

Review Article

## Emerging Trends in Therapeutic Monoclonal Antibody Bioanalysis: Artificial Intelligence, Automation, Micro sampling, and Future Perspectives

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**Abstract:** Therapeutic mAbs or biologics as well as engineered, bispecific and conjugate antibody-drug combinations are used to treat cancer, immune-mediated indications, infections and rare diseases. The mAbs, which are present in many complex, protein-rich biological matrices, require a holistic bioanalytical approach to address pharmacokinetics/pharmacodynamics (PK/PD), immunogenicity, biomarkers, molecular integrity, and drugs and drug-related species. This review discusses emerging methods expected to shape the future of mAb bioanalysis from time-consuming workflows to digital, miniaturized and automated processes, providing enhanced information and greater productivity. In particular, it describes AI/ML, automation and high-throughput platforms, microsampling, advanced MS and integrated digital workflows. AI/ML applications have demonstrated improved analysis of complex datasets, including Raman-based prediction with 2.4% error versus 14.6% using linear analysis, XGBoost-based N-glycan quantification consistent with LC-MS ( $R^2 > 0.95$ ), and convolutional neural networks achieving  $R^2$  values of 0.94–0.99 for charge-variant and protein monitoring. However, most applications remain centered on process monitoring and physicochemical characterization rather than fully validated clinical bioanalysis. Automated and high-throughput LC-MS and immunoassay workflows improve throughput, reproducibility, and operational consistency, with applications including therapeutic drug monitoring of free and total infliximab. Microsampling approaches such as dried blood spots, volumetric absorptive what is the future of central laboratories? Microsampling, and dried capillary blood allow low-volume and decentralized sampling, with the reported strong serum concordance ( $R > 0.95$ ) and high ADA agreement. Nevertheless, many challenges are faced with matrix effects, hematocrit, stability, extraction efficiency, validation and regulatory acceptance. Success in the future will rely on integrated, standardized, interpretable, and fit-for-purpose workflows synergistically leveraging microsampling, automation, advanced MS, and AI-based data interpretation.

**Keywords:** Therapeutic Monoclonal Antibodies, Bioanalysis, Artificial Intelligence, Automation, Microsampling; Mass Spectrometry, Ligand-Binding Assays.

## 1. INTRODUCTION

Therapeutic monoclonal antibodies (mAbs) are the most prominent class of biopharmaceuticals owing to their high target selectivity and wide-ranging utilization in Oncology, Autoimmune and Inflammatory diseases, infectious diseases, as well as other chronic and rare diseases [1-3]. Studies show that the continuous development of conventional, engineered, bispecific and ADC formats will potentially improve the therapeutic potential of antibody-based medicines [4, 5]. Furthermore, the increasing molecular complexity requires the new parameters for a robust and insightful bioanalytical assessment [6, 7]. Bioanalysis of therapeutic mAbs is beyond measuring the drug concentrations. PK/PD, immunogenicity, biomarker, molecular integrity, and characterization of drug related species are anticipated to be important during drug development [8-10]. Owing to their large molecular size and high structural complexity as well as the protein-rich biological matrices, mAbs are inherently more challenging to quantitatively analyze than traditional small molecules [11-13]. As a result, LBAs, for example ELISA and ECL, and MS-based strategies remain essential analytical platforms for the bioanalysis of therapeutic mAbs [14-16]. The existing technologies are proven to be reproducible in analytical

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performance. However, increasing sample numbers, complex molecules formats and large analytical data sets indicate that a higher level of work flow efficiency might be desirable. Traditional lab procedures will probably involve repeated sampling, sample preparations, data processing and interpretation of the results [17-19]. Automation was shown to be able to reduce the amount of manual process as well as increasing the throughput and reproducibility while micro sampling methods were able to reduce the biological material volume needed [20-23]. In addition, the recent work demonstrated that micro sampling techniques combined with automated analytical work flows is a promising future trend of bioanalysis [24, 25]. Simultaneously, certain novel techniques such as high-resolution mass spectrometry, multiplexed assays, miniaturized analytical systems, and digital data processing are also expected to drive the progress of therapeutic monoclonal antibody analysis [26, 27]. Additionally, applications and advancements of artificial intelligence (AI) or machine learning (ML) are also being advanced, where they have emerged as an efficient and useful approach to analyze huge amount of analytical data, detect patterns, facilitate prediction, and support decision-making [28-30]. Although in current contexts, AI/ML is still in the early stage of applications in quantitative therapeutic monoclonal antibody bioanalysis, its challenges in data quality, model validation, reproducibility, explainability, and regulatory acceptance should be considered [31, 32]. While the AI/ML advancements may be more advanced in antibody discovery and development rather than in routine quantitative bioanalysis, this represents a promising future analytical research field [33]. In this context, emerging technologies are set to translate therapeutic mAb bioanalysis from traditional, laborious, large-volume workflows to more automated, miniaturized, data-driven, and integrated analytical solutions [33, 34]. For this reason, this review focuses on recent advances in AI & machine learning; automation and high-throughput analysis; micro sampling; new MS-based platforms; and integrated digital bioanalytical workflows for therapeutic mAbs [35]. In addition, the highlighted analytical applications, their strengths and limitations, and their predicted impact on the throughput, robustness, cost, and future scalability of therapeutic mAb bioanalysis are discussed [36].

## 2. AI/ML Applications in Therapeutic mAb Analytical Assessment

AI/ML is increasingly being integrated with analytical platforms to improve the identification, quantification, characterization, and quality assessment of therapeutic monoclonal antibodies (mAbs). Raman spectroscopy combined with machine learning has enabled rapid mAb identification and quantification with improved prediction accuracy compared with conventional linear analysis. [37]. XGBoost-based analysis of LC–fluorescence data has shown strong agreement with LC–MS for N-glycan quantification, supporting rapid glycan assessment [38].

Machine-learning models applied to  $^1\text{H}$ -NMR have enabled quantitative monitoring of multiple metabolites during adalimumab biosimilar processing, demonstrating the potential of AI-assisted spectroscopy for bioprocess monitoring [39]. Similarly, Raman spectroscopy coupled with convolutional neural networks has achieved high predictive performance for mAb charge variants, supporting real-time monitoring of charge-related CQAs [40].

AI-assisted high-resolution mass spectrometry and multi-attribute methodologies can facilitate simultaneous assessment of sequence variants, post-translational modifications and other CQAs, thereby supporting comprehensive mAb characterization [41]. ML-based PAT models can further establish relationships between critical process parameters and CQAs, enabling predictive process monitoring and quality control [42].

Advanced ML, deep learning, graph neural networks and protein-language models are also being explored for predicting aggregation, viscosity, solubility, stability and other developability attributes of mAbs [43]. XGBoost-based models have demonstrated improved developability prediction with increasing training-data availability, supporting high-throughput candidate screening [44].

The integration of AI with automated and online analytical platforms is facilitating multi-attribute and near-real-time monitoring of biotherapeutics [45]. Computational approaches can additionally support immunogenicity assessment, including epitope prediction and interpretation of ADA/NAb-related analytical challenges [46]. Hybrid AI/ML–mechanistic models have also demonstrated potential for improving chromatographic purification, yield and impurity control [47].

Collectively, these studies demonstrate that AI/ML is evolving from individual analytical applications toward integrated, predictive mAb quality assessment. However, broader validation, data standardization, model transferability, explainability and regulatory acceptance remain important challenges for routine bioanalytical implementation [37–47].

**Table 1: AI/ML applications relevant to therapeutic mAb analytical assessment**

| Author, year                 | Therapeutic mAb / material                      | Analytical platform | AI/ML approach                            | Main outcome                                         | Bioanalytical relevance                     |
|------------------------------|-------------------------------------------------|---------------------|-------------------------------------------|------------------------------------------------------|---------------------------------------------|
| Le <i>et al.</i> , 2018 [37] | Infliximab, bevacizumab, rituximab, ramucirumab | Raman spectroscopy  | Collaborative ML; optimized preprocessing | Prediction error: 2.4% vs 14.6% with linear analysis | Rapid mAb identification and quantification |

| Author, year                            | Therapeutic mAb / material          | Analytical platform                      | AI/ML approach                                   | Main outcome                                               | Bioanalytical relevance                                       |
|-----------------------------------------|-------------------------------------|------------------------------------------|--------------------------------------------------|------------------------------------------------------------|---------------------------------------------------------------|
| Shrivastava <i>et al.</i> , 2024 [38]   | Commercial/in-house mAbs; N-glycans | LC–fluorescence                          | XGBoost                                          | LC–MS agreement: $R^2 > 0.95$ ; RMSE $< 0.5$               | Rapid glycan quantification; LC–MS support                    |
| Shi <i>et al.</i> , 2026 [39]           | Adalimumab biosimilar process       | $^1\text{H}$ -NMR                        | ML quantitative modelling                        | Models for 20 metabolites                                  | Rapid bioprocess monitoring; indirect bioanalytical relevance |
| Nitika <i>et al.</i> , 2024 [40]        | mAb charge variants                 | Raman + process-scale CEX                | CNN                                              | $R^2 = 0.94$ – $0.99$ for charge species/protein           | Real-time charge-variant monitoring                           |
| Singdevsachan <i>et al.</i> , 2026 [41] | Monoclonal antibodies               | MAM–HRMS                                 | Targeted/untargeted analytics; hybrid approaches | Multiple CQAs, PTMs and sequence variants monitored        | Comprehensive characterization and QC                         |
| Puranik <i>et al.</i> , 2022 [42]       | Biopharmaceuticals, including mAbs  | PAT; real-time monitoring                | ML; statistical/multivariate modelling           | CPP–CQA relationship prediction                            | Process monitoring; formulation and stability                 |
| Montefusco-Pereira, 2026 [43]           | mAbs and biopharmaceuticals         | Biophysical/formulation assays           | ML, DL, GNNs, protein language models, XAI       | Predicts aggregation, viscosity, solubility and shelf-life | Stability and CQA prediction                                  |
| Arsiwala <i>et al.</i> , 2025 [44]      | 246 antibodies                      | HT developability assays                 | XGBoost                                          | Prediction improved with training-data size                | High-throughput developability assessment                     |
| Rathore & Sarin, 2024 [45]              | Biotherapeutics, particularly mAbs  | Online/real-time analytical platforms    | Advanced analytics; automation                   | Increased online and multi-attribute monitoring            | Future real-time mAb bioanalysis                              |
| Al Meslamani <i>et al.</i> , 2025 [46]  | Biologics and emerging modalities   | Immunogenicity/binding/functional assays | AI, RWE, epitope prediction, NLP                 | Addresses assay interference and matrix/dilution bias      | ADA/NAb assessment and immunogenicity                         |
| Wang <i>et al.</i> , 2026 [47]          | PEGylated biopharmaceutical         | Anion-exchange chromatography            | Hybrid AI/ML–mechanistic model                   | 12% higher yield; 33% lower HMW impurities                 | AI-assisted purification and impurity control                 |

### 3. Automation and High-Throughput Bioanalysis

Automation and high-throughput (HT) analytical workflows are increasingly being adopted to improve the speed, reproducibility, and scalability of therapeutic mAb characterization and bioanalysis. Automated sample preparation combined with LC/MS-based multi-attribute monitoring enables targeted peptide assessment across multiple LC/MS systems, supporting mAb characterization, release testing, and stability studies [48].

Chromatography-free MS/MS approaches using direct infusion and multiplexed parallel reaction monitoring can reduce analysis time to approximately one minute per sample, providing a high-throughput strategy for therapeutic mAb quantification [49]. Robotic liquid handling combined with 96-well plate processing has similarly enabled automated free and total infliximab quantification while reducing hands-on analytical time, supporting therapeutic drug monitoring [50].

End-to-end automation has also been demonstrated through integration of robotic liquid handling, automated purification and sample preparation, LC–MS characterization, and cloud-based data processing. Such workflows enable high-throughput intact, reduced, and peptide-mapping analyses with reduced manual intervention [51]. Automated immunocapture coupled with top- and middle-down LC–MS/MS can facilitate sensitive proteoform characterization of therapeutic mAbs in plasma, supporting pharmacokinetic and bioanalytical investigations. [52]

Automated multicycle immunoaffinity enrichment has further improved sample processing efficiency while maintaining suitable sensitivity, accuracy, and precision for discovery pharmacokinetic studies [53]. Integration of automated capillary electrophoresis, LC, MS, and high-resolution MS platforms can improve analytical resolution, sensitivity, and throughput during mAb bioanalytical development [54].

Automation is also extending to data processing and glycoproteomic analysis. High-throughput LC–MS glycopeptide workflows incorporating automated visual curation can process large datasets within hours while improving repeatability and reporting consistency [55]. Fully automated immunoaffinity purification–CE–MS workflows reduce manual processing steps and improve analyte isolation for ADME and biotransformation studies of complex biologics [56].

Automated electrochemiluminescence immunoassays integrated with laboratory information management systems can provide comparable sensitivity and precision to conventional ELISA while expanding analytical range and reducing operator-related errors [57]. Overall, these developments demonstrate a shift toward automated, integrated, and high-throughput analytical workflows that can accelerate mAb characterization, pharmacokinetic assessment, therapeutic drug monitoring, and routine bioanalysis [48–57].

**Table 2: Automation and high-throughput approaches for therapeutic mAb bioanalysis**

| Author, year                            | Therapeutic mAb                | Analytical approach                                   | Automation/ HT feature                                                        | Key outcome                                                           | Application                             |
|-----------------------------------------|--------------------------------|-------------------------------------------------------|-------------------------------------------------------------------------------|-----------------------------------------------------------------------|-----------------------------------------|
| Hashii <i>et al.</i> , 2025 [48]        | Therapeutic IgG mAbs           | LC/MS-MAM                                             | Automated sample preparation                                                  | Precise targeted peptide monitoring; compatible with 4 LC/MS systems  | Characterization, release, stability    |
| Zhang <i>et al.</i> , 2021 [49]         | Humanized therapeutic mAbs     | Chromatography-free MS/MS                             | Direct infusion + multiplexed PRM                                             | ~1 min/sample; high-throughput quantification                         | Bioanalysis                             |
| Sam <i>et al.</i> , 2026 [50]           | Infliximab                     | Targeted LC–MS/MS                                     | 96-well plate + robotic handling                                              | Free/total IFX; free IFX 0.5–50 µg/mL; reduced hands-on time          | Therapeutic drug monitoring             |
| Waldenmaier <i>et al.</i> , 2023 [51]   | Biotherapeutics                | Integrated LC-MS; intact/reduced MS + peptide mapping | Robotic liquid handling, automated purification/preparation, cloud processing | End-to-end automation; high-throughput MS characterization            | Biotherapeutic characterization         |
| Singdevsachan <i>et al.</i> , 2026 [52] | Pembrolizumab                  | Top-/middle-down LC–MS/MS                             | Automated immunocapture                                                       | Sensitive proteoform characterization in mouse plasma                 | PK/bioanalysis                          |
| Dong <i>et al.</i> , 2021 [53]          | Surrogate mouse IgG1           | Immunoaffinity LC–MS/MS                               | Automated multicycle enrichment; capture antibody reused 6×                   | LOQ 5 ng/mL; good accuracy/precision                                  | Discovery PK studies                    |
| Kallam <i>et al.</i> , 2025 [54]        | Monoclonal antibodies          | LC, MS, CE; HRMS/automated CE                         | Automated CE; HT analytics                                                    | Improved resolution, sensitivity and throughput                       | mAb bioanalytical development           |
| Pongracz <i>et al.</i> , 2025 [55]      | mAb glycoproteomics            | LC-MS glycopeptide quantitation; GlycoDash            | Automated visual curation; R Shiny HT workflow                                | Large datasets curated within hours; improved repeatability/reporting | Glycoproteomics; glycosylation          |
| Han <i>et al.</i> , 2021 [56]           | Peptibodies, mAbs, bispecifics | Immunoaffinity purification–CE–MS                     | Fully automated IA–CE–MS                                                      | Fewer steps; optimized analyte isolation                              | ADME/biotransformation; biologic design |
| Emrich <i>et al.</i> , 2026 [57]        | Clinical/non-clinical analytes | Automated ECL immunoassay; ELISA comparison           | Elecsys automation + LIMS integration                                         | Comparable sensitivity/precision; wider range; reduced human error    | PK/PD and routine bioanalysis           |

#### 4. Micro Sampling Strategies for Therapeutic mAb Bioanalysis

Microsampling approaches are increasingly being explored to reduce blood-volume requirements and enable more convenient pharmacokinetic (PK) and bioanalytical assessment of therapeutic mAbs. Volumetric absorptive microsampling (VAMS) combined with LC–MS/MS has demonstrated good agreement with conventional serum measurements in non-human primate studies, although factors such as EDTA-related matrix effects require careful validation [58].

Dried blood spot (DBS) and other microsampling approaches can facilitate capillary and potentially home-based sampling for therapeutic drug monitoring. However, hematocrit-dependent blood distribution and conversion of whole-blood measurements to serum concentrations remain important analytical considerations [59]. DBS-based quantification of therapeutic mAbs such as crenezumab and etrolizumab has demonstrated the feasibility of serum-calibrated PK analysis, with hematocrit correction supporting improved serum concentration estimation [60].

Dried capillary blood sampling has also been evaluated in clinical studies for simultaneous PK, anti-drug antibody (ADA), and neutralization assessments. Strong serum–capillary concentration correlation and high agreement for ADA classification demonstrate the potential of microsampling for decentralized clinical bioanalysis [61]. More broadly, dried microsampling combined with MS-based protein analysis can reduce sampling burden and improve sample logistics, although challenges remain in sample preparation, analytical sensitivity, and turnaround time [62].

VAMS has further demonstrated advantages for quantitative bioanalysis through controlled-volume collection, simplified storage and shipment, self-sampling potential, and reduced biological material requirements. These characteristics may be particularly valuable in PK and toxicokinetic studies involving therapeutic proteins while also reducing blood-volume constraints and, in some settings, animal use [63].

Overall, microsampling provides a promising pathway toward patient-centric, low-volume and decentralized mAb bioanalysis, but broader implementation requires standardized validation of hematocrit effects, matrix conversion, analyte stability, extraction efficiency, and comparability with conventional serum/plasma methods [58–63].

**Table 3: Micro sampling strategies for therapeutic mAb bioanalysis**

| Author, year                     | Therapeutic mAb(s)                     | Micro sampling strategy | Analytical method              | Sample/study type              | Main findings                                                                                              |
|----------------------------------|----------------------------------------|-------------------------|--------------------------------|--------------------------------|------------------------------------------------------------------------------------------------------------|
| Gao <i>et al.</i> , 2021 [58]    | Therapeutic mAb                        | VAMS®                   | LC–MS/MS                       | NHP PK; clinical investigation | Good VAMS–serum correlation; EDTA affected internal-standard response; validation recommendations proposed |
| Mingas <i>et al.</i> , 2021 [59] | Therapeutic mAbs                       | DBS/microsampling       | Immunoassay/ligand-binding     | TDM; inflammatory diseases     | Convenient capillary/home sampling; hematocrit remains a major limitation                                  |
| Yang <i>et al.</i> , 2023 [60]   | Crenezumab, etrolizumab                | Mitra/Tasso-M20 DBS     | Bioanalytical PK methods       | PK analysis                    | Serum-calibrated quantification feasible; hematocrit used for serum conversion                             |
| White <i>et al.</i> , 2024 [61]  | RSM01                                  | Dried capillary blood   | PK, ADA, neutralisation assays | Phase 1 clinical study         | Serum–capillary correlation $R^2 > 0.95$ ; ADA agreement: 96% individual, 93% status                       |
| Halvorsen & Reubsaet, 2025 [62]  | Protein analytes; therapeutic proteins | Dried Micro sampling    | MS-based protein analysis      | Clinical/research review       | Lower sampling burden; challenges include sample preparation and response time                             |
| Protti <i>et al.</i> , 2025 [63] | Therapeutic/biological analytes        | VAMS                    | Quantitative bioanalysis       | PK/toxicokinetic review        | Accurate volume collection; simpler storage/shipping, self-sampling and reduced material/animal use        |

## 5. Challenges and Future Perspectives

In quantitative therapeutic mAb bioanalysis, while many new technologies and innovations are moving quickly, new approaches face many technical validation and regulatory challenges. Micro sampling approaches are limited by the amount of sample they can handle (e.g., effect of hematocrit), the recovery, analyte stability, differences between serum/plasma and capillary blood, etc., requiring a careful bridging study and assessment of matrix effects, recovery, stability, and correlation with classic sampling methods. Micro fluidics and automation platforms offer increased throughput and reduced operator variability but come with issues of instrument integration, carryover, reagent stability, system failure, and method transfer.

HRMS and integrated CE-MS methods offer greater molecular information but require specialized equipment, specialized training, and more data analytics capability.

Most applications are focusing on characterization rather than a fully validated quantitative PK approach.

Additionally, artificial intelligence/machine learning introduces challenges of data quality, dataset representativity, model validation, reproducibility, traceability, explainability, and method transferability across different labs. Although AI has shown great promise in antibody characterization and analysis of analytical data, routine clinical mAb bioanalysis remains an aspirational goal. Looking forward, we believe that emerging technologies will gradually complement current mainstream quantitative approaches rather than replace them.

Micro sampling may ease the sampling burden, automation may standardize workflows, HRMS may expand molecular characterization, and AI/ML may accelerate the interpretation of complex data, leading to faster, lower volume, more reproducible, and even decentralized bioanalysis.

These approaches will need to be properly validated, fit for purpose, standardized, and have good data integrity and computational transparency for regulatory acceptance before they can be widely adopted. The most likely near term strategy would be to combine emerging approaches with established quantitative methods, with analytical robustness and reliability as central tenets.

## 6. CONCLUSION

What can be expected from the future of therapeutic mAb bioanalysis? The future of bioanalysis is far from a simple choice of the best tool from the current toolbox; in fact, it seems that we can expect a combination of tools more than a single new technique. The bioanalysis landscape is moving forward towards technologies that combine automation, miniaturisation, high throughput and information-rich results and methods.

The technical advances described here show that it is unlikely that the new tools will replace the established ligand-binding and MS methods, but a combination of complementary techniques working to specific analytical goals will probably be the most meaningful path forward. Smaller blood volumes could be achieved with techniques such as dried blood spots, volumetric absorptive micro sampling and capillary sampling, which could also lead to more patient-centric repeated PK studies. Automation can improve accuracy and throughput of sample processing, while high-resolution MS, multiplexed analysis and microfluidic devices could provide improved molecular information on a smaller sample and analysis volume. It is also clear that there is increasing activity around combining these technologies with digital data processing and automation.

Although we are a long way from replacing established quantitative bioanalytical methods, AI and machine learning may bring value to this automation-driven trajectory in terms of data processing, pattern recognition and decision support. Future AI advances will need to be validated and standardised, with secure data and, finally, acceptance by regulators.

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## Author Contributions

Rajesh Guntupalli: Conceptualization, Supervision, Project administration, writing – review & editing, Mounika Peruboyena Conceptualization, Investigation, Resources, writing – original draft, Visualization; Bhagya Lakshmi Prathipati Literature search and analysis, Critical revision; Rohita Kokkiligadda Literature search and analysis, Writing – review & editing.

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