

Mouse IgG Assay for Cedex Bio and Bio HT Analyzers

Reliable and convenient automated determination

Mouse immunoglobulin G antibodies (IgG) are commonly used for specific detection of protein targets in research, in-vitro diagnostics (IVD), and pharmaceutical development of therapeutic antibodies. In development and bio-manufacturing of recombinant monoclonal mouse IgG, there is a need for reproducible determination of the IgG concentrations for in-process control and quality control. The test kit for Cedex Analyzers enables automated determination of mouse IgG with high precision, short time to result and high convenience.

Assay principle

The immunoturbidimetric assay uses anti-mouse IgG-antiserum from sheep which forms a precipitate with mouse IgG from a sample. The emerging precipitation is measured by photometric absorption at 340 nm.

All relevant subclasses of mouse IgG antibodies (IgG1, IgG2a, IgG2b) can be detected with this kit.

The calibration with the provided calibrator solution from Roche results in a good accuracy for most of the common mouse IgG products. In case of uncommon products, optimal accuracy of the determination can be achieved using the specific IgG product for custom calibration of the test.

Benefit from a wide and sensitive measuring range

The same reagent can be used with several protocol settings to cover a wide concentration range of IgG:

Protocol	Measuring range
MIGLB	10 – 200 mg/L IgG
MIGHB	200 – 1500 mg/L IgG
MIGHD	1500 – 7500 mg/L IgG, up to 150 g/L with auto-dilution



Reliable determination for the right decisions

Perfect test linearity and accuracy:

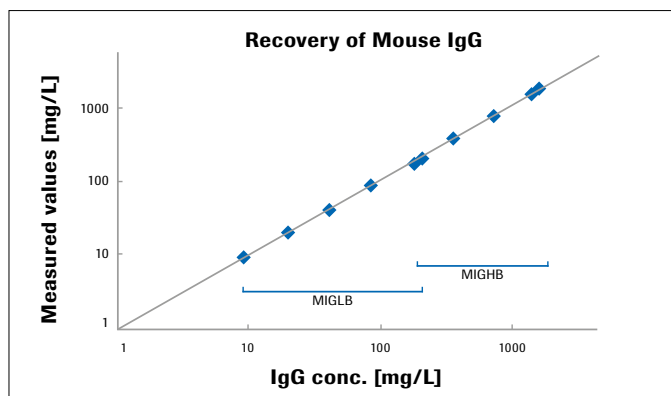


Figure 1: Recovery of Mouse IgG spiked into cell culture medium RPMI-1640 on a Cedex Bio HT Analyzer, showing a consistent accuracy over the wide range of the test protocols MIGLB and MIGHB.

High test precision

	Level 1	Level 2	Level 3
Mean	68 mg/L	472 mg/L	946 mg/L
CV in-run	1.0%	1.9%	1.5%
CV inter-run	1.6%	1.4%	1.6%

Representative performance data from several Cedex Bio HT Analyzers are shown. Results obtained in individual laboratories may differ. Coefficients of variation (CV) were calculated for in-run precision (n=21) and inter-run precision (on 10 days).

Ordering information

Product	Pack size	Catalog no.
Mouse IgG Bio	4 × 50 tests	08 377 944 001
Mouse IgG Bio HT	200 tests	08 377 979 001
Calibrator F Bio	6 × 1 mL	08 377 987 001
Control F Level 1 Bio	6 × 1 mL	08 377 995 001
Control F Level 2 Bio	6 × 1 mL	08 378 002 001
Control F Level 3 Bio	6 × 1 mL	08 378 029 001

Regulatory disclaimer

For use in quality control/manufacturing process only.

Trademarks

CEDEX is a trademark of Roche.

custombiotech.roche.com/cedex

Please contact your local CustomBiotech representative

Europe, Middle East, Africa, Latin America

Phone +49 621 759 8580
Fax +49 621 759 6385
mannheim.custombiotech@roche.com

United States

Phone +1 800 428 5433, ext. 14649 (toll-free)
Fax +1 317 521 4065
custombiotech.ussales@roche.com

Canada

Phone +1 450 686 7050
Fax +1 450 686 7012
custombiotech.can@roche.com

Japan

Phone +81 3 6634 1046
Fax +81 3 5479 0585
japan.custombiotech@roche.com

Asia Pacific

Phone +65 6371 6638
Fax +65 6371 6601
apac.custombiotech@roche.com

Published by

Roche Diagnostics GmbH
Sandhofer Straße 116
68305 Mannheim
Germany

© 2018 Roche Diagnostics GmbH
All rights reserved.