



The NHLS HTA Unit List of Prequalified IVD Products: 2013

Year	Type of evaluation	Project Number	IVD Technology Name	Supplier	Manufacturer
2013	New Instrument	HTP12-0022	SG Vacutainer tubes	The Scientific Group	The Scientific Group
2013	New Instrument	HTP12-0027	ACL TOP 300/ 500	Beckman Coulter	Instrumentation laboratory (Part of Werfen Group)
2013	New Instrument	HTP12-0029	EASY RA	Medical Electronic Distributors (Pty) LTD, (M.E.D)	Medica
2013	New Instrument	HTP12-0040	Stratus	Siemens Pty (LTD)	Siemens
2013	New Instrument	HTP12-0046	Sysmex 500i	Roche Products (Pty)LTD	Sysmex
2013	New Instrument	HTP12-0055	Symex XN 2000	Roche Products (Pty)LTD	Sysmex
2013	New Instrument	HTP13-12	iQ™200 System	Beckman Coulter	Iris International
2013	New Instrument	HTP13-15	Architect c4000	Abbott Laboratories	Copan Italia S.p.A
2013	New Instrument	HTP13-32A	Therascreen RGQ mutation assays – Kras	Whitehead Scientific	QiaGen N.V.
2013	New Instrument	HTP13-32B	Therascreen RGQ mutation assays – Braf	Whitehead Scientific	QiaGen N.V.
2013	Reagent Upgrade	HTP12-0047	Calcium GEN2 reagent	Roche Products (Pty)LTD	Roche Diagnostics
2013	Reagent Upgrade	HTP12-0059	Calcium reagent	Roche Products (Pty)LTD	Roche Diagnostics
2013	Reagent Upgrade	HTP13-10	Tropinin I	Siemens Pty (LTD)	Siemens

* Denotes new entries

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2013	Reagent Upgrade	HTP13-27	ALPi reagent and ALPi Calibrator	Siemens Pty (LTD)	Siemens
2013	New Reagent	HTP12-0052	HIV LFC	Atomo Diagnostics	Atomo Diagnostics
2013	New Reagent	HTP12-0062	CI8200 – HBA1C	Abbott Laboratories (Pty)LTD	Abbott Laboratories
2013	POCT Instrument	HTP12-0035	AQT90	Radiometer	Radiometer
2013	POCT Instrument	HTP12-0037	Geenius HIV 1/2	Bio-Rad laboratories	Bio-Rad instrument
2013	POCT Instrument	HTP12-0053	Afinion: HBA1c	Alere Healthcare	Axis Shield
2013	POCT RDT	HTP12-0004	Parahit f Ver 1.0 - Device & Parahit Total Ver 1.0 - Device.	Span Diagnostics Ltd	Span Diagnostics Ltd
2013	POCT RDT	HTP12-0032	Cryptococcus LFC	Hain Lifescience	Immuno-Mycologics Inc (Immy)

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