

LabChip GXII Touch protein assay portfolio.

Key features

- Fast quantitative results, molecular weight sizing, and relative percent purity in as fast as 42 seconds
- One platform, multiple assays available to characterize protein(s) of interest
- High- and low-throughput assay setup options
- Review and export results in multiple formats

Introduction

The LabChip® GXII Touch™ protein characterization system uses a single sipper microfluidic chip to rapidly characterize protein samples from 24-, 96- or 384-well plates. The microfluidics chip technology automatically stains, destains, electrophoretically separates and analyzes the protein samples. After the LabChip® instrument optics detect the laser-induced fluorescent signal, easy to use system software automatically analyzes the data and provides the user with protein concentration, molecular weight sizing and percent purity using ladder and marker calibration standards. Digital data results are immediately available for review or reporting in virtual gel, electropherogram or table summary formats (Figure 1).

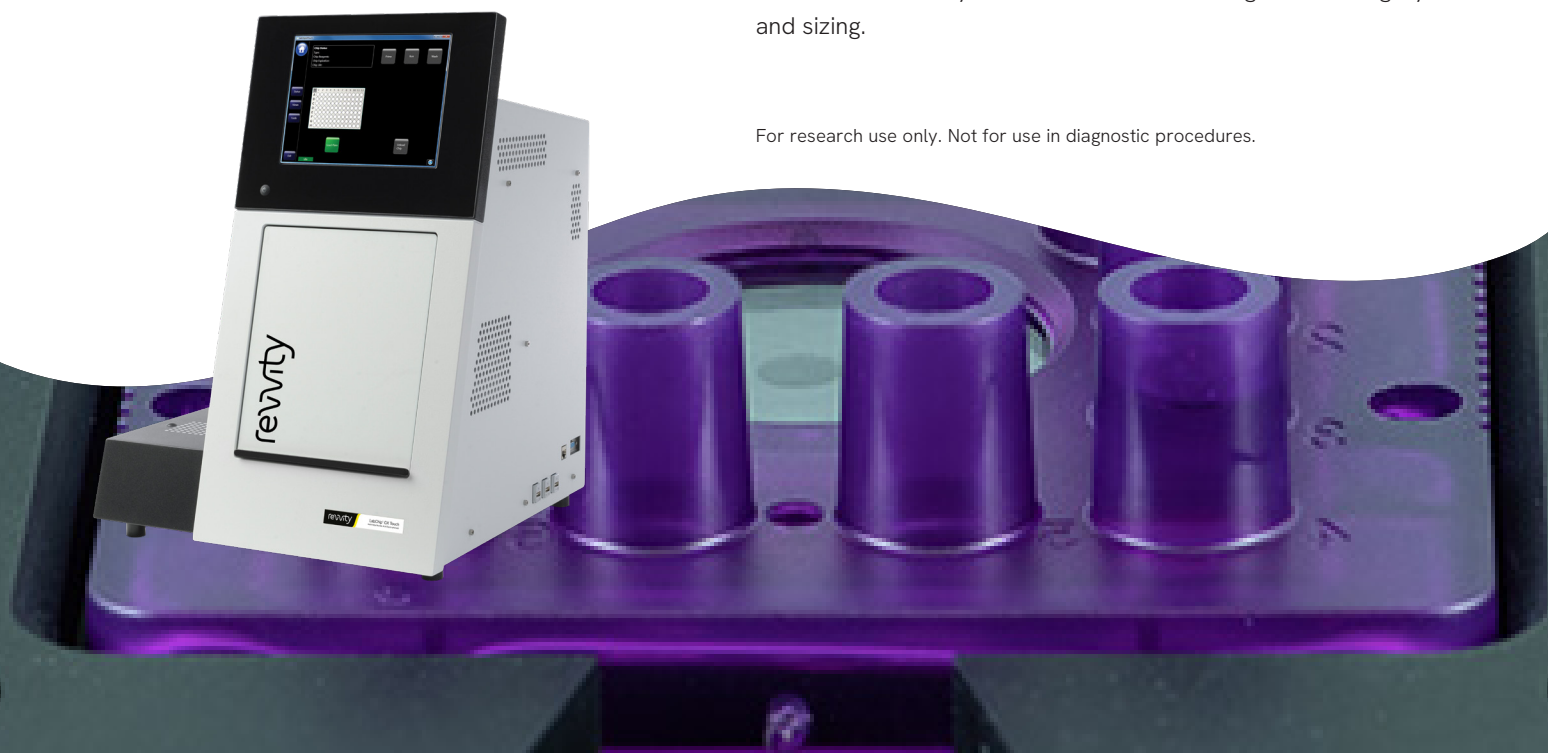
Choose from multiple assays to characterize protein(s) of interest - from the ProteinEXact™, Protein Express, Pico and Low Molecular Weight assays for concentration, molecular weight sizing, and percent purity for each detected peak within the sample; in addition, rapid Glycan Screening and Charge Variant analysis can be performed on the same system.

The AAV E/F Characterization Assay and the AAV Pico Protein Assay are two of the newest addition to the Gene Therapy portfolio.

These E/F Characterization Assays offers information about the Empty/Full ratio of the viral particles analyzed at a concentration of 1E12 VP/mL. Both this assay and the Pico Protein Assay offer information on Viral Protein (VP) stoichiometry, purity and sizing. The AAV DNA assay offers information about genomic integrity and sizing.

For research use only. Not for use in diagnostic procedures.

LabChip GXII Touch protein characterization system



- Two platforms for greatest efficiency: high-throughput (up to 96/384 samples) or lower throughput (up to 48 samples) provide complete automated analysis of proteins in as few as 42 seconds
- Automated analysis provides significant cost savings relative to the materials and labor required to run manual gels for protein analysis
- Easy to use digital format facilitates review, export, and archiving of data
- Extended workflow setup allows a single chip preparation to support multiple sample processing runs within an eight-hour window
- Flexible data display options - Results shown in your choice of virtual gel, electropherogram graph or tabular formats

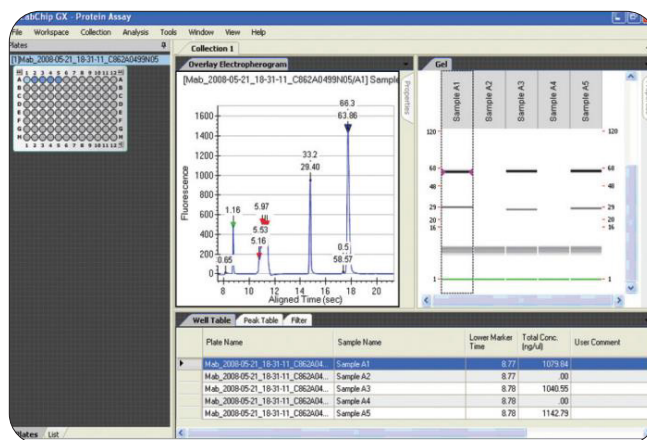


Figure 1. Shown is the graphical user interface for the LabChip® GXII Touch™ software. Results can be displayed and exported as virtual gels, electropherograms, or data tables

Specifications for LabChip Protein Assays:

	ProteinEXact™	Protein Clear™ HR	Protein Express	Pico Protein	Low Molecular Weight	Glycan Screening	Charge Variant
Sizing Range	6.5 kDa – 250 kDa	14 kDa – 250 kDa	14 kDa – 200 kDa	14 kDa – 200 kDa	5 kDa – 80 kDa		
Sizing Precision RSD (CV)	2.31	Sizing Precision RSD (CV) <2% Relative Migration Time Precision RSD (CV) <2% Percent Purity Reproducibility <0.5% mAb, non-reduced main peak <5% All other peaks	± 20%	± 20%	± 20%	CV <2.5%	
Sizing Resolution*	± 10% difference in molecular weight	Resolution >1.0 for VeriMAB reference standard by full width half max	± 10% difference in molecular weight	± 10% difference in molecular weight	14-80 kDa ± 10% < 14 kDa ± 20%		Comparable to IEX and conventional CZE
Linear Dynamic Range	10-2000 ng/μL	10 - 1000 ng/μL (mAb, non-reduced main peak)	5.0 – 2000 μg/mL	antibodies 50 ng/mL -500 μg/mL (4 logs) other protein 10 ng/mL - 100 μg/mL (4 logs)	30 - 2000 μg/mL (BLG, CAII in PBS)		
Maximum Total Protein Concentration	2 mg/mL	2 mg/mL	10 mg/mL		10 mg/mL		10 mg/mL
Sensitivity Limit of Detection (LOD)	0.2 ng/μL	5 μg/mL (mAb, non-reduced main peak)	5 μg/mL	0.1 % of total protein	4 μg/mL CAII (8 μg/mL BSA) in PBS	Assay precision is <4 % for the major glycan peaks	
Quantitation Reproducibility	<10%		30 % CV up to 120 kDa		30 % CV up to 120 kDa	CV<10 % for peak ≥2.5 % of total glycan	CV < 5 % for varying concentration from 1-3 mg/mL CV< 3% at constant concentration
Maximum Salt Concentration	1M NaCl at pH 6.5 to 8.5	1M NaCl at pH 6.5 to 8.5	1M NaCl at pH6.5 to 8.5		0.5 M Total Salt		
Chip Primes per Reagent Kit	10	10	10	4	4	4	N/A
Chip Sample Lifetime	400	400	400	400	400	400	500
Sample Analysis Time	65 sec	65 sec	42 sec	42 sec	60 sec	68 sec	90-110 sec

* Resolution is defined as the difference in migration times divided by the sum of the full width half max for two closely migrating peaks

Specifications for LabChip Protein Assays for Gene Therapy:

	AAV E/F characterization Assay	AAV Pico Protein Assay
Sizing Range	14 kDa - 200 kDa	14 kDa - 200 kDa
Sizing Resolution	±10% difference in molecular weight	±10% difference in molecular weight
Sizing Accuracy	±20%	±20%
Minimum Sample Volume	10 µL	5 µL
Minimum AAV Sample Concentration	1E12 VP/mL (or 1E12 GC/mL for high population of empty AAV)	1E12 VP/mL (or 1E12 GC/mL for high population of empty AAV)
Protein LOD in original sample	10 pg/µL	10 pg/µL
AAV Sample Buffer	PBS + (0.01% Tween or 0.001% Pluronic)	PBS + (0.01% Tween or 0.001% Pluronic)
Empty/Full Linearity	0.95	N/A
AAV Pico assay sensitivity	10 pg/µL	10 pg/µL
Protein Carry-Over	≤ 0.5%	≤ 0.5%
AAV DNA Carry-over	≤ 0.5%	N/A
AAV Protein Analysis Time	40 s / sample	40 s / sample
AAV DNA Analysis Time	82 s / sample	N/A
Samples run per chip preparation	24	24
Sample per reagent box	250	250

Ordering Information

Assay	LabChip GXII Touch HT Chips	LabChip GXII Touch 24 Chips	Reagent Kit
Protein Express	760499	CLS138950	CLS960008
Protein Express (4-pack of 760499)	760528		
Protein Express Bulk Sample Buffer			760518
Pico Protein	760499	CLS138950	760498
Pico Protein (4-pack of 760499)	760528		
Pico Protein Bulk Sample Buffer			760414
Pico Protein Bulk Labeling Dye			760519
Low Molecular Weight	760524	CLS138951	760573
Glycan Screening	760524	CLS138951	760525
Glycan Release and Labeling			760523
Charge Variant	760435	CLS138949	CLS760670
Protein Clear™ HR	CLS148695	CLS148696	CLS960014
ProteinEXact™	CLS150337	CLS150338	CLS150466
AAV E/F characterization Reagents Bundle	CLS158860		CLS159124
AAV Pico Protein	CLS157612		CLS159123

