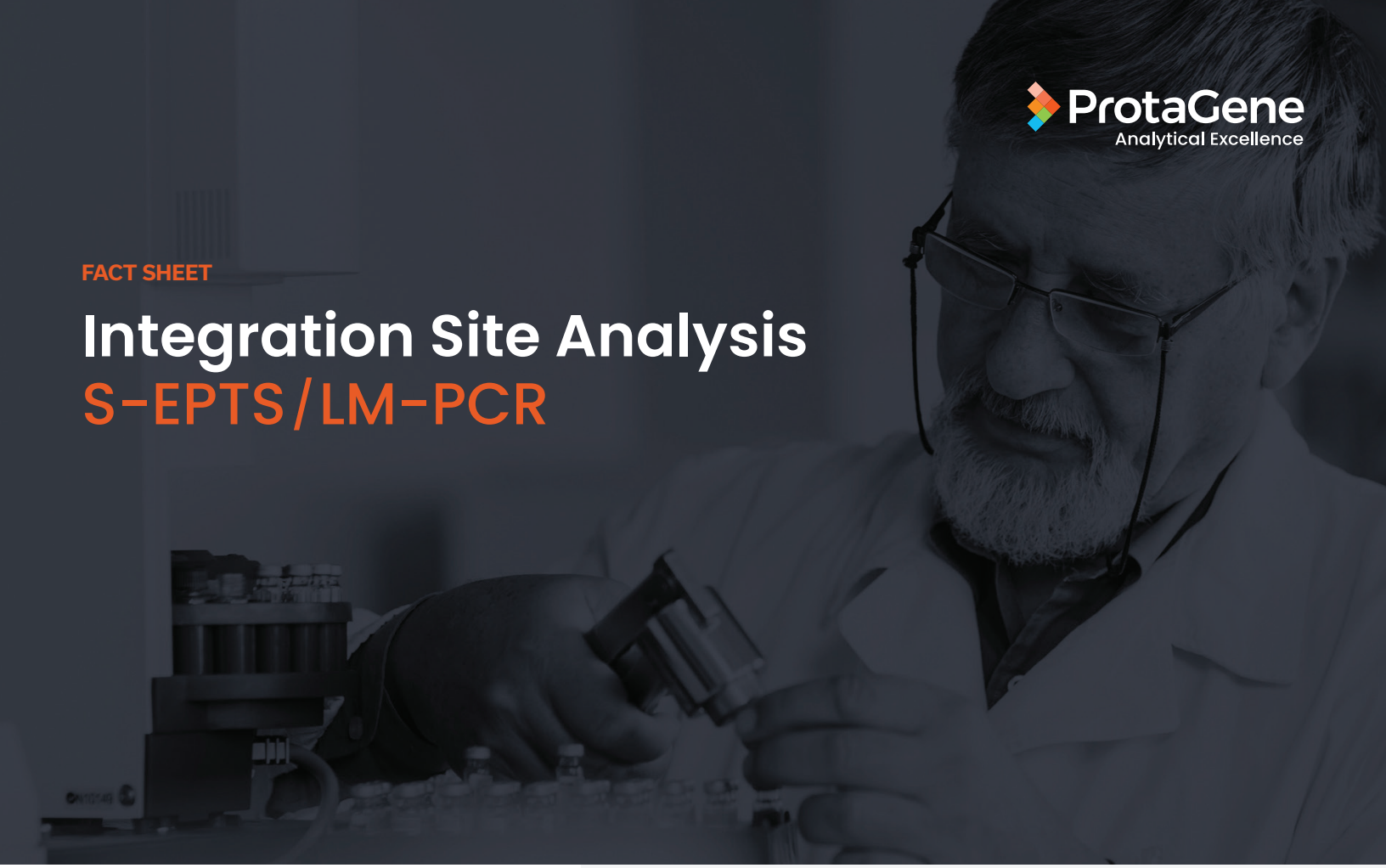

ProtaGene
Analytical Excellence

FACT SHEET

Integration Site Analysis
S-EPTS/LM-PCR

For more than 20 years, GeneWerk, now part of ProtaGene, has pioneered and advanced Integration Site Analysis (ISA). Our S-EPTS/LM-PCR approach is the first validated ISA, and datasets have been positively reviewed by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Your Partner in Vector Integration Site Analysis

With over 20 years' experience in gene therapy and vector safety assessment, including over 130 peer-reviewed publications and over 50 cell and gene therapy clinical trials, ProtaGene's team of experts work with clients across the globe in vector integration site programs.

From project design and execution, through to data interpretation and regulatory approval, we provide agile, customer-focused solutions to support clients at every stage of the vector safety assessment process.

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Analytical Excellence

Europe
Inselwiesenstraße 10
74076 Heilbronn Germany

North America
4 Burlington Woods Drive
Burlington, MA 01803 USA

ProtaGene.com
info@protagene.com

Why S-EPTS/LM-PCR?

LAM-PCR has been the gold standard for ISA for over 20 years. Widely recognized by the scientific community, industrial partners and regulatory bodies, it has been applied in numerous early-stage gene therapy pre-clinical studies and clinical trials. Indeed, it allows us to identify 17 out of 20 Serious Adverse Events in previous clinical trials.

S-EPTS/LM-PCR takes the science behind LAM-PCR to the next level eliminating restriction enzyme-associated biases and reducing amplification steps. It delivers a superior assay performance in terms of quantification, precision and accuracy, as well as reproducibility. Our optimized workflow enables us to provide fast-track services oriented to clinical scenarios where, for example, pre-infusion analysis of CAR-T drug products are required, or eventual Serious Adverse Events demand faster turnarounds.

S-EPTS/LM-PCR is attracting increasing attention from the industry and has already been successfully employed in numerous clinical trials and regulatory filings.

Enabling Today's Therapeutics

Partnering for Pipeline Success

De-risking Regulatory Approvals

Advancing Gene Therapy Platforms

Providing Expert Support at Every Stage

ProtaGene delivers a full service tailored to the needs of each client, from receiving samples to report delivery, including sample QC, library preparation, next generation sequencing, bioinformatics analysis and reporting.

In addition to our basic analyses focusing on integration site mapping and quantification of individual frequencies, we have available advanced bioinformatics packages for a deeper characterization of your vector's integration profile allowing for deeper safety assessments. Our expert team will also work with you for the development of customized techniques or analysis workflows in order to support your investigations or eventual regulatory requestions.

Working With Us

ProtaGene provides cell and gene therapy sponsors with patient testing services in compliance with guidance by the FDA and EMA.

We are recognized as a leading provider of ISA services and provided the safety assessment of different gene therapy vector platforms and cell therapies for submission to regulatory agencies.

Our test menu also includes vector persistence testing, gene editing on-/off-target analysis, vector copy number, quality control of vector batches, immune repertoire analysis, and dedicated bioinformatics studies.

With a focus on vector safety, characterization, and efficacy, our employees work in compliance with GCP and in line with GLP standards in a BSL-2 classified state-of-the-art genomics and bioinformatics laboratory.

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v.122022