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Maurice vs BioPhase 8800 vs LabChip GXII Touch Compared

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Published by IntuitionLabs · 2026-11-12 · maurice vs biophase 8800 vs labchip gxii touch · maurice vs biophase · biophase 8800 · labchip gxii touch · maurice cesds · ce-sds protein purity · capillary electrophoresis protein analysis · cief charge variants · 21 cfr part 11 ce software

Original article: https://intuitionlabs.ai/articles/maurice-vs-biophase-8800-vs-labchip-gxii-touch



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Executive Summary

This report compares three protein-purity platforms as assay-and-data workflows rather than as boxes: the Bio-Techne **Maurice** family, the SCIEX **BioPhase 8800**, and the Revvity **LabChip GXII Touch**. No source read for this report supplies a same-material, same-lab, independent comparison of all three on current configurations, so no platform is ranked. The decision that the evidence does support is which assay type, software edition and data path match a given intended use. All product facts below are dated to retrieval on 2026-11-12 and are vendor statements unless a peer-reviewed or regulatory source is named.

The timely change is on the SCIEX side. SCIEX announced BioPhase software 1.6 on September 28, 2026, listing user management, audit trails, electronic signatures and project management tools (sciex.com). The 1.6 release notes state that the Audit Trail workspace is not available in workstation mode (download.sciex.com), and that the new Instrument API must be installed by a SCIEX field service employee (download.sciex.com). The software validation summary on file covers components released June 2024, so a 1.6-specific validation document was not located.

The three systems measure different things. BioPhase 8800 offers eight parallel capillaries and a choice of native fluorescence (NF), ultraviolet (UV) or laser-induced fluorescence (LIF) detection (sciex.com). Maurice runs CE-SDS with UV absorbance at 220 nm (www.bio-techne.com) and is also positioned for charge analysis (www.bio-techne.com). LabChip GXII Touch is a microfluidic system that reads 24-, 96- or 384-well plates (resources.revvity.com). Detector choice changes reported purity: for non-reduced NISTmAb (the antibody shown in the note's Figure 2 for the PA 800 Plus), SCIEX reports 95.45% by LIF on a PA 800 Plus against 97.57% by UV on the same platform (sciex.com).

Regulatory text sets what a records workflow must demonstrate, not what any product guarantees. 21 CFR Part 11 asks for secure, time-stamped audit trails (www.ecfr.gov), and Revvity's own manual states that its GxP option alone does not ensure compliance (fgu.cas.cz). ICH Q14 describes transfer to a different location as needing a bridging strategy (database.ich.org), so "unchanged transfer" should not be assumed.

The recommended path is a predefined same-material pilot. Score precision, resolution of named critical pairs, quantitation limits, repeat rate, reviewer time and traceability, then compute cost per accepted report with buyer inputs. A sensitivity illustration in this report shows that, for fixed-cost items, moving utilization from 90% to 50% raises cost per accepted report by a factor of about 1.8 at a 2% rejection rate (arithmetic, not a price claim).

Introduction and Background

Protein purity for a monoclonal antibody (mAb) is rarely one number. Size variants (fragments, aggregates, non-glycosylated heavy chain), charge variants and glycan occupancy each need their own assay. Proteins also carry an inherent degree of structural heterogeneity (database.ich.org). ICH Q6B notes that determining absolute and relative purity of biological products is analytically challenging and method-dependent (database.ich.org), and that purity is assessed by a combination of procedures (database.ich.org). It names capillary electrophoresis alongside polyacrylamide gel electrophoresis among the accepted electrophoretic approaches (database.ich.org). Maurice, BioPhase 8800 and LabChip GXII Touch overlap on capillary or microfluidic sodium dodecyl sulfate (CE-SDS) size assays, but they diverge on charge assays, detectors, plate formats and software.

This report is written for analytical-development scientists, quality control (QC) method owners, automation leads and laboratory informatics architects. It treats three use cases separately: **mAb development**, where method flexibility and resolution of critical pairs dominate; **high-throughput screening**, where plate format and walk-away operation dominate; and **QC release**, where validated software, review workflow and record retention dominate. Adeno-associated virus (AAV) capsid work is covered only where assay-specific evidence exists, namely one 2024 presentation discussed below.

IntuitionLabs perspective. IntuitionLabs is not an instrument or software vendor, so it is not one of the options compared here. The framing suggested here is: choose an assay and a record architecture first, then test candidate instruments against both. That framing is consistent with ICH Q14, which says the analytical target profile (ATP), the intended purpose and performance criteria, drives the choice of technology (database.ich.org).

Scope and evidence rules

- **Primary sources only.** Product facts come from manufacturer pages, release notes and manuals. Where a manufacturer authored a comparison involving a competitor, it is labelled a vendor claim and not repeated as a ranking.
- **No hands-on benchmarking.** This comparison is based on published vendor and literature material, not instrument testing. Cells in the pilot table that require measurement are left blank for the buyer to fill.
- **Gated literature.** Bio-Techne's Maurice versus LabChip NISTmAb summary page identifies a reduced and non-reduced comparison on a National Institute of Standards and Technology reference antibody (www.bio-techne.com). The full note sits behind a form on that page; the findings here draw on a separately hosted vendor PDF of a Maurice versus LabChip note. No independent numerical comparison of all three platforms is publicly available in the sources reviewed.

- **Separate layers.** Raw traces, processed peaks and reports are treated as three different records throughout. PIC/S defines raw data as the original record (picscheme.org).

Define the critical quality attribute first

Start from the attribute and the decision it supports. ICH Q14 describes an ATP as the intended purpose, the attributes to be measured and performance criteria (database.ich.org). ICH Q2(R2) states the validation objective as demonstrating fitness for the intended purpose (database.ich.org). A practical ATP for a CE-SDS purity assay names the analyte, reduced or non-reduced condition, the critical pair (for example non-glycosylated heavy chain versus heavy chain), the reportable quantitation limit and the acceptance range. Without it, vendor speed figures cannot be compared because they describe different readouts.

Bio-Techne Maurice

Capabilities

Bio-Techne's current Maurice family comprises Maurice, Maurice C, Maurice S and MauriceFlex, per its consumables pages (retrieved 2026-11-12) (www.bio-techne.com). The base Maurice is positioned as a combined imaged capillary isoelectric focusing (icIEF) and CE-SDS instrument (www.bio-techne.com), while the S variant is the CE-SDS configuration with Turbo CE-SDS or CE-SDS PLUS cartridges (www.bio-techne.com). Cartridge compatibility is model-specific: the CE-SDS PLUS cartridge lists Maurice (090-000), MauriceFlex (090-158) and Maurice S (090-001) (www.bio-techne.com), and charge cartridges list Maurice, MauriceFlex and Maurice C.

Published run times differ by cartridge: Turbo CE-SDS lists 5.5 minutes for reduced IgG and 8 minutes for non-reduced IgG (www.bio-techne.com). CE-SDS detection is UV absorbance at 220 nm (www.bio-techne.com). A cartridge is listed at 100 guaranteed injections and a maximum of 500 for some cartridge types (www.bio-techne.com). A vendor application note describes up to 48 samples per batch (resources.bio-techne.com).

Calibration and standards are sold as consumables. Molecular weight markers are supplied from 10 kDa upward (www.bio-techne.com), and a cIEF system suitability kit exists for Maurice and Maurice C (www.bio-techne.com). A vendor note states a CE-SDS size range of 10 to 240 kDa (resources.bio-techne.com), whereas the marker set sold spans to 270 kDa, so the validated range for a given product should be confirmed in writing.

Adoption and evidence base

For charge analysis, a multi-company icIEF study comparing Maurice and iCE3 is summarized in a 2025 review, which reports 19 participating companies (www.frontiersin.org). A GMP-environment instrument change study to Maurice C reported that a quantitation-limit-level peak was more robust on Maurice C (pmc.ncbi.nlm.nih.gov), while noting that numeric resolution could not be compared because peaks were not baseline separated (pmc.ncbi.nlm.nih.gov). Both concern icIEF, not CE-SDS purity.

For CE-SDS, the public evidence is vendor-authored. Bio-Techne reports percent peak area relative standard deviations (RSDs) of 1% or less for all peaks across an injection batch on CE-SDS PLUS (resources.bio-techne.com), and states comparability of CE-SDS PLUS with a United States Pharmacopeia (USP) protocol

for mAbs (www.bio-techne.com). These are manufacturer statements, not independent validation.

Strengths and limitations

- **Strength: one platform for size and charge.** Maurice covers CE-SDS and icIEF in one family, which suits teams that want one vendor for orthogonal assays.
- **Strength: documented access-control option.** Compass for iCE offers optional Access Control; when enabled users must log in (www.bio-techne.com) and data files are signed and encrypted against unauthorized changes (www.bio-techne.com).
- **Strength: CDS paths.** Bio-Techne documents Empower driver support across several cartridges (www.bio-techne.com) and a Chromeleon path with manual pI recalibration (www.bio-techne.com). These are supported alternatives to native Compass, not equivalents of it.
- **Limitation: edition and model dependence.** The Authorization Server is listed on the download page for use with Compass for iCE (www.bio-techne.com), and Compass 4.1.0 is listed for Windows 11 64-bit (www.bio-techne.com). Which models and cartridges each control module covers should be confirmed for the exact configuration.
- **Limitation: calibration sensitivity in charge assays.** An independent paper reports that the infliximab main-peak pI on Maurice depended on the pI-marker calibration choice, giving 7.56 in one fit (www.nature.com). Calibration settings belong in the method record.
- **Limitation: unknown public export specification.** The Compass page describes review and data reports, but no Bio-Techne page read states native file formats. An independent paper describes raw data export as text files (www.nature.com) for an older software version.

SCIEX BioPhase 8800

Capabilities

The BioPhase 8800 uses eight capillaries in parallel, with an eight-capillary cartridge as the consumable (sciex.com). The product page lists NF, UV and LIF detection, with UV described as a bridge to legacy data. SCIEX states that NF permits quantitation of low-level impurities down to 0.01% (sciex.com), a vendor claim to be tested against your own impurity limits. Kit-based workflows include CE-SDS for size heterogeneity and native capillary zone electrophoresis (CZE) for charge heterogeneity (sciex.com).

Throughput claims need careful reading. A SCIEX tech note states a method that can analyze 192 reduced samples in 14 hours (sciex.com). The same note defines a data point as one separation from one well using one capillary (sciex.com) and a run as eight data points. Parallel channels therefore multiply data points per run but do not by themselves define end-to-end throughput, which also includes preparation, conditioning and review.

What the September 2026 update changes, and what remains unproven

SCIEX's September 28, 2026 announcement describes BioPhase software 1.6, adding user management, audit trails, electronic signatures and project management tools (sciex.com) and an Instrument API through which external software can interact via remote sequence execution (sciex.com). The software downloads

page lists BioPhase Project Management Software 1.6 (sciex.com). Release notes add Windows 11 support; version 1.5 had been documented for Windows 10 and had added NF acquisition and analysis (download.sciex.com).

The software page describes two operating models. Enterprise mode adds controlled access management, audit capabilities and user permissions (sciex.com), while workstation mode is a streamlined environment for method development, sequence creation and data analysis. The release notes state electronic signatures use a user ID and password combination (download.sciex.com), project access is controlled user by user, and the Audit Trail workspace is unavailable in workstation mode (download.sciex.com). For a regulated lab, the edition therefore changes the record, not only the interface.

The API scope is narrower than "data integration" might suggest. The API page describes remotely starting, monitoring and stopping sequence runs (sciex.com) and access to project and sequence information. The product page positions it for existing laboratory automation platforms. The release notes add that the API must be installed by a SCIEX field service employee (download.sciex.com). No page read documents result export to an ELN or LIMS through the API, so that remains a vendor question.

Unproven items as of 2026-11-12:

- **Validation of 1.6.** The validation summary found covers components released June 2024 (sciex.com).
- **Driver parity.** The Empower driver release notes read are for the 1.5 generation and require Empower 3 (FR4) or later (download.sciex.com); a driver release matched to 1.6 was not found.
- **Export formats.** The documented sequence-editor reports are Summary, Detailed and one further report type; raw-data export formats are not publicly documented in the pages reviewed; ask SCIEX.
- **Performance of the update.** The announcement's productivity statements are vendor claims. No independent measurement of 1.6 was found.

Adoption and evidence base

All BioPhase 8800 numeric evidence found is SCIEX-authored. For CE-SDS with native fluorescence, SCIEX reports RSD below 0.1% for relative migration time and below 0.4% for corrected peak area percent of the heavy chain (sciex.com). For cIEF on NISTmAb, SCIEX reports a 96-well plate in about 12 hours compared with 5 days on a single-capillary instrument (sciex.com). These show intended performance under vendor conditions; they are not a reproduction in a buyer's matrix.

Strengths and limitations

- **Strength: parallel capillaries and detector choice.** Eight channels and NF, UV or LIF options suit method development across analytes.
- **Strength: Enterprise-mode controls.** Access management, audit capabilities and user permissions are described for Enterprise mode, as noted above.
- **Strength: alternate CDS path.** The Empower driver stores multi-capillary data with linked sample information (sciex.com) and lets users apply Empower's 21 CFR Part 11 toolset (sciex.com). SCIEX reports separations comparable to those from native software.
- **Limitation: detector-dependent response.** SCIEX states fluorescence modes do not provide the uniform response of UV absorbance (sciex.com), so purity values are method-specific.

- **Limitation: version coverage.** Validation documentation, driver versions and API scope should be requested for the exact release.

Revvity LabChip GXII Touch

Capabilities

LabChip GXII Touch is a microfluidic electrophoresis system with a single-sipper chip handling samples from 24-, 96- or 384-well plates (resources.revvity.com). Revvity lists throughput up to 384 samples per run (resources.revvity.com) and chip life up to 400 runs (resources.revvity.com). Its software reports concentration, sizing and percent purity using ladder and marker calibration (resources.revvity.com), with results as virtual gel, electropherogram or table. The product note places glycan screening and charge variant assays on the same system.

For the Protein Clear HR assay, the user guide specifies a sizing range of 14 to 250 kDa (resources.revvity.com), resolution above 1.0 for the VeriMAb reference (resources.revvity.com) and percent purity reproducibility below 0.5% for the main non-reduced IgG peak (resources.revvity.com). These are vendor specifications under defined conditions. A vendor note describes a two-step calibration (resources.revvity.com), and the product note defines resolution as the migration-time difference divided by the summed peak widths (resources.revvity.com). Confirm that your acceptance criteria use the same definition.

Software, records and data export

LabChip GX Reviewer is described as the foundational software included with every instrument (resources.revvity.com). The optional GxP module adds technical controls and traceable audit histories (resources.revvity.com), and is described as supporting alignment with FDA 21 CFR Part 11. A Revvity flyer lists comprehensive audit logs among its security features (resources.revvity.com). The product note lists a GMP, 21 CFR Part 11 compliant software option (resources.revvity.com).

Export is better documented than for the other two. A user manual (Rev. B, hosted on a third-party site and dated 2018, so version-dated) states that peak and well tables export to CSV or XML (fgu.cas.cz) and that raw data can be exported as CSV, XML or AIA (fgu.cas.cz). The assay guide describes automatic export of results tables (resources.revvity.com). The same manual cautions that the GxP option alone does not ensure 21 CFR Part 11 compliance (fgu.cas.cz). A Waters Empower driver, listed as LabChip Empower Driver 1.0, appears in the brochure (resources.revvity.com).

Adoption and evidence base

A peer-reviewed 2014 study of a LabChip GXII with therapeutic antibodies reported intermediate precision of 18 determinations at 2.1% RSD or less (www.jstage.jst.go.jp), and noted that absolute purity values in peak area percent differed from conventional capillary SDS electrophoresis, attributed to detection methods (www.jstage.jst.go.jp). That is an older chip generation and software, so it informs method behavior rather than current performance. A vendor note reports a NISTmAb monomer purity of 98.52% by microfluidic CE-SDS and 98.47% on a SCIEX PA 800 Plus (resources.revvity.com), and a per-sample analysis time of 65 seconds (resources.revvity.com).

Strengths and limitations

- **Strength: plate-native format.** Direct 384-well processing suits screening and early development.
- **Strength: documented export.** CSV, XML and AIA export paths are described in the manual, subject to checking against the current software.
- **Limitation: resolution definition and range.** The assay specifies 14 to 250 kDa; fragments or aggregates outside a validated range need a different assay.
- **Limitation: current software facts undocumented.** Current software version, release dates and service terms are not publicly documented in the vendor pages reviewed; request them in the quote.
- **Limitation: regulated edition is a separate module.** The GxP option is optional.

Feature Comparison

Table 1 below is a row-level evidence matrix. It records only what a read page states; "not found" means the item was not publicly documented in the vendor pages reviewed in November 2026, not that the capability is absent; confirm with the vendor. Cells that depend on the installed configuration are marked "confirm". Editions differ, and no row should be read as meaning that all editions share the same controls.

System and assay	Analyte or material in sources	Detector	Cartridge or chip	Software and version	Raw record and export	Calibration or standards	Access-control module
Maurice, CE-SDS PLUS or Turbo	IgG standards, NISTmAb in vendor notes (resources.bio-techne.com)	UV 220 nm	CE-SDS PLUS cartridge, model-specific	Compass for iCE 4.1.0, Windows 11	Signed, encrypted data files with Access Control; native format not found	MW markers	Optional Access Control with Authorization Server
Maurice, cIEF or icIEF	mAb charge variants	Confirm per model and cartridge	cIEF and icIEF 400 cartridges	Compass 4.1.0 or Empower ICS v1.2	Text export in an older version	pI markers, suitability kit	As above, or CDS controls (www.bio-techne.com)
BioPhase 8800, CE-SDS	Non-reduced IgG (NISTmAb per the note's Figure 2 caption) (sciex.com)	NF, UV or LIF	Eight-capillary cartridge	BioPhase 1.6 (announced Sept 28, 2026)	PDF reports; raw export not found	Kit-specific (confirm)	Enterprise mode with Project Management
BioPhase 8800, cIEF or CZE	NISTmAb cIEF in SCIEX note	UV 280 nm in note; native CZE listed	Eight-capillary cartridge	BioPhase 1.6; Empower driver 1.5 generation	Folder acquisition or Empower database	Kit-specific (confirm)	Audit Trail unavailable in workstation mode
LabChip GXII Touch, Protein Clear HR	VeriMAb, NISTmAb in vendor notes	Fluorescence-based (confirm for current chip)	HT chip, up to 400 runs	GX Reviewer; optional GxP module	CSV, XML, AIA export (2018 manual)	Ladder and markers	Optional GxP module

System and assay	Analyte or material in sources	Detector	Cartridge or chip	Software and version	Raw record and export	Calibration or standards	Access-control module
LabChip GXII Touch, charge and glycan	Not stated in pages read	Confirm	Confirm	Confirm	Confirm	Confirm	Optional GxP module

The matrix shows three asymmetries. First, Maurice and BioPhase publish more consumable and cartridge detail, while LabChip publishes more about export formats. Second, access-control and audit functions sit in optional or mode-specific components for all three, so purchase scope matters. Third, the evidence-date column in practice is "page retrieved 2026-11-12"; several pages carry no publication date, so version currency must be confirmed in a vendor quote.

Native software versus supported external data paths

Table 2 maps data paths. The Empower driver paths are shown only because all three vendors document one; this report does not compare chromatography data systems, and an existing integration is only one supported path.

Path	What the vendor documents	Record layers to confirm	Gaps found
Maurice native (Compass)	Login, signed and encrypted files with Access Control	Raw trace, processed peaks, report	Export formats not stated on vendor pages
Maurice with Empower	Control of Maurice cartridges with Part 11 compliance-readiness described (www.bio-techne.com)	Raw data in CDS database, reintegration history	Whether native and CDS results match for your method
BioPhase native, workstation mode	Method development, sequences, analysis	Raw files in selected folder	No Audit Trail workspace
BioPhase native, Enterprise mode	Access management, audit, permissions	Project-managed records	Validation evidence for 1.6
BioPhase with Empower driver	Linked sample information and Part 11 toolset	CDS database	Driver version versus 1.6
BioPhase Instrument API	Remote start, monitor, stop of sequences	Run metadata, not documented as results export	Result and ELN/LIMS export scope
LabChip native (GX Reviewer)	Peak integration, sizing, quantification	Raw, peak table, report	Current software version
LabChip with GxP module	Controls and audit histories	Audit history, signatures	Not sufficient alone
LabChip with Empower driver	Driver listed	CDS database	Chip and assay coverage

Read the table by record layer. A **raw trace** is the first capture, a **processed peak table** is the product of integration parameters and calibration, and a **report** is a rendering. The FDA data-integrity question-and-answer document defines an audit trail as a secure, computer-generated, time-stamped record (www.fda.gov) and describes audit trail review as comparable to assessing cross-outs on paper (www.fda.gov). If reintegration is a normal part of CE-SDS review, the audit trail should show who changed integration, when, and why. Part 11 signature manifestations carry the date and time of signing (www.ecfr.gov). EU Annex 11 asks that reasons for changes to GMP-relevant data be documented (health.ec.europa.eu).

Performance and Benchmarks

What the public evidence does and does not show

No peer-reviewed head-to-head of all three platforms was found. Public comparisons are vendor-authored, run on different material and configurations, and read here as design information. Bio-Techne's gated summary lists the compared parameters as linearity, sensitivity, precision, reproducibility and resolution (www.bio-techne.com), but its numeric results are not in the public summary. A vendor PDF reports Maurice limits of detection and quantitation of 3.7 and 20.1 micrograms per milliliter for a spiked species in non-reduced samples (resources.bio-techne.com); it should be read with the study design in view, not as a general limit.

Detector and response factor effects

Detector choice changes what "purity" means. SCIEX's own comparison reports non-reduced NISTmAb purity (per the note's Figure 2) on a PA 800 Plus of 95.45% by LIF, below the UV value, and states that fluorescence modes lack UV's uniform response. A pilot should therefore hold detector, labeling chemistry and integration rules constant per platform and report them with each result.

Size and charge assays are not interchangeable

CE-SDS reports size variants under denaturing conditions, whereas cIEF, icIEF and CZE report charge. A 2025 review summarizing a mAbs study states that cIEF and icIEF may not be considered directly interchangeable (www.frontiersin.org), and NIST describes CE-SDS as orthogonal to size-exclusion chromatography (SEC) (pmc.ncbi.nlm.nih.gov). NIST also qualified cIEF for structural pI characterization and CZE for routine charge monitoring (link.springer.com). Treat each assay as its own method, so a "Maurice vs BioPhase cIEF" comparison must name the exact charge technique on each side.

CE-SDS versus SDS-PAGE for mAb purity

CE-SDS offers on-column quantitation, higher resolution and automation compared with slab-gel SDS-PAGE according to a NIST paper (pmc.ncbi.nlm.nih.gov). A 2012 study repeating one sample 21 times by SDS-PAGE reported large standard deviations for chain percentages (pubs.rsc.org), while the validated CE-SDS method showed RSD below 2.0% for corrected area percentage (pubs.rsc.org). NIST's paper describes a qualified CE-SDS method for which intermediate precision was assessed as coefficients of variation (pmc.ncbi.nlm.nih.gov). Microfluidic systems add a third class: the 2014 LabChip study reported precision of 2.1% RSD or less yet different absolute purity values from capillary SDS.

The Lilly 2024 AAV presentation: scope limits

A presentation at the CE Pharm Symposium 2024 (dated September 16, 2024) compared CE-SDS platforms for AAV capsid purity and viral protein (VP) ratios (www.casss.org). It treats CE-SDS as an alternative to SDS-PAGE for capsid purity, defines purity as the sum of VP1, VP2 and VP3 percentages, and notes low protein content as the reason LIF is favored for AAV (www.casss.org). The same AAV9 sample measured on a PA800+ with different detections gave different VP ratios (www.casss.org), and the presenter states that dye selection has significant impact on the VP ratio (www.casss.org).

Applicability limits are strict. The work covers AAV capsids, not mAbs; it reflects instrument configurations of 2024; and its summary describes evaluation on AAV CE-SDS (www.casss.org). Its detector and software observations should not be applied to current 2026 configurations without rechecking, and no performance conclusion from it is carried into this report. The useful generalization is methodological: labeling and detection choices shape reported ratios, so they belong in the method definition.

Interlaboratory evidence on transfer

Method transfer evidence exists at the technique level. An interlaboratory CE-SDS validation covered 13 laboratories in 13 companies on four commercial capillary electrophoresis platforms (pubmed.ncbi.nlm.nih.gov), and an earlier icIEF study across laboratories reported apparent pI RSD below 0.8% (pubmed.ncbi.nlm.nih.gov). A QbD-based CE-SDS validation reported meeting required criteria (pubmed.ncbi.nlm.nih.gov). The abstracts read do not give per-platform numerics, so they show that transfer is feasible under controlled protocols, not that any method transfers unchanged. ICH Q14, adopted on 1 November 2023 (database.ich.org), frames transfer as needing a bridging strategy (database.ich.org). Pharmacopoeial capillary electrophoresis chapters in the ICH regions are described as interchangeable (fda.gov), but that concerns the general chapter, not equivalence between instruments.

Data Analysis and Evidence

Same-material pilot design

Table 3 below defines the pilot. Every result cell is intentionally blank: the point is that the buyer fills it from measurements, not from brochures.

Pilot element	Definition to fix before testing	Result per platform (buyer fills)
Material	One reference mAb lot plus a stressed lot, reduced and non-reduced	
Repeatability and intermediate precision	Use ICH Q2(R2) definitions (database.ich.org), and state the range (database.ich.org); set analysts, days and cartridges or chips	
Resolution	Named critical pairs, with the formula stated	
Specificity	Interference by other substances (database.ich.org)	

Pilot element	Definition to fix before testing	Result per platform (buyer fills)
Quantitation limit	Lowest amount determined with suitable precision and accuracy (database.ich.org)	
Repeat rate	Share of runs repeated for system suitability or integration failure	
Analyst review time	Minutes per report including reintegration	
Traceability checks	Raw trace, integration parameters, reviewer edits, signature, export identifiers	

The pilot should include a traceability exercise using a buyer-controlled sample record: acquire, review with a deliberate reintegration, export, and import into the target ELN, LIMS or CDS, then verify that identifiers, integration parameters and audit entries survive. Part 11 asks for authority checks so that only authorized individuals can alter records (www.ecfr.gov) and for signatures linked to their records (www.ecfr.gov). FDA guidance states that shared login credentials prevent identifying a unique individual (www.fda.gov), so the pilot should use named accounts. Part 11 also asks that system access be limited to authorized individuals (www.ecfr.gov) and that each identification code and password combination be unique (www.ecfr.gov). PIC/S says audit trail functionality should be enabled and locked at all times (picscheme.org), and that review of audit trails should be part of routine data review (picscheme.org). FDA frames review frequency as risk-based (www.fda.gov) and its guidance is non-binding (www.fda.gov). FDA describes data integrity as the completeness, consistency and accuracy of data (www.fda.gov), and PIC/S states its guide interprets existing requirements without adding regulatory burden (picscheme.org).

Cost per accepted report

Use this formula with buyer-supplied inputs:

Cost per accepted report = (annualized instrument + service + software + standards + cartridges or reagents + analyst labor + rework + integration) divided by accepted reports

where accepted reports equal reports attempted multiplied by one minus the rejection rate. No prices are given here because none were retrieved; quotes should be obtained in writing for the exact configuration. Part 11 expects validation of systems (www.ecfr.gov), so validation labor belongs in the software or integration line.

Throughput figures in vendor documents define different units, so convert them carefully. SCIEX's 192 samples in 14 hours is 13.7 samples per hour end to end under its stated conditions, or 35 minutes per eight-capillary run across 24 runs (arithmetic). Revvity's 65 seconds per sample times 384 samples is about 6.9 hours of separation time, excluding preparation and chip handling (arithmetic). Maurice's Turbo CE-SDS lists 5.5 minutes for reduced IgG, cited above. These numbers come from different assays, material and unit definitions, so they must not be ranked against each other.

Sensitivity illustration (Hypothetical Example)

The following index uses only arithmetic, no prices. For fixed-cost lines (annualized instrument, service, software), cost per accepted report scales as 1 divided by (utilization times (1 minus rejection rate)), relative to a fully used instrument with zero rejection (index 1.00). For variable lines (cartridges, reagents, labor), it scales as 1 divided by (1 minus rejection rate).

- **Utilization 90%:** index 1.13 at 2% rejection, 1.17 at 5%, 1.23 at 10%.
- **Utilization 70%:** index 1.46 at 2% rejection, 1.50 at 5%, 1.59 at 10%.
- **Utilization 50%:** index 2.04 at 2% rejection, 2.11 at 5%, 2.22 at 10%.
- **Variable lines only:** index 1.02 at 2% rejection, 1.05 at 5%, 1.11 at 10%.

Utilization, not nominal channel count, dominates the fixed-cost lines in this illustration. Use your own utilization and rejection ranges, and add rework hours from the pilot's review-time and repeat-rate cells.

Decision Scenarios by Use Case (Hypothetical Examples)

These scenarios are hypothetical (Hypothetical Example) and illustrate decision logic only.

- **mAb development lab with orthogonal needs.** A team needing CE-SDS and a charge assay on one vendor may shortlist Maurice or BioPhase, because both document size and charge workflows. The pilot should test the specific charge technique on each.
- **Screening group with plate libraries.** A group processing 384-well plates may start from LabChip GXII Touch, whose published format is 24-, 96- or 384-well plates, then check whether chip-based resolution meets its critical-pair criteria.
- **QC lab with an existing CDS.** A QC lab may prefer a documented CDS path; all three vendors document an Empower driver: Maurice (www.bio-techne.com), BioPhase (sciex.com) and LabChip (resources.revvity.com). Native and CDS results should still be compared.

Implications and Future Directions

The September 2026 SCIEX release shifts the BioPhase 8800 conversation from capillary count toward records. That is relevant because the first-order differences among the three systems in a regulated lab may be edition scope, audit-trail availability and export path. The EU consultation on a revised Annex 11 emphasizes lifecycle management of computerised systems (health.ec.europa.eu), which points to software versioning and change control as continuing evaluation criteria, though the revised text is a draft issued for consultation, the consultation period has closed, and final adoption has not been confirmed here. Annex 11 also asks that application validation and infrastructure qualification be addressed (health.ec.europa.eu) and that access authorization changes be recorded (health.ec.europa.eu).

Vendor questions

- **Versions.** Which exact software, firmware, cartridge or chip and driver versions will ship, and which validation package covers them?

- **Editions.** Which controls (audit trail, signatures, access) are in the quoted edition, and which need an add-on module?
- **Raw record.** What are the native raw-data format, retention location and archive behavior, and can raw data be re-opened without the instrument?
- **Reintegration.** Are integration parameters, manual edits and reprocessing versions captured in the audit trail with reasons?
- **Export.** Which formats carry sample IDs, integration parameters and calibration, and has export to the target LIMS or ELN been tested?
- **API scope.** Does the BioPhase Instrument API provide results or only run control? For LabChip, which integration kit applies?
- **Standards.** Which calibration standards and suitability criteria are mandatory, and who supplies them?
- **Service.** What are installation (for example field-installed API), response times and software update policy?

Evidence gaps

- **Independent three-way data.** None is publicly available in the sources reviewed; the full Maurice versus LabChip note is gated.
- **Current versions.** LabChip software version history and BioPhase 1.6 validation are not publicly documented in the sources reviewed.
- **Pricing and service quotes.** Not publicly available; none are asserted here.

Technical controls alone do not establish compliance; they are inputs to a validated process with procedures, training and review. Laboratories should involve their quality unit and, where needed, qualified regulatory or computerized-system validation professionals. This article is not a substitute for that review.

Frequently Asked Questions (FAQs)

Maurice vs BioPhase 8800 protein purity: which is better?

No public independent evidence ranks them on current configurations. Both document CE-SDS workflows, with Maurice using UV 220 nm and BioPhase offering NF, UV or LIF. Decide with a same-material pilot.

BioPhase 8800 vs Maurice for cIEF: what differs?

BioPhase lists native CZE for charge heterogeneity and a cIEF kit, while Maurice lists cIEF and icIEF 400 cartridges. Charge techniques are not interchangeable (www.frontiersin.org), and NIST qualified CZE for routine charge monitoring (link.springer.com).

LabChip GXII Touch vs capillary electrophoresis: how do they differ?

LabChip uses a microfluidic chip with 24-, 96- or 384-well plates, while capillary systems use cartridges. A 2014 study found similar profiles but different absolute purity values versus capillary SDS.

CE-SDS vs LabChip for protein purity analysis: can results be pooled?

Not without a bridging study. ICH Q14 describes comparative analysis of representative samples as part of transfer strategy (database.ich.org). Detector and labeling differences alone can move reported purity.

What data workflow supports protein purity review?

Separate raw trace, processed peaks and report, and verify that audit entries, integration parameters and identifiers survive export. Table 2 maps documented paths, and PIC/S expects audit trail review within routine data review (picscheme.org).

What does LabChip GXII Touch protein characterization data analysis provide?

GX Reviewer provides peak integration, sizing and quantification, with CSV, XML and AIA export described in a 2018 manual.

Does Maurice CE-SDS meet 21 CFR Part 11?

Bio-Techne documents optional Access Control and describes Empower control as compliance-ready. Compliance depends on validation and procedures, since Part 11 requires validation of systems (www.ecfr.gov) and EU Annex 11 expects validated applications (health.ec.europa.eu).

Is CE-SDS better than SDS-PAGE for mAb purity?

NIST lists on-column quantitation, resolution and automation as CE-SDS advantages, and ICH Q6B accepts both approaches (database.ich.org). The choice depends on the ATP, and a validated CE-SDS method reported corrected-area-percentage RSD below 2.0% (pubs.rsc.org).

Conclusion

The three platforms are best treated as three assay-and-record architectures. Maurice combines size and charge in one family with an optional access-control module and documented CDS paths. BioPhase 8800 offers eight parallel capillaries, three detector modes and, with software 1.6, Enterprise-mode records and an Instrument API whose scope is run control and project information. LabChip GXII Touch offers plate-native microfluidic analysis and the most explicit export documentation among the three, with a separate GxP module.

Because the independent evidence is thin and vendor documents describe different assays, the defensible selection method is procedural: define the critical quality attribute and ATP, shortlist by assay type, request edition-specific controls in writing, run a same-material pilot with predefined criteria, test export into the target record system, and compute cost per accepted report from buyer inputs. Methods should be expected to need bridging, not to transfer unchanged.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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