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NEWSLETTER

BE THE KEY PLAYER IN LIFE SCIENCES-DIAGNOSTICS & DRIVE INNOVATION FOR MAKING A HEALTHIER WORLD.

IgG-Fc: A core target in immuno-diagnostics

Advancements in cardiotoxicity testing

Conference Participation

Annual town hall FY 24-25

Yashraj Bharati Samman 2025

EST: 1999
NAVI MUMBAI, INDIA

2015
BERLIN, GERMANY

2018
DELAWARE, USA

IgG-Fc: A Core Target In Immuno-diagnostics

The Fc (fragment crystallizable) region of immunoglobulin G (IgG) is a highly conserved domain responsible for interacting with Fc receptors on immune cells and with complement proteins, initiating key effector functions such as antibody-dependent cellular cytotoxicity (ADCC), complement-dependent cytotoxicity (CDC) and phagocytosis. Structurally, it forms the constant region of the antibody and remains consistent across IgG subclasses.

The stability and uniformity of the Fc domain across IgG molecules make it ideal for detecting anti-IgG antibodies and serving as a standard or reference in immunoassay calibration and control systems. Anti-human IgG-Fc antibodies are widely used in detecting patient-derived IgG antibodies in serological assays for infectious disease, autoimmunity and allergy. The Fc domain also plays a central role in secondary detection strategies. Enzyme or fluorophore conjugated secondary antibodies targeting IgG-Fc regions are routinely used in various immunoassays (ELISA, CLIA, Western blotting, LFA) because of their flexibility and scalability.

Native IgG-Fc antigen is one of the critical reagent to support the diagnostic applications. The native antigen is processed from purified human serum IgG through enzymatic digestion and chromatographic separation. This retains its glycosylation heterogeneity and structural integrity. In comparison to recombinant alternatives, the native IgG-Fc displays high affinity of the antigen in Fc-binding assays and greater biological relevance in diagnostic applications.

The purified IgG-Fc protein is used to immunize animals to produce IgG-Fc antisera, which complements the antigen in diagnostic assays. These antisera contains diverse population of antibodies that recognize multiple epitopes, resulting in superior sensitivity and robust signal generation (due to high avidity) in assays such as ELISA, Western blotting, immunoprecipitation, Immunoturbidimetry, etc.

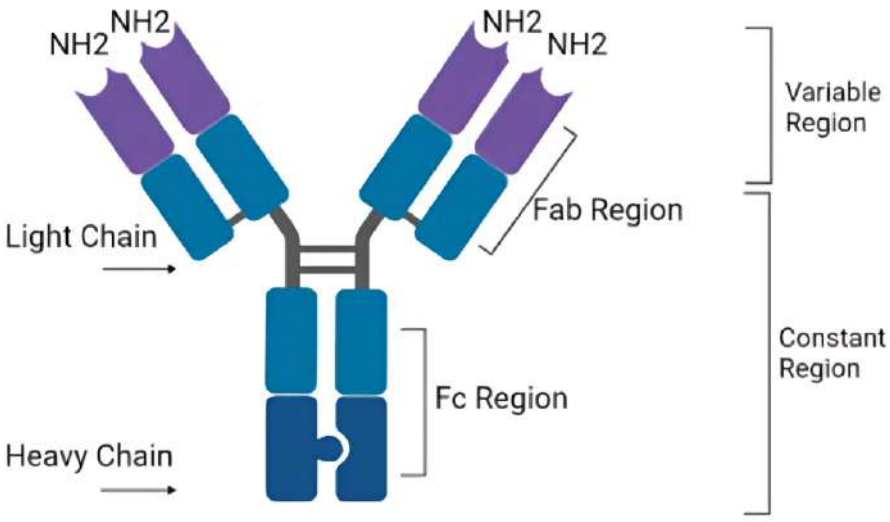


Fig. Immunoglobulin structure depicting different domains

At Yashraj Biotechnology Ltd., we provide

- Immunogen-grade native human IgG-Fc antigen with >98% purity, characterized using SDS-PAGE, Western blotting and SEC-HPLC and devoid of any Fab (Fragment antigen-binding) part of the antibody.
- Goat antiserum against human IgG-Fc which demonstrates sensitivity in Immunoturbidimetry comparable to market leaders and monospecificity in Immunoelectrophoresis. We also offer affinity- purified and fractionated anti-IgG-Fc.

Advancements in Cardiotoxicity Testing with CiPA-Qualified Human iPSC-Derived Cardiomyocytes

In 2005, the International Council on Harmonization (ICH) published the S7B and E14 regulatory guidelines to assess new medications proarrhythmic potential. They were put into place after it was shown that the human ether-à-go-go related gene (hERG) encodes the fast delayed rectifier potassium current (IKr) and that inhibiting this current is linked to the potentially fatal arrhythmia Torsades de Pointes (TdP) and a prolonged QT interval. The guidelines includes evaluating the new drugs for their ability to block the hERG channel in vitro and prolong the QT interval of the ECG in preclinical studies and clinical trials.

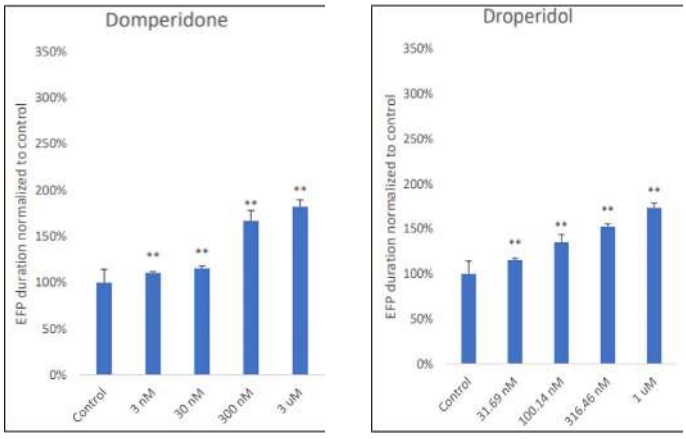
Since the method is highly sensitive, it has been shown to be successful in keeping proarrhythmic medications off the market. However, the specificity of these markers is limited and the association between proarrhythmic liability, QT prolongation and hERG inhibition is only weak. This has led to many medications that have effects on hERG and QT prolongation but minimal real danger of TdP being deprioritized, not allowed to be developed further, or, if they are licensed, having their clinical usage restricted by unwarranted warnings on product labels. Therefore, to overcome these shortcomings, the Food and Drug Administration (FDA) started the CiPA program in July 2013, which seeks to increase the accuracy of cardiac liability prediction and lower costs. CiPA is based on the following three elements:

1. A panel of human ventricular ion channels will be used to profile the compounds.
2. To provide a proarrhythmic risk rating, this in vitro data will be integrated into an in silico model of a human action potential.
3. To validate the risk classification obtained from the in silico model, compounds will be evaluated using cardiomyocytes produced from human induced pluripotent stem cells (iPSCs).

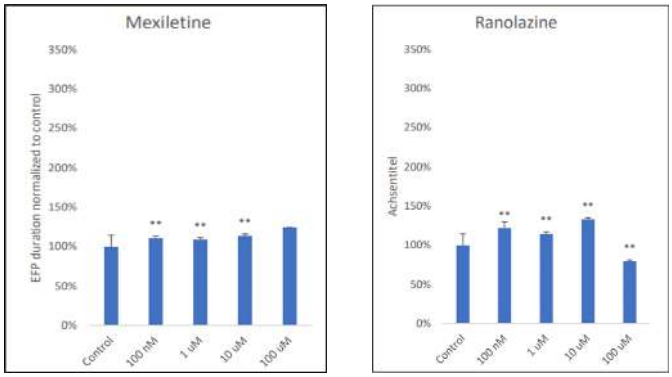
A) Risk category

Risk Category	% Prolongation of QT intervals
High Risk	165% -344%
Intermediate Risk	113% -139%
Low Risk	79% -113%

C) Intermediate risk compound



B) Low risk compound



D) High risk compound

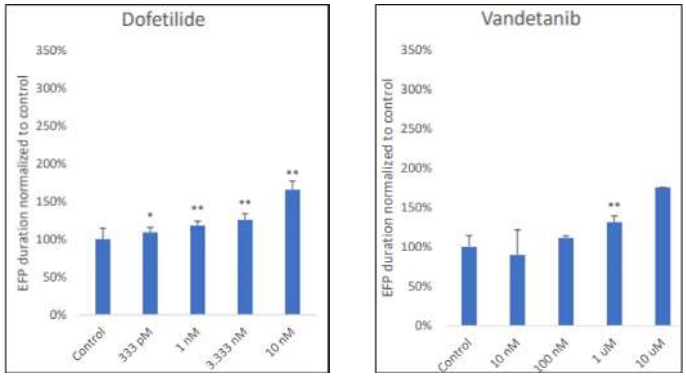


Fig. (A) Table summarizing QT interval prolongation thresholds used to classify compounds as high, intermediate, or low risk, based on the percentage of field potential duration (FPD) prolongation relative to control. (B–D) Bar graphs showing dose-dependent FPD changes induced by YBLiCardio cells. FPD values were normalized to DMSO-treated controls.. *p <0.05, **p <0.01.

Advancements in Cardiotoxicity Testing with CiPA-Qualified Human iPSC-Derived Cardiomyocytes

The program is led by a steering team that organizes working groups to handle each of the three CiPA components. The European Medicines Agency (EMA), Health Canada, Japan National Institute of Health Sciences (NIHS), Cardiac Safety Research Consortium (CSRC), Safety Pharmacology Society (SPS), Health and Environmental Sciences Institute (HESI), Pharmaceuticals and Medical Devices Agency (PMDA) and the United States Food and Drug Administration (US FDA) are among the partners that make up the CiPA Steering Team. Each of these organizations supplies scientific specialists to staff each working group and supports project administration.

One of the most transformative elements of CiPA is its use of cardiomyocytes derived from reprogrammed human iPSCs. These cells retain human-specific genetic and physiological characteristics, offering a more accurate representation of how human hearts respond to drugs compared to animal models or isolated tissue. These cardiomyocytes can detect dynamic changes in beat rate, rhythm and action potential duration, providing critical insight into drug-induced arrhythmias.

Recently, the IDD team of Yashraj Biotechnology Ltd. has published a ground-breaking study in YBLiCardio highlighting the potential of CiPA-qualified human induced pluripotent stem cell (iPSC)-derived cardiomyocytes as a transformative tool in cardiotoxicity assessment *(Amit Khanna et al. : https://doi.org/10.1016/j.tiv.2025.106100)*. This innovative approach marks a significant step forward in predicting drug-induced arrhythmias, a leading cause of drug withdrawals and safety concerns.

Compound	HESI risk	duration
Verapamil	low	79%
Cisapride	intermediate	86%
Diltiazem	low	93%
Nitrendipine	low	97%
Clozapine	intermediate	106%
Loratadine	low	106%
Clarithromycin	intermediate	107%
Metoprolol	low	109%
Risperidone	intermediate	111%
Tamoxifen	low	113%
Nifedipine	low	113%
Terfenadine	intermediate	116%
Ondansetron	intermediate	122%
Mexiletine	low	124%
Pimozide	intermediate	130%
Ranolazine	low	133%
Chlorpromazine	intermediate	133%
Astemizole	intermediate	139%
Dofetilide	high	165%
Ibutilide	high	166%
Droperidol	intermediate	173%
Vandetanib	high	176%
Azimilide	high	176%
Domperidone	intermediate	182%
Disopyramide	high	217%
Quinidine	high	249%
Sotalol	high	275%
Bepridil	high	344%

Heatmap of all tested compounds (on YBLiCardio cells) ranked by normalized FPD duration. Compounds are annotated with their HESI CiPA risk classification and grouped based on increasing QT prolongation.

Exhibiting in ADLM 2025 in IL, Chicago

Yashraj Biotechnology Ltd. is proud to exhibit at ADLM 2025, where we'll meet existing clients, explore collaborations and build new partnerships.

We're showcasing our high-quality native and recombinant antigens, now complemented by our growing portfolio of monoclonal antibodies (via hybridoma and our proprietary recombinant APD library).

This year, we're also introducing polyclonal antibodies, making our offering truly comprehensive. With this expansion, YBL is evolving from a raw material supplier to a full-spectrum strategic partner for the IVD industry.

BIO Boston 2025

Yashraj Biotechnology Ltd recently exhibited at BIO International Convention in Boston, Massachusetts, one of the world's leading biotechnology conferences, as part of the ABLE Pavilion.

The event brought together global leaders, innovators and investors and we were delighted by the quality of interactions and the strong international interest in India's biotech capabilities. It was a proud moment to represent India's scientific excellence on such a prestigious platform.

The conference opened with inspiring remarks from Dr. Kiran Mazumdar- Shaw, followed by Dr. Jitendra Kumar, MD of BIRAC, who highlighted India's expanding innovation ecosystem. Their leadership reflects the momentum and ambition that Indian biotech is gaining globally.

Yashraj Biotechnology Ltd. remains committed to advancing science and innovation on the global stage.

MPS World Summit

Yashraj Biotechnology Ltd. had the privilege of participating in the MPS world summit held from June 9 - 13 in Brussels, Belgium. The event brought together global leaders, researchers and innovators dedicated to advancing micro physiological systems.

We showcased our comprehensive range of iPSCs and primary cell products and services, purpose-built to accelerate innovation in this dynamic field.

Throughout the summit, our team engaged in valuable conversations with key stakeholders in the MPS community. It was a great opportunity to exchange ideas, explore collaborations and contribute to the shared vision of building a healthier, more innovative future through next-generation cell technologies.

Annual Town Hall FY 24-25

The FY 24-25 celebration marked a defining moment for YBL, bringing every member together under the unifying theme of “Dream. Drive. Deliver.” It was a time to honour our achievements, recognize the relentless efforts of our teams and reaffirm our shared vision for the future.

Our leadership reflected on the past year’s milestones and set a bold direction ahead, fuelling our belief that Together, Hum Honge Kamyab, Har Din (We Shall Overcome, Everyday). With big dreams in our hearts, the drive to excel in our actions & a promise to deliver with purpose, we move forward - stronger, united & ready to redefine success once again.

DREAM
DRIVE
DELIVER

Yashraj Bharati Samman 2025 – Honouring real heroes

We're proud to announce the third edition of Yashraj Bharati Samman 2025 - an initiative by Yashraj research foundation (YRF) to recognize those creating real impact at the grassroots level. Selected through a year-long, rigorous process by experts from IRMA, the recipients were felicitated on April 20 at NCPA Mumbai, in the presence of esteemed dignitaries including Shri. C.P. Radhakrishnan - Governor of Maharashtra, Shri. Dilip Walse-Patil - former Speaker of the Maharashtra legislative assembly and Shri. Amitabh Kant - G20 Sherpa of India, ex-CEO of the Niti Aayog. Each awardee received a medal, citation and INR 1.01 crore for their incredible work.

Innovation in healthcare

Jan Swasthya Sahyog (JSS) - bringing compassionate, community-rooted healthcare to rural Chhattisgarh.

Transforming people's lives

Pratham Education Foundation – redefining education access across India with inclusive, ground-breaking models.

Ethical governance

Service Plus by NIC - digitally transforming citizen services across the country with transparency & efficiency

Desilting of 4 check dams at Anwir, Talasari

We're happy to share that YRF, in collaboration with the government, has successfully completed desilting of 4 check dams at Anwir, Talasari (Palghar). Originally built by the soil and water conservation department, these dams had reduced storage due to silt. This effort will restore water capacity, improve groundwater levels and support farmers with water for a second crop, boosting rural livelihoods.

Products, Solutions & Services

In-vitro diagnostics (IVD)

- Native Antigens
- Recombinant Antigens
- Molecular Enzymes
- Molecular Diagnostics (Kits)
- Monoclonal Antibodies (mAbs)
  - Hybridoma (Animal based)
  - Antibody Phage Display (APD)
- Polyclonal Antibodies (pAbs)

Integrated drug discovery & development (IDD)

- **iPSC** cell lines
- Primary skin cells
- **YBL** iCardio - Cardiomyocytes
- **YBL** iHepato - Hepatocytes

Contract research and manufacturing

Our Certifications

A17976 ISO 9001:2015 — Yashraj Biotechnology Ltd.

A17976 ISO 13485:2016 — Yashraj Biotechnology Ltd.

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