

List of Large Molecules Methods

Analyte	Matrix	Sensitivity	Method	Status
Adalimumab	Human Serum	110.0 ng/mL	ELISA	Under Development
Adalimumab immunogenicity assay	Human Serum	-	ELISA	Under Development
Bevacizumab	Human Serum	2.0 µg/mL	ELISA	Validated
Bevacizumab immunogenicity assay	Human Serum	124.0 ng/mL	ELISA	Developed
Enoxaparin Sodium Anti Factor IIa	Human Plasma	0.030 IU/mL	Chromogenic	Validated
Enoxaparin Sodium Anti Factor Xa (Chromogenic assay)	Human Plasma	0.050 IU/mL	Chromogenic	Validated
Enoxaparin sodium Anti Factor Xa (Clotting assay)	Human Plasma	0.075 IU/mL	Clot based	Validated
Erythropoietin	Human Serum	3.5 mIU/mL	ELISA	Validated
Erythropoietin Immunogenicity assay	Human Serum	248.48 ng/mL	ELISA	Validated
Follicle stimulating hormone (FSH)	Human Serum	30.0 pg/mL	CMIA	Validated
GCSF	Human Serum	250.0 pg/mL	ELISA	Developed
GCSF immunogenicity assay	Human Serum	-	ELISA	Under Development
Glucose	Human Serum	25 mg/dL	Chromogenic (GOD-POD)	Under Development
Growth Hormone	Human Serum	75.0 pg/mL	ELISA	Validated
Hemolytic potential of drug	Human blood	-	Chromogenic	Under Development
Hep test (LMWH by Anti-Xa)	Human Plasma	0.075 IU/mL	Clot based	Validated
Her2	Human Serum	78.1 pg/mL	ELISA	Under Development
Insulin Like Growth Factor-I (IGF-I)	Human Serum	0.094 ng/mL	ELISA	Validated
Levothyroxine	Human Serum	3.5 µg/mL	ELISA	Validated
Lio thyronine	Human Serum	0.5 ng/mL	ELISA	Validated
LMWH Anti Factor IIa	Human Plasma	0.030 IU/mL	Chromogenic	Validated
LMWH Anti Factor Xa	Human Plasma	0.050 IU/mL	Chromogenic	Validated
LMWH for APTT	Human Plasma	NA	Clot based	Validated
Peg-GCSF	Human Serum	250.0 pg/mL	ELISA	Under Development
Rituximab	Human Serum	1.5 µg/mL	ELISA	Under Development
Rituximab immunogenicity assay	Human Serum	-	ELISA	Under Development
Teriparatide	Human Plasma	20.0 pg/mL	ELISA	Developed
Tissue factor pathway inhibitor (TFPI)	Human Plasma	31.25 ng/mL	ELISA	Validated
Trastuzumab	Human Serum	1.0 ug/mL	ELISA	Under Development
Trastuzumab immunogenicity assay	Human Serum	-	ELISA	Under Development

Last updated on 5th July'17

Immunogenicity Testing

We are able to perform immunogenicity testing for antibodies to immunogenic drugs. We deploy a three tiered evaluation approach:

- Anti-drug antibody screening test
- Positive ADA confirmation test
- Titration

Generally, floating cut points are used. Study specific cut points are calculated using baseline samples.

We have capabilities of detecting anti-drug antibodies by

- Indirect / bridge ELISA
- Confirmatory Assays using immuno-depletion

We have immunogenicity testing methods for

- EPO
- Bevacizumab
- GCSF