proteindynamic SOLUTIONS

BIOPHARMACEUTICAL ANALYSIS IN REAL-TIME

Multiple attributes on a single platform

Deamidation | Protein Identification | Stability
Aggregation | Bacterial Detection | Endotoxins

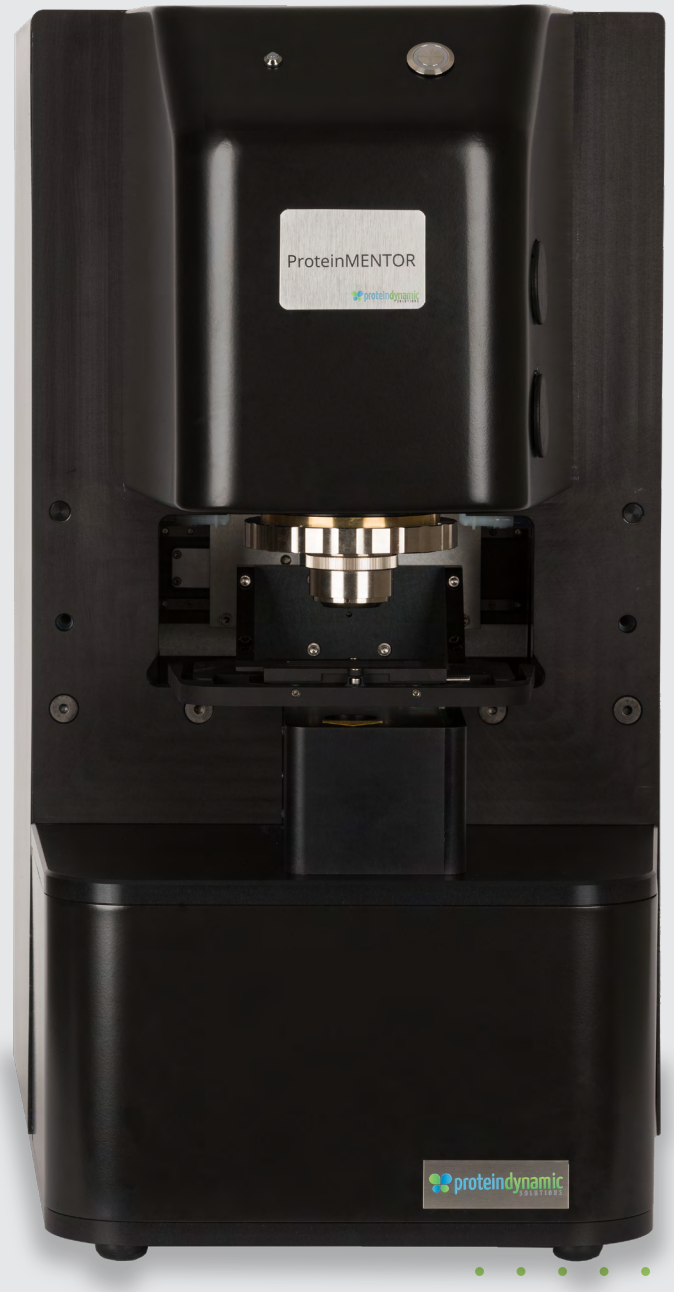
ProteinMENTOR®

BENEFITS

No sample preparation • Multi-attribute • Low sample volumes • Automated platform • Multiplexed analysis • Small footprint • 21 CFR Part 11 compliant

WHY QCL-IRM?

Infrared spectroscopy, especially using quantum cascade lasers, is extremely sensitive to conformational changes. QCLs offer fast acquisition without the need for cooling systems and deliver the highest signal-to-noise ratios.



WHY MICROSCOPY?

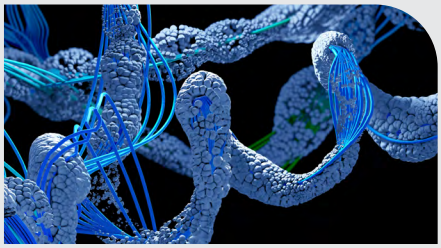
Using only one microliter of sample, hyperspectral images can uncover aggregates, particulates and self-association. The unique slide cell array and accurate thermal heating, allow for real-time changes in proteins to be monitored.

APPLICATIONS

- Deamidation
- Aggregation
- Bacterial Detection
- Endotoxin Testing
- Stability
- Protein Identification
- Epitope Mapping
- Crystallization Screen
- Protein/Protein Interactions

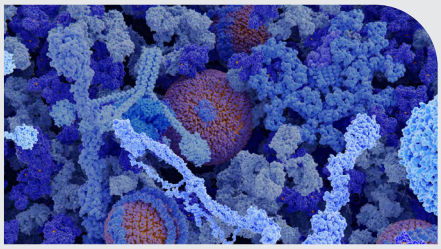
ENHANCE CRITICAL QUALITY ATTRIBUTE MONITORING – WITH A COMPLIANT SOLUTION

Essential applications for optimized drug candidate selection, formulation and release testing



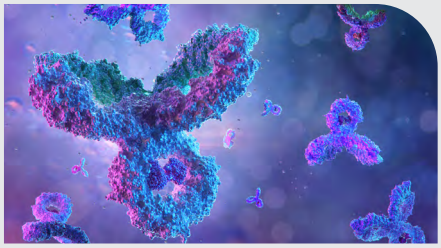
DEAMIDATION

With ProteinMentor, deamidation can be both characterized and quantified on a single platform in real-time, without sample preparation. The full-length protein can be analyzed in formulation.



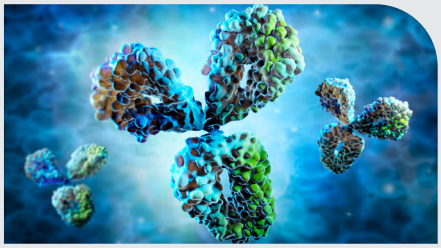
AGGREGATION

ProteinMentor allows for the direct visualization of aggregates and the determination of the regions, amino acids and mechanisms that lead to aggregation. Detecting changes in the protein structure that may lead to the onset of aggregation reduces the risk of immunogenicity.



STABILITY

ProteinMentor can determine the onset of a thermal transition and the actual thermal transition temperature of a therapeutic protein. This approach offers increased understanding of how these elements contribute to a therapeutic protein's stability.



PROTEIN SECONDARY STRUCTURE

ProteinMentor can be implemented to assess changes in protein secondary structure and to understand the impact that process changes or purification steps have on the protein structure. Such in-depth understanding leads to the development, production and release of safe, stable and effective therapeutics.

BACTERIAL & ENDOTOXIN DETECTION

ProteinMentor provides a dynamic fingerprint of changes occurring within the mix of cells from a bioreactor. Using the dedicated application packages for bacterial and endotoxin detection, contamination can be detected 50% earlier than with traditional approaches

proteindynamic SOLUTIONS

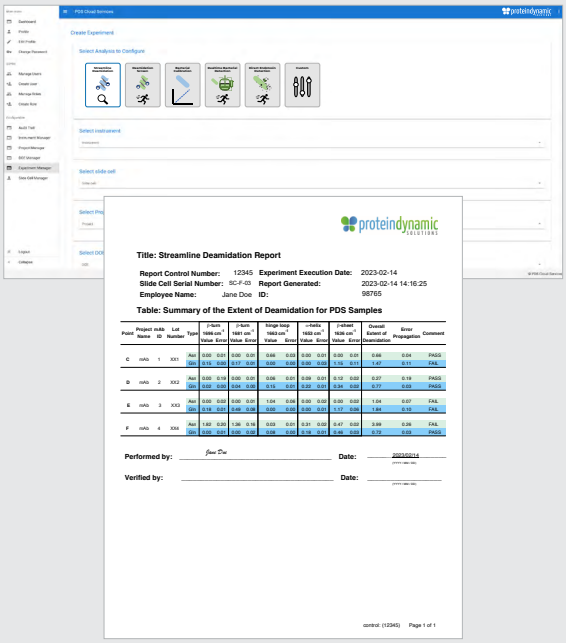
ProteinMentor is a Quantum Cascade Laser-based IR microscope that offers:

- Fast image acquisition
- High signal-to-noise ratio
- Rapid collection of multiplexed data
- 2D data correlation to resolve subtle spectral changes
- Thermal control to test stability under a range of environmental temperatures in real-time

The unique design of the microscope stage and slide cell array (SCA) allows samples to be monitored under controlled thermal conditions, with a fixed path length, which is critical for both reproducibility and accuracy.

The proprietary multi-well slide cell arrays enable:

- Comparison between multiple samples and/or against reference standards
- Small sample volumes (only 1-2 µL) to conserve valuable drug product
- No time-consuming or costly sample preparation steps
- No tags, labels, or probes are required



Title: Streamline Deamidation Report

Report Control Number: 12345 Experiment Execution Date: 2023-02-14
Slide Cell Serial Number: SC-F-03 Report Generated: 2023-02-14 14:16:25
Employee Name: Jane Doe ID: 98765

Table: Summary of the Extent of Deamidation for PDS Samples

Point	Project Name	mAb ID	Lot Number	Type	β-turn 1696 cm⁻¹ Value	β-turn 1681 cm⁻¹ Value	Error	fringe loop 1663 cm⁻¹ Value	Error	α-helix 1650 cm⁻¹ Value	Error	β-sheet 1636 cm⁻¹ Value	Error	Overall Extent of Deamidation	Error Propagation	Comment
C	mAb	1	XX1	Act	0.00	0.01	0.00	0.01	0.66	0.03	0.00	0.01	0.00	0.01	0.66	0.04	PASS
				Obs	0.13	0.03	0.17	0.01	0.59	0.03	0.00	0.00	1.15	0.11	1.47	0.11	FAIL
D	mAb	2	XX2	Act	0.00	0.19	0.00	0.01	0.06	0.01	0.09	0.01	0.12	0.02	0.27	0.19	PASS
				Obs	0.02	0.05	0.04	0.00	0.16	0.01	0.33	0.01	0.34	0.03	0.77	0.03	PASS
E	mAb	3	XX3	Act	0.00	0.02	0.00	0.01	1.04	0.06	0.00	0.00	0.00	0.00	1.04	0.07	FAIL
				Obs	0.18	0.01	0.49	0.08	0.00	0.00	0.00	0.01	1.17	0.05	1.69	0.10	FAIL
F	mAb	4	XX4	Act	1.82	0.20	1.36	0.16	0.03	0.01	0.31	0.02	0.47	0.02	3.99	0.26	FAIL
				Obs	0.00	0.01	0.00	0.00	0.08	0.02	0.18	0.01	0.46	0.05	0.72	0.03	PASS

Performed by: Jane Doe Date: 2023/02/14

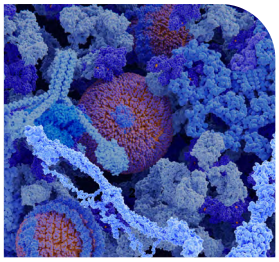
Verified by: Date:

control: (12345) Page 1 of 1

For each sample well the ProteinMentor software generates

- A hyperspectral image, which may be interrogated to track and differentiate between extraneous contaminants and/or the formation of aggregates, disordered structures, and crystals.
- A traditional IR trace showing change of peak shape and maxima position over stress (such as steps in a temperature ramp)
- A plot of the peak maxima for the protein of interest. This indicates the condition of onset of structural change, such as the transition temperature.
- 2D IR correlation plots which indicate the regions, specific amino acids, & secondary structures involved in structural changes such as instability, aggregation or ligand binding.

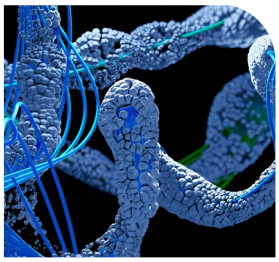
PUBLISHED, PEER-REVIEWED, COMPLIANT TECHNOLOGY



APPLICATION NOTE

Real-time assessment of thermal perturbation of therapeutic proteins: Aggregation

APPLICATION NOTE



APPLICATION NOTE

Streamlined Deamidation Assessment During Thermal Stress

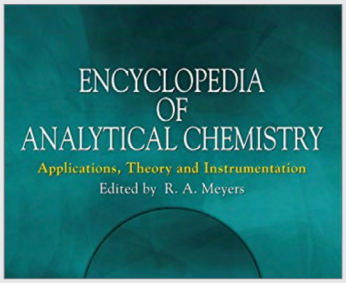
APPLICATION NOTE

analytical chemistry

Developability Assessment of an Isolated CH2 Immunoglobulin Domain

Anal. Chem. 2021, 93, 3, 1342–1351

READ MORE



Two-Dimensional Correlation and Two-Dimensional Co-Distribution Spectroscopies of Proteins

READ MORE

NSF

National Science Foundation, Small Business Innovation Research awardee. Multiple awards for early-stage product development 2015 SBIR Phase I & IB, 2016 SBIR Phase II, 2018 SBIR Phase IIB

READ MORE

21 CFR PART 11 COMPLIANT | ALCOA+

Laboratory data must be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, available (ALCOA+)

21 CFR PART 11 | ALCOA+

WHAT PEOPLE ARE SAYING

"A simple assay that can detect minor changes in the secondary or tertiary structure of proteins brings huge benefit."

"Faster, higher throughput methods that give us better information along the way, provide a more robust process."

"These analyses allow for the evaluation of the stability of the protein sub-populations within a sample without any sample preparation steps."

"ProteinMENTOR has a lot of advantages over the gold standard for deamidation. You can do more, you can run more samples, you can run more quickly."

Protein Dynamic Solutions offers a complete package for applications in biopharmaceutical testing with the ProteinMentor platform, our dedicated slide cell arrays, maintenance contracts and validation packages.

SPEAK TO US ABOUT YOUR NEEDS

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Advance your Critical Quality Attribute Analysis with ProteinMENTOR

Enhance regulatory compliance

Increase speed to market

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