

## // SFIDA – SINGLE PARTICLE ANALYSIS FOR CNS DIAGNOSTICS AND QC OF BIOPHARMACEUTICALS

Ref-No: TA-S0030

### BACKGROUND

sFIDA (surface-based fluorescence intensity distribution analysis) is a platform technology for quantitating and sizing single protein aggregates. sFIDA combines the selectivity of an immunological assay with the sensitivity of high-resolution fluorescence microscopy. It features single particle sensitivity and absolute specificity for aggregates. The technology was developed for oligomer-based diagnostics of Alzheimer's and Parkinson's disease as well as for single particle analysis in development and QC of biologicals.

### PROBLEM

Protein aggregation is the key pathological hallmark in neurodegenerative disorders. Therefore, many therapeutic strategies aim to prevent aggregate formation, especially of neurotoxic small oligomers. However, quantification of oligomers in body liquids as a biomarker is hampered by the low concentration of oligomers and the presence of monomers.

In biopharmaceutical products, protein aggregates can cause serious side effects when applied to humans. Especially subvisible particles are critical due to their immunogenicity. However, there is a lack of methods to monitor aggregate formation in the subvisible size range.

### SOLUTION

- sFIDA quantitates oligomers as CNS biomarker at femtomolar concentrations in body liquids.
- sFIDA quantitates aggregates in biopharmaceutical products in sizes ranging from 10 nm to 50 µm.



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### DEVELOPMENT STATUS

Trial

### CATEGORIES

//Medicine and  
pharmaceutics //Diagnostics

## SCOPE OF APPLICATION

- sFIDA can be used in pre-clinical and clinical studies of neurodegenerative disorders. It helps selecting and stratifying patients that will most likely respond to the treatment. sFIDA enables assessing mechanism of action and target engagement as well as therapy monitoring and outcome measure at the molecular level.
  - In development and formulation studies of biopharmaceuticals, sFIDA can be used for early detection and quantitation of subvisible particles.
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## SERVICE

sFIDA is currently available for analysis of cerebrospinal fluid samples. Validation of a sFIDA-based blood test is pending.

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