



The NHLS HTA Unit List of Prequalified IVD Products: 2016

Year	Type of evaluation	Project Number	IVD Technology Name	Supplier	Manufacturer
2016	Instrument Upgrade	HTP15-60	Easyfix Interlab G26	Separation Scientific SA (Pty)LTD	Interlab
2016	New Instrument	HTP13-12B	iQ™200 System	Beckman Coulter South Africa (Pty) LTD	Iris International
2016	New Instrument	HTP12-0061B	Cell Dyn Ruby	Abbott Laboratories (Pty)LTD	Abbott Diagnostics
2016	New Instrument	HTP15-03	MTM II - Vacuum tissue processor	IMP Scientific	SLEE Medical GMBH
2016	New Instrument	HTP14-10	Cobas 6800 & 8800 System	Roche Products (Pty) LTD	Roche Molecular Systems, Inc
2016	New Instrument	HTP15-01	Hematek 3000	Siemens (Pty) LTD	Siemens Healthcare Diagnostics, Inc
2016	New Instrument	HTP15-05	VITROS 3600	Humor Diagnostica	Ortho Clinical Diagnostics
2016	Reagent Upgrade	HTP14-24	GenoType MTBDRsl Ver 2.0	Hain Lifescience SA (Pty)LTD	Hain Lifescience GmbH
2016	Reagent Upgrade	HTP15-23	Creatinine 2: Dimension®	Siemens (Pty) LTD	Siemens Healthcare Diagnostics, Inc
2016	New Instrument	HTP16-05	Variant II Turbo HBA1c II	Bio-Rad Laboratories (Pty) Ltd	Bio-Rad Laboratory, Inc
2016	New reagent	HTP16-03	Intrinsic factor Ab	The Scientific Group	IMMCO Diagnostics, Inc
2016	New reagent	HTP14-16	Access 25 (OH) Vitamin D Total	Beckman Coulter South Africa (Pty) LTD	Beckman Coulter, Inc
2016	New Reagent	HTP15-43	Antibody to Cyclic Citrullinated Peptide	Roche Products (Pty) LTD	Roche Diagnostics GmbH

* Denotes new entries

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2016	New Reagent	HTP13-42	STAT High Sensitive Troponin-I	Abbott Laboratories (Pty) LTD	Abbott Ireland
2016	New Reagent	HTP12-0063	Advia Centaur Syphilis	Siemens (Pty)LTD	Siemens Healthcare Diagnostics Inc
2016	POCT Instrument	HTP15-17	Stat strip glucose hospital meter	NB Diagnostics (Pty)Ltd	Nova Biomedical
2016	POCT Instrument	HTP16-26	Alere q: HIV-1/ 2 Detect	Alere Healthcare (Pty)LTD	Alere Technologies GmbH
2016	POCT Instrument	HTP14-23	Coag Sense PT/INR monitoring system	Biomed Healthcare	CoaguSense, Inc
2016	POCT Instrument	HTP15-07	MicroINR meter	The Scientific Group	iLine Microsystems S.L.
2016	POCT Reagent	HTP15-45	Xpert® HIV-1 Qual	Cepheid (Pty) LTD	Cepheid AB
2016	POCT Reagent	HTP15-30	Xpert® Flu/RSV XC	Cepheid (Pty) LTD	Cepheid AB
2016	POCT Reagent	HTP15-36	Xpert® HCV Viral load	Cepheid (Pty) LTD	Cepheid AB
2016	POCT RDT	HTP16-23	Multisure HIV1,2 Rapid Test	Dr. Temp (Pty) LTD	MP Biomedical Asia Pacific Pte Ltd.
2016	POCT RDT	HTP16-22	HIV1,2 Rapid Test	BioTech Africa	BioFocus Co.Ltd

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