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Biomarker-Based Linkages between Infection and Oncology for Translational Decision Support

[1] Kazeem Abdulrazaq, [2] Habeeb Damilola Yusuf, [3] Sylviastella Favour Peteranaba, [4] Helen Ekwi Osinem, [5] Florence Eribenne

[1] Department of Public Health Sciences, New Mexico State University, Las Cruces, New Mexico, United States of America
[2] University of Ilorin Teaching Hospital, Ilorin, Nigeria
[3] Independent Researcher, Nigeria
[4] Department of Nursing Services, Jos University Teaching Hospital (JUTH), Jos, Nigeria
[5] Bay Cove Human Services, Boston, MA, United States of America

Corresponding Author: **Kazeem Abdulrazaq, Habeeb Damilola Yusuf**

Abstract

Infectious disease and oncology maintain separate biomarker ecosystems and separate decision-support tools, yet they increasingly share molecular substrates, analytical platforms, diagnostic problems, and causal biology. This narrative review examines developments connecting the two fields: Host-response protein signatures moving into deployed use, plasma cell-free DNA emerging as a shared substrate as microbial sequencing entered formal diagnostic criteria while tumour-derived sequencing entered adjuvant treatment decisions, circulating viral tumour DNA functioning simultaneously as an infection and a cancer marker, and a published critique of reproducibility in the cancer microbiome literature. These are considered alongside evidence on diagnostic infrastructure, data governance, model oversight, health system financing and workforce capability, supply integrity, and population surveillance, which prior reviews have treated separately. Read together, they identify an integration that is technically available but unimplemented, since the same plasma specimen can yield both microbial and tumour-derived results that are nonetheless generated and interpreted in isolation. The constraints are evidentiary, infrastructural, and governance-related rather than analytical.

Keywords: Host Response Biomarkers, Circulating Tumour DNA, Microbial Cell-free DNA, Molecular Residual Disease, Clinical Decision Support, Antimicrobial Stewardship, Diagnostic Infrastructure, Health Data Governance

1. Introduction

A clinician assessing a febrile patient with a haematological malignancy must answer several questions simultaneously. Is the fever infectious, and if so is the organism bacterial, viral, or fungal? Is it instead attributable to the tumour or to the therapy directed against it? Should antimicrobials be started, continued, or withdrawn? Should immunosuppression be added or reduced? These questions belong nominally to different specialties, yet they arise from one patient at one moment and are answered from one blood draw.

Biomarker development has not been organised accordingly. Infection biomarkers developed within microbiology and critical care, oriented toward triage, antimicrobial stewardship, and mortality prediction. Cancer biomarkers developed within pathology and medical oncology, oriented toward diagnosis, prognosis, treatment selection, and surveillance. The two literatures cite one another rarely, the two laboratory workflows rarely share specimens, and the two families of decision-support tools rarely share an interface. Reviews of diagnostic integration across microbiology, virology, and serology workflows reach a similar conclusion from the infection side, identifying workflow fragmentation rather than assay performance as the binding constraint on diagnostic yield (Asiedu, 2023).

Four considerations make this separation increasingly difficult to sustain. First, a substantial minority of cancers worldwide are attributable to infectious agents, principally *Helicobacter pylori*, human papillomavirus (HPV), hepatitis B and C viruses, and Epstein-Barr virus, with estimates placing the infection-attributable fraction near 13% of global incidence and the burden

concentrated in low- and middle-income regions (de Martel *et al*., 2020). Second, plasma cell-free DNA contains fragments of both human tumour origin and microbial origin in the same tube, so distinguishing them is a bioinformatic rather than a pre-analytical decision. Third, contemporary cancer therapy produces inflammatory syndromes that phenocopy sepsis, including cytokine release syndrome after chimeric antigen receptor (CAR) T-cell therapy and immune-related adverse events after checkpoint blockade, in patients who are concurrently at elevated infection risk. Fourth, the same sequencing platforms, multiplex immunoassay analysers, and machine-learning pipelines now serve both domains.

A less frequently stated fifth consideration follows directly from the first four: Translation is not solely a laboratory matter. A conceptual model developed in health systems research argues that scientific innovation fails to improve patient outcomes in the absence of effective healthcare delivery infrastructure (Ilodigwe & Adesemoye, 2019b), and empirical work on large laboratory networks treats healthcare infrastructure as a public health intervention rather than as a passive container for clinical activity (Aminu-Ibrahim & Ogbete, 2023). Work on biomarker-based risk stratification in Sub-Saharan Africa makes the same point clinically, where composite indices assembled from routinely available measurements have been proposed precisely because they do not require infrastructure that is unavailable (Okwah, 2022).

Existing reviews address the biomarker evidence and the delivery evidence in isolation. The present review considers them jointly. Doing so brings into view a linkage that current systems do not yet operationalise, and it locates the obstacles to realising it in literatures that biomarker validation studies seldom cite. The aim is to describe recent developments and to specify what would be required to convert these linkages into decision support usable at the bedside.

2. Methods

Literature was identified from indexed bibliographic sources, with emphasis for the biomarker evidence on recent primary studies and guideline revisions, supplemented by a broader implementation literature covering diagnostic infrastructure, health informatics, data governance, regulatory science, pharmaceutical supply, and clinical service delivery. Prospective clinical cohorts, real-world implementation studies, formal guideline revisions, and methodological critiques bearing on reproducibility were prioritised. Commercial assay claims were included only where supported by peer-reviewed primary data and are identified as such. This is a narrative review; no formal quality scoring or meta-analysis was performed, and the synthesis is interpretive.

The principal developments examined are summarised below.

Area	Clinical question	Development examined
Virus-driven malignancy	Did an infection cause this cancer?	Circulating viral tumour DNA in HPV-driven oropharyngeal carcinoma
Shared substrate	Can one specimen serve both fields?	Microbial cell-free DNA sequencing in diagnostic criteria
Therapy-related inflammation	Is this fever infection or treatment effect?	Procalcitonin and cytokine profiling after CAR T-cell therapy
Microbial modifiers	Does microbial context alter treatment effect?	Reproducibility critique in the tumour microbiome literature

3. Biomarker Linkages Between Infection and Oncology

3.1 Circulating Viral Tumour DNA in Virus-Driven Malignancy

In HPV-associated oropharyngeal squamous cell carcinoma, tumour cells shed fragmented viral DNA into plasma. That DNA is viral in sequence and tumour-derived in origin. It therefore functions as an infection biomarker and a cancer biomarker at once, and clinically it behaves as the latter. The assay with the largest accumulated evidence base detects tumour tissue modified viral (TTMV) HPV DNA, representing circulating fragmented post-apoptotic tumour-associated HPV DNA rather than free viral genome from productive infection. That distinction is what allows the marker to track tumour burden rather than carriage.

Recent reports have strengthened the surveillance case. A retrospective observational cohort of 543 patients across eight United States cancer centres, all of whom had completed curative-intent therapy for HPV-associated oropharyngeal carcinoma between February 2020 and January 2022, evaluated the negative predictive value of TTMV-HPV DNA during post-treatment surveillance (Hanna *et al*., 2023). This extended earlier work reporting high positive predictive value for two consecutively positive results, with a median lead time of several months to biopsy-proven recurrence (Berger *et al*., 2022; Chera *et al*., 2020). Liquid biopsy performance for both diagnosis and surveillance in the same disease has been assessed separately (Ferrandino *et al*., 2023), with additional surveillance data reported alongside it (Kuhs *et al*., 2023) and an accompanying analysis of the economics of substituting or supplementing imaging-based surveillance (Lin *et al*., 2023).

The interpretive challenge is quantitative. Where an oncogenic virus is present both in tumour cells and, at lower copy number, in non-malignant tissue or as latent carriage, usefulness depends on threshold placement rather than on detection. The broader lesson from diagnostic integration research is that assay-level accuracy is necessary but not sufficient, because the interpretive framework surrounding a quantitative result determines whether it alters management (Asiedu, 2023).

Three claims are supported with reasonable confidence: The marker has high negative predictive value in surveillance, two consecutive positive results carry high positive predictive value, and clearance kinetics during chemoradiation are prognostic. It is not established that acting on the marker improves survival. Surveillance biomarkers are vulnerable to lead-time bias, and detection of recurrence several months earlier improves outcomes only where an effective earlier intervention exists. National guideline bodies have not incorporated the marker into standard surveillance algorithms. The gap between analytical maturity and guideline endorsement recurs throughout this review and corresponds to the gap identified in health systems research between innovation and delivery (Ilodigwe & Adesemoye, 2019b).

Etiologic linkage also operates at population scale, where the relevant markers are those of exposure and pathogen circulation rather than of tumour burden. Integration of artificial intelligence with biosensors for rapid detection of antimicrobial-resistant foodborne organisms illustrates the detection layer of such surveillance (Olorunkosebi *et al*., 2023). Exposure surveillance in the feed and food chain is directly pertinent, since aflatoxin B1 is an established hepatocarcinogen and contamination is measured at the point of animal feed rather than at the point of human consumption; quantification of aflatoxin in commercially available poultry feeds demonstrates the measurement problem in the setting where the exposure originates (Tawose *et al*., 2023). Related work characterising physiological and stress indicators in scavenging poultry populations (Oluwadele *et al*., 2023), phenotypic characterisation of indigenous flocks (Ekeocha *et al*., 2021), and the physiological consequences of specific feed compositions (Aye & Tawose, 2015; Aye & Tawose, 2016) describes the production systems within which such exposures are generated and would need to be monitored. These literatures bear on oncology because the infection- and exposure-attributable cancer burden is generated upstream, years or decades before malignancy. The oncology endpoint is concrete rather than diffuse: Human exposure biomonitoring for aflatoxin typically relies on aflatoxin-albumin adducts or urinary metabolites as individual-dose biomarkers, and aflatoxin B1 is a recognised co-factor with chronic hepatitis B infection in the causation of hepatocellular carcinoma, the same malignancy for which viral integration signatures are discussed below as a circulating biomarker. Exposure surveillance in the feed chain and molecular surveillance of established hepatitis B infection therefore address different points on one causal pathway toward the same cancer.

The design principle generalises, though the underlying molecular event is not identical across pathogens. Where an oncogenic virus is clonally present in tumour cells and absent or quantitatively distinct in non-malignant tissue, its circulating DNA becomes a high-specificity tumour marker, as with plasma Epstein-Barr virus DNA in nasopharyngeal carcinoma. That instance, like TTMV-HPV DNA above, reflects circulating episomal viral DNA shed from clonal tumour cells and quantified as viral load or fragment burden. Hepatitis B integration signatures in hepatocellular carcinoma instantiate a mechanistically distinct version of the same principle: The marker there is not free episomal viral DNA but a host-genome integration junction created when the virus inserts into the tumour cell genome, so detection depends on junction-spanning sequencing rather than on viral-load quantification. The rate-limiting step for the episomal-DNA markers is establishing the threshold separating carriage from malignancy; for integration-junction markers it is instead identifying and validating recurrent, tumour-specific junction sites.

3.2 Plasma Cell-Free DNA as a Substrate Shared by Both Fields

Plasma cell-free DNA contains human and microbial fragments. Oncology uses the former, infectious disease the latter. Until recently these were separate tests on separate specimens sent to separate laboratories.

Shotgun metagenomic sequencing of plasma microbial cell-free DNA has moved from novelty to qualified acceptance. The most consequential development is regulatory rather than technical: The 2023 revision of the Duke criteria for infective endocarditis, produced with the International Society for Cardiovascular Infectious Diseases, incorporates pathogen detection by metagenomic sequencing into its microbiologic criteria (Fowler *et al*., 2023). A classification system that had rested on blood culture for decades formally admits sequence-based evidence.

The limiting property of these assays is not sensitivity but the capacity to distinguish a detected organism that explains the syndrome from one that is transient, colonising, or contaminating. Detections of uncertain significance are common, and diagnostic stewardship at institutions offering the assay has tended to tighten over time, moving from unrestricted ordering toward mandatory specialist review. Investigators have responded by framing the question as which trial is actually needed and proposing a randomised controlled design for plasma metagenomic sequencing in patients with haematological malignancy and febrile neutropenia (Hogan *et al*., 2023), which is the population situated precisely at the infection and oncology intersection.

In parallel, and using the same specimen type, tumour-informed circulating tumour DNA (ctDNA) assays have established molecular residual disease as a decision variable in early-stage solid tumours. The GALAXY observational arm of the CIRCULATE-Japan platform reported on 1,039 patients with stage II to IV resectable colorectal cancer (Kotani *et al*., 2023). Post-surgical ctDNA positivity at four weeks was associated with substantially higher recurrence risk (hazard ratio 10.0), was the strongest prognostic factor in stage II and III disease (hazard ratio 10.82), and identified the subgroup deriving benefit from adjuvant chemotherapy (hazard ratio 6.59). The design logic for molecular residual disease-guided adjuvant treatment has been described separately (Sato *et al*., 2023).

The observation that follows is straightforward but consequential. The same plasma specimen can in principle be interrogated for both microbial and tumour-derived cell-free DNA, yet in practice it almost never is. The two assays are ordered by different services, run in different laboratories, reported into different sections of the record, and interpreted without reference to each other. For a neutropenic patient with resected colorectal cancer and unexplained fever, both answers are relevant at once. A combined report stating that no explanatory pathogen was detected above threshold while molecular residual disease was detected with rising tumour fraction describes a clinical situation entirely different from the same fever accompanied by a detected *Escherichia coli* signal and undetectable

ctDNA. No deployed system produces that combined report. The obstacle is informatic and financial rather than scientific, and adjacent diagnostic domains offer precedent: Automated detection algorithms applied to imaging data demonstrated decades ago that the constraint on computational diagnostic support is rarely the algorithm and usually the integration pathway (Ejofodomi *et al*., 2014).

3.3 Pre-Analytical and Laboratory Process Determinants of Assay Performance

Both assay families are unusually sensitive to pre-analytical conditions. Cell-free DNA is low in abundance, fragmented, and vulnerable to genomic DNA contamination from leukocyte lysis. Time to centrifugation, tube chemistry, temperature, and transport handling materially affect results, which makes the shared substrate as much a logistics problem as an analytical one. The underlying mechanism is general laboratory-medicine knowledge rather than assay-specific: Standard collection tubes do not arrest leukocyte metabolism, so when plasma separation is delayed, leukocytes progressively lyse and release high-molecular-weight genomic DNA that dilutes, and can swamp, the comparatively small fraction of cell-free fragments actually shed by tumour or pathogen. This is the rationale both for prompt centrifugation when standard anticoagulant tubes are used and for the alternative of drawing into specialised cell-stabilising tubes that chemically preserve leukocyte integrity and tolerate a longer interval before processing. Because this contamination manifests as a silent dilution of signal rather than an overt assay failure, pre-analytical deviation is generally undetectable from the sequencing or immunoassay output alone, which is why process controls of the kind described below are a design requirement rather than an operational preference.

Design work on scalable blood collection networks addresses the upstream segment of this chain, where specimen quality is determined before the sample reaches any instrument (Ogbete *et al*., 2022). Laboratory spatial planning bears simultaneously on diagnostic accuracy, safety, and clinical throughput, which is relevant because throughput pressure is a common cause of pre-analytical deviation (Ogbete *et al*., 2018). For molecular assays, contamination control is a facility design question as much as a protocol question, and regulatory-compliant design systems for molecular and pathology laboratories in highly controlled environments address unidirectional workflow, air handling, and physical separation of amplification from extraction (Ogbete *et al*., 2019). Laboratory designs developed for pandemic preparedness provide a template for surge-capable molecular testing that is directly transferable to metagenomic sequencing workloads (Aminu-Ibrahim *et al*., 2022).

Variability within a compliant facility is a process problem, and the operations literature supplies the relevant methods. Standard operating procedures have been characterised as strategic assets rather than documentation overhead, which is the appropriate framing for pre-analytical protocols whose deviation is invisible in the final result (Eyetsemitan *et al*., 2022). Structured process optimisation approaches have been applied to cycle time and defect reduction in operational settings (Ezeugwa *et al*., 2023a; Oyeleye *et al*., 2022), and adaptations of these methods for smaller organisations are pertinent to laboratories lacking dedicated quality engineering capacity (Ambali *et al*., 2021). Translating regulatory requirements into executable workflows is itself a design task (Eyetsemitan *et al*., 2021), as is the governance alignment required when specimen collection, transport, and analysis sit with different organisations (Eyetsemitan *et al*., 2020). Structured validation before deployment (Eyetsemitan *et al*., 2023b) and managed change during transition to a new assay or platform (Eyetsemitan *et al*., 2023a) determine whether a validated method survives contact with routine operation. An assay validated in a reference laboratory and deployed into a facility with different air handling, specimen transport times, and power stability is not the same assay; analytical validity is a property of the assay in its setting.

3.4 Discriminating Infection From Therapy-Related Inflammation

Distinguishing bacterial infection from non-bacterial inflammation is among the oldest unresolved problems in acute care, and it is harder in oncology, where the differential includes tumour fever, chemotherapy effects, cytokine release syndrome, immune-related adverse events, engraftment syndrome, and transfusion reactions, in patients whose capacity to mount conventional inflammatory responses is pharmacologically suppressed.

The most mature entrant is a three-protein signature integrating TNF-related apoptosis-inducing ligand (TRAIL), interferon-gamma induced protein 10 (IP-10, also designated CXCL10), and C-reactive protein, computationally combined into a single score with defined interpretive bands: Low scores indicating viral or other non-bacterial aetiology, an intermediate equivocal band, and high scores indicating bacterial infection or co-infection (Stas *et al*., 2022). The biological logic explains both the strengths and the failure modes. TRAIL and IP-10 are interferon-pathway-associated and rise preferentially in viral infection, whereas C-reactive protein is a general acute-phase reactant that rises more steeply in bacterial infection. Combining an up-regulated viral axis with an up-regulated bacterial axis yields better discrimination than either alone, because the score reads the shape of the host response rather than its magnitude.

This signature is supported by multiple independent validation efforts spanning emergency department and urgent-care settings. A recent review situated host-response biomarkers within emergency department sepsis assessment and observed that of the hundreds of biomarkers evaluated for infection and sepsis diagnosis, only a handful see large-scale clinical use (Turgman *et al*., 2023). Real-world evidence from urgent care settings examined the effect of the test on patient management (Tsalik *et al*., 2023). Sepsis-specific sub-analyses assessed performance against expert panel adjudication in patients meeting systemic inflammatory response syndrome criteria (Stas *et al*., 2022), within the framework established by consensus sepsis definitions (Singer *et al*., 2016). The assay's stated limitations include unreliability in chronic infections and inflammatory conditions, and performance has been examined in *Mycoplasma pneumoniae* community-acquired pneumonia, an atypical bacterial pathogen where an interferon-skewed host response might be expected to mislead a bacterial-versus-viral classifier (Papan *et al*., 2023).

Translation stalls in the immunocompromised host. Host-response signatures are trained and validated predominantly

in immunocompetent emergency department populations, whereas the neutropenic, lymphodepleted, or steroid-exposed patient is a different biological system in which the interferon axis, the acute-phase response, and the cellular effectors generating the measured signal are all perturbed by cancer therapy. Calibration cannot be assumed to transfer, since a given score may carry different post-test probabilities in an immunocompetent adult and in a patient five days after lymphodepleting chemotherapy, and the equivocal band is likely to widen in exactly the population where the decision is hardest.

CAR T-cell therapy presents a particularly difficult version of the problem. Cytokine release syndrome is driven by excessive cytokine release, predominantly interleukin-6, and is treated with interleukin-6 receptor blockade and corticosteroids, whereas sepsis results from a dysregulated response to infection and requires antimicrobials. The syndromes share fever, hypotension, and multi-organ dysfunction, and the treatments are close to opposites, since immunosuppression may worsen untreated sepsis while antimicrobials in pure cytokine release syndrome add resistance pressure without benefit. Clinicians consequently treat both empirically. Cytokine-profiling work in critically ill children identified 23 cytokines differing significantly between the two conditions and found that markedly elevated interferon-gamma, or mildly elevated interferon-gamma combined with low interleukin-1-beta, associated with cytokine release syndrome (Diorio *et al*., 2020). That work also found interleukin-6 alone to be a poor discriminator, since high values occur in both conditions, and general markers such as ferritin, D-dimer, and C-reactive protein are elevated in inflammatory states of any cause. Recent contributions have been pragmatic: Procalcitonin has been evaluated specifically as a predictor of bacterial infection in CAR T-cell therapy recipients (Powell *et al*., 2023), and a formal guidance document on the clinical use of procalcitonin supplies the interpretive framework that had been missing (Chambliss *et al*., 2023). Composite indices derived from routine laboratory values have been proposed partly because they require no specialised assay and can be computed from data already recorded, a design principle recurring in cardiometabolic risk stratification where indices assembled from routinely available measurements have been evaluated against outcomes because they are deployable where specialised assays are not (Okwah, 2022).

3.5 Clinical Workflows Through Which Results Become Actions

A biomarker result changes nothing unless a workflow converts it into an action, and in febrile neutropenia that workflow is predominantly nursing-led and stewardship-governed. The relevant literature is substantial and usually absent from biomarker papers.

Antimicrobial stewardship provides the governance structure through which a de-escalation recommendation becomes a de-escalation, and policy-based models for strengthening stewardship programmes in emerging economies describe the institutional preconditions (Fapohunda *et al*., 2023c). Infection prevention and control compliance in tertiary hospitals determines the baseline nosocomial risk against which any biomarker's post-test probability is computed (Omaghomi *et al*., 2022). Frameworks for strengthening patient safety in high-acuity nursing units address the environment in which febrile neutropenia is managed (Fapohunda *et al*., 2023b).

Recognition and escalation depend on communication and analytic structures. Multidisciplinary collaboration has been linked to patient outcomes in emergency departments (Ohunyon *et al*., 2023), decision delay has been treated as a measurable target for real-time informatics and performance analytics (Nnaji & Akinlolu, 2022), and analytics-driven approaches to workflow inefficiency address the throughput conditions under which protocol adherence degrades (Nnaji & Akinlolu, 2023). Staffing determines whether any of this is executable, and governance-driven approaches to workforce planning and nurse-patient ratio optimisation address the constraint that most directly limits protocol adherence in high-acuity units (Omaghomi *et al*., 2023). Continuity across the episode matters as well, since care-coordination frameworks for reducing readmissions among chronic disease patients (Akinlolu *et al*., 2023) and integration of screening into primary care in low-resource settings (Akinlolu *et al*., 2022) describe the mechanisms by which an inpatient result does or does not influence subsequent outpatient management.

The safety science literature offers a transferable model for how such systems detect their own failures. Near-miss and hazard observation data have been examined as an underused source of predictive signal (Arumosoye & Obriki, 2019), with proactive hazard recognition and reporting systems developed to convert that signal into intervention (Obogo *et al*., 2021) and internal audit systems designed to verify that conversion actually occurs (Obogo *et al*., 2020a). Data-driven risk control models describe how routinely collected operational data can be used for prospective rather than retrospective safety management (Obriki & Arumosoye, 2018), an approach extended to hazard identification from digital data streams (Obriki & Arumosoye, 2023) and to continuous monitoring architectures (Obriki *et al*., 2023). Readiness for acute deterioration has been modelled as an organisational capability rather than an individual one, both for emergency response (Arumosoye & Obriki, 2023) and for evacuation and preparedness in dense occupancy settings (Obriki *et al*., 2022b). Applied to diagnostics, these frameworks suggest that misinterpretation of an ambiguous biomarker result is a reportable near-miss event, and that laboratories and clinical units plausibly lack the surveillance apparatus to detect it, an inference drawn from the industrial-safety-science analogy above rather than direct evidence from diagnostic settings.

3.6 Tumour Microbiome Signatures and Reproducibility

The proposition that microbial content of tumours and of the gut modifies cancer biology and treatment response has strong mechanistic support in specific settings, including *Helicobacter pylori* in gastric malignancy, *Fusobacterium nucleatum* in colorectal cancer, and gut community composition as a modifier of immune checkpoint inhibitor response. The stronger claim, that pan-cancer microbial signatures detectable in tumour and blood sequencing data can serve as diagnostic classifiers, was advanced in a widely cited analysis of The Cancer Genome Atlas covering 33 cancer types and more than 18,000 samples (Poore *et al*., 2020).

A re-analysis published in October 2023 concluded that major data analysis errors invalidate those findings (Gihawi *et al*., 2023b). The stated concerns are specific: Machine-

learning models rested on genera implausible in human disease, including species associated only with extreme environments, marine habitats, or plants, and the normalisation and batch-correction pipeline is argued to have introduced rather than removed artefact. A companion paper raises caution regarding the specificities of pan-cancer microbial structure (Gihawi *et al*., 2023a). The exchange is unresolved at the time of writing, and the outcome will bear directly on whether microbial signatures can be used as classifiers at all.

The episode is more useful as a specification than as an academic dispute. The failure mode is generic and will recur, since high-dimensional features, low signal-to-noise ratio, reference-database contamination, batch structure correlated with the outcome of interest, aggressive normalisation, and a flexible classifier together produce impressive discrimination that does not reflect biology. Every ingredient is present in the multi-omic integration described above. Practical safeguards follow: External validation in an independently generated cohort rather than a held-out split of the same dataset; routine biological plausibility screening of top features, treating implausible features as evidence of pipeline failure rather than as discovery; performance reporting stratified by batch and site; contamination control as a primary analysis with documented negative controls; and preference for low-dimensional, mechanistically motivated panels where these achieve comparable performance.

The governance literature has converged on similar requirements from a different direction. Model risk management and algorithmic accountability frameworks developed for regulated financial services specify independent validation, documented model inventories, and challenge functions with authority to block deployment (Ominyi & Anichukwueze, 2023). Systematic evaluation of artificial intelligence applications in software testing describes the verification methods available when the artefact under test is itself a model (Borah *et al*., 2022), and detection architectures constrained by physical models rather than by correlation alone illustrate the value of embedding domain plausibility into the detector rather than screening for it afterward (Ojukwu *et al*., 2023). Where models must be adapted for constrained deployment settings, parameter-efficient methods reduce the retraining burden that otherwise discourages recalibration (Oyesiji *et al*., 2023). A diagnostic classifier is a model in the sense these frameworks intend, and applying them is the mechanism that would plausibly have identified the microbiome dispute before publication rather than after.

4. Enabling Conditions, Discussion, and Conclusion

4.1 Diagnostic Laboratory Infrastructure

Every assay described above assumes a laboratory capable of running it, and that assumption is unevenly satisfied. The infrastructure literature treats it as a design problem with measurable outputs.

Sustainable diagnostic laboratory infrastructure models developed for emerging and resource-constrained health systems set out the base case (Aminu-Ibrahim *et al*., 2018), while capital project delivery models address financing and execution of high-risk healthcare infrastructure in developing national systems (Aminu-Ibrahim *et al*., 2019). Infrastructure-driven expansion of diagnostic access across underserved and rural regions bears directly on the geographic inversion described below, in which infection-attributable cancer burden and diagnostic capacity are distributed inversely (Aminu-Ibrahim *et al*., 2020), and coordinated multi-site expansion requires programme management structures distinct from single-project delivery (Aminu-Ibrahim *et al*., 2021).

Facility-level design decisions carry analytical consequences that are easy to underestimate. Beyond the containment and spatial planning considerations noted above, sustainable materials selection and energy efficiency strategies affect the stability of temperature-sensitive analytical environments (Ogbete *et al*., 2020), risk-managed construction strategies govern delivery in highly regulated environments (Ogbete *et al*., 2021), and lifecycle performance evaluation of purpose-built diagnostic laboratories connects design choices to long-term delivery capability (Ogbete *et al*., 2023). The evaluative question that most infrastructure programmes leave unanswered is whether investment translates into measurable diagnostic and population health output, and treating infrastructure itself as an intervention makes that question answerable (Aminu-Ibrahim & Ogbete, 2023).

4.2 Governance of Combined Infection and Oncology Biomarker Data

A combined report pairs pathogen identification with tumour genomic information for a named patient. Each element is sensitive independently, and together they constitute one of the more consequential data objects in clinical medicine. Two governance problems are specific to that combination rather than to either data type on its own. The first is re-identification risk: Pathogen strain data and tumour mutational signatures are each separately quasi-identifying, and reporting them together narrows the anonymity set further than either would alone, so de-identification standards adequate for a pathogen report or a tumour genomic report considered in isolation are not necessarily adequate for the combined object. The second is regulatory classification conflict: Pathogen sequence data is often treated as public-health surveillance data subject to mandatory-reporting obligations, whereas germline or somatic tumour genomic data is treated as intimate personal health information subject to stricter consent and data-minimisation requirements, and a single report spanning both can sit ambiguously between the two regimes. The governance literature surveyed below was not developed for this specific object, but each stream addresses a component of the problem these two failure modes create.

Legal and ethical risk modelling in enterprise data protection governance addresses the normative layer above the technical controls, including the classification question of which regime a combined pathogen-tumour report falls under (Mbonu *et al*., 2018), and comparative analysis of data protection regulations and secure implementation strategies across jurisdictions matters for multi-site studies and international reference laboratories (Mbonu *et al*., 2019), as does explicit harmonisation across differing privacy regimes (Ominyi & Anichukwueze, 2022a) and cross-border data privacy governance for distributed platforms (Annan, 2022). Embedding privacy considerations into system design rather than appending them afterward has been treated as a structuring principle in transaction and restructuring contexts (Ominyi, 2021), and integration of compliance obligations following organisational

consolidation is directly relevant where laboratory networks merge (Ominyi, 2020).

Access control is central not only because the two halves of the report have different professional audiences, but because the re-identification risk described above means the combined record needs tighter controls than either half would require alone. Identity and access management integration strategies in hybrid and multi-cloud environments (Mbonu *et al*., 2020) and cloud identity and access governance optimisation at enterprise scale (Mbonu *et al*., 2022b) describe the mechanisms, with federated and distributed identity models addressing the multi-institution case (Oshoba *et al*., 2019) and directory infrastructure providing the operational substrate (Ladapo *et al*., 2019). Data protection impact assessment models provide the formal instrument for evaluating a proposed integration before deployment (Mbonu *et al*., 2022a), privacy-oriented access control policy design has been reviewed systematically (Ladapo *et al*., 2023b), and attribute-based encryption offers a mechanism for enforcing fine-grained access in shared pipelines (Shittu & Nabil, 2023).

Platform architecture determines whether these controls are enforceable. Scalable and secure cloud architectures for enterprise messaging (Ahmed & Odejobi, 2018a), resource allocation and placement models in data centres (Ahmed & Odejobi, 2018b), constraint satisfaction approaches to resource allocation (Ahmed *et al*., 2019), predictive scaling under variable load (Ahmed *et al*., 2020), performance evaluation under high concurrency (Odejobi & Ahmed, 2018b), and complexity-aware database optimisation (Odejobi *et al*., 2019) collectively describe the substrate on which a combined reporting platform would run, where sequencing workloads are bursty and latency requirements differ sharply between the protein and sequencing layers. Infrastructure-as-code governance provides reproducible and auditable configuration (Mbonu *et al*., 2020b), blockchain-enabled audit trails address configuration provenance (Oshoba *et al*., 2020), and continuous cloud misconfiguration monitoring addresses the most common practical failure mode in such deployments (Aliliele *et al*., 2023a).

Operational security and assurance complete the picture. Applications of artificial intelligence to secure software testing and automated regression control describe verification at the code layer (Mbonu *et al*., 2021b), lessons from offline assessment of security-critical systems describe evaluation where live testing is not permissible (Ladapo *et al*., 2018), and characterisation of directory-service attack patterns and signatures describes a common intrusion route into clinical infrastructure (Ladapo *et al*., 2023a). Service management structures determine incident response in practice (Ladapo *et al*., 2022), and log analytics and automated incident response architectures provide the detection layer (Mbonu *et al*., 2019). Risk-based prioritisation frameworks are needed because controls cannot be applied uniformly (Aliliele *et al*., 2023b), risk-based business intelligence architecture describes how governed data becomes analysable (Mbonu *et al*., 2021a), audit automation reduces the cost of continuous control verification (Mbonu *et al*., 2022), forensic analytics illustrate reconstruction after the fact (Mbonu *et al*., 2021), and predictive analytics for institutional risk management demonstrate the same governance requirements in an adjacent setting (Aliliele *et al*., 2023c). Digital transformation and supply chain integration under formal control regimes (Mbonu *et al*., 2020a) describes the organisational change accompanying such deployments.

Human factors determine whether controls hold. Authentication behaviour and data-protection compliance among administrative staff (Onche & Ogbonna, 2022), information-security awareness and records confidentiality in institutional registries (Onche *et al*., 2020), and information-security risk arising from personal device use in administrative settings (Onche *et al*., 2023) describe the failure modes that technical architecture alone does not prevent, and which apply directly to clinical environments where results are handled by staff outside the laboratory.

4.3 Design and Oversight of Cross-Domain Decision Support

A workable decision-support configuration has several components, each with supporting evidence. The clinical implication of the pattern described in Section 3.2 is direct: Because a single specimen already yields both kinds of result, what is missing is not new biology but a decision-support layer built to use what the specimen already provides.

A single plasma draw supports host-response protein measurement, microbial cell-free DNA sequencing, and tumour cell-free DNA analysis. The immediate implementation task is aliquot logistics and turnaround-time reconciliation, since host-response protein assays return within roughly an hour while sequencing assays return in a day or more. These layers therefore inform sequential decisions rather than a single one, and the interface must reflect that; data-driven lifecycle performance management approaches developed for complex delivery programmes provide a usable planning frame (Adelanwa *et al*., 2023a).

Reporting should be probabilistic rather than binary. Both fields have suffered from threshold-based reporting that discards information, since a ctDNA result reported as detected or not detected conceals tumour fraction, and a metagenomic result reported as a list of organisms conceals abundance relative to the assay's own reference distribution. Decision support should present likelihood ratios against an explicit pre-test probability and should make the equivocal zone visible rather than forcing it into a binary, following the interpretive banding used by host-response signatures (Stas *et al*., 2022).

Calibration should be context-aware, and this component does not currently exist. A biomarker's post-test probability depends on host immune status, which in oncology is a documented, time-varying quantity: Days since chemotherapy, absolute neutrophil count, lymphodepletion regimen, steroid dose, prior CAR T-cell infusion date, and checkpoint inhibitor exposure, all already recorded. Context-aware calibration means interpreting the same assay value against a different reference distribution depending on where the patient sits in the treatment course. Decision support systems for healthcare operations and resource planning describe the general architecture (Adelanwa *et al*., n.d.), and related applications include early detection systems for non-communicable disease (Afrihyia *et al*., 2023), risk stratification frameworks for large-scale preparedness (Oparah *et al*., 2021), and predictive maintenance modelling, structurally the same problem of anticipating failure from routine telemetry (Mayo *et al*., 2021). Anomaly detection methods developed for fraud and

risk detection in public systems address the analogous task of flagging results inconsistent with an expected distribution (Adelanwa *et al*., 2023b).

Output must link to action. Each state should map to a defined action set: Continue empiric antimicrobials, de-escalate, add antifungal coverage, initiate interleukin-6 blockade, escalate imaging, or trigger multidisciplinary review. Antimicrobial stewardship provides the existing governance structure for the infection half (Fapohunda *et al*., 2023c) and molecular tumour boards for the oncology half, but neither currently holds jurisdiction over the combined output.

Finally, performance requires monitoring. Predictive performance degrades as populations, pathogen prevalence, treatment regimens, and assay versions change, so any deployed model requires prospective calibration monitoring, defined performance floors triggering review, version control linking each historical result to the model that generated it, and a documented decommissioning pathway. The regulatory literature supplies the compliance frame: Clearance and approval frameworks operating across jurisdictions illustrate how the same artefact is assessed under differing regimes (Ominyi & Anichukwueze, 2020), systematic comparison of compliance regimes across emerging and developed markets describes the resulting divergence (Ominyi & Anichukwueze, 2021), disclosure obligations demonstrate how reporting requirements are specified and enforced once a domain is regulated (Ominyi & Anichukwueze, 2022b), and questions of ownership and authorship in AI-generated works affect the provenance of algorithmically derived clinical reports (Annan, 2023).

4.4 Financing, Workforce, and Organisational Capability

Biomarker adoption is a financing decision before it is a clinical one. Health insurance financing mechanisms and provider payment reform determine whether a test that reduces downstream costs is reimbursed at all (Ilodigwe & Adesemoye, 2019a). Where incentives are misaligned between the entity bearing the assay cost and the entity capturing the saving, a cost-effective test remains unfunded. A combined infection-oncology report compounds this problem rather than merely inheriting it, because it does not map onto existing reimbursement categories: Payment systems built around a single-assay claim have no ready mechanism for a report that jointly returns a pathogen result and a tumour fraction, so a combined product can be clinically superior to two separate tests yet commercially unviable under current billing architecture until a corresponding payment pathway exists.

The data layer is equally determinative. A governance and architecture framework for interoperability, data quality, and advanced analytics at national scale describes what must exist before cross-domain reporting is technically possible (Ilodigwe & Adesemoye, 2021). Pharmacy-led delivery and access models illustrate one route to extending service reach without proportional capital expenditure (Ilodigwe & Adesemoye, 2020), which matters for specimen collection and result follow-up in systems where laboratory access is concentrated in tertiary centres. Interoperability failure is not an abstract data-quality concern in this setting; it is the specific reason a microbial cell-free DNA result and a tumour-informed ctDNA result, generated from the same patient in the same week, are rarely viewed side by side. The national-scale interoperability layer this literature describes is therefore a precondition for the combined report discussed throughout this review, not a general infrastructure good that happens to be relevant.

Workforce preparation is the most frequently neglected component. Data-informed digital learning platforms for healthcare and STEM environments (Orise & Niniola, 2020) and real-time analytics and performance dashboards in health professional training (Orise & Niniola, 2022) describe how interpretive competence for probabilistic diagnostic output would be built and monitored, while privacy, safeguarding, and ethical data practice in health education technology describe the constraints under which such training data may be used (Orise & Niniola, 2023). Integrative models addressing socioeconomic inequity in service delivery describe the populations in which capability gaps concentrate (Akinse *et al*., 2023), and business intelligence applied to resource allocation illustrates how capability and capacity decisions can be made against measured demand rather than historical allocation (Owoade *et al*., 2022). The competency gap is specific rather than generic: Clinicians and laboratory staff must learn to read a likelihood ratio against a shifting pre-test probability, interpret an equivocal host-response band, and reconcile a rising tumour fraction with a metagenomic detection list, none of which resembles the binary positive-or-negative reporting that most current training assumes. Without investment in that specific competence, the decision-support configuration described in Section 4.3 remains technically available but practically unusable, reproducing at the interpretive layer the same innovation-without-delivery gap that recurs throughout this review.

These three components are interdependent rather than sequential. A funded assay with no interoperable reporting layer still cannot be delivered as a combined result, and an interoperable reporting layer read by an untrained workforce still fails to change management at the bedside. Financing, data architecture, and workforce capability therefore constitute one organisational capability rather than three separable projects, which is why this section is treated as co-equal in scope to the governance requirements described in Section 4.2: A combined report that is secure and compliant but unfunded, unintegrated, or uninterpreted delivers no more clinical benefit than no combined report at all.

4.5 Reagent, Medicine, and Supply Chain Integrity

An assay is only as reliable as its reagents, and a biomarker-guided treatment decision only as good as the medicine subsequently administered. Both are supply chain questions routinely omitted from biomarker validation studies.

Traceability and chain-of-custody integrity in pharmaceutical distribution provides a frame applying equally to diagnostic reagents (Aneke & Adesemoye, 2019), and risk-based decision making in good manufacturing practice environments describes the quality system producing them (Aneke & Adesemoye, 2020). Corrective and preventive action effectiveness and root-cause methodology determine whether failures are detected and closed (Aneke *et al*., 2022a), and data integrity and governance failures in regulated life sciences operations describe how quality signals are lost (Aneke *et al*., 2023). Degradation of temperature-sensitive enzymes, probes, and control materials produces analytical failures that present as biological variability, which makes these controls directly

relevant to assay reproducibility.

Detection of substandard and falsified products bears on both halves of this review. Risk-based interdiction models address the trade and import compliance route (Aneke & Adesemoye, 2021), and the contribution of medicine quality failures to the emergence and spread of antimicrobial resistance connects supply integrity directly to stewardship (Aneke *et al*., 2022b). Early warning and regulatory response models for essential medicine shortages describe the anticipatory layer (Eze *et al*., 2022a), regulatory readiness maturity models describe the capability required to participate in international supply (Eze *et al*., 2022b), and supply chain governance linked to environmental risk management and sustainable access describes the system-level target (Eze *et al*., 2023).

Access and affordability determine whether a recommendation is actionable for the individual patient. Supply chain inefficiencies and medication affordability in resource-constrained systems have been reviewed directly (Asiedu & Asiedu, 2023b), alongside last-mile distribution barriers to underserved communities (Asiedu & Asiedu, 2022). Systematic interaction screening frameworks address the parallel safety question of what occurs when a recommended agent meets an existing regimen (Asiedu, 2022). Resilience under disruption has been modelled for humanitarian logistics using predictive analytics and localised distribution (Anene & Clement, 2022), a pattern applicable to reagent continuity during outbreak surges. Comparative work on bioavailability and cost-effectiveness of alternative product forms (Asiedu & Asiedu, 2023a) and on antimicrobial activity of traditionally used botanicals (Gbadamosi & Obogo, 2013) is relevant where formal supply is intermittent and substitution occurs regardless of guideline status.

4.6 Population Surveillance and Equity in Diagnostic Access

The infection-attributable cancer burden is concentrated in low- and middle-income countries while the technologies reviewed here are concentrated in high-income ones. This inversion is a surveillance problem before it is a treatment problem.

Data-driven approaches to strengthening national health surveillance describe the system layer (Ogunboye *et al*., 2023), with big data-enabled predictive models for anticipating infectious disease outbreaks at population and regional level (Oparah *et al*., 2022) and frameworks for national real-time surveillance dashboards designed for stakeholder rather than analyst use (Oparah *et al*., 2023). Governance of these systems determines whether they produce action: Public health governance models using process optimisation and performance metrics for regulatory oversight (Anioke & Atima, 2023a), informatics frameworks oriented toward protecting vulnerable populations through data-driven policy enforcement (Anioke & Atima, 2023c), and business intelligence applications for resource allocation and programme accountability (Anioke & Atima, 2023b) describe the mechanisms by which surveillance output becomes resource deployment.

Equity in access to the diagnostics themselves is the binding constraint. Telehealth has been reviewed as a mechanism for bridging rural and urban disparities in access, with attention to what it can and cannot substitute for (Fapohunda *et al*., 2023a). Chronic disease risk stratification conducted in African populations demonstrates both the feasibility and the value of biomarker research outside high-income settings (Okwah, 2022), and biomarker science conducted in the settings bearing the burden yields different and more transferable calibration than biomarker science imported wholesale. Assays requiring cold-chain plasma shipment and centralised sequencing are poorly matched to these settings, and development of low-complexity host-response assays and point-of-care viral load quantification merits priority on burden grounds alone. In concrete terms, low-complexity here means an assay that does not depend on continuous cold-chain storage or mains power, that can be interpreted by non-specialist nursing or laboratory staff after brief training rather than requiring molecular pathology expertise, and that returns a result within a single clinic visit rather than requiring batch-run centralised processing. An assay meeting those constraints, even at reduced analytical precision relative to centralised sequencing, would extend surveillance capability to settings that the assays described elsewhere in this review cannot reach.

4.7 Limitations

This review is narrative rather than systematic. Sources were selected for relevance and were not scored for methodological quality, and no protocol was registered, so selection and interpretation bias cannot be excluded. The biomarker evidence is drawn disproportionately from studies conducted in high-income settings, which limits transferability of the reported performance estimates to the populations bearing most of the infection-attributable cancer burden. Much of the implementation literature considered consists of conceptual frameworks and narrative syntheses rather than controlled evaluations, so its role here is to identify determinants of translation rather than to quantify their effects. Several biomarker findings reviewed derive from single-institution retrospective cohorts or from studies with commercial sponsorship, and effect estimates from such designs are prone to optimism. The dispute over microbial signatures in tumour sequencing data is active and unresolved, so conclusions drawn from that literature are provisional. Finally, the central observation that microbial and tumour-derived cell-free DNA can be recovered from a single specimen is supported by the analytical properties of the assays rather than by a study that has performed both and reported combined interpretation, so it remains a proposition to be tested rather than a demonstrated result.

4.8 Conclusion

The current literature marks a transition. Host-response signatures have moved into real-world use with measurable effects on prescribing, microbial cell-free DNA sequencing has entered formal diagnostic criteria, tumour-derived cell-free DNA has entered adjuvant treatment decisions in resectable colorectal cancer with effect sizes rarely seen in prognostic biomarker research, circulating viral tumour DNA has demonstrated, in virus-driven malignancies where the marker is clonally tumour-derived, that the distinction can dissolve, and a published reproducibility critique in the tumour microbiome field has supplied a necessary methodological discipline.

What remains absent is integration. These advances have occurred in parallel, using overlapping technology on identical specimens, without informing one another at the point of care. A clinician facing an ambiguous fever in a

patient with cancer still assembles the picture by hand, from reports that were each generated correctly but never designed to be read together.

Closing that gap is not principally a discovery problem. It requires linked validation cohorts, randomised evidence of clinical utility of the kind already proposed for febrile neutropenia (Hogan *et al*., 2023), integrated reporting infrastructure, laboratory environments designed for the assays they run, data governance adequate to the sensitivity of the combined record, model oversight equal to the complexity of the classifiers, supply chains delivering reliable reagents and the medicines that follow from the result, and a workforce equipped to interpret probabilistic output. Trials of molecular residual disease-triggered and viral ctDNA-triggered intervention with survival endpoints will determine whether these markers function as decision variables or remain prognostic information (Sato *et al*., 2023), threshold-setting frameworks for detections of uncertain significance remain underdeveloped, and cost-effectiveness evidence exists only in fragments (Lin *et al*., 2023). The operational consequence, stated plainly, is that none of the preceding requirements is optional: A financing gap, an unintegrated data layer, or an untrained workforce each independently blocks delivery regardless of how mature the underlying biomarker science becomes (Ilodigwe & Adesemoye, 2019b). These are tractable objectives, and the foundation now in place makes them worth pursuing.

5. Declarations

Ethics approval and consent to participate: Not applicable. This is a narrative review that does not involve human participants, human tissue, or identifiable patient data.

Consent for publication: Not applicable.

Availability of data and materials: Not applicable. No new datasets were generated or analysed; all sources discussed are cited in the reference list.

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