Development and Characterization of a Biodegradable Medical Diagnostic Test Cassette: Material Selection, Decomposition Investigation and Environmental Impact

[1]Minocha Dr. Pramod Kumar, [2]Kothwala Dr. Deveshkumar Mahendralal, [3]Shaikh Amirhamzah Mahmadiqbal, [4]Rathod Sumit Pravin, [5]Sabu Albin Xavier

Meril Life Sciences Pvt. Ltd.
Bilakhia House, Survey No.135/139, Muktanand Marg, Chala, Vapi-396191,
Gujarat, India.

Abstract- **Medical products, particularly diagnostic and testing cassettes, are commonly designed for single-use, resulting in massive amounts of plastic waste. The disposal of these plastic-based medical items, which are primarily composed of non-biodegradable materials, poses a significant challenge as they take an incredibly long time to degrade naturally. Consequently, these discarded medical products accumulate in the environment, exacerbating the already pressing issue of inefficient solid waste management, such as overflowing landfills. To address this problem, the present invention has delved into the development of biodegradable diagnostic cassettes with superior mechanical properties and faster biodegradation rates. The study provides valuable insights into the optimal combination of additives and their concentrations, which enhance the biodegradability, flexibility, durability, stability, and appearance of these cassettes. By employing such advancements, this invention contributes to the creation of sustainable and environmentally friendly diagnostic equipment for medical purposes, thereby addressing the critical need for more eco-conscious solutions in the healthcare industry.**

Keywords: **Biodegradable medical products, Sustainable diagnostic cassettes, Plastic waste reduction, Eco-friendly healthcare solutions and Biodegradation-enhancing additives.**

1. Introduction

The recent COVID-19 pandemic has highlighted the significant advancements in diagnostic testing accessibility for both medical professionals and public health purposes. [1] [2]. Point-of-care tests (POCTs) for COVID-19 are used every day in hospitals, primary care settings, workplaces, and people's homes throughout the world. Although the Covid-19 pandemic is in an endemic phase, the viral load and the emergence of possible new variants are ongoing and must continue to be monitored. As such, point-of-care tests are common tests that are used daily in many other tests for malaria, dengue, HIV, pregnancy, etc. According to predictions, the market for these tests from $43.3 billion in 2022 to $72 billion in 2024, growing at a 10% annual pace [3]. However, the widespread use of POCT devices in health systems and communities around the world has unintended consequences for the environment and human health. The majority of single-use POCT devices are produced from non-renewable plastic materials, contributing to the rising worldwide tide of medical waste. A significant amount of POCT diagnostic waste is infectious waste, which should be collected separately and cleaned to eliminate the risk of infection [5].

Most infectious trash is burned, contributing to greenhouse gas (GHG) emissions. Many health facilities in low- and middle-income countries (LMICs) lack incinerators entirely, do not have the fuel to run them, or cannot operate them at required temperature thresholds [6] [7] [8]. In such cases, used testing instruments are frequently burned in open pits on the grounds of health facilities or at municipal waste sites [9]. Burning plastic garbage at low temperatures releases harmful pollutants such dioxins and furans in addition to greenhouse gases (GHG) [10]. Additionally, a lot of POC waste in LMICs is disposed of in landfills or municipal water systems, raising the possibility that health professionals, waste workers, and members of the general public will come into contact with the hazardous chemicals they contain, like the cyanide derivatives used in PCR cartridges [11].

In conclusion, it has been established that PLA is a fresh substrate material that is appropriate for the manufacture of environmentally friendly microfluidic devices for POCT applications. It has also been established that PLA is compatible with prototype processes including 3D printing and laser cutting [12] [14] [15]. There are many non-biodegradable diagnostic cassettes available in the market which is composed of plastic and harms the environment when it is left for waste after its use. Hence, there are some additives available in the market that has been used in the

aforementioned research study for the production of environmentally sustainable microfluidic device. The environmental advantage of biodegradable bioderived polymers consists in the use of renewable raw ingredients, with combustion as the end-of-life scenario. The advantages of a landfill will include both the raw materials and quick degradation in addition to the former. [17] [18]. In the natural environment, PLA doesn't deteriorate easily [19]. Specific waste management techniques, such as segregated collection and commercial composting facilities, are required for PLA biodegradation. While this is practical and thus appealing for high-income nations, in an LMIC setting and taking landfills into consideration, PLA solutions would have no additional positive environmental effects beyond the use of renewable raw materials [20] [21].
The aim of the research study is to create a biodegradable diagnostic cassette by incorporating two specific additives that are water resistant. These additives are combined with other monomers to enhance the physical, chemical, and mechanical characteristics of the resulting polymer. The study emphasizes the importance of using these additives to improve the properties of the biodegradable diagnostic cassette, which could lead to the development of more efficient and environmentally friendly diagnostic cassettes compared to those made from non-biodegradable polymers.

2. Materials and Method

The present research study describes a method for producing a biodegradable medical diagnostic cassette. This cassette is designed to degrade naturally over time. It can be utilized in various diagnostic testing cassettes, including those used for detecting human chorionic gonadotropin (hCG), performing RT-PCR tests, identifying malaria, and conducting antigen assays. Diagnostic testing cassettes are typically used for rapid antigen-antibody examinations and are intended for single-use. The technique employed in this invention involves incorporating water-soluble synthetic linear polymers (additives) and fibrous residues from plant raw materials, such as sugarcane bagasse. These raw materials undergo a process known as pulp molding, which is a form of injection molding technique used to create the cassette. The additives used in the cassette's production are water-resistant, ensuring that if the analyte solution (the solution used in diagnostic tests) accidentally comes into contact with the cassette body, it will not affect its integrity.

2.1 Preparation of bagasse cassette:

Sugarcane bagasse, a fibrous residue obtained when juice is extracted from sugarcane, is typically considered waste in the food sector. However, a new invention seeks to recycle this readily available resource by transforming it into the cassette of the present invention. The bagasse contains cellulose, hemicellulose, lignin, water, as well as small amounts of soluble solids (such as sugars) and carbohydrates (like ash). To begin the process, a predetermined amount of water is mixed with the bagasse, effectively turning it into a pulp. Physical agitation of the pulp is then performed by stirring it. This agitation loosens the plant raw material and improves its accessibility for further processing. After the pulp undergoes 24 hours of resting period, it is converted into paper. This conversion process involves various steps, including refining and drying the pulp. By utilizing sugarcane bagasse and its components, the invention takes advantage of an existing resource that would otherwise be discarded as waste.

In summary, the invention proposes the recycling of sugarcane bagasse, a residue left after extracting juice from sugarcane, to create a cassette. This process involves converting the bagasse into a pulp by adding water, physically agitating it, and allowing it to rest for 24 hours. The resulting pulp is then transformed into paper. By repurposing this natural resource, the invention offers an environmentally friendly solution while utilizing a readily available material.

A recently developed paper with exceptional properties is being considered as a replacement for hardwood pulp due to its short fibers that exhibit minimal tearing and strong reinforcement abilities. To assess its suitability, the paper is stored for a few days before being utilized as a raw material for bagasse test cassettes. Before being molded into cassettes for testing, the paper is liquefied since it contains small fibers that lack sufficient cohesion in the test molds. To address this issue, additives such as Tert-Butyl Acrylamides (TBAA) and Polyacrylamide (PAM) are introduced and thoroughly mixed.

2.2 TBAA as a beneficiary additive in manufacturing biodegradable cassette:

TBAA (tert-butyl acrylamide) is a component of a liquid emulsion that enhances the strength, heat sealing, and moisture resistance of cellulosic fibers, improving their binding qualities. It acts as a retention aid, increasing the flocculating tendency of fibers and additives. TBAA is non-flammable, non-toxic, and non-hazardous, performing effectively under typical conditions. It can be copolymerized with other monomers to create biodegradable polymers with improved resistance to degradation. When used in biodegradable cassettes, TBAA enhances toughness without compromising biodegradability, offering a balance between performance and eco-friendliness. Its use improves strength, heat sealing, moisture resistance, and flocculating propensity, making it a valuable and safe additive for enhancing cellulosic fibers.

2.3 PAM as a beneficiary additive in manufacturing biodegradable cassette:

PAM dissolves in water and contains active amide groups and double bonds on its main chain. PAM is derived from monomers like acrylic acid and acryl amide. To enhance its biodegradability, PAM can be modified by co-polymerizing it with other monomers like lactide or glycerol dimethacrylate. This creates a biodegradable polymer that is more resistant to degradation from heat, moisture, or microorganisms. PAM acts as a reinforcing and strengthening agent, aiding in the dispersion and retention of fibers. When added to slurry, it causes rapid flocculation of existing fibers and fillers. Finer fibers and fillers adhere to the surface of longer fibers, facilitating dehydration of the slurry and improving the retention of fine particles.

These additives are combined with acrylamide-2-methylpropane sulfonic acid copolymer and other water-soluble monomers. The resulting mixture is poured into a mold while the filter suction absorbs any lumps or unwanted solid waste, ensuring a slurry-like consistency with no solid portions present. The additives play a crucial role in enhancing the fiber bonding within the slurry, thereby improving the cassette's ability to retain water over an extended period without deformation.

Subsequently, the slurry-filled mold is transferred to a chamber where it undergoes a second molding process while being subjected to high temperature and dry hot pressure under vacuum conditions. This stage facilitates the evaporation of excess water from the slurry. After passing through the mold, the material is cut into shapes resembling test-molded cassettes and allowed to cool. Finally, the biodegradable test-molded cassettes are extracted from the machine, representing the end product of the process. Hence, a new type of paper with remarkable properties is being evaluated as a potential replacement for hardwood pulp. By transforming the paper into slurry and incorporating additives to enhance fiber bonding, the resulting material can be molded into biodegradable test cassettes. The process involves a combination of storage, liquefaction, additive mixing, molding, drying, and shaping, ultimately resulting in the production of durable, environmentally friendly test-molded cassettes. The prototype is shown in the figure.01

(A) Front body

(B) Back body

Figure.01 Unveiling the Prototype for a Biodegradable Diagnostic Test Cassette.

Bagasse is a fibrous material derived from sugarcane, known for its larger pores that allow it to absorb fluids like water and other liquids over a period of approximately 3-4 hours. The material's significant surface area and distribution of pores contribute to its excellent adsorption capacity. Bagasse test kits are utilized to prevent the spread of fluids resulting from accidental spills on surfaces, thus minimizing any interference with test results. These kits are particularly effective in maintaining the integrity of the testing process. Capillary action, which refers to the ability of a liquid to flow in narrow spaces without external forces, is influenced by the composition and structure of bagasse cassettes and testing strip paper chromatography. Bagasse cassettes primarily focus on the interaction between fluids and specific reagents or elements within the cassette, while paper chromatography employs specialized chromatography paper for qualitative and quantitative analysis in scientific research and other testing procedures. The speed and range of capillary action are affected by the pore size and porosity of the material being used. Bagasse cassettes are especially useful in point-of-care or at-home diagnostic procedures due to their simplicity, user-friendliness, and ability to provide rapid results. They serve as a practical solution in various testing scenarios.

Hence, TBAA used in the production of biodegradable cassettes, offered several benefits. It enhanced the toughness of the polymer without compromising its biodegradability. This meant that incorporating TBAA into biodegradable cassettes improved the physical characteristics of the polymer while still allowing it to break down naturally over time. TBAA proved to be a safe and effective option that could be copolymerized to create biodegradable polymers with improved durability. The incorporation of TBAA in biodegradable cassettes provided a balance between physical performance and eco-friendliness, making it a beneficial choice in their production. On the other hand, incorporating PAM additives into the cassette formulation increased its resistance to water and prolonged its shelf life, making it easier to use and dispose of in an environmentally friendly manner. The modification of PAM's structure allowed for the creation of biodegradable cassettes that were less prone to degradation. PAM, a water-soluble polymer, was used in the production of these cassettes and could be modified by co-polymerizing it with other monomers to enhance its biodegradability. The addition of PAM improved fiber dispersion and retention in the cassette slurry, simplifying the dehydration process.

In conclusion, PAM and TBAA offer distinct contributions to the production of biodegradable cassettes due to their contrasting chemical structures and properties. PAM, as a water-soluble linear polymer, exhibits notable water absorption capacity. In contrast, TBAA acts as a monomer that enhances the toughness of the polymer while maintaining its biodegradability.

3. Result and Discussion

The aim of the research was to examine how bagasse cassette samples degrade under real-time in-vitro conditions. Before the study commenced, a thorough visual inspection was carried out to ensure that the samples were free from cracks, bends, or any surface abnormalities that could potentially affect the degradation process.

To simulate the in-vitro degradation environment, a sterile glass beaker was prepared and filled with 400 ml of Phosphate Buffer Solution (PBS). The Bagasse Cassette samples were fully submerged in the beaker containing the PBS solution. To prevent any loss of the solution and maintain a controlled environment, the beaker was sealed either with a glass lid or covered with aluminum foil throughout the entire duration of the study.

The sealed glass beaker, containing the Bagasse Cassette samples, was then placed in an oven and incubated at a constant temperature of 37°C ± 3°C. At every alternate day, the Bagasse Cassette was carefully withdrawn from the PBS solution, and a visual inspection was conducted to observe any changes in the cassette's surface or any signs of degradation. Additionally, images of the cassette samples were captured on each alternate day, allowing for a visual record of the degradation process.

The study continued until the Bagasse Cassette samples underwent complete degradation, meaning that they reached a state where they could no longer serve their intended purpose. Visual inspections for alterations in surface characteristics or structural integrity were performed every alternate day to monitor the progression of degradation.

The degradation testing of the Bagasse Cassette was terminated once the complete degradation of the samples had occurred. The collected data from the real degradation study, including the visual observations and recorded images taken at different time intervals, are summarized in Table.01. This table provides a consolidated overview of the observed changes in the Bagasse Cassette samples throughout the course of the study, allowing for a comprehensive understanding of their degradation behavior under the given experimental conditions.

Sr. No	Real Time IVD Days	Visual Inspection
1	Initial (0 day)	No observable changes were noted.
2	After 30 Days	The bagasse cassette has been transformed into smaller fragments.
3	After 55 Days	The bagasse cassettes underwent a transformation, resulting in a powdered form, which was subsequently fully dissolved in the PBS solution.

Table.01 Visual examination was conducted at regular time intervals.

Figures.02, 03, and 04 illustrate real-time in-vitro degradation behavior observed for biodegradable bagasse cassette.

Figure.02 Bagasse cassette at the initial day

Figure.03 Bagasse cassette after 30 days

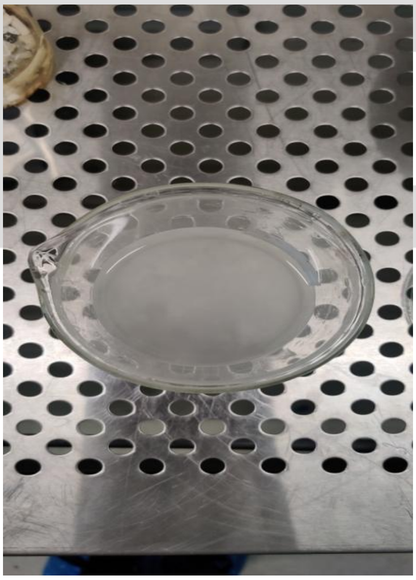

Figure.04 Bagasse cassette after 55 days

4. Conclusion

In conclusion, the experimental evaluation of the bagasse immune chromatographic test cassette provided compelling evidence of its successful performance and compatibility. The incorporation of a water-resistant coating enhanced its ability to withstand liquid droplets, guaranteeing dependable and precise outcomes. Moreover, the cassette's tape could be discarded without harm, even in unfavorable conditions, highlighting its environmentally conscious design. Notably, the components of the cassette decomposed rapidly, presenting a sustainable solution for diagnostic testing.

Collectively, these findings underscored the potential of bagasse-based cassettes as a highly promising alternative in the realm of immune chromatographic testing. The use of such cassettes offered an effective, eco-friendly, and sustainable approach to diagnostic procedures, potentially revolutionizing the field and opening new avenues for advancements in healthcare.

REFERENCES:

1. P. Ondoa, Y. Kebede, M. Massinga Loembe, J. N. Bhiman, S. Kifle Tessema, A. Sow, A. Alpha Sall and J. Nkengasong, Lancet Microbe, 2020, **1**(3), E103–E104
2. S. Kleinert and R. Horton, Lancet, 2021, **398**, 1945–1947
3. Point of Care & Rapid Diagnostics Market - Global Forecast to 2027|MarketsandMarkets, https://www.marketsandmarkets.com/Market-Reports/point-of-care-diagnostic-market-106829185.html?gclid=Cj0KCQjwxtSSBhDYARIsAEn0thSq_WeoIJSYBUDc_RasH1oIbxcHQBjkcZlRi_96XlBe3oziTCKIYMQaApjCEALw_wcB, (accessed 12 April 2022).
4. K. A. Fleming, S. Horton, M. L. Wilson, R. Atun, K. Destigter, J. Flanigan, S. Sayed, P. Adam, B. Aguilar, S. Andronikou, C. Boehme, W. Cherniak, A. N. Cheung, B. Dahn, L. Donoso-Bach, T. Douglas, P. Garcia, S. Hussain, H. S. Iyer, M. Kohli, A. B. Labrique, L.-M. Looi, J. G. Meara, J. Nkengasong, M. Pai, K.-L. Pool, K. Ramaiya, L. Schroeder, D. Shah, R. Sullivan, B.-S. Tan and K. Walia, Lancet, 2021, **398**, 1997–2050
5. Y. Chartier, J. Emmanuel, U. Pieper, A. Prüss, P. Rushbrook, R. Stringer, W. Townend, S. Wilburn and R. Zghondi, Safe management of wastes from health-care activities, 2nd edn, 2014
6. Street, E. Vernooij and M. H. Rogers, Glob. Health, 2022, **18**, 1–7
7. J. M. Chisholm, R. Zamani, A. M. Negm, N. Said, M. M. Abdel Daiem, M. Dibaj and M. Akrami, Waste Manage. Res., 2021, **39**, 1149–1163
8. World Health Organization and The United Nations Children's Fund, WASH in health care facilities: Global Baseline Report, 2019
9. S. F. Hayleeyesus and W. Cherinete, J. Health Pollut., 2016, **6**, 64–73
10. Safe management of wastes from health-care activities, World Health Organization, 2ndedn,2014
11. C. O. Odhiambo, A. Mataka, G. Kassa and P. Ondoa, J. Hazard. Mater. Lett., 2021, **2**, 100030
12. M. Tothill, M. Partridge, S. W. James and R. P. Tatam, J. Micromech. Microeng., 2017, **27**, 035018
13. E. Ongaro, I. Keraite, A. Liga, G. Conoscenti, S. Coles, H. Schulze, T. T. Bachmann, K. Parvez, C. Casiraghi, N. Howarth, V. La Carubba and M. Kersaudy-Kerhoas, ACS Sustainable Chem. Eng., 2018, **6**(4), 4899–4908
14. V. Romanov, R. Samuel, M. Chaharlang, A. R. Jafek, A. Frost and B. K. Gale, Anal. Chem., 2018, **90**, 10450
15. L. P. Bressan, C. B. Adamo, R. F. Quero, D. P. De Jesus and J. A. F. Da Silva, Anal. Methods, 2019, **11**, 1014–1020
16. G. Gaál, T. A. da Silva, V. Gaál, R. C. Hensel, L. R. Amaral, V. Rodrigues and A. Riul, Front. Chem., 2018, **6**, 151
17. S. Ghoshal, M. A. Khan, R. A. Khan, F. Gul-E-Noor and A. M. S. Chowdhury, J. Polym. Environ., 2010, **18**, 216–223
18. T. Lin, C. Lu, L. Zhu and T. Lu, AAPS PharmSciTech, 2011, **12**, 172
19. M. A. Elsawy, K. H. Kim, J. W. Park and A. Deep, Renewable Sustainable Energy Rev., 2017, **79**, 1346–1352
20. J. G. Rosenboom, R. Langer and G. Traverso, Nat. Rev. Mater., 2022, **7**, 117–137
21. Gaberščik, S. Mitchell and A. Fayne, Smart Innov. Syst. Technol., 2021, vol. 200, pp. 205–214