EDCTP Contract N^0 RIA2020EF-2918

Rapid diagnostics for COVID-19: manufacturable in Africa to increase affordability, improve epidemic preparedness and strengthen local resilience

Deliverable report

Deliverable number	D7.1
WP no/title	7/ Route to Market
Deliverable title	Report and dataset on legal and regulatory landscape for PATHPOD and similar IVDs in Ghana
Responsible partner	UCAM/AVOMA
Due date	M18
Actual submission date	M 10

History of changes:

Date	Version no	Comments
14/05/21	1	Initial deliverable
05/08/22	2	Included updated ARIPO dataset information

Delivery Type

R	Report	✓
DEM	Demonstrator, pilot, prototype, plan designs, new or revised health policies etc	
DEC	Websites, patents filing, press & media actions, etc	
OTHER	Other	

Dissemination Level

PU	Public	✓
RE	Restricted to a group specified by the consortium.	

Partner	Contribution to this deliverable
UCAM	All initial work completed by UCAM
AVOMA	Consultation on industrial landscape and proofing

1. Status of the Deliverable

This deliverable is now final.

2. Summary of the results

The goal of D7.1 was to generate a report and dataset on legal and regulatory landscape for PATHPOD and similar *in vitro* diagnostics (IVDs) in Ghana. This work was undertaken through a combination of secondary data analysis, literature review, online information sources and discussions with in-country partners.

Intellectual Property Landscape

The current analysis indicates that there should be freedom to operate in Ghana for the core technologies used in AfriDx and AfriMx. There are underlying international patents on enzymes that are planned for use in the AfriDx test but the underlying RT-LAMP technology is now in the public domain due to patent expiry. Data collected from the African Regional Intellectual Property Organization (ARIPO) suggests that the relevant patents which are still active in the US and other jurisdictions were never filed or are not in force in the African nations whose databases are accessible via ARIPO.

As Ghana has not made their patent database searchable, we requested data from the Registrar General's Department on patents related to *in vitro* diagnostics (IVDs) but this was not supplied. The Registrar General confirmed that diagnostics per se are not patentable under Ghanaian law. This is true in many jurisdictions but the underlying technologies as well as *in vitro* methods that are not practiced on the human body are generally considered patentable in most jurisdictions. A follow up enquiry thus requested information on all patents assigned to specific IPC patent classification codes of interest to diagnostic technologies but no response was received.

The majority of international applicants use ARIPO and we have found no clear evidence for domestic patenting of IVD innovations from collaborators. On this basis, we are not considering changing the current design of the AfriDx IVDs in order to ensure freedom to operate. The use of different core enzymes that are fully in the public domain, close to patent expiry or have favourable technology licensing terms can be considered in WP3 and on-going polymerase design being undertaken beyond this project by the UCAM team may yield an enzyme that will attract independent patent protection. All these approaches would reduce potential third party in-licensing costs for commercialisation partners and from the work undertaken in this project, compensation for enzyme activity can be achieved even with less active out-of-patent enzymes to produce satisfactory results.

Regulatory Landscape

The regulatory landscape in Ghana for IVDs is relatively simple as there is one National Regulatory Authority (NRA): the Medical Devices Department (MDD) of the Food and Drugs Authority (FDA). However, due to the lack of experience at the Ghana FDA with regulation of locally manufactured products as opposed to imported products, there is likely to be a longer turnaround time on approval. Approval of each product takes a minimum of six months and new manufacturers would need to apply for a manufacturing license in advance of product registration.

In addition, to address the regional market it would be advantageous for a legal manufacturer of the AfriDx or AfriMx test kits to undergo World Health Organisation Prequalfication (PQ). This will aid in gaining regulatory approval elsewhere in the continent and also provide access to technical assistance from the WHO Local Production Assistance Unit and the PQ inspection and audit teams, who would conduct gap analyses and report on remedial actions needed to meet PQ standards.

Work has begun to map the process in more detail for D7.3 (Regulatory information compiled for IVD use in Ghana).

3. Description of work performed and obtained results

3.1 Intellectual Property Landscaping

The intellectual property landscape for IVDs is complex due to the multiple technologies and processes that make up a single IVD and its use for a specific diagnosis. In European and most African patent law, including in Ghana, “diagnostic methods practiced on the human or animal body” are not patentable. This does not extend to IVDs or underlying technologies and products e.g. devices, reagents. It is intended to prevent the patenting of the process of making a diagnosis

by comparing data obtained from a patient to a "normal" value and deriving a link to a particular disease state. Therefore, most of the technologies underlying AfriDx are patentable subject matter.

In Ghana patents are governed under the Patent Act, 2003 (Act 657). Ghana is a signatory to major international patent protocols and agreements including the Harare Protocol, which it ratified in 1984 (Obeng Manteaw, 2016). This empowers the African Regional Intellectual Property Organization (ARIPO) to receive and process patent applications on behalf of Ghana and other state parties to the protocol. ARIPO also receives international patent applications under the Patent Cooperation Treaty (PCT), whereby applicants can designate Ghana or any other any of the Contracting State(s). Applicants can file with ARIPO or with any of the Contracting States to enter this process.

For this reason we undertook a landscaping analysis into three levels: i) the international patent landscape for the core technologies in the current AfriDx and AfriMx designs; ii) the regional IVD patent landscape in Africa drawing on ARIPO data; iii) the national IVD patent landscape in Ghana.

3.1.1 Patent landscaping for AfriDx technologies

The primary IPC codes of relevance for IVDs are summarised in Appendix 1 and a combination of codes and keyword searches were used to filter relevant patents for RT-LAMP techniques and associated enzymes on lens.org.

The following information summarises the patent landscape for core AfriDx technologies. We have excluded searching for patents specifically on SARS-CoV-2 diagnostics as patent applications are typically published no earlier than 18 months after submission. Therefore, very few patents will be publicly accessible at the current time.

Technology	**Key Patents**	**Comment on AfriDx plans**
Recombinant Bst DNA Polymerase	Production of Bst-LF US 5830714 A (Priority Apr 17, 1996) Status: Expired Bst 2.0 from NEB US 9157073 B1 (Priority: Aug 31 2012) Status: Active in US and Europe, not found in Africa	The original DTU PATHPOD uses Bst 2.0 which is patented in some jurisdictions but no evidence could be found of a patent being in force in Africa. The UCAM work on BST has used both BST_{LF} and BST2.0, so that information on both options is available. BST_{LF} is in the public domain and can be used if preferred.
Recombinant Reverse Transcriptase	There are many public domain RTs with expired patents including the MMLV derivative sold as Superscript III	AfriDx is currently using RTX which is patented to 2037 (US10323243B2) and RTx but is

	US 7056716 B2 (Priority: Mar 15 2000) Patents are still in force for later MMLV derivatives and also RTs that were reverse engineered from DNA polymerases such as RTX.	exploring alternatives such as MMLV and Tth RT. No RTs were found with active patents in the ARIPO database.
Loop mediated isothermal amplification	LAMP foundational technique US 6410278 B1 (Priority Nov 9, 1998) Status: Expired Detection of loop-mediated isothermal amplification reaction by turbidity derived from magnesium pyrophosphate formation was published by the same inventors in 2001.	AfriDx is using a turbidity-based method which is now in the public domain. If this was to change then there are active patents covering fluorescent, colorimetric and probe-based readout technologies but there is no evidence that they are in force in Africa.

Table 1: Core molecular diagnostic technologies used in the AfriDx project.

3.1.2 IVD patent landscape in Africa

The full dataset of 13,613 patents from 1960-2022 was downloaded from the African Regional Intellectual Property Organization (ARIPO). The dataset was initially downloaded from the publication server for the ARIPO Journal and searched manually for any patents related to IVDs. However, the available methods to download this dataset would only provide up to 10,000 records leaving a gap in the data.

An alternative dataset was then scraped from the ARIPO E-Service database using Octoparse (see detailed methodology in Appendix 2) using the IPC classifications in Appendix 1. The data was deduplicated and filtered according to status, with only active or pending patents included and expired or withdrawn patents excluded (Appendix 2, Table S1).

These datasets were then further screened for relevance to IVDs. We identified 21 potential patents of interest for IVD technologies (Appendix 3) which could be broken down into the following categories:

Type of Patent	**Number of patents**
Devices	7
Disease Specific IVDs	10 (primarily TB)
Other	4

Table 2: Categorisation of IVD-related patents from the ARIPO database.

None were directly related to technologies being used by AfriDx e.g. generic development of isothermal nucleic acid amplification technologies and immunoassays. None would have potential to block freedom to operate.

Note: This assessment was made based on the technical content alone and was not subjected to scrutiny by a patent attorney.

3.1.3 Searches of Ghanaian patent database

Patents in Ghana are registered via the Registrar General's Department within the Ministry of Justice and Attorney General. UCAM have requested records directly from the Registrar, in order to analyse those relevant to IVDs and therefore ascertain the patent landscape for IVDs in Ghana. We requested data on all patents registered under relevant IPC codes (Appendix 1) but this data was not provided.

We believe that on the balance of probability based on ARIPO data, there is likely to be freedom to operate for the commercialisation of PATHPOD and related IVDs in Ghana. In 2019, Ghana received 20 direct patent applications compared to 625 ARIPO PCT-based applications[1] suggesting that very few patents are submitted via the direct national route.

Subsequent commercialization partnerships would still need to undertake due diligence and obtain formal legal advice.

3.2 Non-patent intellectual property rights

Non-patent intellectual property rights or existing contractual obligations impacting the use of the PATHPOD system (TATAA) and/or local productions of enzymes (UCAM) are largely Material Transfer Agreements (MTAs) that govern the use of materials such as cell lines and plasmids.

These MTAs are issued by DTU and UCAM and contain a non-commercial use clause. If a licensing arrangement were to go ahead then a commercial MTA would need to be negotiated although as most materials are DNA, there is nothing to stop a manufacturer synthesising that DNA *de novo* whereby it would not carry restrictions. For this reason, without patent protection on the expression and use of the DNA sequences, MTAs increase transactional costs but are weak instruments for controlling use of materials in this context.

3.3 Patenting novel AfriDx and AfriMx in Ghana and Africa

As part of the AfriDx commercialisation strategy, it may be necessary or desirable to patent certain aspects of AfriDx technology in Ghana or other countries in Africa. Research using online resources from the Ghanaian government, WIPO, ARIPO, patent attorneys and the academic literature was

1 https://www.aripo.org/wp-content/uploads/2020/07/2019-ARIPO-Annual-Report.pdf

therefore undertaken to understand the routes available and general considerations for patenting strategies in Africa.

Patent law in Ghana works very similarly for other jurisdictions (Patent Act, 2003 (Act 657)). Patents are actively examined and if granted they are valid for 20 years from the filing date. An annual fee is to be paid, starting one year after the filing date of the application.

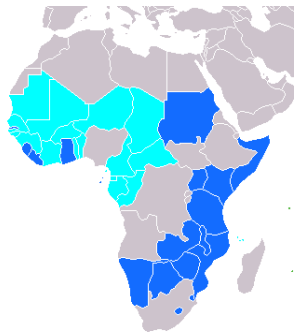


Figure 1: Map of ARIPO member countries (dark blue) and OAPI member countries (light blue). Source: Cxw on Wikimedia Commons, image is in the Public Domain

Patents for Ghana could therefore be filed locally with the Ghana patent office or via ARIPO. The total fees for submitting a PCT National Phase patent to Ghana for a small company (< 25 employees) would be 2500 GHS plus 1,437 USD international filing fee plus page surcharges over 30 pages. In addition, search fees would be payable.

To obtain patent protection across the rest of Sub-Saharan Africa, all countries have their own national offices and IP legislation apart from members of the Organisation Africaine de la Propriété Intellectuelle ("OAPI")[2] who act as a bloc and manage patent applications only via OAPI which thus gives protection across all states.

Applications can be made via ARIPO for any ARIPO states, with an initial fee of 290 USD and an additional fee per designated state of 85 USD[3]. In addition to search, publication and grant fees, the annual fees scale by designated state and vary from 50 USD per state in Year 1 to 330 USD per state in Year 15.

National registration is the only method possible in South Africa and Nigeria as they are members of neither ARIPO or OAPI.

The costs for patenting across multiple jurisdictions can increase dramatically[4], with like for like applications costing 5,200 USD across a 20 year lifetime in South Africa, 30,000 US in OAPI and 38,000 USD for three designated states in ARIPO. Some companies advise focusing on the largest economies in Africa with four patent filings, taking advantage of the regional offices to save time and expenses compared to national filings and also enable patents in English to be filed in countries where English is not an official language. This would result in a patenting strategy including filings via:

- ARIPO (multiple states are possible. When looking at the most populous countries, those with the highest GDP and those with the wealthiest citizens, Ghana is in each list along with

2 Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal, Togo, and Union of the Comoros

3 https://www.aripo.org/wp-content/uploads/2022/01/Patent-Fees.pdf

4 https://www.ipwatchdog.com/2017/08/04/costs-patenting-in-africa/id=86500/

Sudan. Tanzania, Kenya, Zambia, Uganda, Botswana, Namibia and Swaziland also feature in at least on category[5])

- OAPI – as a convenient way of covering a large number of countries.
- South Africa – as an economic hub of the continent.
- Nigeria – as the largest population in Africa and an economic hub of Northern/West Africa

South Africa and Nigeria do not examine patents, so little to no additional cost would be incurred for these applications.

Route to market including IP strategy will be considered in more detail in D7.3.

3.4 Regulatory landscape for PATHPOD and similar IVDs in Ghana

IVDs in Ghana are regulated by the Medical Devices Department (MDD) of the Food and Drugs Authority under the Food and Drugs Act, PNDCL 3058 (1992), the Food and Drugs (Amendment) Act, 1996, Act 523 and the Public Health Act, 2012.

Medical devices are classified in Ghana into Class I, II, III, and IV, following the European system. COVID diagnostics are classified as Class IV as per Appendix IV Part 2 of the Guideline of Medical Device Registration:

"An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as Class II, unless (a) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease if there is a risk of propagation in the Ghanaian population, in which case it is classified as Class IV;".

As SARS-CoV-2 is a transmissible agent that causes a life-threatening disease and there is a risk of propagation in the Ghanaian population, COVID-19 tests would be classified as Class IV medical devices if sold as a test kit for professional or self-administered use. However the PATHPOD can be broken down into different components that are being produced, potentially by different manufacturers.

3.5 Regulatory process for PATHPOD and similar IVDs in Ghana

In order to register, a dossier of information (Table 3) and a fee are submitted to the Ghana FDA along with a fee. Applications typically take a minimum of six months to process.

5 https://ideanav.co.za/aripo-patent-selecting-countries/

AfriDx Component	**Risk Class**	**AfriDx Manufacturing Plan**	**Regulatory Documents Required**	**Comments**
PATHPOD instrument	I	Outsourced		
Enzymes and/or antibodies	II	Local manufacturing	Control of starting materials Source of materials – proteins, etc. Method of manufacture and purification Characterisation Specification and COAs	
Buffers	II	Local manufacturing	Control of starting materials Source of materials Method of manufacture and purification Characterisation Specification and COAs	
Controls and calibrators	IV	Outsourced, in country formulation	Control of starting materials Source of materials Method of manufacture and purification Characterisation Specification and COAs	
Primers	II	Outsourced	Control of starting materials Source of materials Method of manufacture and purification Characterisation Specification and COAs	
Full SARS-CoV-2 RT-LAMP Kit	IV	Local finishing and packing	*In addition to component level info* *Manufacturing Process:* Release specification Shelf-life Specification *Finished Product:* Specificity Sensitivity Accuracy Stability - Justification of Shelf-life	Approval certificate needed from FDA for any clinical trials.
SARS-CoV-2 AfriMx rapid test strip	IV	Local assembly and packing	*In addition to component level info* *Manufacturing Process:* Release specification Shelf-life Specification *Finished Product:* Specificity Sensitivity	

			Accuracy Stability - Justification of Shelf-life	

Table 3: Risk classification and information to be submitted to regulator for PATHPOD devices.

The applicants must also adhere to the "Essential Principles applicable to IVD Medical Devices" in the Ghana FDA Guidelines.

20. Chemical, physical and biological properties

20.1 The IVD medical devices should be so designed and manufactured to ensure the characteristics and performance referred to above. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte (measurand) to be detected (such as biological tissues, cells, body fluids and microorganisms), taking account of its intended purpose.

20.2 The IVD medical devices should be so designed, manufactured and packaged to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device.

20.3 The IVD medical devices should be so designed and manufactured to reduce, as far as reasonably practicable and appropriate, the risks posed by substances that may leach or leak from the IVD medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

20.4 IVD medical devices should be so designed and manufactured to reduce, as far as reasonably practicable and appropriate, risks posed by the unintentional ingress or egress of substances into or from the IVD medical device taking into account the device and the nature of the environment in which it is intended to be use

How to best deliver on these will be further developed in D7.3 (Regulatory information compiled for IVD use in Ghana).

4. References

Obeng Manteaw, Samuel. "Ghana's Patent Law and Practice: A Critical Analysis of Patents Act, 2003 (Act 657)." U. Ghana LJ 29 (2016): 1.

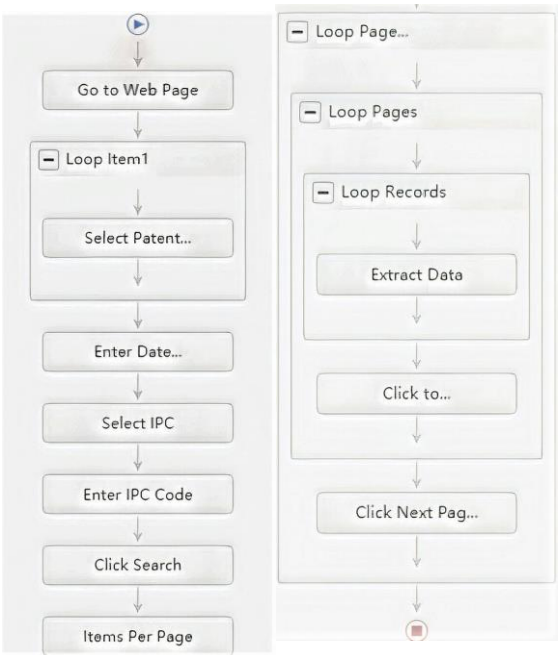
WIPO. "PCT Applicant's Guide – International Phase – Annex C." 2022. Available from https://www.wipo.int/export/sites/www/pct/guide/en/gdvol1/annexes/annexc/ax_c_gh.pdf

Appendix 1 – Primary IPC Codes relevant to *In Vitro* Diagnostics

IPC Code	Description
B01L 3/00	Containers or dishes for laboratory use, e.g. laboratory glassware (bottles B65D; apparatus for enzymology or microbiology C12M 1/00); Droppers (receptacles for volumetric purposes G01F) [2006.01]
G01N 33/50	Chemical analysis of biological material, e.g. blood, urine; Testing involving biospecific ligand binding methods; Immunological testing (measuring or testing processes other than immunological involving enzymes or microorganisms, compositions or test papers therefor, processes of forming such compositions, condition responsive control in microbiological or enzymological processes C12Q) [2006.01]
C12N 9/00	Enzymes, e.g. ligases (6.); Proenzymes; Compositions thereof (preparations containing enzymes for cleaning teeth A61K 8/66, A61Q 11/00; medicinal preparations containing enzymes or proenzymes A61K 38/43; enzyme containing detergent compositions C11D); Processes for preparing, activating, inhibiting, separating, or purifying enzymes [2006.01]
C12N 11/00	Carrier-bound or immobilised enzymes; Carrier-bound or immobilised microbial cells; Preparation thereof [2006.01]
C12N 15/00	Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; Use of hosts therefor (mutants or genetically engineered microorganisms C12N 1/00, C12N 5/00, C12N 7/00; new plants A01H; plant reproduction by tissue culture techniques A01H 4/00; new animals A01K 67/00; use of medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases, gene therapy A61K 48/00; peptides in general C07K) [2006.01]
C12Q	Measuring or testing processes involving enzymes, nucleic acids or microorganisms (immunoassay G01N 33/53); compositions or test papers therefor; processes of preparing such compositions; condition-responsive control in microbiological or enzymological processes [3]

Appendix 2 – Octoparse Method

1. Go to ARIPO Advanced Search website
2. Uncheck Utility Model, Industrial Design, Trademark checkboxes
3. Enter date range 01011960~04222022
4. Enter IPC categories as per Appendix 1 [only one per search]
5. Click Search
6. Adjust items per page from 10 to 40
7. Extract data, looping through each record on the page
8. Click next page button and repeat
9. Click next button to bring up next five pages and repeat until end.



The Octoparse Template ARIPO_Database is filed with the D7.1 data at the following doi: 10.5281/zenodo.6619229

Scraped data was exported to LibreOffice Calc and filtered by patent status (Table S1) and reviewed manually for relevance to IVDs and AfriDx technologies.

The full dataset is ARIPO Dataset_v2.ods and can be found at the following doi: 10.5281/zenodo.6619229

Patent Statuses Included	**Patent Statuses Excluded**
Granted or registered application	Expired
Substantive Examination	Withdrawal of application or patent
Pending grant	Lapse operation
Formality in-progress	

Table S1: Patent statuses included and excluded from ARIPO database search results.

Appendix 3 – IVD-relevant patents identified

Title	Status	Filing Date	Applicant	Abstract	Category
MOLECULAR DIAGNOSTIC ASSAY SYSTEM	Pending grant	22.07.2016	CEPHEID	Improved sub-assemblies and methods of control for use in a diagnostic assay system adapted to receive an assay cartridge are provided herein. Such sub-assemblies include: a brushless DC motor, a door opening/closing mechanism and cartridge loading mechanism, a syringe and valve drive mechanism asse...	Devices
MICROFLUID CHIP-BASED, UNIVERSAL COAGULATION ASSAY	Granted or registered applicatio n	09.09.2015	PEROSPHERE TECHNOLOGIES INC.	A microfluidic, chip-based assay device has been developed for measuring physical properties of an analyte (particularly, whole blood or whole blood derivatives). The technologies can be applied to measure clotting times of whole blood or blood derivatives, determine the effects of anticoagulant dru...	Devices
SYSTEM FOR MICROBIAL SPECIES DETECTION, QUANTIFICATION AND ANTIBIOTIC SUSCEPTIBILITY IDENTIFICATION	Substantiv e Examinati on	28.08.2019	MICROFLUIDIC BIOLOGICS CORP.	Several microfluidic chips are used to significantly accelerate the time to identify and quantify microbes in a biological sample and test them for antibiotic resistance, particularly for urinary tract infections. A first microfluidic chip uses antibody or similar probes to identify and quantify any...	Devices
SYSTEMS AND METHODS FOR MOBILE DEVICE ANALYSIS OF NUCLEIC ACIDS AND PROTEINS	Substantiv e examinati on	14.03.2014	NANOBIOSYM, INC.	A portable system for extracting, optionally amplifying, and detecting nucleic acids or proteins using a compact integrated chip in combination with a mobile device system for analyzing detected signals, and comparing and distributing the results via a wireless network. Related systems and methods a...	Devices
Assays	Granted or registered applicatio n	16.03.2009	CLONDIAG GMBH	A method for assaying a sample for each of multiple analytes is described. The method includes contacting an array of spaced-apart test zones with a liquid sample (e.g., whole blood). The test zones disposed within a channel of a micro fluidic device. The channel is defined by at least one flexible ...	Devices
BIOSENSOR WITH POROUS WICKING LAYER	Substantiv e Examinati on	15.05.2019	LIFE SCIENCE BIOSENSOR DIAGNOSTICS PTY LTD	The present invention relates to organic thin film sensors and the preparation and use thereof in sensing applications, and in particular in glucose sensing. The sensor is characterised by a layered structure comprising a porous wicking layer whose surface is configured to receive a liquid sample. A...	Devices
METHODS OF DIAGNOSING AND TREATING ABIRATERONE ACETATE - GLUCOCORTICOID - RESISTANT OR - SENSITIVE METASTATIC CASTRATION RESISTANT PROSTRATE CANCER	Substantiv e examinati on	29.09.2017	JANSSEN PHARMACEUTICA NV	Disclosed herein are novel biomarkers for detecting resistance and sensitivity to abiraterone acetate-glucocorticoid treatment in a patient having metastatic castration resistant prostate cancer. Also provided are methods of diagnosing and treating abiraterone acetate-glucocorticoid resistant and ab...	Disease Specific IVD
BIOMARKERS OF TRAUMATIC BRAIN INJURY	Substantiv e examinati on	30.01.2017	THE UNIVERSITY OF BIRMINGHAM	Provided is a method of diagnosing and/or monitoring traumatic brain injury (TBI) in a subject. The method comprises determining a level of at least one miRNA in a fluid sample	Disease Specific IVD

				from the subject. The miRNA may be selected from miR-425-5p, miR-502, miR-21 and miR-335. The method may involve determinin...	
HIGH THROUGHPUT CELL-BASED SCREENING FOR APTAMERS	Substantive examination	03.08.2017	MeiraGTx UK II Limited	The invention provides eukaryotic cell-based screening methods to identify an aptamer thatspecifically binds a ligand, or a ligand that specifically binds an aptamer, using apolynucleotide cassette for the regulation of the expression of a reporter gene where thepolynucleotide cassette contains a...	Other
METHOD AND KIT FOR IDENTIFYING GENE MUTATIONS	Pending grant	03.11.2016	UNIVERSITY OF PRETORIA	This invention relates to a method of identifying mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, a kit for performing said method, and furthermore to isolated nucleotide sequences being complementary to one or more mutations of the CFTR gene. According to a first a...	Disease Specific IVD
PRIMER SET, PROBE, AND KIT FOR DETECTING SCHISTOSOMA HAEMATOBIUM	Substantive Examination	16.12.2020	JIANGSU INSTITUTE OF PARASITIC DISEASES | JIANGSU QITIAN GENE BIOTECHNOLOGY CO., LTD.	A primer set for detecting S. haematobium includes an upstream primer and a downstream primer. The upstream primer includes a sequence of SEQ ID NO: 1; and the downstream primer includes a sequence of SEQ ID NO: 2. The disclosure also provides a probe and a kit for detecting S. haematobium. The prim...	Disease Specific IVD
DIAGNOSIS AND TREATMENT OF INFECTIOUS DISEASE	Substantive examination	17.06.2016	CAMBRIDGE ENTERPRISE LIMITED	Diagnosis and Treatment of Infectious Disease Methods are described for determining whether a subject suffering from, or suspected of suffering from, an infectious disease caused by a microbe is infected with a strain of the microbe that is susceptible to an antimicrobial agent, where there exist di...	Other
METHOD FOR ASSESSING SUSCEPTIBILITY OF A VIRUS TO TREATMENT BY MEASURING ENZYME ACTIVITY AND A SYSTEM THEREFORE	Substantive Examination	03.07.2018	CAVIDI AB	The present invention relates to a method for assessing susceptibility of a virus to treatment with a drug inhibiting an enzyme of the wild-type virus comprising the steps: a)extracting the viral enzyme from a sample containing the virus; b) measuring the viral enzyme activity both in the absence of...	Other
CONVECTIVE PCR AMPLIFICATION DETECTION SYSTEM AND CONVECTIVE PCR AMPLIFICATION DETECTION METHOD	Substantive examination	16.01.2018	BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO., LTD. | BEIJING UNIVERSITY OF CHEMICAL TECHNOLOGY	Disclosed are a system and a method for detecting convective PCR amplification. The system comprises: a microfluidic chip, comprising a storage structure, a convective PCR tube, an FTA film and a waste liquid receiving structure, wherein a first end of the convective PCR tube is in communication wit...	Devices
GENETICALLY MODIFIED STRAINS OF MYCOBACTERIUM SMEGMATIS	Pending grant	31.03.2017	University Of The Witwatersrand, Johannesburg	The present invention relates to a recombinant bacterium based on a non-pathogenic bacterium that has a modified genome containing a nucleic acid of interest from a pathogen that is detected by a molecular diagnostic assay and that mimics the diagnostic profile of the pathogen. The invention further...	Other
Method for assessing the viability of viruses with lymphotropism	Granted or registered application	21.05.2013	MKRTCHYAN Leonardovich Ovik	Use: medicine and biotechnology.Aim: to increase the reliability of determining infection by viruses with lymphotropism, to eliminate false negative reactions in testing blood for the presence of lymphotropic viruses during EIA	Disease Specific IVD

				and PCR testing, and to detect viruses with lymphotropism in biological...	
SALIVARY BIOMARKERS OF BRAIN INJURY	Substantive Examination	14.02.2020	MARKER DIAGNOSTICS UK LIMITED	Methods of diagnosing, monitoring, treating, and predicting the course of traumatic brain injury (TBI), including mild traumatic brain injury (mTBI), include determining a level of at least one RNA biomarker (e.g., miRNA) in a saliva sample from a subject. Also described are sensor elements, detecti...	Disease Specific IVD
USE OF BIOMARKERS IN IDENTIFYING CANCER PATIENTS THAT WILL BE RESPONSIVE TO TREATMENT WITH A PRMT5 INHIBITOR	Pending grant	26.02.2018	JANSSEN PHARMACEUTICA NV	The present invention concerns a method of identifying a patient that is likely to beresponsive to treatment with a protein arginine N-methyltransferase 5 (PRMT5) inhibitor comprising: evaluating a biological sample from the patient for the presence of a pliceosome alteration, wherein the presence ...	Disease Specific IVD
METHOD FOR DIAGNOSING TUBERCULOSIS	Granted or registered application	26.02.2015	STELLENBOSCH UNIVERSITY	A method for diagnosing tuberculosis (TB) is provided. The method comprises the step of detecting a panel of at least four biomarkers in an unstimulated blood sample from a subject, the biomarkers being selected from the group consisting of complement factor H, apolipoprotein (APO)-A1, pre-albumin, ...	Disease Specific IVD
A method for identifying bacteria in a sample	Granted or registered application	06.05.2011	UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	This invention describes a method for identifying bacteria. In particular, this invention relates to a method for identifying and quantifying mycobacteria from a sputum sample taken from a subject using flow cytometry. Further described is the use of flow cytometry to identify and quantify Mycobacte...	Disease Specific IVD
METHODS RELATING TO TUBERCULOSIS	Formality in-progress	05.03.2020	PBD BIOTECH LIMITED | THE UNIVERSITY OF NOTTINGHAM	The invention relates to a method of diagnosis of tuberculosis (TB)disease in asubject. The method comprises admixing a Mycobacteria-specific bacteriophage with asample of peripheral blood mononuclear cells(PBMCs) from the subject, followed by determination of the presence or absence of a Mycobacter...	Disease Specific IVD