



The NHLS HTA Unit List of Prequalified IVD Products: 2017

Year	Type of evaluation	Project Number	IVD Technology Name	Supplier	Manufacturer
2017	Sysmex XNL550	HTP16-21	Sysmex XNL550	Roche Products (Pty) LTD	Sysmex Corporation
2017	New Instrument	HTP13-13	Bactec FX	Becton Dickinson (Pty) LTD	Becton Dickinson
2017	New Instrument	HTP15-32	Thunderbolt 2 – Automated ELISA processing instrument	Hain Lifescience SA (Pty) LTD	Gold Standard Diagnostics
2017	New Instrument	HTP15-38	Plab ELISA – Automated ELISA processing instrument	Site Tech	Adaltis
2017	New reagent	HTP16-02	BRAHMS CgA II KRYPTOR	Humor Diagnostica	Thermo Fisher Scientific BRAHMS GmbH
2017	New reagent	HTP16-42	BK Virus R-gene	Biomerieux South Africa	Argene SA. Parc Technologique delta sud
2017	New reagent	HTP16-07	chromID® CARBA SMART Agar	Biomerieux South Africa	Biomerieux S.A.
2017	New reagent	HTP16-16	Mediace RPR Gen.2	Roche Products (Pty) LTD	Sekisui Medical CO., Ltd.
2017	New reagent	HTP15-31	ALPHA Cryptococcal Antigen enzyme immunoassay	Hain Lifescience SA (Pty) LTD	Immuno-Mycologics Inc (Immy)
2017	New reagent	HTP15-37	Premier™ Cryptococcal Antigen enzyme immunoassay	Site Tech	Meridian Biosciences, Inc
2017	POCT Reagent	HTP15-13	Xpert® FII & FV assay	Cepheid (Pty) LTD	Cepheid AB