YENEPOYA

(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Details of the Collaborative Activity

2019-2021

Name of the Collaborating Institute: Prantae Solutions Pvt. Ltd., Bhubaneshwar

Name of the Collaborating Department: Yenepoya Medical College Hospital

Activities:

Clinical Trail Project:

A clinical agreement was signed between the institutes Prantae Solutions Pvt. Ltd., Bhubaneshwar and Yenepoya Medical College Hospital on 21st November 2019.

As a part of the study, YIT provided microalbumin testing services to Dr. Raghavendra Rao, YMC for the Project titled "Evaluation of a fluorescence-based urine Albumin analysis and comparison with the gold standard with human urine sample"

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
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University Road, Deralakatte
Mangalore-575 018, Karnataka

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA44458933257020R
Certificate Issued Date	:	21-Nov-2019 05:55 PM
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Unique Doc. Reference	:	SUBIN-KAKACRSFL0806438661028492R
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Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT WITH PRANTAE
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Second Party	:	PRANTAE SOLUTIONS PVT LTD
Stamp Duty Paid By	:	YENEPOYA DEEMED TO BE UNIVERSITY
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

NAVAYUGA MULTIPURPOSE CO-OP. SOCIETY LTD. Ph:4285977 Central Avenue Building Opp:STATE BANK MANGALURU-1

Please write or type below this line

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (this "Agreement"), dated as of 22nd November, 2019 (the "Effective Date"), is entered into between Prantae Solutions Private Limited (OPC), (the "Sponsor"), Dr. Mohamed Hafeezulla Shariff, Dr. Rekha PD, Dr. Raghavendra U (the "Investigators") and Yenepoya (Deemed to be University), (the "Institution"; with the Sponsor and the Investigators, the "Parties"; each, a "Party").

WHEREAS, the Sponsor desires to conduct a clinical study/validation (the "Study") of Sponsor's method, test kit and device as part of a clinical validation study under a protocol entitled ***Evaluation of a novel method for urine albumin analysis with the NABL approved***

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Dr Hamsaveena Somayaji K.S. Registrar Yenepoya(Deemed to be University)

Registrar Yenepoya (Deemed to be University) University Road, Deralakatte Mangalore 575 018

method (the "Protocol"), a copy of which is attached hereto as Annexure I;

WHEREAS, the Institution has the facilities and expertise to conduct the Study; and

WHEREAS, the Study is intended to test the Sponsor's method, test kit and device which may advance scientific and medical knowledge, with a due regard for patient safety;

NOW, THEREFORE, in consideration of the mutual promises set forth in this Agreement, the Parties hereby agree as follows:

1. SCOPE OF WORK.

1.1 Investigators. The Institution shall conduct and supervise the Study through Dr. Mohamed Hafeezulla Shariff, Dr. Rekha PD and Dr. Raghavendra U (the "Investigators"), who are the employees of the Institution. The Institution shall notify the Sponsor promptly if any of the Investigators are unable or unwilling to continue the Study or if the Investigator's affiliation with the Institution ceases, whereupon the Sponsor will have a right of approval with respect to the designation of a new Investigator.

1.2 Conduct of the Study. The Institution shall (and shall cause the Investigator to) conduct the Study in accordance with this Agreement, the Protocol (as amended from time to time), all reasonable written instructions of the Sponsor, and all applicable laws and regulations ("Applicable Law"); provided, however, that the Institution may deviate from the Protocol and such instructions to the extent that the safety of Study Subjects so requires. The Institution shall refrain from, and shall cause the Investigator and any other employee, contractor, or agent performing or assisting with the Study on behalf of the Institution (such employees, contractors, and agents, including the Investigator, "Study Staff") to refrain from, using the "method, test kit and device" in any manner that is contrary to the provisions of, or outside the scope of, the Protocol or that is contrary to such written instructions.

1.3 Approvals. The Institution shall seek approval of the Study, the Protocol, and a written form of Informed Consent (as defined in Section 1.4) mutually acceptable to the Institution and the Sponsor, from the appropriate Scientific Review Board (the "SRB") and Institutional Ethics Committee (IEC), and also shall seek any other approvals required for the Study from other applicable internal safety or review boards.

1.4 Informed Consent. The Investigator(s) shall obtain from each person participating in the Study (a "Study Subject") a valid informed consent (the "Informed Consent"), signed by the Study Subject (unless such signature is waived by the IEC) and appropriately documented. The Investigator(s) shall conduct the Study in a manner consistent with the Informed Consents and all other applicable consents. Informed consent should be translated in the language known to the subject and read over to him/her.

1.5 Human Materials. The Institution shall comply with Applicable Law in the collection, storage, and transfer of any samples or other human materials taken from Study Subjects and shall obtain any consents required from Study Subjects for the use of such materials in accordance with the Protocol. Any use of such materials by a Party, whether in the Study or

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otherwise, shall be consistent with such consents and Applicable Law.

1.6 Amendment of the Protocol. The Sponsor may amend the Protocol at any time. Any such amendment shall be in writing and sent to the Institution and will not take effect until approved by the IEC. Following any such amendment to the Protocol, either Party may propose a related amendment to this Agreement (including the Payment Schedule, as defined in Section 3.3). The Parties shall negotiate in good faith with respect to any such proposed amendment. If the Parties are unable to agree upon such an amendment to this Agreement, either Party may terminate this Agreement pursuant to Article 9.

1.7 Supervision. The Institution shall supervise those Study Staff employed by the Institution, and shall ensure (directly in the case of employees, and by contract in the case of contractors) that all Study Staff are appropriately trained, qualified, and certified, and are informed of and abide by the applicable terms of this Agreement.

2. RECORDS, REPORTING, AND AUDITS.

2.1 Study Records. The Institution shall keep and maintain, diligently and in sufficient detail to satisfy all applicable legal requirements, such Study data and records as are required by the Protocol and Applicable Law (the "Study Documents"), including any Source Documents and Study Deliverables (each as defined in Section 4.1).

2.2 Record Retention. The Institution shall retain the Study Documents in accordance with Applicable Law. At the Sponsor's request and expense, the Institution shall retain the Study Documents for up to three years beyond the period required by Applicable Law. After the required retention period (including any additional period requested by the Sponsor pursuant to this Section 2.2) has expired, the Institution shall provide the Sponsor sixty (60) days' written notice before destroying any Study Deliverables.

2.3 Study Subject Medical Information. The Sponsor may access the Study Documents during regular business hours, upon reasonable advance notice to the Institution. The Sponsor shall comply with Applicable Law regarding the confidentiality of Study Subjects' medical records and other health information, shall hold the Study Subjects' personal identifying information in confidence, and shall act in accordance with the Informed Consents and relevant law. If the Sponsor removes such records without such permission, it shall immediately return them to the Institution. The Sponsor shall not attempt to contact / should not contact any Study Subject except to the extent expressly permitted by the IEC or as required to comply with Applicable Law.

2.4 Periodic Reporting. The Institution shall provide to the Sponsor the Study Deliverables (as defined in Section 4.1), containing the data specified in the Protocol and prepared in the manner specified in the Protocol, at the intervals indicated in the Protocol or as otherwise agreed in writing by the Parties.

2.5 Audits by the Sponsor. The Institution shall make available to the Sponsor (or its agent) the Study site, the Study Staff, and, subject to Applicable Law relating to patient confidentiality, all Study Documents for purposes of review and audit upon reasonable

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advance notice during regular business hours. If the Investigator(s) fails to correct any violations of the Protocol, this Agreement, or Applicable Law found in such audit after receiving written notice thereof, the Sponsor may provide notice to the Institution of such violations, whereupon the Institution shall promptly take action to correct them.

2.6 Audits by Regulatory Authorities. The Institution shall provide the Sponsor prompt, advance notification of any audit by a regulatory authority, which audit is directly related to the Study (or, when advance notification is impracticable, prompt notification of any completed audit). To the extent possible, the Institution shall permit the Sponsor to review and comment in advance on any written communication from the Institution to the regulatory authority in connection with such an audit; provided, however, that such review does not adversely impact the timeliness of the Institution's response to the regulatory authority. The Institution shall promptly provide the Sponsor with copies of all communications between the Institution and the regulatory authority related to such audit unless prohibited from so doing by the regulatory authority and shall promptly take action to correct any deficiencies found by the regulatory authority during the audit. With respect to any audit by any regulatory authority, which audit is not directly related to the Study, the Institution shall promptly notify the Sponsor of any findings of such an audit that would be likely to have an adverse effect on the Institution's ability to conduct the Study.

3. SPONSOR OBLIGATIONS.

3.1 Compliance with Law. The Sponsor shall comply with Applicable Law in the performance of its activities relating to the Study and shall obtain all approvals and consents required in connection with such activities. The Sponsor shall conduct such Study-related activities in a manner consistent with the Informed Consents and all other applicable consents.

3.2 Supply of method, test kit and device. The Sponsor shall supply the Institution with quantities of the test kit and device adequate for the Institution to conduct the Study in accordance with the Protocol. The method, test kit and device shall remain the sole property of the Sponsor. The Institution shall take reasonable steps to ensure that it has adequate supplies of the test kit and device, shall store, use, handle, and return or dispose of the test kit and device in accordance with the Protocol, and shall not use any test kit after its labeled expiration date.

3.3 Payments. The Sponsor shall make payments to Institution according to the payment schedule attached hereto as Annexure II (the "Payment Schedule") and shall reimburse the Institution for post-termination expenses pursuant to Section 9.5. The Sponsor shall not be liable for any payments beyond those set out in Section 7.1, Section 9.5, and this Article 3.

3.4 Subject Injury. The Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a Study Subject that is directly related to the administration of the test or the proper performance of any other procedure, each in accordance with the Protocol and the Sponsor's written instructions to the Institution. The Sponsor is not required under this Section 3.4 to provide compensation for (a) other injury

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or illness- related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the Institution nor the Study Subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the Protocol or other misconduct or negligence, in each case by any agent or employee of the Institution (including the Study Staff), or (d) medical expenses for injury or illness unrelated to the test/device and unrelated to the proper performance of any other procedure required by the Protocol or Sponsor's written instructions to the Institution.

3.5 Registration of Study. The Sponsor shall register the Study at (i) www.ctri.nic.in, and (ii) any other registry the requirements of which are consistent with the guidelines of the International Committee of Medical Journal Editors ("ICMJE") on trial registrations, in each case to the extent required by the ICMJE guidelines (as in effect at the time the Study begins) in order for the Study results to be eligible for publication in an ICMJE journal.

3.6 Malfunction of the test kit and device. In case of any injury to the Study Staff due to malfunction of the test kit or device or due to improper instructions or training by the Sponsor for the use of the test and device; the Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness. The malfunctioning test kit and / or device shall be replaced by the Sponsor without any cost to the Institution.

4. OWNERSHIP OF DATA, RECORDS, AND INTELLECTUAL PROPERTY.

4.1 Ownership of Data and Records. All rights, title, and interest in (i) the completed case report forms, any electronic databases required to be created under the Protocol, and any Study reports prepared by the Institution for the Sponsor (including, with respect to the data contained in such case report forms, electronic databases, and reports, only the compilation of data or any substantially similar compilation) (collectively, "Study Deliverables"), (ii) the Protocol, (iii) the operations manuals provided by the Sponsor for use at the Study site, and (iv) any other scientific, technical, business, or other data or information relating to the Drug or this Agreement that is disclosed to the Institution by the Sponsor ((ii) through (iv) collectively, the "Sponsor Data"), including copyrights in the Study Deliverables and the Sponsor Data, shall be the sole and exclusive property of the Sponsor. All rights, title, and interest in (x) "Source Documents" (as defined by International Conference on Harmonization (ICH) Guidance E6 "Good Clinical Practice") generated by the Institution in the course of the Study, and (y) all documents other than the Study Deliverables that the Protocol requires the Institution to deliver to the Sponsor, shall be the sole and exclusive property of the Institution; provided, however, that Sponsor shall have the right to use the information and data contained in the documents described in clause (y) for any purpose whatsoever, subject to Applicable Law and the terms of the Informed Consents.

4.2 Disclosure Obligation. The Institution shall promptly disclose, and shall cause the Study Staff to promptly disclose through the Institution, to the Sponsor in writing any (a) patentable inventions ("Inventions") made in the performance of the Study by or on behalf of the Institution, and (b) any know-how, unpatentable inventions, or other discoveries made in the performance of the Study by or on behalf of the Institution.

4.3 Ownership of Inventions. As between the Parties, the Sponsor shall own all right, title,

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and interest in and to any Invention (i) made solely by employees or agents of the Sponsor; (ii) made in the performance of the Study solely by employees or agents of the Institution or jointly by employees or agents of the Institution and employees or agents of the Sponsor that relates to the method, test kit and device or (iii) made in violation of the Protocol. Any other Invention made jointly by employees or agents of the Institution and employees or agents of the Sponsor shall be jointly owned by the Sponsor and the Institution, and any other Invention made solely by the Institution's employees or agents shall be the sole and exclusive property of the Institution.

4.4 No Implied License. No license to either Party's preexisting intellectual property is granted to the other Party under this Agreement.

5. CONFIDENTIALITY.

5.1 Obligations. For purposes of this Agreement, the following is "Confidential Information": (a) Sponsor Data disclosed by the Sponsor to the Institution in electronic or written form that is marked "Confidential" or that is generally regarded as confidential; (b) Sponsor Data disclosed orally by the Sponsor to the Institution that is reduced to writing within thirty (30) days and marked "Confidential" or that is generally regarded as confidential; and (c) Study Deliverables. As per the terms of this Agreement the Institution shall maintain the confidentiality of the Confidential Information and may not transfer or disclose Confidential Information to any third party other than the IEC and other applicable internal safety and review boards, except as provided in Section 5.3 or the Protocol. Further, the Institution may use Confidential Information (including the Study Deliverables) in performing the Study, for the provision of related patient care, but shall not use any Confidential Information (including Study Deliverables) for any other purpose.

5.2 Exceptions. Notwithstanding Section 5.1, information shall be deemed not to be Confidential Information to the extent that it:

(a) is or later becomes publicly known other than through a breach of this Agreement by the Institution, its employees, or its agents (including the Investigator(s));

(b) is lawfully made available to the Institution, its employees, or its agents (including the Investigator(s)) by a third party that the Institution reasonably believes owes no obligation of confidentiality to the Sponsor; or

(c) was already known to or is independently developed by the Institution, its employees, or its agents (including the Investigator(s)), as evidenced by written records.

5.3 Permitted Disclosures. Notwithstanding Section 5.1, Confidential Information may be disclosed to the extent that it:

(a) is disclosed to Study Staff, but only to the extent required in connection with the performance of the Study, and only if such Study Staff are subject to obligations of confidentiality and non-use at least as restrictive as those in this Article 5;

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(b) is disclosed to Study Subjects or prospective Study Subjects as reasonably necessary or appropriate in the course of discussions regarding the Informed Consent, or the performance of the Study;

(c) is disclosed to personnel at other study sites as required for the performance of the Study;

(d) is disclosed to a physician or a Study Subject as reasonably necessary or appropriate in connection with the medical treatment of the Study Subject;

(e) is disclosed to employees of the Institution for patient care, but only if such employees are subject to obligations of confidentiality and non-use at least as restrictive as those in this Article 5; or

(f) is required to be disclosed by the Institution by law or by order of any governmental authority; provided, however, that, except with respect to disclosures made pursuant to Section 2.6, the Institution shall use reasonable efforts to disclose the minimum Confidential Information necessary to comply with such requirement, and the Institution shall give the Sponsor advance notice of the disclosure when practicable, and prompt notice of the disclosure otherwise, to permit the Sponsor to seek a protective order to limit the disclosure.

5.4 Data in Source Documents. The Institution shall not make available to any third party, without the prior written consent of the Sponsor, the data that is contained in the Study Deliverables (whether or not such data is also contained in the Source Documents or any other document or database owned or controlled by the Institution), in a manner that would reasonably enable such third party to reconstruct the compilation of data contained in the Study Deliverables (or to construct a substantially similar compilation).

5.5 Confidentiality of Terms. Each Party shall maintain the confidentiality of the terms of this Agreement, subject to Section 6.7 and the exceptions set forth in Sections 5.2 and 5.3.

6. PUBLICATION.

6.1 Use of Name. Neither Party may use the name, logo, or trademark of the other Party or its employees or affiliates in any press release, publicity, or advertising without the prior written approval of the other Party, except as required by Applicable Law or expressly permitted by this Agreement.

6.2 Publication in List of Trials. The Institution shall have the right to include the Study title and any other information publicly available on any registry in which the Study is listed pursuant to Section 3.5, in any list of active or past clinical trials conducted by the Institution published on the Institution's website or in an Institution print publication; provided, however, that no additional information, whether about the Study, the method, test kit and device, or the Sponsor, may be included. Notwithstanding the foregoing, the Institution may include in its grant applications the Study title and a description of the Study as required in connection with those applications.

6.3 Acknowledgment. If required by the journal to which a Manuscript is submitted, the

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Sponsor shall publicly acknowledge in any Manuscript the Institution's contribution to the research.

7. INDEMNITIES AND INSURANCE.

7.1 Indemnification. The Sponsor shall indemnify, defend, and hold harmless the Institution and its officers, directors, employees, and agents from any loss, liability, damage, or expense (including reasonable attorneys' fees and costs until such time as the Sponsor assumes the defense) from any claim of bodily injury or property damage that may arise directly from the administration of the method, test kit and device or the proper performance of any procedure required by the Protocol or the Sponsor's written instructions; provided, however, that to the extent that the claim is a direct result of (a) the failure of the Institution or one of its officers, employees, or agents (including the Investigator(s)) to follow the Protocol or the Sponsor's written instructions (each when applicable), accepted medical practice, or Applicable Law, or (b) any other negligence or willful misconduct of the Institution or one of its officers, employees, or agents (including the Investigator), the Sponsor shall have no such obligation, and the Institution shall indemnify, defend, and hold harmless the Sponsor (and its officers, directors, employees, and agents, as applicable) from any loss, liability, damage or expense, but only to the extent arising from any such claim.

7.2 Indemnification Procedure. The Party seeking indemnification (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") of any claim, loss, or expense likely to lead to a claim for indemnification, along with all material related information. If such notice is not prompt, the Indemnitor's obligation under this Article 7 will be reduced to the extent that such delay prejudices the Indemnitor's defense of the claim. The Indemnitor shall have the right to manage the defense and settlement of any claim, except that the Indemnitor may not enter into any settlement admitting fault on behalf of the Indemnitee without the Indemnitee's prior written approval. The Indemnitee may not enter into any settlement of any such claim without the written permission of Indemnitor. The Indemnitee shall reasonably cooperate with the Indemnitor in the defense of the claim. The Indemnitee may hire its own counsel, at its own expense, to monitor the defense. In addition, the Indemnitee may elect to assume control of the defense of such claim, in which case the Indemnitor shall have no obligation to indemnify or further defend the Indemnitee with respect to such claim.

7.3 Insurance. During the term of this Agreement the Sponsor shall carry liability insurance in the type and amount appropriate and customary for the conduct and sponsorship of clinical trials. The Sponsor shall provide to the Institution a certificate of such insurance.

8. REPRESENTATIONS AND COVENANTS

8.1 Regulatory Approvals. Each Party represents that it has and will maintain during the term of this Agreement all regulatory approvals required for the conduct of its respective activities in connection with the Study, and that all the persons who perform activities under

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this Agreement on its behalf (including, in the case of the Institution, the Study Staff) have and will have the necessary expertise, training, qualifications, and certifications.

8.2 Debarment. The Institution certifies that it will not engage, directly or indirectly, any person (including the Investigator(s)) to perform services under this Agreement if (a) that person is debarred by any regulatory bodies or to the Institution's knowledge is threatened with debarment by a pending proceeding, action, or investigation, or (b) that person is otherwise disqualified under national or state law, or to the Institution's knowledge is threatened with such disqualification by a pending proceeding, action, or investigation, from participating in the Study. The Institution certifies that it will immediately notify the Sponsor in writing if any such debarment, exclusion, or disqualification occurs, or if any such debarment, exclusion, or disqualification proceeding, action, or investigation is commenced or, to the Institution's knowledge, is threatened, with respect to any such person.

8.3 Fair Market Value. Each Party represents that the compensation provided under this Agreement represents the fair market value of the activities performed by the Institution, has been negotiated in an arm's-length transaction, and has not been determined in any manner with regard to any implicit or explicit agreement to provide favorable procurement decisions with regard to the sponsor's products, or to the value or volume of any business or referrals generated between the Parties.

8.4 No Charge. The Institution covenants that it will not charge any Study Subject for (i) the test, or (ii) any items or services that are funded by the Sponsor under this Agreement or that are provided without charge by the Sponsor for Study purposes.

8.5 Power and Authority. The Institution represents that it has the requisite power and authority to cause all Study Staff to comply with the Institution's obligations under this Agreement, including, but not limited to, its obligations under Articles 1, 2, 3, 4, 5, and 6.

8.6 No Conflicting Obligations. The Institution represents and covenants that none of the Institution or any member of the Study Staff is or will become subject to any conflicting obligations that would materially interfere with the performance of the Study or any of the Institution's other obligations under this Agreement. The Parties agree that the conduct of other clinical trials targeting the same disease or patient population as the Study does not necessarily constitute such a conflicting obligation.

8.7 Institution Disclosures. The Institution: (a) shall cause the Investigator to provide to the Sponsor a signed, completed Form FDA-1572 and a *curriculum vitae* or other statement of qualifications showing the education, training, and experience that qualifies the Investigator(s) as an expert in the clinical investigation of the test under investigation; (b) shall cause, before the commencement of the Study, during the course of the Study, and for up to one year after the completion or termination of the Study, at the Sponsor's reasonable request, the Investigator and any sub-investigator to disclose to the Sponsor (and afterwards to notify the Sponsor of any relevant changes to) any financial arrangement between the Sponsor and the investigator (whether Investigator(s) or sub-investigator, and including any spouse or dependent child thereof; any such person, a "Clinical Investigator") as to which the value of the compensation could be influenced by the outcome of the Study, any significant payments of other sorts from the Sponsor to any Clinical Investigator, any

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Prantae Soultions Pvt. Ltd. (OPC)

Prantae Soultions Pvt. Ltd. (OPC)
Dr. Sumona Karjee Mishra
Director

Dr. Sumona Karjee Mishra
Managing Director
Prantae Soultions Pvt. Ltd. (OPC)
N3/232, IRC Village,
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[INVESTIGATORS]:

26/11/2019

Name: Dr. RAGHAVENDRA . U .
Title: Investigator

26/11/2019

Name: Dr. M.H. Shamee
Title: Investigator

P.D.

Name: DR. REKHA P.D.
Title: Investigator

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proprietary interest in the method, test kit and device held by any Clinical Investigator, or any significant equity interest in the Sponsor held by any Clinical Investigator (for purposes of this Section 8.7, the terms "significant equity interests," "proprietary interests," and "significant payment of other sorts" shall have the meanings set out in 21 CFR § 54); and (c) shall comply, and shall ensure that the Investigator(s) and any sub-investigator comply, with all applicable disclosure requirements related to conflict of interest that areimposed by the FDA or other regulatory or governmental authorities.

8.8 Conflicts of Interest. The Institution represents that it has a system in place to manage, eliminate, or otherwise resolve conflicts of interest. The Sponsor shall not and shall cause its agents and contractors to refrain from, making any payments directly to Study Staff for performing the activities set out in the Protocol.

9. TERM AND TERMINATION.

9.1 Term. This Agreement shall take effect on the Effective Date and shall expire one year after the completion of the Study, unless terminated earlier pursuant to this Article 9.

9.2 Sponsor Termination. The Sponsor may terminate this Agreement (a) upon thirty (30) days' written notice to the Institution, in its sole discretion; (b) upon thirty (30) days' written notice to the Institution, for failure of the Sponsor and the Institution to agree upon a new Investigator (s) pursuant to Section 1.1; (c) upon written notice to the Institution, if enrollment at the Study site justifies such termination, in the sole discretion of the Sponsor; (d) upon written notice to the Institution, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Section 1.6; (e) upon oral notice (promptly followed by written notice) to the Institution, if approval for the Study is not granted or is revoked by the relevant IEC; (f) upon oral notice (promptly followed by written notice) to the Institution, if any person performing activities under this Agreement is debarred, excluded or disqualified from participation in any federal health care program; or (g) upon oral notice (promptly followed by written notice) to the Institution, if the Sponsor determines that termination of the Study is necessary for the safety of the Study Subjects.

9.3 Termination by Institution. The Institution may terminate this Agreement (a) upon thirty (30) days' written notice to the Sponsor, for failure of the Sponsor and the Institution to agree upon a new Investigator(s) pursuant to Section 1.1; (b) upon written notice to the Sponsor, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Section 1.6; or (c) upon oral notice (promptly followed by written notice) to the Sponsor if the Institution determines that termination of the Study is necessary for the safety of the Study Subjects.

9.4 Termination for Material Breach. Either Party may terminate this Agreement upon written notice to the other Party if the other Party materially breaches this Agreement and the breaching Party fails to cure the breach within thirty (30) days after receipt of written notice of the breach from the other Party.

9.5 Procedures Upon Early Termination. If this Agreement is terminated before completion of the Study, the Institution shall cease enrolling Study Subjects immediately (or,

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in the case of termination by the Sponsor, as soon as the Institution has been notified of such termination), and shall cease conducting the procedures set out in the Protocol to the extent that doing so is medically permissible and appropriate. The Sponsor and the Institution shall negotiate in good faith on the subsequent treatment or transfer of the Study Subjects. In case of termination of the Study before completion, the Sponsor shall reimburse the Institution for (i) obligations incurred in accordance with the Study budget that cannot be cancelled or mitigated by the Institution using reasonable efforts, (ii) reasonable costs incurred in connection with the safe withdrawal of Study Subjects from the Study, and (iii) mutually agreed post-termination expenses.

9.6 Return of Property. Upon termination or expiration of this Agreement, the Institution shall, and shall cause the Investigator(s) to, return to the Sponsor, at the Sponsor's expense, within thirty (30) days any remaining test kits (except as required by law), any equipment on loan or lease from the Sponsor, and any copies of Confidential Information provided by the Sponsor that are in the possession or under the control of the Institution or the Investigator(s); provided, however, that the Institution may retain any copies of such Confidential Information to the extent required by Applicable Law. At the Sponsor's request and expense, the Institution shall dispose of the remaining test kits in accordance with Sponsor's instructions, subject to Applicable Law.

9.7 Final Accounting. The Institution shall deliver to the Sponsor, within ninety (90) days after expiration or early termination of this Agreement, a final accounting of amounts due (and reasonable supporting documentation, which requirement shall be satisfied by properly completed case report forms as to completed visits by Study Subjects), taking into account payments made and not yet made under the Payment Schedule, and expenses reimbursable pursuant to Section 9.5, from one Party to the other Party. Undisputed amounts due shall be paid within sixty (60) days thereafter.

9.8 Survival. The rights and obligations of the Parties that have accrued prior to the expiration or termination of this Agreement, and Sections 1.2, 1.5, 1.7, 2.2, 2.3, 2.5, 2.6, 3.2, 3.3, 3.4, 8.2, 8.4, 8.5, 8.6, 8.7, 8.8, 9.5, 9.6, 9.7, Articles 4, 5, 6, 7, 10, and this Section 9.8 shall survive the expiration or termination of this Agreement.

10. MISCELLANEOUS.

10.1 Remedies and Waiver. The remedies provided in this Agreement are not exclusive and the Party suffering from a breach or default of this Agreement may pursue all other remedies, both legal and equitable, alternatively or cumulatively. No express or implied waiver by a Party of any breach or default will be construed as a waiver of a future or subsequent breach or default. The failure or delay of any Party in exercising any of its rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

10.2 Independent Contractor. In performing activities under this Agreement, the Institution, including the Investigator and its other employees, is operating as and has the

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status of an independent contractor to the Sponsor, and shall not act as and is not an agent or employee of the Sponsor. The relationship between the Parties does not constitute a partnership, joint venture, or agency. Neither Party shall have the authority to bind the other Party without that other Party's express, written permission.

10.3 Force Majeure. Noncompliance by a Party with this Agreement due to any cause beyond the reasonable control of the Party, such as war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers (each, an event of "Force Majeure"), shall not constitute a breach of this Agreement. That Party shall be excused from performance under this Agreement to the extent and for the duration of such event of Force Majeure; provided, however, that it first notifies the other Party in writing thereof and that it uses reasonable efforts to cause such event of Force Majeure to abate.

10.4 Choice of Law. This Agreement is governed by the laws of the State of Karnataka, without regard to its rules of conflicts of laws. Any legal disputes shall be resolved in the jurisdiction of courts of Mangalore.

10.5 Notices. The Parties shall send notices in writing, referencing this Agreement. Notice shall be deemed given: (a) when delivered personally; (b) one (1) day after having been sent by email, with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) two (2) days after deposit with a nationally recognized overnight carrier, with written verification of receipt. Notice shall be given to the addressee below (or to such other addressee as a Party subsequently designates pursuant to this Section 10.7):

To the Institution:

Yenepoya (Deemed to be University)
University Road, Deralakatte,
Managalore, Karnataka 575018

Attention: Registrar

***with a copy to* the Investigators**

Yenepoya (Deemed to be University)
University Road, Deralakatte,
Managalore, Karnataka 575018

Attention: Dr. Raghavendra U, Dr. Mohamed Hafeezulla Shariff and Dr. Rekha PD

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To the Sponsor:

Prantae Soultions Pvt. Ltd. (OPC)
312, KIIT Technology Business Incubator,
Campus 11, KIIT (Deemed to be University)
Bhubaneswar, Odisha 751024

Attention: Dr. Sumona Karjee Mishra

10.6 No Third-Party Beneficiary. This Agreement is for the sole benefit of the Parties and does not confer any rights on any third party.

10.7 Entire Agreement; Amendments. This Agreement, together with the Exhibits hereto, constitutes the entire agreement of the Parties with respect to its subject matter, and supersedes all previous written or oral representations, agreements, and understandings between the Parties with respect to that subject matter. This Agreement may only be amended by a written document signed by both Parties. In the event of any conflict between the terms of the Protocol and this Agreement, this Agreement shall control.

10.8 Severability. If any provision of this Agreement is held to be unenforceable for any reason, that unenforceability shall not affect the enforceability of any other provision of this Agreement, and the Parties shall negotiate in good faith to substitute an enforceable provision with similar terms.

10.9 Counterparts. This Agreement may be executed in three (3) or more counterparts, each of which is deemed an original, but all of which together constitutes one instrument.

10.10 Headings. The Section and Article headings in this Agreement are for reference only and shall not affect the interpretation or meaning of any provision of this Agreement.

10.11 Interpretation. Unless the context of this Agreement requires otherwise, words of one gender include the other gender; words using the singular or plural number also include the plural or singular number, respectively; the terms "Article" and "Section" refer to the specified Article and Section of this Agreement; and the term "including" means "including, without limitation."

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Annexure I

Clinical Investigation Plan

Title of the Clinical Investigation

Evaluation of a fluorescence based urine albumin analysis (CDSCO Test License: **MFG/TL/IVD/2019/000098**) and comparison with the gold standard (currently practiced method in the Yenepoya pathological lab) with human urine sample.

Clinical Investigation Number

PS/YU/MA_CT001

Version/Date

Version 1.0
Date: 01/12/2019

Sponsor

Prantae Solutions Private Limited (OPC)
Odisha, India.

Principle Investigator, coordinating Investigator and Investigation site

PI:	Dr. Raghavendra U
Co-PI:	Dr. M.H. Sherif Dr. Rekha P.D.
Investigation Site:	Central Laboratory, Yenepoya Medical Hospital, Deralakatte, Mangalore – 575018.

Introduction

Urine albumin content is one of the well-established non-invasive biomarkers for various clinical conditions. Increasing evidence towards the chronic kidney disease (CKD) and, in particular, the cardiovascular risks that CKD imposes, more sensitive detection of albumin in urine are required[1]. The most common method of urine albumin measurement is (94%) immunoassay-based of which mostly (85%) immuno-turbidimetric[2]. However, it poses certain limitation like, high cost, storage condition and sensitive only to immunologically active form of albumin. Albumin in the urine is exposed to a wider range of pH and ionic strength than found in plasma; other potentially modifying factors include the presence of high concentrations of urea,

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glucose and ascorbate, and cleavage by peptidases[3]. Thus, there may chances of under-representation of the urine albumin[4] and hence in the diagnosis. Thus, it is vital to research and experiment new methods to exploit the possibilities to overcome such bottlenecks that exist in the presently practiced methods. We propose an innovative patented technology based on fluorescent dye to quantify urine albumin from a range covering micro-albumuniuria to proteinuria.

Objective of the study

Objective 1: To compare between a novel urine protein analysis kit (under CDSCO Test License: **MFG/TL/IVD/2019/000098**) and gold standard (immuno-turbidometric method) for urine micro-albumin quantification with urine sample under clinical setting.

Objective 2: To analyze the data obtained from the two methods of measurements to determine the sensitivity, specificity, LOD and correlation coefficient and comparative analysis with the gold standard (immuno-turbidometric method).

Need for the study

The present immunological methods have certain drawbacks beside the cost and storage conditions that might impact the diagnosis of the disorder. An alternative to immunological method that not only reduce the cost of test and need for special storage condition but also able to detect total albumin content of the urine not just limited to the immune-reactive species of albumin is developed. Therefore, upon extensive screening, a newer fluorochrome has been identified with high specificity towards the albumin at the same time non-responsive to the urine microbial load, pH and other metabolites. This has been transformed into a cartridge for simple usage and analysis.

Research Question

The question to be addressed through this research are

1) Does the novel urine analysis kit is capable of estimating the amount of albumin in urine?
2) What is the level of accuracy of estimation of albumin in urine with novel urine analysis kit in comparison to the gold standard (immuno-turbidometric method)

Justification for the study

Kidney disorder is one of the major global healthcare burdens, where the prevalence rate is 10% and still growing. It has been noted that the kidney-disorder most often progress silently without any associated clinical symptom manifestation. As a consequence in majority of the cases it progresses undiagnosed till it reaches the terminal or irrecoverable stage.

Urine micro-albumin has been one of the well-established biomarkers for early identification of kidney damage. It is one of the routinely practiced methods under the

clinical settings. Presently, the microalbumin tests are primarily immunological method based either reporting as chromogenic color reaction as in Micral test or turbidimetric immunoassay.

We have developed a novel method with granted patent for urine albumin detection that is non-immunological method. This cost effective and simple method under laboratory condition is highly correlating with the gold standard like turbidimetric immunoassay. However, we understand that the method cannot be considered of any clinical relevance unless tested with real biological samples and made a head on comparison with the gold standard. Thus, a study will be conducted with patient/volunteer urine sample to do comparative analysis for the performance of the method for the purpose of urine micro-albumin analysis.

Study Design and Protocols

Study Duration
2-6 months

Study sample size
262 2* = 524 samples *In duplicates

Study Area
Yenepoya Medical College, Mangalore.

Study Sample
Urine (middle stream of the random urine)

Enrolment Procedure
1. Brief introduction of the study,
2. Matching of inclusion criteria
3. Informed consent form for participation in the study.

Inclusion Criteria
- Healthy Individuals with no previously known renal disorder history.
- Individuals within the age group of 18-45 years.

Exclusion Criteria
- Individual with clinically established renal disorder and /or
- Individual with suspected case of UTI and/or
- Individual who are pregnant

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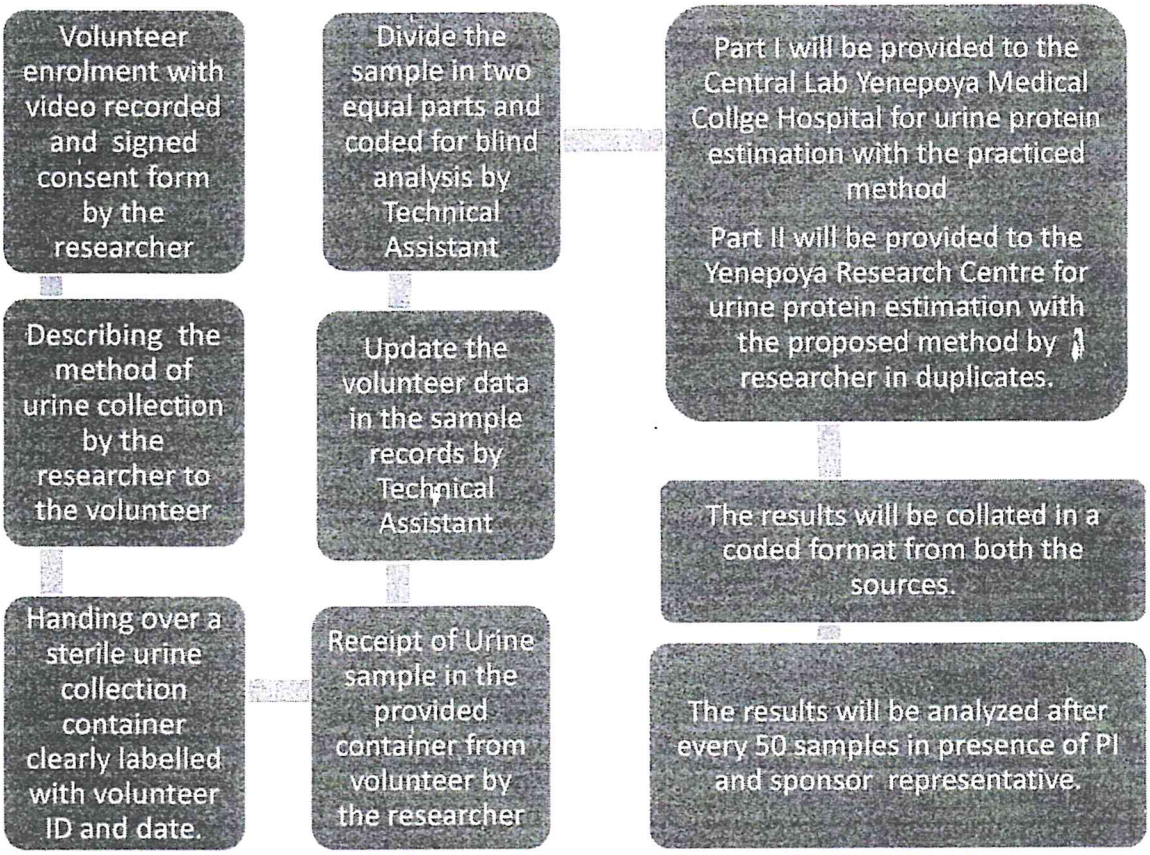
Flow chart to depict study design



Working protocols for sample analysis

Protocol for urine sample analysis using the cartridge (CDSCO Test License: MFG/TL/IVD/2019/000098)

1. Take out fresh cartridge from the sealed package [a].
2. Place the cartridge over a horizontal platform with its flat bottom
3. Remove the cap and add 1ml urine from the urine sample container from the mouth of the cartridge
4. Let it stand undisturbed for 40 seconds [b].
5. Put back the cap and shake it by gentle taping with finger on the walls (4-5 times).

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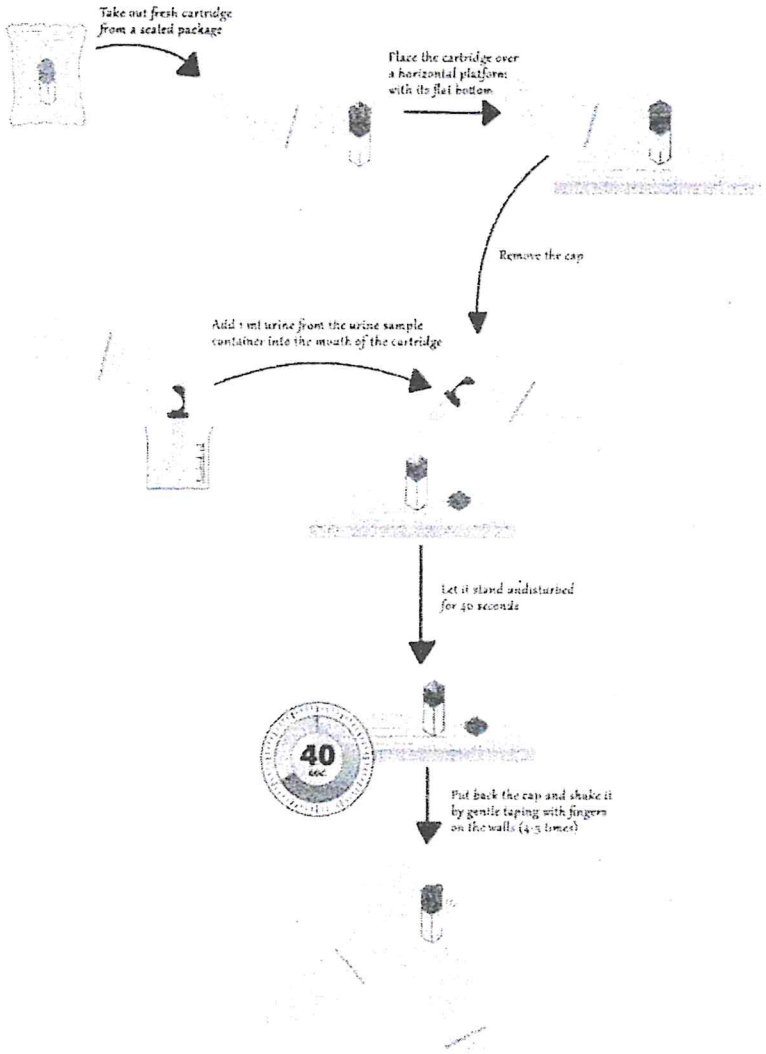
6. Take the reading in the Fluorescence spectrophotometer (PUDR2#0010.01) using the provided software (PUS2#0010.03).



Protocol for operation of Fluorescence spectrophotometer (PUDR2#0010.01) and use of the provided software (PUS2#0010.03).

1. Power on the Fluorescence spectrophotometer (PUDR2#0010.01) [c, d].
2. Open the software (PUS2#0010.03) and select for albumin measurement from the dashboard from the program [e].
3. Place the cartridge in the sample holder in the Fluorescence spectrophotometer.
4. Press the capture button on the dashboard.
5. Save the result in the folder with proper ID.

Notes

a: Ensure the package is properly sealed and not damaged and cartridge is in proper form. Note down the UID of the cartridge for records.
b. The time is required for filtration and should be checked by observing the amount of urine collected at the transparent bottom part of the cartridge.
c: The wire connection should be made proper and power should be fed from the appropriate power points
d: Fluorescence spectrophotometer should be powered on at least 2 minutes prior to operation in order to ensure proper stabilization of the laser.
e: Software should be properly opened and proper program selection should be made.

Data management

1. All the volunteer consent should be video recorded and stored.
2. All the volunteer consent forms should be properly filled, signed and stored.
3. All the collected volunteer information form details and sample ID should be stored in the prescribed format.
4. All sample results should be properly recorded with proper ID both in hardcopy (In the provided record notebook) and softcopy format.
5. All results should be presented with the proper ID after every 50 samples to the PI and representatives of sponsors for the analysis.
6. All Video recorded consents, consent forms and sample results should be handed over with proper ID both in hardcopy (In the provided record notebook) and softcopy format to the sponsor at the end of the project.
7. All test cartridges received from the sponsor should be indexed with their UIN.
8. All the packaged test cartridges received from the sponsor should be recorded for the quality audits

Clinical data collection

Not required for the proposed study.

Materials and equipment from sponsor

1. Disposable sterile urine collection containers volume 30 ml.
2. Disposable sterile cartridge for urine albumin quantification, manufactured under the CDSCO Test License: **MFG/TL/IVD/2019/000098**
3. Pipette P1000 Manual with an adjustable volume capacity of 100-1000 microliters.
4. Fluorescence spectrophotometer with customized software calibrated to estimate urine albumin content. (Name of the equipment: PUDR2#0010.01 Name of the software: PUS2#0010.03)

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Annexure II

Payment Schedule

The Institution has agreed to provide the services outlined in the table below to the Sponsor as per the Clinical Trial Agreement (CTA) and the charges are outlined accordingly.

Sl. No	Description	Total Cost
1	Test for micro albumin - Sample Handling Charges (524 samples @ Rs. 50)	26,200
2	Investigators fees	40,000
3	Site Coordinator fees	8,000
4	Contingency	2,000
Total		**76,200**

Any other services provided by either the Institution or its affiliated organisations including Yenepoya Foundation for Technology Incubation ("Incubator") will be costed extra and a consolidated invoice will be raised by the Incubator which is payable as per the terms and conditions outlined in the respective invoice.

The sponsor agrees to pay 60 % of the total costs before the initiation of the study and the rest 40 % is payable at the time of completion of the study.

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