

# Nanoparticle *In Vitro* Toxicity Testing Contract Services

Nanoparticles are between 1 - 100nm in diameter. In biomedical applications they can be used for drug delivery, cosmetics and have potential use in cellular therapy and regenerative medicine. However, nanoparticles have been shown to exhibit toxicity to living and primary tissues and organs. Regulatory agencies are now looking at the effect of nanoparticles in more detail to assess their potential toxicity and safety.

## HemoGenix® Offers *In Vitro* Nanoparticle Toxicity Testing Contract Services

### Benefits of Outsourcing *In Vitro* Nanoparticle Toxicity Testing to HemoGenix®

- Nanoparticle Toxicity Testing is performed in accordance with recommended assays from the National Institute of Health (NCI) Nanoparticle Characterization Laboratory (NCL) (see over).
- Many Nanoparticle Toxicity Testing protocols can also be performed using more advanced, alternative assays that have been validated according to FDA Bioanalytical Method Validation and provide the necessary measurement assurance parameters.
- At HemoGenix®, we believe that toxicity and safety testing should be performed on fresh, primary cells, (preferably of human origin) as much as possible so that potential surprises during later stage developmental testing do not occur.
- All Nanoparticle Toxicity Testing studies are available as non-GLP or GLP contract services.
- HemoGenix® will work closely with other contract research organizations (CROs) that are performing *in vivo* Nanotoxicity Toxicity/Cell Contact Testing to provide a seamless report that can be submitted to regulatory agencies.
- Those nanotoxicity assays that use an ATP bioluminescence readout also include full standardization and validation.
- Many assays listed on the other side of this flyer can be multiplexed with other endpoints. This allows more information to be accrued from the same sample, thereby providing a more cost-effective and efficient study.
- Many of the assays used in the Nanoparticle Toxicity Testing Panel use specialized, high performance media to provide the maximum growth and sensitivity for the assays.
- Initial study reports are usually delivered within 5-7 business days after completion of the study.
- All studies for Nanoparticle Toxicity Testing are QA audited prior to releasing the Final Report.
- All contract services are confidential and include exceptional customer service.

**All of the assays provided for the *In Vitro* Nanoparticle Toxicity Testing Panel are also available as individual assays for other drug development applications.**



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Recommended NCL Assay / Protocol	NCL Protocol Number	Alternative Assay
Mouse granulocyte-macrophage (GM) colony-forming unit (CFU) assay	ITA-3	HALO®-Tox HT for multiple cell populations (stem and progenitors) from multiple species
Leukocyte proliferation assay	ITA-6	ImmunoGlo™-Tox HT from different tissues and multiple species
Nitric oxide (NO) production by RAW264.7 macrophage cell line	ITA-7	NO production by macrophage cell lines and primary macrophages
Chemotaxis assay using human HL-60 cell line	ITA-8	Calcein-AM real-time fluorescence chemotaxis using HL-60 and primary human peripheral blood or bone marrow cells
Zymosan phagocytosis assay using luminol on the HL-60 cell line	ITA-9	Same, but including primary human peripheral blood or bone marrow cells
Analysis of IL-8, IL-1b, TNF alpha, IGNgamma by normal human peripheral blood mononuclear cells by ELISA	ITA-10, 22, 23, 24, 25	Same, but including bone marrow
Effects on peripheral blood monocyte-derived dendritic cell maturation using flow cytometry	ITA-14	Same
Oxidative stress on Hep-G2 hepatocyte using the glutathione assay	GTA-3	Same, but using also primary hepatocytes and/or other cells
Lipid peroxidation assay on Hep-G2 cells	GTA-4	Same, but using also primary hepatocytes and/or other cells
Reactive oxygen species (ROS) assay on Hep-G2 hepatocytes	GTA-7	Similar, but using also primary hepatocytes and/or other cells
Kidney cytotoxicity assay using MTT and LDH assays on LLC-PK1 kidney cells	GTA-1	STEMGlo™-Tox HT and LDH fluorescence assays using kidney cell lines or primary kidney cells
Hep-G2 hepatocyte cytotoxicity assay using MTT and LDH assays	GTA-2	HepatoGlo-Tox HT and LDH fluorescence assays using Hep-G2 and primary hepatocytes
Kidney apoptosis assay for caspase 3 using LLC-PK1 cells	GTA-5	Similar, but also using primary kidney cells
Caspase 3 and 3/7 apoptosis assays on Hep-G2 cells	GTA-6 & GTA-14	Similar, but also using primary hepatocytes. Luminescence caspase 3/7 assay

Consider HemoGenix® Your *In Vitro* Contract Service Provider