

The NHLS HTA Unit List of Prequalified IVD Products: Dec 2024

Year	Type of Product	Project Number	IVD Technology Name	Supplier	Manufacturer
2024	New Instrument	HTP22-01	EntericBio® Dx assay	Pro med Diagnostics (Pty) Ltd	Serosep Ltd.
2024	New Instrument	HTP18-25B	FilmArray V2: RP2	Biomerieux South Africa (Pty) Ltd	BioFire Diagnostics LLC
2024	New Instrument	HTP19-10B	QIAstat-Dx: Respiratory panel	Qiagen SA (Pty) Ltd	QiaGen N.V.
2024	POC Instrument	HTP19-04	Pathfast	MSQ DIAGNOSTICS	LSI Medience Corporation
2024	New Reagent	HTP22-08	HISTO TYPE Rainbow QS6	Ilex South Africa (PTY) Ltd	BAG Diagnostics GmbH
2024	New Reagent	HTP23-08	Atellica® CH Alpha-1-antitrypsin (AAT)	Siemens Healthcare Diagnostics Products Ltd	Siemens Healthcare Diagnostics Products GmbH
2024	New Reagent	HTP23-11	Sentinel Ceruloplasmin	Siemens Healthcare Diagnostics Inc	Sentinel CH. SpA
2024	New Reagent	HTP23-57	MONOFLUO Pneumocystis jirovecii IFA Test	Bio-Rad Laboratories (Pty) Ltd	Bio-Rad Laboratories, Inc
2024	New Reagent	HTP17-05	Immulite 2000 Xpi Syphilis	Siemens Healthcare (Pty) LTD	Siemens Healthcare Diagnostics Products Ltd
2024	New Reagent	HTP20-37	ComASPTM Colistin	Davies Diagnostics (PTY) Ltd	Liofilchem S.r.l.
2024	New Reagent	HTP21-29	Xpert® MTB/XDR assay	Cepheid (Pty) LTD	Cepheid AB
2024	New Reagent	HTP23-34	Rapid Polymyxin Pseudomonas	Humor Diagnostica (Pty) Ltd	ELITech Microbio
2024	New Reagent	HTP19-17	cobas® HCV + control	Roche Products (Pty) LTD	Roche Diagnostics GmbH
2024	New Instrument	HTP20-18	UniCel® DxH 900	Beckman Coulter South Africa (Pty) LTD	Beckman Coulter, Inc
2024	New Instrument	HTP20-15	Abon Syphilis Ultra Rapid	Abbott Rapid	Abon Biopharm

			Test Strip	Diagnostics (Pty) Ltd	(Hangzhou) Co.,Ltd
2024	New Reagent	HTP21-07	Alinity m HBV Assay	Abbott Laboratories (Pty)LTD	Abbott Molecular Inc.
2024	New Reagent	HTP22-36B	Alinity m CMV Assa	Abbott Laboratories (Pty)LTD	Abbott Laboratories (Pty)LTD