Scalable Urine Test for Microplastics and Nanoplastics: Development Progress, Regulatory Strategy, and Planned Observational Study

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Abstract Microplastics and nanoplastics (MPs/NPs) have been increasingly reported in human biological systems, yet scalable routine monitoring tools remain limited. Current approaches rely largely on specialized laboratory workflows that are expensive, slow, contamination-sensitive, and not designed for repeat home use. This paper outlines progress toward a smartphone-based urine assay intended for environmental exposure awareness and longitudinal wellness monitoring. The program includes prototype development, regulatory planning through FDA Pre-Submission engagement (Q-Sub submitted), and a planned observational study beginning in late summer or fall 2026. The broader goal is to make routine exposure measurement more accessible, practical, and scalable.

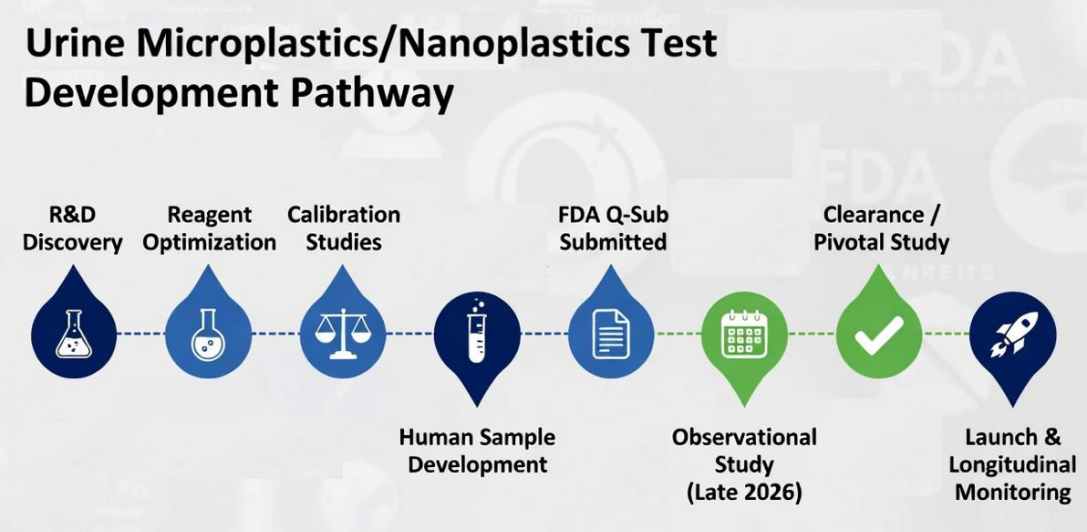


Figure 1. Proposed Development Pathway for a Scalable Urine Microplastics/Nanoplastics Test Platform. Schematic roadmap illustrating progression from early discovery through translational development and potential commercialization. Initial phases include assay R&D, reagent optimization, calibration studies, and human sample feasibility development. These steps are followed by regulatory engagement through FDA Pre-Submission (Q-Sub), a planned observational study to evaluate decentralized real-world use, and subsequent clearance/pivotal studies if pursued. The final stage envisions launch with longitudinal monitoring capabilities to enable repeat environmental exposure assessment over time.

1. Introduction

Many important health metrics became actionable only after testing moved beyond specialized laboratories into routine workflows. Examples include home pregnancy tests, glucose monitoring, ovulation tests, urine dipsticks, and at-home infectious disease testing during and after COVID-19. These tools did not eliminate laboratories, but they expanded access,

convenience, and frequency of measurement. A similar opportunity may exist for environmental exposure monitoring.

2. Evidence of Microplastics and Nanoplastics in Human Urine

Microplastics and nanoplastics have now been detected in multiple human tissues and fluids, including blood, placenta, brain, and arterial plaques. More recently, a small but growing body of research has identified MNPs in human urine, suggesting that renal filtration may play a role in their elimination or redistribution.

Key early studies include:

- Pironti et al. (2023) provided the first published evidence using Raman microspectroscopy, detecting microplastics (primarily PVA, PVC, PP, and PE) in 4 out of 6 urine samples from healthy volunteers.
- Rotchell et al. (2024) analyzed 38 urine samples from healthy donors and endometriosis patients using μFTIR spectroscopy, identifying multiple polymer types while highlighting important contamination control challenges.
- Song et al. (2024) examined 12 urine samples from urban and rural Chongqing using both Py-GC/MS and LDIR, finding significantly higher levels and polymer diversity in urban participants.
- Ji et al. (2025) quantified MNPs (≥300 nm) in 18 urine samples using double-shot Py-GC/MS with internal standard calibration, reporting an average concentration of approximately 0.27 μg/mL.

A 2025 scoping review by O'Callaghan et al. synthesized available evidence and noted MNPs in roughly 54% of urine samples across studies.

Table 1. Summary of Representative Human Urine MNP Studies

Author / Year	n (Urine Samples)	Key Contribution
Pironti et al. (2023)	6	First published evidence of MPs in human urine
Barnett et al. (2023)	9	Snapshot study using FTIR / Raman
Massardo et al. (2024)	10	Urine + kidney tissue; strong contamination controls
Rotchell et al. (2024)	38	Largest early cohort; healthy vs. endometriosis comparison
Song et al. (2024)	12	Urban vs. rural exposure comparison
Ji et al. (2025)	18	Quantitative mass concentration via Py-GC/MS

These studies provide important foundational evidence. However, they remain limited by small sample sizes, predominantly cross-sectional designs, and reliance on centralized laboratory methods that are difficult to scale for repeated or population-level monitoring.

3. Why Urine Is a Practical Matrix

Urine offers several practical advantages for scalable monitoring:

- Non-invasive collection
- Familiar sampling process for participants
- Suitable for repeated weekly, monthly, or longitudinal testing
- Compatible with home, clinic, workplace, and research settings

- Lower logistical burden than many invasive sampling approaches
- Potential utility for population surveillance and intervention studies

These characteristics make urine especially attractive for understanding exposure dynamics over time rather than relying solely on single timepoint snapshots.

4. Why Lab-Based Methods Do Not Scale Easily

Existing laboratory methods face barriers for routine consumer or population-scale use:

- Specialized labs and specialized instrumentation (costing $500,000 or $1 million+ all together)
- Send-out logistics
- Contamination control complexity (potential plastic contamination at almost every step)
- Higher cost per test (at least thousands)
- Long turnaround times (3 days to weeks)
- Limited throughput
- Sparse access in many regions

These limitations make monthly or repeated household monitoring difficult.

Because of these constraints, practical routine or population-scale monitoring of microplastics/nanoplastics in urine has remained out of reach. Scalable new methods are therefore urgently needed to track human exposures regularly and explore their potential links to disease. This is the challenge the EcoExposure urine test was designed to solve.

5. Internal Human Urine Data Supports Advancement of the Program

The current development program is supported by prior internal wet-lab studies already performed in human urine matrices. In these experiments, spiked human urine samples were evaluated across a range of microplastic and nanoplastic conditions using standardized optical imaging and computational analysis. Although many samples appeared visually similar to the naked eye, reproducible differences in optical structure were observed, including changes in spatial heterogeneity, aggregation behavior, and temporal evolution. These findings provided early evidence that meaningful particulate-associated signals could be generated and interpreted in real urine samples rather than only in environmental water systems.

Additional internal observations strengthened the rationale for continued development. Nanoplastic-associated conditions demonstrated earlier and more pronounced spatial organization at comparable low concentrations, consistent with surface-area–dependent interaction behavior. Control conditions and reduced-particulate samples showed improved clarity, yet structured signatures associated with particle presence persisted, supporting that the observed outputs were not simply caused by nonspecific biological background noise. Results were also consistent across experiments conducted over an extended development period, supporting reproducibility of the core signal framework.

These internal data are the primary reason the program is continuing through further R&D, regulatory planning, and preparation for larger observational studies. The platform therefore

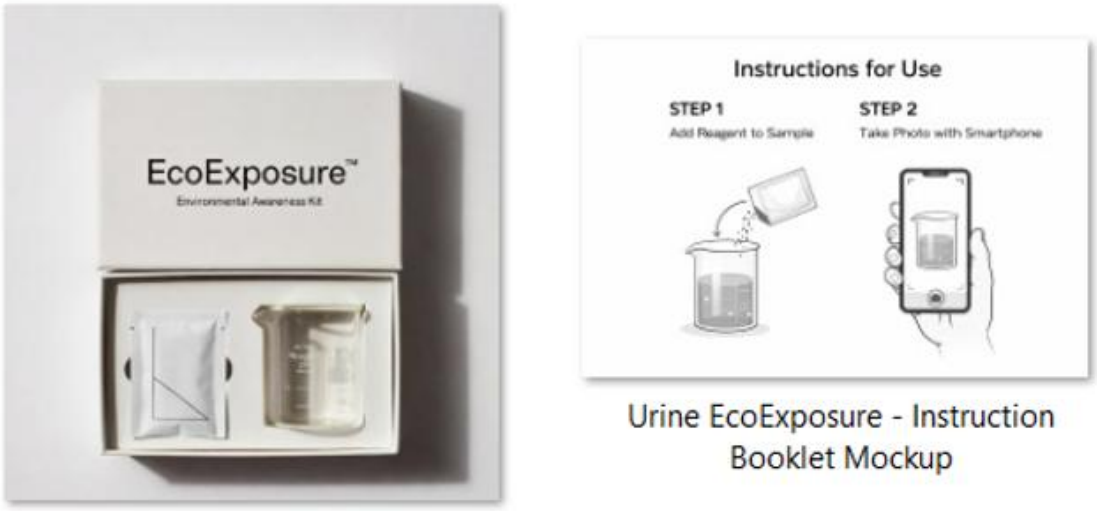
advances from real urine-matrix experimental evidence already generated in the laboratory, rather than from concept alone. Importantly, these findings should be viewed as developmental proof-of-concept rather than final validation; broader analytical studies and prospective evaluations remain planned.

6. Product Concept

The proposed workflow is intentionally simple:
Collect Sample → Add Reagent → Capture Image → Analyze

The platform uses smartphone imaging / digital camera imaging and computational interpretation of optical interaction patterns rather than requiring traditional laboratory instrumentation in the home. The intended early use case is environmental exposure awareness and trend monitoring, not disease diagnosis.

Figure 2. Conceptual Consumer Kit and Simplified Instructions for Use for a Scalable Urine Microplastics/Nanoplastics Test. Representative mock-up of the EcoExposure™ Urine Environmental Awareness Kit (left) and accompanying quick-start instruction booklet (right). The design emphasizes a low-friction workflow consisting of sample collection, single-step reagent addition, and smartphone image capture. Simple packaging and intuitive instructions illustrate how environmental exposure monitoring tools may be translated from laboratory concepts into practical home, clinic, field, or public-health deployment formats.



6A. Importance of Larger Sample Volumes in Urine: A Poisson Sampling Perspective

Urine MNP concentrations are typically low and highly variable between individuals and even within the same person over time. Because particles are sparsely and randomly distributed, detection in small sample volumes is governed by Poisson statistics. In such regimes, the probability of capturing zero particles (a false negative) remains high unless the sampled volume is large enough to yield a meaningful expected particle count (λ). The use of a standard glass beaker providing a larger intact sample volume directly addresses this statistical reality: it increases λ, substantially reduces the chance of missing particles, and improves detection

reliability without requiring complex concentration steps or laboratory equipment. This volume-aware approach is especially important for decentralized, at-home testing where a single small aliquot could easily produce misleading “non-detect” results.

7. Similarity to Existing Consumer and Point-of-Care Testing Trends

Consumers are already comfortable using home and app-connected health tools. Examples include urine dipstick readers, fertility monitoring systems, kidney health home tests, CGMs, wellness biomarker platforms, and telehealth-enabled diagnostics. The proposed urine MPs/NPs workflow fits within the broader trend toward decentralized measurement and digital health participation.

8. Comparison to Existing At-Home Urine Testing Platforms

Several commercial platforms already demonstrate public acceptance of smartphone-connected urine analysis for wellness tracking.

Table 2. Selected At-Home Urine Testing Platforms (No Sample Mailing Required)

Platform	Primary Parameters Measured	FDA Status	Intended Use Category	Time to Result	Relevance to MNP Monitoring
Healthy.io (Minuteful Kidney / Dip.io)	Albumin, creatinine, ACR	510(k) cleared (Class II)	Prescription diagnostic aid (kidney health)	Minutes	Strongest regulatory precedent for smartphone-based urine analysis
Vivoo	Hydration, pH, ketones, sodium, vitamin C, etc.	Wellness / not cleared for diagnosis	General wellness / lifestyle tracking	~90 seconds	Demonstrates consumer comfort with app-connected urine testing
Urinify	Leukocytes, nitrite, pH (UTI indicators)	Wellness / informational only	Symptom tracking	<2 minutes	Shows acceptance of rapid at-home dipstick + app workflows
Withings U-Scan (Nutrio / Calci)	Nutritional/metabolic markers, hydration, calcium	Marketed as wellness (no diagnostic clearance for urine cartridges)	Consumer wellness / preventive health	Automatic (toilet-installed)	Illustrates passive, continuous monitoring models

The proposed EcoExposure™ urine MNP assay builds on this established category while addressing a new environmental exposure domain.

9. Regulatory Progress
A Pre-Submission (Q-Sub) has been submitted to obtain FDA feedback regarding classification, intended use framing, analytical validation expectations, decentralized home-use considerations, software/algorithm documentation, and future study design considerations. Early engagement is intended to clarify the most appropriate pathway as development continues.

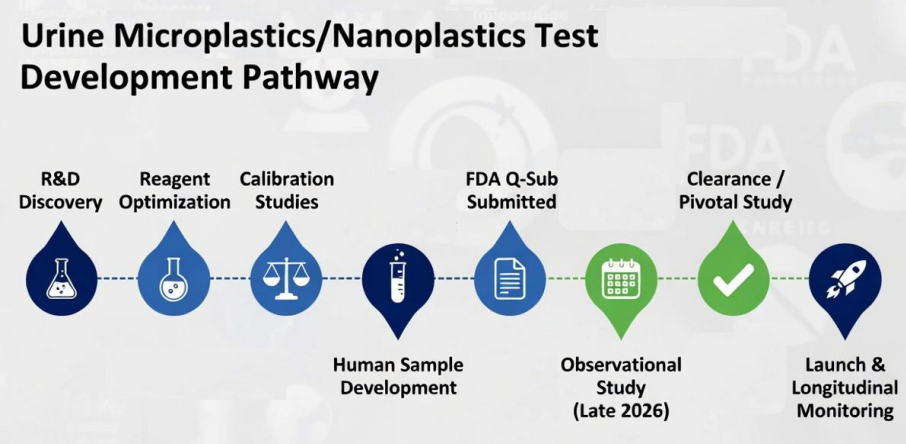
10. Wellness Positioning and Responsible Use
At the current stage, the goal is not to assign specific disease risk from any single result. Instead, the early value proposition is awareness of environmental exposure, repeat monitoring over time, understanding personal variation, identifying changes in patterns, and enabling future research datasets. This distinction is important because measurement can be useful even before every clinical implication is fully known.

11. Planned Observational Study (Late Summer / Fall 2026)
A planned observational study is expected to explore feasibility of repeated urine monitoring in real users. Potential goals include baseline variation between individuals, month-to-month variability, usability of home workflows, image quality in decentralized settings, participant engagement, and generation of longitudinal datasets. This type of real-world evidence may be more informative than isolated one-time snapshots.

12. Intended Use Is Not Limited to At-Home Testing; Clinics, Research, Public Health
Although decentralized home testing is an important long-term advantage of scalable urinary monitoring, the platform is not limited to consumer at-home use. The same core workflow may also be deployed in physician offices, occupational health programs, public health screening sites, wellness centers, research studies, and laboratory or near-patient environments.

This flexibility is important strategically and operationally. In some settings, supervised on-site testing may be preferred for workflow control, quality assurance, or pilot implementation. In other settings, home collection may improve convenience, participation, geographic reach, and cost efficiency. Accordingly, the value of the platform is not tied to one setting, but to the ability to support multiple deployment models using a common scalable framework.

For the planned observational study, home-based participation is being considered primarily because it lowers participant burden, reduces logistics costs, and enables broader real-world enrollment. However, future regulated or research-use implementations may include clinic-based or supervised workflows where appropriate.



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13. Parallel R&D Benefits for Future Blood Testing

Development of a urine-based platform may also accelerate future blood-based testing because many core scientific and engineering challenges overlap across biological matrices. Although urine and blood differ substantially in composition, both programs can benefit from shared advances in reagent optimization, optical signal generation, contamination control, image analysis, calibration strategy, software infrastructure, and decentralized user workflows.

14. Why Timing Matters

Evidence regarding human exposure to MPs/NPs continues to grow, alongside ongoing discussion of possible links to inflammation, cardiovascular disease, fertility concerns, metabolic dysfunction, gastrointestinal disorders, neurobiology, and cancer-related pathways. Important uncertainties remain, but waiting for perfect certainty before building measurement tools may slow progress. Scalable exposure monitoring can begin while the science continues to mature.

15. Future Vision

Over time, environmental exposure monitoring could evolve into personal longitudinal dashboards, research registries, population exposure maps, integration with lifestyle data, targeted follow-up studies, and preventive health frameworks. The first step is simply making measurement practical.

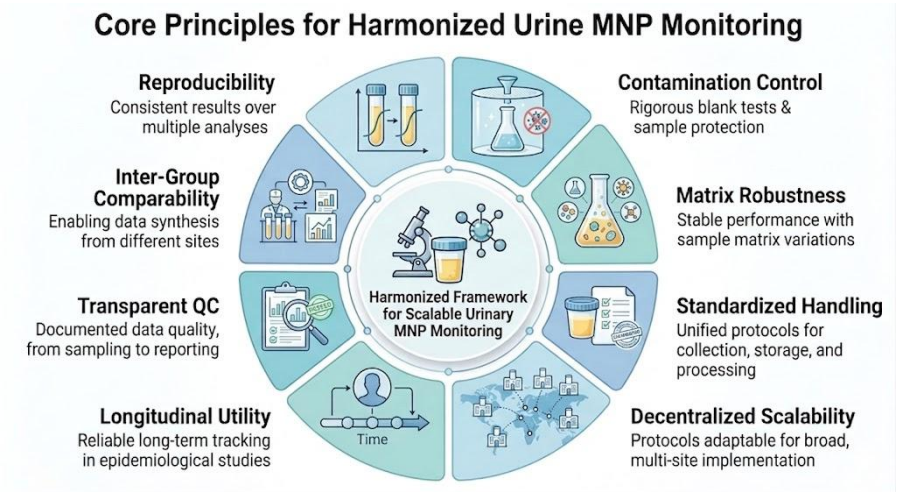
16. Need for Shared Standards Across Methods

As urinary microplastic and nanoplastic testing evolves, progress will depend not only on new technologies but also on shared quality expectations across different methods. A recently proposed harmonized framework emphasizes technology-agnostic principles such as

reproducibility, standardized sample handling, contamination control, matrix robustness, calibration rigor, transparent quality systems, and longitudinal utility. The goal is not to force one analytical method, but to create common standards by which multiple approaches can be fairly evaluated.

Such a framework may be especially valuable for translational and regulatory pathways. Clear expectations around controls, documentation, workflow consistency, software versioning, reporting conventions, and fit-for-purpose validation can reduce ambiguity for developers and reviewers alike. As consumer, wellness, research-use, and potential clinical applications emerge, harmonized principles may help accelerate responsible innovation while preserving scientific rigor.

Figure 3. Core principles for a harmonized framework for scalable, reproducible, and decentralized microplastic and nanoplastic (MNP) monitoring in human urine. The circular diagram centers on a technology-agnostic approach and highlights eight essential requirements: reproducibility, contamination control, matrix robustness, standardized handling, decentralized scalability, longitudinal utility, transparent quality control, and inter-group comparability. This framework is designed to support consistent data quality across laboratory, field-deployable, and at-home methods such as the EcoExposure™ platform.



17. Conclusion

Home and point-of-care testing transformed many other areas of health monitoring. Environmental exposure measurement may be next. A scalable urine test for microplastics and nanoplastics could help move the field from rare research laboratory snapshots to routine, real-world understanding of human exposure. If exposure matters, measurement should not remain limited to specialized laboratories alone.

Representative References

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