Association of Medical Laboratory Diagnostics Suppliers (Suing through its officials; John Karume – Chairman Paul Wambura – Treasurer Feroz Nawab – Secretary) v Kenya Medical Laboratory Technicians And Technologists Board; Pharmacy and Poisons Board (Interested Party) (Miscellaneous Application E043 of 2021) [2025] KEHC 7574 (KLR) (Judicial Review) (3 June 2025) (Judgment)

Neutral citation: [2025] KEHC 7574 (KLR)

REPUBLIC OF KENYA

IN THE HIGH COURT AT NAIROBI (MILIMANI LAW COURTS)

JUDICIAL REVIEW

MISCELLANEOUS APPLICATION E043 OF 2021

JM CHIGITI, J

JUNE 3, 2025

BETWEEN

ASSOCIATION OF MEDICAL LABORATORY DIAGNOSTICS SUPPLIERS (SUING THROUGH ITS OFFICIALS; JOHN KARUME – CHAIRMAN PAUL WAMBURA – TREASURER FEROZ NAWAB – SECRETARY) ..... APPLICANT

AND

THE KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD ..... RESPONDENT

AND

PHARMACY AND POISONS BOARD ..... INTERESTED PARTY

JUDGMENT

1. On 21st December 2020, the Respondent issued a memo directing all its clients that the renewal of licenses for all laboratories for the year 2021 should be lodged not later than the 31st March 2021 and that the said registration would be subject to evidence that the test kits/reagents and equipment being used for clinical lab tests are validated by the Respondent. The memo was purportedly issued pursuant to Section 25 of The Medical Laboratory Technicians and Technology Act Cap 253 A as read with *Legal Notice no.113 of 2011*. The Respondent directed further that all suppliers, vendors and distributors must also be registered by the Respondent.

2. On 12th March 2021 the Respondent issued another memo referring to the previous one dated 21stDecember 2020 in which they referred to the renewal of facility licenses contingent on evidence

that test kits/reagents and equipment being used in clinical testing are validated by the Respondent. The Respondent maintained that issuance of pre-validation registration certificates was an ongoing activity further stating that they were being reminded to renew their licenses for the year 2021. The memo further directed that the intended recipients provide details of all reagents, kits, equipment/ analyzers, chemicals and consumables used in their facilities.

3. The Respondent issued another memo dated 15thFebruary 2021, to members of the Exparte Applicant asserting that the Respondent is mandated by law to validate invitro diagnostics (IVDs).

4. In Addition to the foregoing, a number of the Exparte Applicant's members received SMSs from the Respondent to provide evidence of certification for test kits/reagents and equipment from external bodies such as United States Food and Drug Administration (FDA).

5. This has precipitated the filing of the application before this court for determination dated 5th April 2021 wherein the Applicant seek the following orders:

    1. Orders of Certiorari quashing the memos dated 21stDecember 2020 and 12th March 2021 issued by the Respondent requiring kits/Reagents and equipment used for clinical lab tests be validated by the Respondent and all suppliers, vendors and distributors to be registered with the Respondent.

    2. Orders of Prohibition prohibiting and restraining the Respondent either by itself, agents, employees or whatsoever means from taking steps, actions and measures to enforce its memo dated 21st December 2020 and 12 March 2021.

The Applicants case;

6. The application is supported by that verifying Affidavit and a supplementary affidavit of Feroz Nawab, the Secretary of the Applicant.

7. It is the Applicants' case that the Interested Party has over the years exercised the role contemplated in the said Memo pursuant to *Legal Notice 192 of 2010* and Gazette Notice No. 1879 dated 21 March 2014 and clarified by the Ministry of Health and the Interested Party.

8. The Applicants argue that the Respondent herein had filed Judicial Review Application at High Court of Kenya. Nairobi being JR. Miscellaneous Application No. 229 of 2014 against among others, the Interested Party challenging *Legal Notice No.192 of 2010* and Gazette Notice No. 1879 dated 21st March 2014 with regard to the mandate of the Pharmacy and Poisons Board regulating laboratory equipment and reagents. The Respondent withdrew from the proceedings on August 2014.

9. The *Health Act* 2017, the Ministry of Health has not given guidance on the sole regulatory body responsible for medical laboratory equipment and reagents.

10. It is argued that the Legal Notice 113 is not in tandem with the global equipment and reagent verification standards as stipulated on ISO/IEC 15189:2012 clause 5.5 to make it implementable.

11. *Legal Notice No.113 of 2011* is ultra vires and a violation of the Kenya Medical Laboratory and Technicians and Technologists Board Act Cap 253A.

12. According to the applicant, there has not been any public participation in enactment of Legal Notice Number 113 of 2011 and neither has it been implemented until the issuance of the Memo dated 21st December 2020.

13. The Applicant argues that The Interested Party has already invested in a wide infrastructure on product registration and evaluation and which achieves product validation.

14. The Applicant argues that there have been constant conflicts between the Respondent and Interested Party on regulation of invitro diagnostics leading to confusion among members of the Applicant. It argues that the Memo dated 21st December 2021 lacks clarity on the process of validation of medical devices by the Respondent. The process and the outcome are vague.

15. It is their case that the accuracy, precision, linearity, robustness and ruggedness of the medical laboratory equipment are affected by movement and environmental factors; therefore, it may not be prudent moving all equipment to the Respondent as intimated in *Legal Notice 113 of 2011* and Memo dated 21st December 2020.

16. The Applicant is concerned that the Memo dated 21st December 2020 by the Respondent introduces parallel regulating regime to that already in place by the Interested Party and will subject members of the Applicant to confusion and unnecessary huge costs in complying with the same.

17. It argues that the business of the Respondent as contemplated under Section 5 of the Medical Laboratory Technicians and Technologies Ac (Cap 253A) does not include manufacture of IVDs, buying, selling, installation, care and maintenance of IVDs or validation of reagents, equipment and test kits.

18. It the Applicant's case that the World Congress of Biomedical Laboratory Science had nothing to do with enactment of *Legal Notice No. 113 of 2011* or regulatory framework for Invitro Diagnostics and neither does Annexure "AA2a" and "AA2b" give such indication. Further the meeting was organized by Association of Kenya Medical Laboratory Scientific Officers (AKLMSO) and not the Respondent.

19. The members of the Applicant were invited and attended the conference as sponsors to exhibit their products and the stakeholder engagements were undertaken after the Legal Notice had already been enacted but no evidence has been tendered on the final report from the stakeholder engagements and none was given.

20. It argues that all imports by the members of the Applicants are subjected to Pre-Export Verification of Conformity (PVOC) to ensures the safety and quality of the imported goods are pursuant to Legal Notice 78 of 15/ 07/2005.

21. It further argues that the importers of among others medical devices must obtain Certificates of Conformity (COC) for their cargo before applying for Import Permits from the Interested Party through the Kenya National Single Window Electronic (Kentrade) System.

22. The Applicant argues further that all suppliers and importers are required to submit manufacture registration and certification from the country of origin. Thereafter the applicant argues that they are required to provide products to be listed for sale in Kenya and have all certificate of analysis and other recognized international certification such as Federal Drug Administration of the United States of America.

23. It argues that there is public a notice by the Kenya Bureau of Standards and the Interested Party as well as Medical Device Registration Certificates for test kits issued by the 1st Interested Party and PVOC Certificate from KEBS.

24. The apparent supremacy wars between the 1st Interested Party and the Respondent has led to some members having no choice but to subject themselves to parallel regulatory requirements of the said regulatory bodies.

25. Validation of the medical devices and IVDS are carried out by third party accredited laboratories in line with WHO guidelines and Kenya Service Accreditation Service *Act No. 17 of 2019*.It is the Applicants case that nothing in the *Legal Notice No. 113 of 2011* provide for accreditation of laboratories and neither are those accredited laboratories reserved for the Respondent.

26. They argue that the case of Republic versus Kenya Medical Laboratory Technicians and Technologists Board & Anor Ex Parte Anil Tailor & 4 Others (2013) EKLR is not relevant. They argue that they are not aware of any attempt by the 1stInterested Party to regulate private medical laboratories.

27. The Interested Party has been recognized as the National Regulatory Authority with respect to medical devices as set out in the excerpt of the World Bank publication on medical devices regulation at Country Level.

Applicant's Submission

28. It is submitted that Section 4 of the *Health Act* Cap 241 of the laws of Kenya provides as follows:

> " It is a fundamental duty of the State to observe, respect, protect, promote and fulfill the right to the highest attainable standard of health including reproductive health care and emergency medical treatment by inter alia" –
>
> developing policies, laws and other measures necessary to protect, promote, improve and maintain the health and well-being of every person;
>
> ensuring the prioritization and adequate investment in research for health to promote technology and innovation in health care delivery;
>
> ensuring the provision of a health service package at all levels of the health care system, which shall include services addressing promotion, prevention, curative, palliative and rehabilitation, as well as physical and financial access to health care;"

29. Section 62 of the *Health Act* further provides as follows:

> " There shall be established by an Act of Parliament a single regulatory body for regulation of health products establishment of a single regulatory body for health and health technologies,"

30. Reliance is placed in the case of ELRC Judicial Review No. E049 of 2023 R v Pharmacy and Poisons Board and Kenya Medical Laboratory Technicians and Technologist Board (Interested Party) in which Lady Justice Ngibuini held with respect of the role of PPB the Respondent: -

> " 64. The Respondent has proved that it indeed is the regulatory body established under Section 62 of the *Health Act* to regulate health products and health technologies and therefore it was within its mandate to invite applications for the positions of In-Vitro Diagnostics Experts and for the positions of Blood and blood products experts" further that
>
> "65. The Act is clear the roles of the Interested Party (KMLTTB) is distinct from the role of the Respondent the Pharmacy and Poisons Board as per the various legislation regulating the two respective bodies"

31. In the matter of Council of County Governors v Attorney General & another [2017] eKLR the guiding principles of interpreting laws to determine their effect and constitutionality were very well

set by the bench as it was then constituted in the High Court at Nairobi. That at any point where a dispute involves the effect of enacted laws, the Courts should first start from a point of view that the statute in question is lawful and must then proceed to determine the object and purpose of the statute for it is important to discern the intention expressed in the Act itself.

32. It is submitted that Members of the Applicant supply equipment used for tests and kits/reagents used for clinical lab tests which has always been regulated by the 1st Interested Party. The memos by the Respondent has exposed members of Applicant to double regulation. It is sun submitted that the memos by the Respondent are ultra vires and have no basis in law.

33. The Respondent is a body established under the *Medical Laboratory Technicians and Technologists Act* Cap 253A Laws of Kenya ("the MLTT Act") and which prescribes its powers.

34. The preamble to the Act sets its object as follows: -

> "An Act of Parliament to provide for the training, registration, and licensing of medical laboratory technicians and technologists, to provide for the establishment, powers, and functions of the Kenya Medical Laboratory Technicians and Technologists Board and for connected purposes"

35. Section 5 of the MLTT Act. Under Section 5 (2), of the said Act, the specific functions of the Respondent are:

> "a. prescribe, in consultation with the College and such approved training institutions as the Board may deem appropriate, the courses of instruction for laboratory technicians and technologists;
>
> b. consider and approve the qualifications of laboratory technicians and technologists for the purposes of registration under this Act;
>
> c. approve institutions for the training of laboratory technicians and technologists;
>
> d. licence and regulate the business and practice of registered laboratory technicians and technologists; and
>
> e. regulate the professional conduct of registered laboratory technicians and technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards". (Emphasis added)

36. In Republic v Kenya Vision 2030 Delivery Board & Another Ex-Parte Eng. Judah Abekah [2014] eKLR, the court emphasized that when interpreting statutes, the literal meaning of the words must be taken into account, and the statute must be read as a whole to avoid inconsistencies. Additionally, the court discussed the ejusdem generis rule, explaining that when general words follow specific words in a statute, the general words should be interpreted as applying only to items of the same kind or class as the specific words listed.

37. It is submitted that a reading of section 5 of the MLLT Act reveals that the Respondent is mandated with the oversight of the education of laboratory technicians and technologists and how they behave (ethics) in the conduct of their profession and not the role that they intend to usurp through the memos.

38. It is submitted that there is no provision under the MLTT Act requiring the registration of member Applicants as intimated in the memo dated 12th December 2020. In fact, the Respondent is categorical that its "memos were not directed to the Applicant" and instead were "reminders to the medical laboratories regulated by the Respondent" as evident at Page 50 of the Respondent's Replying Affidavit dated 20th April 2021 and page 22 and 23 of the Supplementary Affidavit dated 15th June 2021.

39. According to the Respondent it has the mandate to regulate test kits/reagents, IVDs and equipment being used for clinical lab tests pursuant to Section 25 subsection 2 of the MLTT Act read together with *Legal Notice 113 of 2011*(Equipment and Reagents Validation Regulations, 2011).

40. Section 25 Subsection (1) and (2) of the MLTT Act falls under Part IV of the Act which sets out provisions relating to private practice. The said Section 25 provides that: -

> "(1) The Board shall, in regulations, prescribe the terms and conditions of the business and practice of laboratory technicians and technologists engaged in private practice.
>
> (2) Regulations under subsection (1) shall in particular provide for—
>
> (a) the equipment and reagents to be provided in private medical laboratories;
>
> (b) the services to be rendered by laboratory technicians and technologists in private practice; and
>
> (c) the employment of laboratory technicians and technologists in private medical laboratories." (emphasis added).

41. The contemplated regulations under Section 25 are intended to deal with the "business and practice of laboratory technicians and technologists engaged in private practice".

42. Section 25 Subsection (2) sets out three matters that the contemplated Regulations will address and for the present Paragraph *(a)* is the relevant. The question then is what is the scope of the contemplated regulation providing for "the equipment and reagents to be provided in private medical laboratories."

43. The regulations under the said Section 25 of the MLTT Act are intended to deal with the "business and practice of laboratory technicians and technologists engaged in private practice" and not the regulation of test kits/ reagents, equipment used for clinical lab tests and IVDs.

44. Pursuant to Section 25(2)(a) the contemplated Regulations under the said section ought to deal with the manner in which private laboratories are to be stocked and equipped and not validation of the reagents and equipment used in medical laboratories.

45. Reliance is placed on the case of Scion Healthcare Limited & another v Kenya Medical Laboratory Technicians and Technologists Board & another [2020] Justice Mrima relying on Machakos High Court Judicial Review No. 408 of 2017 which made extensive reference to Kisii High Court Judicial Review No. 82 of 2011 quoted the court's interpretation of Section 25(2)(a) of the MLTT Act and said: -

> "It is therefore clear that Section 25(2)(a) is a departure from what appears in the long title and the object and purpose of the Board. By empowering the Board to make regulations providing, not only for terms and conditions of the business and practice of laboratory

technicians and technologists but also providing for the equipment and reagents to be provided in private laboratories, the Act empowers the Board to actually regulate the manner in which private laboratories are to be stocked and equipped.That in my view is an extension of the power of the Board to not only regulate technicians and technologists but to an extent, private laboratories." (Emphasis added)

46. The validation and stocking of medical laboratories are distinct roles noting that Section 25(2) was drafted in the manner contemplating existence of distinct regime for validation of reagents and equipment used in medical laboratories. This is buttressed by the fact that MLTT Act was enacted in 2000 when there was already a regime enacted in 1957that is the *Pharmacy and Poisons Act* Cap 244 of the laws of Kenya ("PPB Act") regulating 'medicinal substances' and 'drugs.'

47. In the memos the Respondents cited *Legal Notice No. 113 of 2011* the Medical Laboratory (Equipment and Reagents Validation) Regulations, 2011 as legal basis for the memos.

48. The said notice purported to extend the Respondent's mandate to include validation of equipment or reagents for use within medical laboratories. The term "validation" is neither used nor defined in the parent MLTT Act.

49. Instead it is defined in said Regulations, 2011 as:

> " the process of authentication undertaken by Board or its appointed agents for the purposes of confirming the quality of medical laboratory reagents and equipment by performing tests to confirm the information provided by the manufacturers relating to their precision, linearity, specificity, sensitivity and accuracy in the description of the equipment, reagents and chemicals for use within medical laboratories in Kenya."

50. The net effect is that the Regulations purported to expand the mandate of the Respondent beyond that which is provided under the parent Act. Had the legislature intended to include the expanded role, the proper way would have been to amend the MLTT Act. The Legal notice No.113 of 2011 is thus ultra vires and therefore void for being inconsistent with the parent Act.

51. In the case of Kenya Hospital Association t/a Nairobi Hospital v Medical Practitioners and Dentists Board & 4 others [2018] eKLR the court reiterated that a regulation cannot amend a Parent Act. The court cited section 31(1)(b) of the *Interpretation and General Provisions Act*, Cap 2 of the Laws of Kenya stipulating that subsidiary legislation cannot be inconsistent with the provision of the Act.

52. The PPB Act makes provisions on the regulation of products that the Respondent is purporting to regulate through its memos. Section 3A, 3B of the PPB Act which were introduced vide Health Laws Amendment Act of 2019 sets out the powers and functions of the Interested Party.

53. Under Section 3A of the PPB Act the powers of the 1st Interested Party include the following with respect to medical products: -

> "(a) formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products
>
> (b) ...
>
> (c) grant or withdraw marketing authorization for medical products subject to appropriate conditions and revise such conditions for marketing authorization as necessary;

(d) ...,(f)...,(g) ...

(h) prescribe the standards appropriate for new medical products; new uses, dosages, and formulations of existing medical products; and such other categories as may be appropriate;

54. Further Section 3B of the PPB Act Subsection (1) gives the Interested Party the responsibility for regulating inter alia health products. Subsection 2 sets out the functions of the Interested Party in relation to regulation of health products, technologies to include: -

" (b) ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality safety and efficacy;

(c) ...

(d) enforce the prescribed standards of quality, safety and efficacy of all medicinal substances manufactured, imported into or exported out of the country;

(e) grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances;

(f) maintain a register of all authorized medicinal substances;

(g) publish, at least once in every three months, lists of authorized or registered medicinal substances and of products with marketing authorizations;"

55. Section 2 of the PPB Act, defines health product to include; medical products as well as medicinal substances, diagnostics, and medical devices. Even though the Act does not define 'medical products', it is safe to conclude that medical product is a type of health product just as the defined by the World Health Organization (WHO). According to the WHO:

" Medical products are medicines, devices, and other items used to diagnose, treat, or prevent diseases or other abnormal conditions. They include pharmaceuticals, biologics, vaccines, and diagnostic tools." (Emphasis Added)

56. Section 2 of the PPB Act further defines medicinal substances to include a product, article or substance which is claimed to be useful for, inter alia, "diagnosing disease or ascertaining the existence, degree or extent of a physiological condition". This definition has largely remained unchanged since the enactment of the Act.

57. Section 2 of the PPB Act gives elaborate definition of medical device to mean "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article— (a) intended by the manufacturer to be used, alone or in combination, for humans or animals for;

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

iii. investigation, replacement, modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life;

iv control of conception;

v disinfection of medical devices; or

vi. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and (b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means" (Emphasis Added).

58. It is submitted that the cumulative effect of Sections 3A and 3B is that PPB, the Interested Party, is the proper single regulatory body mandated to regulate and/or validate test kits/reagents, IVDs and other equipment used for medical tests fall under the definitions of health products and medicinal substances.

59. Section 4 of the *Health Act*, 2017, dictates that it is the fundamental duty of the state to observe, respect, protect, promote and fulfill the right to the highest attainable standard of health by performing among other things, the duty of developing policies, laws and other measures necessary to fulfill the said mandate. The Ministry of Medical Services developed the Guidelines on Submission of Documentation for Registration of Medical Devices available in the PPB website. It provides under Article 3(1) that the guidelines shall apply to:

> " ...medical devices and their accessories. For the purposes of these guidelines, accessories shall be treated as medical devices in their own right."

60. Further, Article 5(3) of the Guidelines defines In-Vitro Diagnostic Devices (IVDs) to mean: medical devices, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles. It is further observed that the Exparte Applicant is mandated with the observation of these guidelines.

61. It is submitted that the above provisions make it clear that the 1st Interested Party is mandated to regulate and validate medical devices, including test kits/reagents, IVDs, and other equipment used for medical tests.

62. It is further submitted that the Respondent has, before the institution of this Application, initiated another application through The Nursing Council of Kenya; Judicial Review Misc Application No.229 of 2014 R vs The Pharmacy and Poisons Board, concerning functions which they seek to usurp through their disputed Memos. The Respondents withdrew from the said application and proceeded to conduct 'Internal Discussions', the outcome of which was a press Statement from the Office of the 2nd Interested Party affirming that the 1st Interested Party is the body mandated to carry out the duty of validating medicines, medical devices, medical equipment and reagents and In-Vitro Diagnostic Devices (IVDs).

63. The 2nd Interested Party in its press statement further affirmed that this role of the 1st Interested Party is supported by *Legal Notice 192 of 2010* and Gazette notice no. 1879 of 21st March 2014. Therefore, these attempts through the memos by the Respondent are ultravires and intent on usurping powers for their unknown gain.

64. These functions the Respondent now seeks to assume,it is submitted are outside its scope of mandate as illustrated, and those functions only fall within the legal mandate of the 1st Interested Party. Members of the Exparte applicant have been taking measures to ensure that they comply with legal provisions

as they are. The Respondent seeking to act outside its scope puts members of the Exparte applicant at risk of unwarranted financial losses and unpredictable business environment.

65. The assumption of these roles by the Respondent, which is the mandate of the 1st Interested Party, would subject members of the Exparte Applicant to unfair administrative action. In light of Article 47 of *the Constitution*, which guarantees the right to fair administrative action, the ex-parte Applicant invokes its right as it is likely to suffer and in line with the position of the court in the matter Nancy Makokha Baraza v Judicial Service Commission & 9 Others [2012]eKLR this court has wide discretion, which is inclusive rather than exclusive and therefore allows this Court to make appropriate orders and grant remedies as the situation demands and as the need arises.

66. They further submit that it is of no use to subject suppliers to double registration and have them register with the Respondent while at the same time registered with another statutorily created body; the 1st Interested party. It is submitted that members of the Applicant are already regulated by the Interested Party.

67. The requirement imposed by the Respondent to provide evidence of certification for test kits/reagents and equipment from United States Food and Drug Administration (FDA) has no basis in law it is submitted.

68. Matters of certification is under the purview of the Kenya Bureau of Standards (KEBS) established under the Kenya *Standards Act* Cap 496. Section (4)(1) specifies these functions as follows: -

> "'(a) to promote standardization in industry and commerce;
>
> (b) to make arrangements or provide facilities for the testing and calibration of precision instruments, gauges and scientific apparatus, for the determination of their degree of accuracy by comparison with standards approved by the Cabinet Secretary on the recommendation of the Council, and for the issue of certificates in regard thereto;
>
> (c) to make arrangements or provide facilities for the examination and testing of commodities and any material or substance from or with which and the manner in which they may be manufactured, produced, processed or treated;
>
> (d) .....
>
> (e) ...
>
> (f) ..;
>
> (g) to assist the Government or any local authority or other public body or any other person in the preparation and framing of any specifications or codes of practice;
>
> (h) to provide for co-operation with the Government or the representatives of any industry or with any local authority or other public body or any other person, with a view to securing the adoption and practical application of standards;
>
> to provide for the testing at the request of the Cabinet Secretary, and on behalf of the Government, of locally manufactured and imported commodities with a view to determining whether such commodities comply with the provisions of this Act or any other law dealing with standards of quality or description." (Emphasis added).

69. The Interested Party is among entities specified as regulatory authority for products under its purview and thus exempt from PVoC program. The Respondent is not listed as such and neither is FDA referred to as the certification body in Kenya.

70. The Section 27 of the *Civil Procedure Act* provides that: -

> "(1) Subject to such conditions and limitations as may be prescribed, and to the provisions of any law for the time being in force, the costs of and incidental to all suits shall be in the discretion of the court or judge, and the court or judge shall have full power to determine by whom and out of what property and to what extent such costs are to be paid, and to give all necessary directions for the purposes aforesaid; and the fact that the court or judge has no jurisdiction to try the suit shall be no bar to the exercise of those powers: Provided that the costs of any action, cause or other matter or issue shall follow the event unless the court or judge shall for good reason otherwise order..."
>
> (2) The court or judge may give interest on costs at any rate not exceeding fourteen per cent per annum, and such interest shall be added to the costs and shall be recoverable as such."

71. They submit that the Exparte Applicant have suffered from the actions of the Respondent and has incurred expenses to right this wrong caused by their decision. We submit that it will be just to award the Exparte Applicant costs.

The Interested Party's Case;

72. The 1st Interested Party supports the application. It relies on the on the Replying Affidavit of Julius Ogato who depones that the Pharmacy and Poisons Board is established under the *Pharmacy and Poisons Act* (Cap 244) as the national medicines regulatory authority in Kenya mandated to protect the health of the public by regulating the profession of pharmacy and ensuring the safety, quality and efficacy of health products and health technologies. He advances the following arguments.

73. The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is established by the *Medical Laboratory Technicians and Technologists Act* No. 10 of 1999.

74. The object and purpose for which the Board is established is to exercise general supervision and control over the training, business, practice and employment of laboratory technicians and technologists in Kenya and to advise the Government in relations to all aspects thereof. The Phrase "Verification" does not have a broader meaning in marketing authorization of medical products and health technologies.

75. The purpose of regulation is to guarantee quality, safety and efficacy/performance of the regulated products which constitutes several processes. Validation or verification is only a step in the regulatory process.

76. The Pharmacy and Poisons Board is responsible for the regulation of health products and technologies, as stipulated under Section 3B of the *Pharmacy and Poisons Act*.

77. This includes the grant or revocation of licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances; health products are defined under section 2 of the said Act to include medicinal substances, medical devices and diagnostics.

> " medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—
>
> (a) intended by the manufacturer to be used, alone or in combination, for humans or animals for —
>
> i. diagnosis, prevention, monitoring, treatment or alleviation of disease diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
>
> ii. investigation, replacement, modification or support of the anatomy or of a physiological process;
>
> iii. supporting or sustaining life;
>
> iv control of conception;
>
> v disinfection of medical devices; or
>
> vi. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
>
> (b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;

78. It is argued that Section 5 of the said *Medical Laboratory Technicians and Technologists Act* No. 10 of 1999 stipulates the objects and functions for which the Kenya Medical Laboratory Technicians and Technologists Board is established—

a. prescribe, in consultation with the College and such approved training institutions as the Board may deem appropriate, the courses of instruction for laboratory technicians and technologists;

b. consider and approve the qualifications of laboratory technicians and technologists for the purposes of registration under this Act;

c. approve institutions for the training of laboratory technicians and technologists;

d. license and regulate the business and practice of registered laboratory technicians and technologists; and

e. regulate the professional conduct of registered laboratory technicians and technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards.

79. The *Health Act*, 2017 envisaged a unified health system including in regulation of health products and health technologies. Section 62 of the *Health Act* obliges parliament to establish a single regulatory body for regulation of health products and health technologies.

80. Parliament, through the Health Laws Amendment Act, March 2019 identified Pharmacy and Poisons Board as the single regulatory body as envisaged under Section 62 of the *Health Act*, 2017.

81. Section 109 of the *Health Act*, 2017 outlaws any sections of the existing health laws that may be in conflict with any sections of the *Health Act*, 2017.

82. The *Health Act* No. 21 of 2017 under Section 60 (2)(c) recognizes the Kenya Medical Laboratory Technicians and Technologists Board as a professional regulatory body in line with the statute for its establishment.

83. However, the Kenya Medical Laboratory Technicians and Technologists Board purports to be the regulator for reagents, medical devices and diagnostics including in-vitro diagnostics, which is strictly within the purview of the Pharmacy and Poisons Board. This has continuously led to confusion among stakeholders as to the proper body from which to obtain marketing authorization.

84. The Kenya Medical Laboratory Technicians and Technologists Board Chairman, in exercise of the powers conferred by section 25 of the *Medical Laboratory Technicians and Technologists Act*, 1999, enacted regulations, Medical Laboratory (Equipment and Reagents Validation) Regulations, 2011.

85. The gist of the regulations was to regulate the business of the laboratory technicians. This included the requirement to only use equipment and reagents validated by Kenya Medical Laboratory Technicians and Technologists Board.

86. Section 25 provides for Terms and conditions of private practice wherein the Board shall, in regulations, prescribe the terms and conditions of the business and practice of laboratory technicians and technologists engaged in Private Practice.

87. The Applicant argues that based on the section under which they are anchored, they were intended to regulate private practice but are extrapolated to include product regulation.

88. Rule 3(2) of the Medical laboratory (equipment and reagents validation) regulations, 2011 provides that; No medical laboratory shall stock, use, handle, distribute or procure the supply of any equipment or reagents for use within medical laboratories in Kenya unless the equipment or reagents have been validated in accordance with these Regulations.

89. In this instance, Rule 3(2), lacks the authority to regulate the business of all medical laboratories from Section 25 of the Mother Act (*Medical Laboratory Technicians and Technologists Act* No. 10 of 1999) which purely dictates the terms and conditions of private practice and should not touch on regulation of the product as the same is being done by the Pharmacy and Poisons Board.

90. The Pharmacy and Poisons Board, regulates the material or mechanism as a medical device. It does not monitor how it is used within a laboratory, which is strictly in the purview of the practitioners regulated by the Kenya Medical Laboratory Technicians and Technologists Board. A unified health system has been envisaged by the law and policy documents, more specifically the mother law, *Health Act*, 2017.

91. The institutions offering lab testing and validation services are manned by professionals regulated by the Kenya Medical Laboratory Technicians and Technologists Board. This forms the nexus between the Pharmacy and Poisons Board and Kenya Medical Laboratory Technicians and Technologists Board in the regulation of medical device and in vitro diagnostics.

92. The Kenya Medical Laboratory Technicians and Technologists Board is not among the institutions offering lab testing and validation services since it does not own a laboratory.

93. The Pharmacy and Poisons Board remains the only agency under the Ministry of health mandated to regulate all medical products and health technologies.

94. Kenya Medical Laboratory Technicians and Technologists Board should immediately withdraw the memo to all Kenya Medical Laboratory Technicians and Technologists Board clients dated 21st December, 2020 and 12th March 2021.

The Interested Parties' Submissions;

95. It submits as follows; that Section 3A stipulates that the Board may-

a. Formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products;

b. grant or withdraw authorization for conducting clinical trials of medical products;

c. grant or withdraw marketing authorization for medical products subject to appropriate conditions and revise such conditions for marketing authorization as necessary;

d. recall medical products from the market;

e. grant or withdraw licenses to manufacturers, wholesalers, retailers, importers, exporters and distributors;

f. investigate conduct related to the manufacture, import, export storage, distribution, sale and use of medical products;

g. levy, collect and utilize fees for services rendered;

h. prescribe the standards appropriate for new medical products; new uses, dosages, and formulations of existing medical products; and such other categories as may be appropriate;

i. constitute technical and expert advisory committees;

j. institute administrative, civil and criminal proceedings;

k. exercise such other powers as necessary for the performance of its functions.

96. Section 3B (2) (a - t) of the Act which provides;

The Board shall perform the following functions in relation to regulation of health products and technologies

a. advise the national and county governments in all matters relating to the safety, packaging and distribution of medicines;

b. ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality safety and efficacy;

c. ensure that the personnel, premises and practices employed in the manufacture, storage, marketing, distribution and sale of medicinal substances comply with the defined codes of practice and other prescribed requirements;

d. enforce the prescribed standards of quality, safety and efficacy of all medicinal substances manufactured, imported into or exported out of the country;

e. grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances;

f. maintain a register of all authorized medicinal substances;

g. publish, at least once in every three months, lists of authorized or registered medicinal substances and of products with marketing authorizations;

h. regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with either the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988;

i. consider applications for approval and alterations of dossiers intended for use in marketing authorization of medicinal substances;

j. inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, and other retail outlets;

k. prescribe a system for sampling, analysis and other testing procedures of finished medicinal products released into the market to ensure compliance with the labeled specifications;

l. conduct post-market surveillance of safety and quality of medical products;

m. collaborate with other national, regional and international institutions on medicinal substances regulation;

n. advise the Cabinet Secretary on matters relating to control, authorization and registration of medicinal substances; and

o. perform any other function relating to regulation of medicinal substances.

97. The key statutory mandate of the PPB is to grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of health products.

98. Section 2 of the Act, health products include human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products.

99. The 1st Interested Party wishes to rely heavily on the provisions of the *Pharmacy and Poisons Act*, Chapter 244 Laws of Kenya (Hereinafter referred to as the Act) which stipulate that the PPB is Kenya's National Medicines Regulatory Authority.

100. By virtue of this provision, the PPB is responsible for setting up appropriate regulatory measures to achieve the highest standards of safety efficacy and quality.

101. For all drugs, medicinal substances and medical devices which are locally manufactured, imported, exported, distributed, sold or used to ensure the protection of the Kenyan public.

102. It submits that the World Health Organization (WHO), defines an IVD is a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely to provide information for diagnostic, monitoring or compatibility purposes.

103. IVDS are intended for use in the collection, preparation, and examination of specimens taken from the human body. Thus, like other medical devices, they are subject to premarket and post market controls.

104. Rule 3 Pharmacy and Poisons (Registration of Drugs) Rules outlines that drugs which include diagnostics must be registered by the PPB prior to importation, manufacture for sale or sell in Kenya.

105. In execution of her statutory mandate, PPB has developed and adopted elaborate guidance document that describes the processes and general requirements to applicants for the submission of applications for medical devices and IVDS registration.

106. It is its further submits that the document outlines the process of evaluation of medical devices and IVD kits by the PPB and incorporates an expert committee on medical devices and IVDS.

107. It is submitted that the Expert Committee which advises the board incorporates expertise from varied professionals including pharmacists, dentists, biomedical engineers, pathologists, hematologists, medical laboratory technologists, among others. Pharmaceutical Regulatory Information Management System (PRIMS) enables applicants to input all data regarding a product prior to any submission.

108. The *Health Act* 2017 Part VII envisages the creation by Parliament of a single regulatory body for health products and technologies.

109. As provided for by the previous Part, the Health Laws (Amendment) Act 2019 identified PPB through amendment of the *Pharmacy and Poisons Act* Cap 244 as the single regulatory body as envisaged under Section 62 of the *Health Act* 2017.

110. Section 63 of the *Health Act* outlines the functions of the single regulatory body, in this case the PPB, which includes amongst others licensing of health products and health technologies.

111. Further, Section 109 of the *Health Act* outlaws any sections of existing health laws that may be in conflict with any sections of the *Health Act* 2017.

112. Section 60 (2) (c) *Health Act* 2017 recognizes KMLTTB as a professional regulatory body with the power to register, license and regulate the business and practice of private medical laboratories.

113. Section 5 of the KMLTTB Act sets out the Objects and functions of the Board (2) Without prejudice to the generality of the foregoing, the Board shall-

    (a) Prescribe, in consultation with the college and such approved training institutions as the Board may deem appropriate, the courses of instruction for laboratory technicians and technologists

    (b) Consider and approve the qualifications of laboratory technicians and laboratory technicians and technologists for purposes of registration under this Act

    (c) Approve institutions for the training of laboratory technicians and technologists

    (d) License and regulate the business and practice of registered laboratory technicians training of laboratory technicians and technologists; and

    (e) Regulate the professional conduct of registered laboratory technicians and technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards

114. Section 25 (1) KMLTTB Act provides for terms and conditions of business practice of laboratory technicians and technologists engaged in private practice, not regulatory powers over medical devices. The purported regulation of medical laboratory equipment and reagents by the Respondent is founded on the regulations developed in the guise of implementing Section 25 (1) of the Act.

115. It is further submitted that The Respondent has no role in regulation of medical products. Her mandate is limited to licensing and regulation of the laboratory facilities to ensure due compliance with the law. Both law and practice grant it no mandate on regulation of such products.

116. In support of this,it places reliance on the Republic v Kenya Medical Laboratory Technicians and Technologists & Another Exparte Nicky Odongo Lubanga [2017] case goes further to prove the 1st Respondent's duties lie outside export and import of medical devices by stating:

> " 19. According to the Respondents, the 1st Respondent is established pursuant to the provisions of section 3 of *Medical Laboratory Technicians and Technologists Act* CAP 253A (hereinafter referred to as "the Act") as a body corporate with perpetual succession mandated by the said provision to be capable of doing or performing all such other acts necessary for the proper performance of the 1st Respondent's functions under the Act whose section 5 provides the object and purpose for which the Board is established as being to exercise general supervision and control over the training, business, practice and employment of Laboratory Technicians and Technologists in Kenya and to advise the Government in relation to all aspects thereof."

117. Despite the foregoing,the respondent has continuously purported to regulate reagents, medical devices and diagnostics which is clearly not within her statutory mandate but that of the PPB. The respondent which is attempting to act beyond her statutory scope.

118. In 2007, WHO through the World Health Assembly advised member states on harmonized regulatory systems in the regulation of medical devices including invitro diagnostics through resolution 67.29 and 60.27.

119. The move by the respondent amounts to fragmentation of regulation as each profession seeks to regulate its own commodities that results in double taxation which countermands public policy and imminent threat to realization of the right to health. The PPB is additionally unable to assure the public on safety, quality and efficacy in line with its mandate.

120. The PPB at no instance approved and/or facilitated the export of the said shipment in question.

121. For the purposes of trade, relating to imports and exports, which is necessary for availability of medicinal substances in the country, the importers and exporters are required to register on the PPB online portal being the National Electronic Single Window System (KENTRADE System).

122. The Kentrade System is a key trade facilitation tool by the Government that enables parties involved in international trade to submit regulatory import and export documentation and to lodge their documents through a single platform.

123. A situation of overlapping mandates would definitely undermine the foregoing milestones.

124. The Interested Parties' submit that: -

a. The Pharmacy and Poisons Board is the sole regulator of health products and technologies, according to the *Health Act* 2017 and the *Pharmacy and Poisons Act* 1989.

b. IVDs fall under medical devices and as such are under the mandate of the PPB which requires them to be subjected to premarket and post market controls, including being registered by PPB prior to importation, manufacture for sale or sell in Kenya.

c. It is not in dispute that the KMLTTB has the power to register, license and regulate the business and practice of private medical laboratories and is a professional regulatory body as under Section 60 (2) (c) of the *Health Act* No 21 of 2017.

d. The Respondents do not have a role in the process of import and export of medicinal substances. (within the confines of the *Health Act* 2017 and the KMLTTB Act 1999)

e. The 1st Interested Party is the body responsible for facilitating import and export of health products and technologies, of which it has set up the KENTRADE System for the registration of related activities.

f. The Respondent has no authority or codes to the KENTRADE System and therefore has no part to play in regulation of export and import of health products and technologies.

125. In closure it submits that The Application dated 5th April 2021, as well as the orders sought therein are meritorious.

The Respondent's case;

126. In opposing the Application, the Respondent relies on the Replying Affidavit of Abdulatif Ali the Registrar Kenya Medical Laboratory Technicians and Technologists Board the Respondent who advances the following arguments.

127. He argues that the Application was filed out of time without leave therefore rendering the proceedings incompetent.

128. He argues that The *Medical Laboratory Technicians and Technologists Act*, CAP 253A Laws of Kenya is an Act of Parliament that commenced operation on 22nd December 2000 to provide for the training, registration and licensing of Medical Laboratory Technicians and Technologists, to provide for the establishment, powers and functions of the Kenya Medical Laboratory Technicians and Technologists Board, and for connected purposes.

129. The Act has elaborate provisions on regulatory mandate of the Respondent. Part III of CAP 253A deals with registration of Laboratory Technicians and Section 19 (1) of CAP 253A prohibits a person to act as a laboratory technician or technologist in any health institution in Kenya unless such person is registered under the said Act and further Section 19 (3) of the said act specifically prohibits anyone in charge of a health institution or any medical laboratory in Kenya from employing a person as a laboratory technician or technologist who is not registered under the Act and Section 19 (4) and (5) provides for penal consequences for violation of the provisions of this section, pursuant to the provisions of Section 21 of CAP 253A the Respondent is mandated to issue practicing certificate and annual licenses authorizing the Medical Laboratory Technicians and Technologists named therein to engage in private practice and by virtue

130. It is the Respondents case that under Section 23 (2) of the said Act every practicing certificate issued runs from 1st January to 31st December each year.

131. Within the ministry of health, various cadre-specific regulatory statutes including They include Nursing Act, Physiotherapy Act, Nutrition and Dietetics Act, Public Officers and Technicians Act, Medical Doctors and Dentists Act, *Medical Laboratory Technicians and Technologists Act* (MLTT Act-Cap 253A) inter alia.

132. They are based on unique and distinct professional curricula of health training focusing on special skills, competencies and knowledge with bias to the particular cadre have been enacted.

133. The said health statutes were enacted to define and delineate specific regulatory functions of each cadre of health professionals within Ministry of Health.

134. Pursuant to Section 5 of CAP 253A, the Respondent is the sole regulatory body in Kenya with legal mandate to exercise general control and supervision over the training, business, practice, and employment of the medical laboratory technicians and technologists.

135. It is the Respondent's case that the business of medical laboratory technicians and technologists contemplated under Section 5 of CAP 253A involves their practice where they engage in hands-on analysis of human specimens using diagnostic test kits, equipment, reagents and accessories (also known as IN-VITRO DIAGNOSTICS-IVDs).

136. It is further the Respondent's case that the business of Medical Laboratory Technicians and Technologists Board as contemplated under Section 5 of CAP 253A also includes teaching training, mentorship, clinical research, manufacture of invitro diagnostics (IVDs), buying, selling, installation, care and maintenance of IVDs and general advisory on all matters relating to the same.

137. Under Section 25 (1) The Board is required, in regulations to prescribe the terms and conditions of the business and practice of laboratory technicians and technologists engaged in private practice and Sections 25 (2) (a) mandates the Respondent to provide in the regulations for the equipment and reagents to be provided in all medical laboratories which therefore gave rise to Legal Notice no. 113 Of 2011.

138. It is the Respondent's case that the enactment of the said regulations pursuant to Section 25 (2) (a) was a vigorous consultative process of Law making with all stakeholders including members of the Applicant.

139. According to the Respondent, *Legal Notice No. 113 of 2011* was the outcome of elaborate stakeholders' meetings at various venues with local, regional and international partners in attendance.

140. The respondent argues that it met and engaged many stakeholders at different venues including Kenyatta International Conference Center where the 29th World Congress of Biomedical Laboratory Science took place from 6th-10th June 2010, prior to the enactment of the Legal Notice No. 113 OF 2011.

141. During the 29th World Congress of Biomedical Laboratory Science at KICC in June, 2010, the Applicant publicly participated in discussions on quality and regulatory framework of Invitro Diagnostics for sustainable business and delivery of quality healthcare services and the current Chairman, Treasurer and Secretary of the applicant, John Karume, Paul Wambura and Feroz Nawab respectively attended a stakeholder meeting at the Sarova Panafric Hotel dated 4th June 2012.

142. The said stakeholders meeting on validation of reagents and equipment at Sarova Panafric Hotel on 4th June 2012, the members of the Applicant who attended and signed the attendance register included Faram E.A. Ltd (listed at No.21), Feroz Nawab-Chemoquip Limited, Deepa Maharaj of Roche-a globally renown manufacturer of IVDs John Karume of Ultralab, Antony Mwenda and Benjamin Njeru of Hass Scientific Ltd.

143. It is the Respondent's case that following enactment of *Legal Notice No. 113 of 2011*, all officials of the Applicant including Firoz Nawab were part of consensus building processes of the implementation of IVD Validation framework led by Prof. Omu Anzala (School of Medicine, University of Nairobi) through the partnership between the respondent and IFC/World Bank.

144. It is its case that another stakeholders meeting for development of policy on validation of invitro diagnostics was held at Enashipai Lodge, Naivasha for three (3) days from 19th to 21st June 2013 where members of the Applicant were in attendance.

145. In partnership with Kenya Trade Network Agency (KENTRADE) (Government Agency under National Treasury) and upon consensus on the implementation strategy for the Legal Notice No.113 OF 201 1, another stakeholders meeting was held with members of the Applicant for purposes of training the vendors/suppliers of IVDs and facilitated by Mr. Eric Lukoyo of the Kenya National Single Window System Implementation Project at Silver Springs Hotel, Nairobi on the 30th April 2015, where the members of the applicant attended.

146. This meeting was sponsored by the Respondent, this training was successful and led to the commencement of IVD products registration, by the Respondent, at points of entry through the KENTRADE single window system.

147. It is the Respondent's case that upon implementation of this noble project to ensure quality of diagnostic test kits, reagents and equipment (IVDs) imported into the country, the 1st interested party attempted to take over the mandate of validation process of IVDs resulting in confusion among vendors/suppliers of IVDs. The 'listing' imposed by 1st interested party does not constitute an activity under validation process in the context of Medical Laboratory practice. However, this interference by the 1st interested party still continues with impunity and connected confusion among members of the Applicant.

148. It is argued that the listing by the 1st Interested Party cannot therefore be considered a parallel regulation of IVDs in the context of Legal Notice No. 1 13 of 201 1 being enforced by the respondent. Some members of the Applicant wish to remain unregulated with unethical businesses practices thus their preference for short cut to comply with requirements of the 1st interested party where technical skills, competencies and knowledge for validation of IVDs is lacking.

149. The Respondent raises a concern that arising from this interference, poor quality IVDs have been imported and put into use in the country without being subjected to validation by the respondent hence the litany of litigations by patients/victims of misdiagnosis and mismanagement.

150. The Respondent argues that the pre-validation certification is part of the initial stages in the long and tedious technical process of validation to ensure only IVDs with good quality test performance are used in the medical laboratories regulated by the respondent and known to the Applicant whose members have started to comply.

151. Following the interference by the 1st Interested Party as mentioned above, the Respondent sought legal interpretation of the Law through a letter to the Attorney General's office who responded with clarifications that the Law is not ambiguous on the role and mandate of the Respondent.

152. It is the Respondent's case that this advisory from the Attorney General did not settle the budding dispute on the role of regulating IVDs between the Respondent and the 1st Interested Party hence culminating in Judicial Review Misc. Application No.229 of 2014 where in the first instance Justice G.v Odunga issued orders of certiorari and prohibition in the presence of Counsel for interested party in open Court against the 1st Interested Party on 16th June 2014.

153. It is argued that the matter was then brought to the attention of the then Health Cabinet Secretary-Mr. James Macharia, who advised the parties and which the respondent duly complied with, to seek Alternative Dispute Resolution in tandem with Government Policy to avoid acrimony between State Agencies.

154. The Principal Secretary for Health issued an advisory referenced MOH/DC/9/1/33 dated 13th October 2020 to one International Health Partner (Clinton Health Access Initiative) citing the capacity of the Respondent to carry out verification and validation of any diagnostic test kits that are used in the Country.

155. The respondent with relevant stakeholders, Kenya Medical Supplies Authority wrote to the Registrar of the respondent on 6th November 2017 and referenced KEMSA/PROC/ADM/201718 to confirm regulatory compliance of members of the applicant in relation to registration.

156. It is the Respondent's case that contrary to this directive, the 1st Interested Party continued to illegally issue import permits on which strength members of the Applicant including a foreign national of Chinese continue to import, sell and distribute invalid Covid-19 (SARS COV-2) testing equipment and kits.

157. It is argued that pursuant to the mandate of the Respondent and in accordance with the provisions of CAP 253K the Respondent conducts regular inspection of Medical Laboratories throughout the Republic of Kenya, to ensure that such facilities conduct their business and practice in strict adherence to and compliance with the provisions of CAP 253A, Those facilities found operating in violation of the provisions of the said act have led to prosecutions of several people in various courts throughout the Republic where the officers of the Respondent are witnesses as the complainants.

158. These inspections and prosecutions are done in public interest and with a view to protecting the larger Kenyan public from unregulated Medical Laboratory practice. Some of the accused persons in these cases have attempted to stop their prosecutions by filing applications for judicial review in various High Courts.

159. It advances an argument that a stay will result in stalling of these criminal matters and some of the accused persons will take advantage to ask for acquittal.

160. It is further its case that as part of greater safeguard on public health interest, the Attorney General has issued another advisory referenced AG/CPT/MOH/141/20 dated 14th September 2020 to the Cabinet Secretary of Health in relation to Petition No. 232 OF 2020 where Anne Wambui Mureithi & Anor have sued the Government (Ministry Of Health) for HIV misdiagnosis using poor quality rapid HIV diagnostic test kits not validated by the respondent which are being used in Kenya to generate false HIV test results hence exposing the Government to unnecessary compensation claims by victims of substandard test kits supplied by the Applicants.

161. The Respondent is concerned that contrary to this directive, members of the Applicant have brought into the market illicit products not validated by the respondent, which are sold/distributed by members of the Applicant for use by medical laboratories purportedly on the strength of listing' by the Interested Party.

162. Kenyans continue to be subjected to risks of biological threats of diagnostic test kits already rejected, delisted and deleted from the list of quality IVDs approved by Global Fund for HIV, Malaria and Tuberculosis.

163. It is its case that in RMC PCR matter No.6654 OF 2014 Republic vs Evans Anyimu Aminga pending before Makadara Law Court which was subject of H.C. JR. No. 347 OF 2014; a patient was issued with a blood test results technically considered as incompatible with life and generated by an equipment supplied by a member of the Applicant. In the matter, the patient was given results indicating that he had 'zero platelets' from a Hematology auto-analyzer in a private laboratory.

164. The respondent argues that it took disciplinary measures against the Mr. Anyimu- a medical laboratory technologist as well as corrective measures against the private laboratory where the patient was attended.

165. It is its case that in instances where the respondent has partnered with the police to prosecute offenders of the Legal Notice No. 113 OF 2011, the charges have been admitted with ease hence appropriate for full trial.

166. It brings out cases relating to counterfeited products being Case number PCR 1636/15, PCR 515/18 1926/20 96/2020, PCR 86/2020 CF 145/2019, Court case number 145/03/2021/ Court case number 145/21/2021 (ongoing).

167. It is the Respondent's case that it has faced various challenges on its regulatory mandate such as whether the power to register license and regulate the business and practice of private Medical Laboratories vests in the Respondent or the Medical practitioners and Dentists Board which was settled in the case of Republic Versus Kenya Medical Laboratory Technicians And Technologists Board & Anor Exparte Anil Tailor & 4 others (2013) eKLR where following a detailed analysis, the Honourable Court held that the regulatory mandate of the Respondent is not limited to public institutions but extends to private Medical laboratories and the Respondent has a regulatory mandate over medical laboratories situated within private health facilities.

168. The Respondent through stringent and effective regulatory surveillance systems continues to expose the dirty businesses with impunity of the Applicant hence the unwillingness of applicant to comply with regulations in Legal Notice No. 1 13 OF 2013, instead willing to be 'regulated' by Interested Party where no quality checks of IVDs are undertaken for want of technical knowledge and competencies.

169. It argues that it has a well laid down structure and processes to execute this mandate of validating invitro diagnostics in tandem with Section 40 of CAP 253A Laws of Kenya, regional and global trends through ISO 15189 and ISO 13485 for the manufacture of quality invitro diagnostics.

170. It further argues that the licensed medical laboratories where validation of IVDs take place, must have a laboratory superintendent and quality assurance manager with qualifications and responsibilities as required by ISO 1 5189.0012 which standard is global for the practice of medical laboratory professionals regulated by the respondent.

171. The Respondent further argues that the registered and licensed medical laboratory professionals who are the end users of the in-vitro diagnostics supplied by the Applicant and who were targeted in the memos referred to by the applicant, have not complained against the memos.

172. The Respondent holds the view that the said memos were not directed at the Applicant who has neither the mandate nor the authority to edit, review, construct or manage the communication between the respondent and the medical laboratories regulated by the respondent.

173. It argues that the capacity for regulating invitro diagnostics is abundantly available at the respondent's disposal and which has been positively recognized by members of the Applicant via email dated 27th May 2020.

174. It is the Respondent's case that in line with global conventions and standards, the respondent also utilizes the Cartagena protocol on biosafety to the convention on biological diversity as part of quality shipment and management of human specimens used in the structured validation of invitro diagnostics.

175. It is its case that all the identified registered and licensed medical laboratories where processes for validation of in-vitro diagnostics is conducted are only legally regulated by the respondent hence there is no parallel regulation in relation to IVD products.

176. It is further its case that all Invitro Diagnostics in the market at the time of enactment of the *Legal Notice 113 of 2011* are identified and registered through the prevalidation segment of the validation processes.

177. It is argued that performance evaluation of invitro diagnostics in the medical laboratories and reviews of technical dossiers of Invitro diagnostic products are part of the wider processes outlined in the structure of validation as *Legal Notice No. 113 of 2011*.

178. It is its case that the Memos dated 21 December 2020 and 12th March 2021 are not new in the validation process but a continuation on conformity with the respondent's previous routine correspondences with medical laboratories. The memos were sent to medical laboratories and not directed to the applicant.

179. In any event it is the Respondent's case the mentioned memos only serve to enhance regulatory portfolio of the respondent among end-user medical laboratory personnel in their routine professional practice within the licensed premises and ensuring Quality Management System for invitro diagnostics to safeguard the health of Kenyans.

180. It argues that prohibiting the respondent from enforcing the ten (10) year old *Legal Notice No. 113 of 2011* would dangerously expose the health of Kenyan public who risk being tested using reagents and equipment whose quality and performance are unknown hence possibility of unreliable, inaccurate results leading to misdiagnosis.

181. It is persuaded that the intention of the Applicants in seeking not to be subject to the regulatory mandate of the Respondent of in vitro diagnostics is contrary to legitimate health expectations of patients and opens flood gates for members of the Applicant to use Kenya as a dumping site for counterfeits rejected in other parts of the globe.

182. It is argued that if stay orders are granted, it will cripple the statutory functions of the respondent thereby negating the gains made and consequently leads to numerous litigations with huge financial compensatory burden on the Government.

183. It argues that ten (10) years have elapsed since enactment of Legal Notice Noel 13 OF 2011 and three hundred thirty-three (333) members of the Applicant in recognition of the mandate of the respondent have applied and been registered by the respondent, the validation of products they deal in is ongoing with 10 having applied for validation since from the time the memo were sent to Medical Laboratories.

184. It further argues that since 2011, over one hundred (100) invitro diagnostic products have been validated and issued with appropriate Form-B certificate by the respondent.

185. It is the Respondent's case that the most detrimental aspect of the Applicant's business is the trade in and or sale of poor quality invitro diagnostics leading to public health threat with attendant misdiagnosis and mismanagement of patients.

186. In Respondent's regulatory framework there are specific responsibilities and legitimate expectations for the manufacturer, the supplier and the regulator.

187. It is the Respondent's case that the global responsibilities of a supplier of invitro diagnostics as per L.N. No. 113 OF 2011 is to register all IVD products with respondent, apply for IVD medical device

Import Permit every time there is importation, Apply for IVD medical device Export Permit every each there is exportation, Update respondent on any events that occur at the principal manufacturer's sites or with products Provide up to date information on business ownership, Inform the board of any incidences and performance issues„ submit agreement with manufacturers, to obtain information from them when requested by the respondent and Ensure information about the device complies with respondent's requirements.

188. It is the Respondents case that Mr. John Karume-Chairman of the Applicant and a Director of Ultralab E.A. Limited and Surgipath E.A. Ltd, both registered by the respondent knowing the capacity and mandate of the respondent, has submitted several requests of invitro diagnostics for validation by the respondent.

189. The Respondents further argue that Mr. James Mwangi-a Director of Chem-Labs Limited, a member of the Applicant- is consciously aware of respondent's mandate and recognizes the technical capacity with clear validation processes and sought registration and product listing by the respondent on November 2012.

190. On 8th April 2020, the same Mr. James Mwangi wrote to the Registrar of the respondent seeking for assistance to validate the MAGLUMI 2019-nCoV lgC/lgM CLIA Assays, which assistance he was accorded efficiently as per the Law.

191. In this instance, the validation data and processes were used to issue validation certificate for the MAGLIJMI 2019-nCoV platform arising from reciprocal recognition applied in terms of test performance of the equipment within a regulated medical laboratory.

192. Mr. James Mwangi wrote an email complimenting the respondent yet today he is part of the applicant challenging the same.

193. Chemoquip Limited wrote a letter of enquiry dated 23rd April 2013 to the Respondent seeking to be advised on processes of validation and registration of PISHTAZ HIV 1/2 ELISA test kit- a clear indication of engagement and recognition of statutory mandate of the respondent by a member of Applicant.

194. Mr. James Mwangi and Paul Wambura both directors of Chem-Labs applied as directors to register a Medical Laboratory known as Human Quality Assessment Services (HuQAS Laboratory) on 29th July 2016. The laboratory was duly registered. file number F504* with Caroline Kageni Mbarire as the laboratory superintendent.

195. It is the Respondent's case that on 3rd May 2019, James Mwangi applied to the Respondent to have the Laboratory superintendent changed from Caroline Kageni Mbarire to Catherine Waithira Mwangj, both regulated professionals by the respondent and which request was accepted by the respondent and the said laboratory has renewed its license from the respondent up to the year 2020.

196. According to the Respondent, the Applicant thus recognized the long-established validation processes including pre-validation registration and mandate of the respondent and sought registration and product listing by the respondent on 1st November 2012.

197. The Respondent argues that it has a statutory mandate and mission to protect the health of all Kenyans by ensuring compliance with standards in medical laboratory sciences and the Respondent is not permitted by law to compromise this standard by varying the set criteria for standards for a particular group including the Applicant. All the other persons regulated by the Respondent always comply with the set standards and there is no particular reason to exempt the Applicant from compliance.

198. The Respondent believes that the Exparte Applicant's application has no merit.

Analysis and determination;

199. Upon perusing the pleadings, the supporting documents, the rival submissions and authorities cited by counsel the following are the issues for determination;

i. Whether this court has jurisdiction.

ii. Whether or not the applicant has made out the case for the grant of the order sought.

iii. Who shall bear the costs.

The issue of jurisdiction;

200. In Samuel Kamau Macharia & Another v Kenya Commercial Bank Limited & 2 Others [2012] eKLR, thus:

> "...A Court's jurisdiction flows from either *the Constitution* or legislation or both. Thus, a Court of law can only exercise jurisdiction as conferred by *the constitution* or other written law. It cannot arrogate to itself jurisdiction exceeding that which is conferred upon it by law. We agree with counsel for the first and second respondents in his submission that the issue as to whether a Court of law has jurisdiction to entertain a matter before it, is not one of mere procedural technicality; it goes to the very heart of the matter, for without jurisdiction, the Court cannot entertain any proceedings. This Court dealt with the question of jurisdiction extensively in, In the Matter of the Interim Independent Electoral Commission (Applicant), Constitutional Application Number 2 of 2011. Where *the Constitution* exhaustively provides for the jurisdiction of a Court of law, the Court must operate within the constitutional limits. It cannot expand its jurisdiction through judicial craft or innovation. Nor can Parliament confer jurisdiction upon a Court of law beyond the scope defined by *the Constitution*. Where *the Constitution* confers power upon Parliament to set the jurisdiction of a Court of law or tribunal, the legislature would be within its authority to prescribe the jurisdiction of such a court or tribunal by statute law..."

201. Article 165(6) of *the Constitution* provides that, "The High Court has supervisory jurisdiction over the subordinate courts and over any person, body or authority exercising a judicial or quasi-judicial function, but not over a superior court."

202. Judicial review orders sought order 53 of The Civil Procedure Rules give this court the power to preside over and determine this case and I so hold. This court is satisfied that this court has jurisdiction to determine this suit.

203. This jurisdiction is however subject to the principles as enunciated in the case of Municipal Council of Mombasa v Republic and Umoja Consultants Ltd, Civil Appeal No. 185 of 2001.

> "Judicial review is concerned with the decision-making process, not with the merits of the decision itself: the court would concern itself with such issues as to whether the decision makers had the jurisdiction, whether the person affected by the decision were heard before it was made and whether in making the decision the decision maker took into account relevant matters or did take into account irrelevant matters..... The court should not act as a Court

of Appeal over the decider which would involve going into the merits of the decision itself such as whether there was or there was not sufficient evidence to support the decision."

204. In the instant suit, this court has noted that the parties have advanced a lot of content that calls for an in-depth merit analysis. For instance, the Respondent argues that; some members of the Applicant wish to remain unregulated with unethical businesses practices thus their preference for short cut to comply with requirements of the 1st interested party where technical skills, competencies and knowledge for validation of IVDS is lacking.

205. The Respondent argues that arising from this interference, poor quality IVDS have been imported and put into use in the country without being subjected to validation by the respondent hence the litany of litigations by patients/victims of misdiagnosis and mismanagement producing evidence of some of cases arising from misdiagnosis.

206. It further argues that following the interference by the 1st Interested Party as mentioned above, the Respondent sought legal interpretation of the Law through a letter to the Attorney General' s office and a response is attached with clarifications that the Law is not ambiguous on the role and mandate of the Respondent.

207. It argues that the then Health Cabinet Secretary-Mr. James Macharia, who advised the parties and which the respondent duly complied with, to seek Alternative Dispute Resolution in tandem with Government Policy to avoid acrimony between State Agencies.

208. The Respondent argues that to this directive, the 1st Interested Party continued to illegally issue import permits on which strength members of the Applicant including a foreign national of Chinese continue to import, sell and distribute invalid Covid-19 (SARS COV-2) testing equipment and kits.

209. Issues whether a stay will result in stalling of these criminal matters and some of the accused persons will take advantage to ask for acquittal and goes ahead to produce a list of some of the pending cases and concluded cases.

210. The evidence of RMC PCR matter No.6654 OF 2014 Republic vs Evans Anyimu Aminga pending before Makadara Law Court which was subject of H.C. JR. No. 347 OF 2014 where in a patient was issued with a blood test results technically considered as incompatible with life and generated by an equipment supplied by a member of the Applicant. In the matter, the patient was given results indicating that he had 'zero platelets' from a Hematology auto-analyzer in a private laboratory.

211. The existence of cases relating to counterfeited products being Case number PCR 1636/15, PCR 515/18 1926/20 96/2020,PCR 86/2020 CF 145/2019, Court case number 145/03/2021/ case number 145/21/2021 (ongoing) via copies of charge sheets after WHO alert on counterfeit HIV test kits and court order.

212. I registered and license issues touching on medical laboratories where processes for validation of in-vitro diagnostics is conducted are only legally regulated by the respondent hence there is no parallel regulation in relation to IVD products it tendered evidence through a list of approved validation centers and criteria for selection of the same.

213. The evidence as tendered through a copy of the list of Applicants members registered with Respondent since 2011 through a validation report as at 10th April, 2021.

214. The issue of the alleged over one hundred (100) invitro diagnostic products have been validated and issued with appropriate Form-B certificate by the respondent.

215. It is argued that given the emerging numerous cases of false laboratory test results relating to the use of invitro diagnostics NOT validated by the respondent, it has become necessary to enhance regulatory vigilance to progressively achieve the envisioned standards of healthcare in Article 43 of *the Constitution*.

216. In Respondent's produced a regulatory framework and a copy of the list of IVD products validated by the Respondent.

217. Issues whether Mr. John Karume-Chairman of the Applicant and a Director of Ultralab E.A. Limited and Surgipath E.A. Ltd, both registered by the respondent knowing the capacity and mandate of the respondent, has submitted several requests of invitro diagnostics for validation by the respondent as set out in the copies of the letters with validation requests to the respondent.

218. The Respondents further argue that Mr. James Mwangi-a Director of Chem-Labs Limited, a member of the Applicant- is consciously aware of respondent's mandate and recognizes the technical capacity with clear validation processes and sought registration and product listing by the respondent on November 2012 as set out in the copies of the letters dated 1st November 2012 and 10th May 2019 plus validation certificate dated 23rd March 2020 issued by respondent.

219. Mr. James Mwangi and Paul Wambura both directors of Chem-Labs applied as directors to register a Medical Laboratory known as Human Quality Assessment Services (huqas Laboratory) on 29th July 2016. The laboratory was duly registered. File number F504* with Caroline Kageni Mbarire as the laboratory superintendent.

220. Whether on 3rd May 2019, James Mwangi applied to the Respondent to have the Laboratory superintendent changed from Caroline Kageni Mbarire to Catherine Waithira Mwangj, both regulated professionals by the respondent and which request was accepted by the respondent and the said laboratory has renewed its license from the respondent up to the year 2020.

221. The Respondent relies on a bundle copy of the company ownership details, certificate of Incorporation and Respondent's registration certificate issued to Huqas Medical Laboratory owned by the Applicant.

222. The respondent's memos dated 21st December 2020 and 12th March 2021 were directed as part routine regulatory engagement with the registered medical laboratories and licensed professionals to ensure quality health service delivery.

223. The foregoing are instances where the parties expected the court to consider what they have advanced as part of their case which calls for an in-depth merit analysis. This court shall not delve into that arena.

224. In so holding this court is guided by the case of Dande & 3 others v Inspector General, National Police Service & 5 others (Petition 6(E007), 4 (E005) & 8 (E010) of 2022 (Consolidated)) [2023] KESC40 (KLR) (16 June 2023) (Judgment),where the supreme court observed that;

> "(85) It is clear from the above decisions that when a party approaches a court under the provisions of *the Constitution* then the court ought to carry out a merit review of the case. However, if a party files a suit under the provisions of Order 53 of the Civil Procedure Rules and does not claim any violation of rights or even violation of *the Constitution*, then the Court can only limit itself to the process and manner in which the decision complained of was reached or action taken and following our decision in SGS Kenya Ltd and not the merits of the decision per se."

Whether the applicant has made out a case for the grant of the orders sought;

225. In order to succeed in the Application, The Applicant has to demonstrate to the court that its case meets and satisfy the principles that have been settled in the case of Pastoli vs Kabale District Local Government Council & Others, [2008] 2 EA 300, where it was held that:

> " In order to succeed in an application for Judicial Review, the applicant has to show that the decision or act complained of is tainted with illegality, irrationality and procedural impropriety.
>
> Illegality is when the decision-making authority commits an error of law in the process of taking the decision or making the act, the subject of the complaint. Acting without Jurisdiction or ultra vires, or contrary to the provisions of a law or its principles are instances of illegality....
>
> Irrationality is when there is such gross unreasonableness in the decision taken or act done, that no reasonable authority, addressing itself to the facts and the law before it, would have made such a decision. Such a decision is usually in defiance of logic and acceptable moral standards.
>
> Procedural impropriety is when there is failure to act fairly on the part of the decision-making authority in the process of taking a decision. The unfairness may be in non-observance of the Rules of Natural Justice or to act with procedural fairness towards one to be affected by the decision. It may also involve failure to adhere and observe procedural rules expressly laid down in a statute or legislative Instrument by which such authority exercises jurisdiction to make a decision."

226. According to section 5 of the Medical Laboratory Technicians and Technologies Act (Cap 253A) powers of the Respondent as does not include manufacture of IVDs, buying, selling, installation, care and maintenance of IVDs or validation of reagents, equipment and test kits.

227. The conflict between the 1st Interested Party and the Respondent has unfairly exposed the Applicants to a parallel regulatory requirement of the said regulatory bodies.

228. This court agrees with the interested party that the purpose of regulation is to guarantee quality, safety and efficacy/performance of the regulated products which constitutes several processes. Validation or verification is only a step in the regulatory process.

229. The Pharmacy and Poisons Board is responsible for the regulation of health products and technologies, as stipulated under Section 3B of the *Pharmacy and Poisons Act* and I so hold.

230. Health products are defined under Section 2 of the said Act to include medicinal substances, medical devices and diagnostics.

> " medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—
>
> (a) intended by the manufacturer to be used, alone or in combination, for humans or animals for —
>
> diagnosis, prevention, monitoring, treatment or alleviation of disease diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

investigation, replacement, modification or support of the anatomy or of a physiological process;

supporting or sustaining life;

control of conception;

disinfection of medical devices; or

providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;"

231. The *Health Act*, 2017 envisaged a unified health system including in regulation of health products and health technologies. Section 62 of the *Health Act* obliges parliament to establish a single regulatory body for regulation of health products and health technologies.

232. Section 109 of the *Health Act*, 2017 outlaws any Sections of the existing health laws that may be in conflict with any sections of the *Health Act*, 2017.

233. Section 60 (2)(c) of The *Health Act* No. 21 of 2017 recognizes the Kenya Medical Laboratory Technicians and Technologists Board as a professional regulatory body in line with the statute for its establishment.

234. The Kenya Medical Laboratory Technicians and Technologists Board Chairman, in exercise of the powers conferred by Section 25 of the *Medical Laboratory Technicians and Technologists Act*, 1999, enacted regulations, Medical Laboratory (Equipment and Reagents Validation) Regulations, 2011.

235. Section 25 provides for Terms and conditions of private practice wherein the Board shall, in regulations, prescribe the terms and conditions of the business and practice of laboratory technicians and technologists engaged in Private Practice.

236. Rule 3(2) of the Medical laboratory (equipment and reagents validation) regulations, 2011 provides that; “No medical laboratory shall stock, use, handle, distribute or procure the supply of any equipment or reagents for use within medical laboratories in Kenya unless the equipment or reagents have been validated in accordance with these Regulations.”

237. Rule 3(2) lacks the authority to regulate the business of all medical laboratories from Section 25 of the Mother Act (*Medical Laboratory Technicians and Technologists Act* No. 10 of 1999) which purely dictates the terms and conditions of private practice and should not touch on regulation of the product as the same is being done by the Pharmacy and Poisons Board and I so hold.

238. The institutions offering lab testing and validation services are manned by professionals regulated by the Kenya Medical Laboratory Technicians and Technologists Board. This forms the nexus between the Pharmacy and Poisons Board and Kenya Medical Laboratory Technicians and Technologists Board in the regulation of medical device and in vitro diagnostics.

239. The Pharmacy and Poisons Board remains the only agency under the Ministry of health mandated to regulate all medical products and health technologies and I so hold.

240. Section 62 of the *Health Act* provides that "There shall be established by an Act of Parliament a single regulatory body for regulation of health products establishment of a single regulatory body for health and health technologies,"

241. The Respondent is a body established under the *Medical Laboratory Technicians and Technologists Act* Cap 253A Laws of Kenya ("the MLTT Act") and which prescribes its powers.

The preamble to the Act sets its object as follows: -

> " An Act of Parliament to provide for the training, registration, and licensing of medical laboratory technicians and technologists, to provide for the establishment, powers, and functions of the Kenya Medical Laboratory Technicians and Technologists Board and for connected purposes"

242. Section 5 (2) (e) of the MLTT Act sets out the specific functions of the Respondent as follows:

> " regulate the professional conduct of registered laboratory technicians and technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards".

243. In the case of Scion Healthcare Limited & another v Kenya Medical Laboratory Technicians and Technologists Board & another [2020] Justice Mrima relying on Machakos High Court Judicial Review No. 408 of 2017 which made extensive reference to Kisii High Court Judicial Review No. 82 of 2011 quoted the court's interpretation of Section 25(2)(a) of the MLTT Act and said:

> " It is therefore clear that Section 25(2)(a) is a departure from what appears in the long title and the object and purpose of the Board. By empowering the Board to make regulations providing, not only for terms and conditions of the business and practice of laboratory technicians and technologists but also providing for the equipment and reagents to be provided in private laboratories, the Act empowers the Board to actually regulate the manner in which private laboratories are to be stocked and equipped. That in my view is an extension of the power of the Board to not only regulate technicians and technologists but to an extent, private laboratories." (Emphasis added)

244. Section 3B of the PPB Act Subsection (1) gives the Interested Party the responsibility for regulating inter alia health products. Subsection 2 sets out the functions of the Interested Party in relation to regulation of health products, technologies to include: -

> " (b) ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality safety and efficacy;
>
> (c) ...
>
> (d) enforce the prescribed standards of quality, safety and efficacy of all medicinal substances manufactured, imported into or exported out of the country;
>
> (e) grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances;
>
> (f) maintain a register of all authorized medicinal substances;

(g) publish, at least once in every three months, lists of authorized or registered medicinal substances and of products with marketing authorizations;"

245. Section 2 of the PPB Act, defines health product to include; medical products as well as medicinal substances, diagnostics, and medical devices. Even though the Act does not define 'medical products', it is safe to conclude that medical product is a type of health product just as the defined by the World Health Organization (WHO). According to the WHO:

> " Medical products are medicines, devices, and other items used to diagnose, treat, or prevent diseases or other abnormal conditions. They include pharmaceuticals, biologics, vaccines, and diagnostic tools." (Emphasis Added).

246. Section 2 of the PPB Act further defines medicinal substances to include a product, article or substance which is claimed to be useful for, inter alia, "diagnosing disease or ascertaining the existence, degree or extent of a physiological condition". This definition has largely remained unchanged since the enactment of the Act.

247. Section 2 of the PPB Act gives elaborate definition of medical device to mean "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals for

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis,monitoring, treatment, alleviation of or compensation for an injury;

iii. investigation, replacement, modification or support of the anatomy or of a physiological process;

iv supporting or sustaining life;

v control of conception;

vi. disinfection of medical devices; or

vii. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means" (Emphasis Added).

248. From the reading of the foregoing provisions, this court is satisfied that the Interested Party, is the proper single regulatory body mandated to regulate and/or validate test kits/reagents, IVDs and other equipment used for medical tests fall under the definitions of health products and medicinal substances.

249. Section 4 of the *Health Act*, 2017, dictates that it is the fundamental duty of the state to observe, respect, protect, promote and fulfill the right to the highest attainable standard of health by performing among other things, the duty of developing policies, laws and other measures necessary to fulfill the said mandate. The Ministry of Medical Services developed the Guidelines on Submission of

Documentation for Registration of Medical Devices available in the PPB website. It provides under Article 3(1) that the guidelines shall apply to:

> " ...medical devices and their accessories. For the purposes of these guidelines, accessories shall be treated as medical devices in their own right."

250. Article 5(3) of the Guidelines defines In-Vitro Diagnostic Devices (IVDs) to mean: medical devices, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

251. The 1st Interested Party is mandated to regulate and validate medical devices, including test kits/ reagents, IVDs, and other equipment used for medical tests.

252. Matters of certification is under the purview of the Kenya Bureau of Standards (KEBS) established under the Kenya *Standards Act* Cap 496. Section (4)(1) specifies these functions as follows:

a. to promote standardization in industry and commerce;

b. to make arrangements or provide facilities for the testing and calibration of precision instruments, gauges and scientific apparatus, for the determination of their degree of accuracy by comparison with standards approved by the Cabinet Secretary on the recommendation of the Council, and for the issue of certificates in regard thereto;

c. to make arrangements or provide facilities for the examination and testing of commodities and any material or substance from or with which and the manner in which they may be manufactured, produced, processed or treated;

253. The court is satisfied that the requirements imposed by the Respondent to provide evidence of certification for test kits/reagents and equipment from United States Food and Drug Administration (FDA) has no basis in law.

254. Article 47 of *The Constitution* provides (1) Every person has the right to administrative action that is expeditious, efficient, lawful, reasonable and procedurally fair.

255. Section 4 of The *Fair Administrative Action Act* provides that all Administrative action to be taken expeditiously, efficiently, lawfully etc.

256. Section 4 (1) Every person has the right to administrative action which is expeditious, efficient, lawful, reasonable and procedurally fair. Section 4 (2) Every person has the right to be given written reasons for any administrative action that is taken against him. Section 4 (3) Where an administrative action is likely to adversely affect the rights or fundamental freedoms of any person, the administrator shall give the person affected by the decision.

257. The impugned memos dated 21stDecember 2020 and 12th March 2021 and the SMS sent or issued by the Respondent cannot be said to be reasonable and procedurally fair. They set terms and conditions which have created confusion and uncertainty.

258. The Memo that was issued on 12th March 2021 making the renewal of facility licenses contingent on evidence that test kits/reagents and equipment being used in clinical testing are validated by the Respondent cannot be to be said to be procedurally fair or reasonable by any standards given that the deadline for compliance was 31st March 2021.

259. The SMSs from the Respondent sent to some of the Applicants members asking them to provide evidence of certification for test kits/reagents and equipment from external bodies such as United States Food and Drug Administration (FDA) is also in this court's view unreasonable in that it doesn't give the Applicant ample notice to comply if at all. In any event, this created yet another requirement that the Applicants should subject themselves to an international regulator on the basis of an SMS. This is not procedurally fair to the Applicants and I so hold.

260. The court is in agreement with the Applicants that the cumulative effect of the impugned memos is that the members of the ex parte applicant were unable to supply IVDs, reagents and test kits to hospital and other clients unless they are validated by the Respondent despite having received approvals from the Interested Party thus leading to double regulation. The Applicant has made out a case of Procedural impropriety on the part of The Respondent.

The issue of costs;

261. In Halsbury's Laws of England, 4th ed Re-Issue [2010], Vol. 10, para. 16:

> " The court has discretion as to whether costs are payable by one party to another, the amount of those costs, and when they are to be paid. Where costs are in the discretion of the court, a party has no right to costs unless and until the court awards them to him, and the court has an absolute and unfettered discretion to award or not award them. This discretion must be exercised judicially; it must not be exercised arbitrarily but in accordance with reason and justice" [emphasis supplied].

262. In Joseph Oduor Anode v Kenya Red Cross Society, Nairobi High Court Civil Suit No. 66 of 2009; [2012] eKLR Odunga, J. thus observed:

> " ...whereas this Court has the discretion when awarding costs, that discretion must, as usual, be exercised judicially. The first point of reference, with respect to the exercise of discretion is the guiding principles provided under the law. In matters of costs, the general rule as adumbrated in the aforesaid statute [the *Civil Procedure Act*] is that costs follow the event unless the court is satisfied otherwise. That satisfaction must, however, be patent on record. In other words, where the Court decides not to follow the general principle, the Court is enjoined to give reasons for not doing so. In my view it is the failure to follow the general principle without reasons that would amount to arbitrary exercise of discretion ..." [emphasis supplied].

263. The *Civil Procedure Act* (Cap. 21, Laws of Kenya), the primary law of judicial procedure in civil matters, thus stipulates (Section 27(1)):

> " Subject to such conditions and limitations' as may be prescribed, and to the provisions of any law for the time being in force, the costs of and incidental to all suits shall be in the discretion of the court or judge, and the court or judge shall have full power to determine by whom and out of what property and to what extent such costs are to be paid, and to give all necessary directions for the purposes aforesaid; and the fact that the court or judge has no jurisdiction shall be no bar to the exercise of those powers:
>
> Provided that the costs of any action, cause or other matter or issue shall follow the event unless the court or judge shall for good reason otherwise order" [emphases supplied].

264. The applicant is entitled to costs.

Disposition;

265. The Applicant has made out a case for the grant of the orders sought. It is evident that the impugned memos as issued by the Respondent has generated an unclear and ambiguous eventuality that makes it legally impossible and difficult for the Applicants to know with certainty which law to follow to their prejudice.

Order;

The application dated 5th April 2021 is allowed.

1. An Order of Certiorari quashing the memos dated 21st December 2020 and 12th March 2021 issued by the Respondent requiring kits/Reagents and equipment used for clinical lab tests be validated by the Respondent and all suppliers, vendors and distributors to be registered with the Respondent is hereby issued.
2. An Order of Prohibition prohibiting and restraining the Respondent either by itself, agents, employees or whatsoever means from taking steps, actions and measures to enforce its memo dated 21st December 2020 and 12th March 2021 is hereby issued.
3. Costs to the Applicant.

DATED, SIGNED AND DELIVERED AT NAIROBI THIS 3RD DAY OF JUNE, 2025.

.....

J.M. CHIGITI (SC)

JUDGE