESS Collection Cell Bank Cell Culture Product Raw material testing Cell line characterization Recommend to test cell banks for virus as early as possible to avoid downstream delays Final product testing

Cultured meat and seafood offers exciting potential as a more ethical and sustainable alternative to traditional farming. However, with production methods parallel to existing biopharmaceutical processes, regulators are requesting similar levels of testing and characterization. Ironically, traditional characterization and adventitious agent testing packages often rely on the use of animal models, which runs counter to the ethical benefits of cultured meat. In addition, these testing and characterization packages are not aligned with the cost and timeline expectations of the cultured meat sector.

Defining a suitable virus testing and cell line characterization strategy is basic good practice. For example, testing the cell banks as early as possible will significantly reduce the impact on development if a viral threat is identified. Adventitious viral threats can also

pose risks not only to the end consumer, but also to the operator within the process.

PathoQuest is a leading provider of services to the highly regulated biopharmaceutical industry, and has a proven track record in providing GMP level NGS characterization and release testing strategies. This experience extends into the cultured meat sector having already submitted data to EFSA (the competent authority for food applications). PathoQuest can offer our agnostic transcriptome assay for the detection of a full range of viruses; as well as working to customer specific requirements with our targeted assay. We are proud to be working alongside the leading companies in cultured meat and seafood by providing our expert knowledge and services in a timely, cost-effective and ethical manner

SAMPLE	SHIPMENT &	STANDARD	FASTTRACK
REQUIREMENTS	STORAGE	TURNAROUND TIME	TURNAROUND TIME
5x10° cells (≥10µg DNA per sample)	Dry Ice / -80°C	6 weeks	3 weeks