

Molecular Sovereignty

Building a Blood Screening Test for the Brazilian Nation

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Abstract

This article interrogates the relationship between the development of national diagnostic technologies and the exercise of sovereignty, by analysing a Brazilian project to produce a nucleic acid test (NAT) for the country's blood screening programme. The concept of 'molecular sovereignty' is proposed to demonstrate that exercising sovereignty demands not only technological resources but also a sufficiently powerful and national imaginary to support local knowledge production as a means of advancing national healthcare priorities. First, this research article contextualises the political importance of blood safety for Brazil during its transition to democracy in the 1980s and the creation of its universal healthcare system. Then, it investigates how adopting the NAT led the state to invest in the production of a national technology. Third, the article unpacks the diagnostic test to consider how certain aspects of the project might ultimately strengthen the ability of global capital to cross national boundaries and create new markets. Lastly, it discusses how the project ended up creating a centralised and 'closed' system to avoid leaving the country vulnerable to the entry of global diagnostic companies. This case demonstrates how the molecularisation of blood, through the construction of a unified healthcare system driven by the constitutional right to health, can be deployed to construct imagined communities on the scale of a nation.

Keywords

Blood, Diagnostic tests, Molecularisation, Sovereignty, Global health, Brazil.

Introduction

On a winter day back in 2014, a researcher at the Institute for Immunological Technology, Bio-Manguinhos, in Rio de Janeiro, walked me through the complex set of circumstances leading up to the development of a screening test for the national blood supply. The Institute, a research and industrial production unit connected to the Ministry of Health, had no prior expertise in developing the kind of molecular tests necessary for blood screening. Nevertheless, according to this researcher, the government refused to purchase either of the two tests currently available on the international market. The issue was not with the quality of those tests but rather with what their purchase would mean for the national public health system. As the researcher put it: 'We were already highly dependent'.

Technological dependency here refers to a country's vulnerability both to infectious diseases and global pharmaceutical capital. The disastrous effects of this dependency and the financial straightjacket to which Big Pharma subjects Global South governments and patients when it comes to medical innovations are well documented in the social science literature (Petryna, Lakoff, and Kleinman 2006; Dumit 2012; Banerjee 2017). For Brazil, that dependency is acute, as the majority of healthcare technologies made available to its public healthcare system, the Sistema Único de Saúde (SUS), are imported from elsewhere. The effects of such vulnerability are multiple. The lack of innovations in the global market for neglected diseases is one key area, a deficiency that makes rendering treatments available for the range of health problems that make up Brazil's disease burden a challenge. This relationship of dependency has also enabled proprietary companies to suddenly increase the prices of HIV viral load tests, for example, or to decide to interrupt the manufacture of certain medical products in favour of more lucrative ones, putting the continuity of Brazilian public health programmes at risk.

The molecular tests employed in blood screening for infectious diseases, though not considered a healthcare priority, nevertheless constitute a global market of growing importance. These tests, based on nucleic acid amplification techniques (known as NAATs or, in this article, NATs), were first developed to supplement serological tests¹ in order to enhance the ability of blood transfusion centres to identify blood-borne diseases, particularly HIV/AIDS and hepatitis. However, there is great disparity in the standardisation of blood safety across different countries. Industrialised countries, driven by the precautionary principle that prevailed following the blood contamination scandals of the 1980s and 1990s, have incorporated new blood screening technologies like NATs despite the reservations

1 A serological test is used to test a body fluid sample for the presence of antibodies (or antigens) against a specific microorganism or pathogen.

of public health experts regarding their cost-effectiveness (Feldman and Bayer 1999; Farrugia 2002). By contrast, some developing countries face a series of considerable challenges throughout their entire blood-safety chain, from implementing a robust, transfusion-transmitted infectious disease testing regime, through donor selection and post-transfusion surveillance, to quality assurance under conditions of unreliable cold-chain management and interrupted power supply (Busch, Bloch, and Kleinman 2019). For low- and middle-income countries like Brazil, providing healthcare under considerable infrastructural constraints, the high incidence of infectious diseases makes the NAT a potentially useful technology for enhancing national blood safety. From the perspective of multinational diagnostic companies, supplying molecular testing in emerging contexts also has commercial advantages in terms of opening up new healthcare markets.

This research article examines the blood screening NAT in Brazil in order to investigate the implications of this emerging market for the molecularisation of healthcare (Clarke et al. 2003; Hogarth, Hopkins, and Rodriguez 2012) in the Global South. The country's history is punctuated by initiatives to mitigate the impact of infectious diseases on its economic and social development. For instance, research institutes still in existence today were set up in the early 1900s to produce vaccines for tropical diseases (Löwy 2006; Benchimol 2017). The connection between a strong national industry and the country's autonomy was first made in the theoretical debates of the 1970s in development studies, to explain Latin American countries' economic dependency on multinational companies. Over a decade later, the role of national industrial production in supporting healthcare policies remained a salient ideological cornerstone in the creation of the SUS.

The intertwining of industrial and healthcare autonomy has formed a focus for academic literature on pharmaceutical autonomy (Flynn 2015; Loyola 2008). It also manifested in Brazil's ambitious industrial policies of the 2000s–2010s, which sought to nationalise production of the various technologies provided by the state through the SUS, such as medicines, vaccines, and diagnostic devices (Gadelha et al. 2013; Cassier and Corrêa 2018). The development of the blood screening test in Brazil offers a fresh perspective on the relationship between pharmaceutical development and sovereignty in the context of the increasing molecularisation of health. By investigating the opportunities for exercising national sovereignty afforded by the NAT test, my analysis both builds upon and departs from those examining product development initiatives for which global health endeavour is central to the underlying rationale (e.g., Lakoff 2010; Nading 2015). In contrast to their emphasis on the pre-eminence and power of global health problems and actors, the development of the Brazilian test is underpinned by a fragile

assemblage of national and global health actors and technologies prompted by, and serving to reinforce, a national healthcare programme.

Drawing attention to how NATs have been developed in the context of an emerging economy will, moreover, help shed light on the extent to which the commodification of health is driven by how molecular tests operate within a nationally organised market. In particular, this case explores the focus that sovereignty gives to the development and deployment of molecular diagnostics and how these are circumscribed by the dynamics of global capital and biovalue—thereby contributing to the debate on what Catherine Waldby (2000; Waldby and Mitchell 2006) has highlighted as the growing instrumentalisation of living beings productivity to serve human projects. To advance that analytical agenda I develop the concept of ‘molecular sovereignty’, combining critical thought on diagnostic innovation with scholarship interrogating sovereignty as a problem of access to treatments and in particular to HIV therapy (Biehl 2007; Nguyen 2010; Petryna, Lakoff, and Kleinman 2006).

Studies of pharmaceutical sovereignty have tended to focus on the case of the HIV epidemic, mapping the opportunities available to countries to work with civil society and generic drug industries in order to challenge patent rights and make affordable medicines that would not otherwise be accessible in developing countries (Biehl 2007). While the production of generics can provide a platform from which to demonstrate and exercise sovereign power (Hayden 2007), exercising sovereignty demands not only technological resources but also a sufficiently powerful (and, as we will see, pragmatic) national imaginary to support a commitment to local knowledge production as a means of advancing national healthcare priorities (Pollock 2019). Local manufacturing of molecular technologies may afford opportunities for the self-affirmation of countries that generics do not, by offering enormous potential for the national implementation of biopolicies such as epidemiological surveillance, blood screening, and other uses relating to the country’s health safety (Kameda et al. 2021).

The article draws on data collected during qualitative fieldwork I carried out while undertaking my doctoral research, between 2014 and 2017, in Brazil (Rio de Janeiro, Brasilia, Sao Paulo, and Curitiba). Inspired by scholarship in the social sciences (Latour 2011), I followed actors involved in the various stages that mark the trajectory of national diagnostic development initiatives. I was also particularly attentive to the different kinds of values arising from the practices of these actors. In this sense I adopted Dussauge, Helgesson, and Lee's (2015) approach to considering values not as stable and predefined entities but as arising from concrete actions, technical practices, and valuation practices.

To grasp how Brazilian scientists, industrial actors, and policymakers created the model of the Brazilian nucleic acid system, I conducted semi-structured interviews and observational visits to both *in vitro* diagnostic (IVD) manufacturing sites and blood screening services. This data was supplemented with observations from short-term volunteer internships in the innovation management departments of the two diagnostic production sites (Bio-Manguinhos and the Molecular Biology Institute of Parana, IBMP) associated with the Oswaldo Cruz Foundation, connected to the Ministry of Health. These experiences enabled me to understand the crucial role of contracts in the public–private partnerships that characterise Brazilian product development ventures.

Across four sections, in this article I demonstrate the degree to which national sovereignty can be exercised by innovative biotechnologies. The first section contextualises the political importance of blood safety to Brazil during its transition to democracy in the 1980s and the creation of its universal healthcare system (SUS). The introduction of a new blood screening test became crucial to Brazil, with the national blood system serving to assert a regime of values rooted in universal access to healthcare.

In the section that follows, I investigate the ways in which the SUS's adoption of the NAT led the country to invest in the production of national technology, reinforcing the connection between sovereignty and autonomy that already prevailed when the project to develop the molecular test was launched.

The third section unpacks the development of the Brazilian test. Through the technological assemblages that make up the NAT, Brazilian actors perform a practical exercise of autonomy and dependency through the creation of production capacities and the maintenance of technological dependency, respectively. Here, I consider the extent to which certain aspects of the Brazilian project afford opportunities to exercise molecular sovereignty or ultimately reinforce the ability of global capital to expand across national boundaries and experiment in new markets by extracting economic value from biological materials of national significance, such as blood, imagined to exist outside the logics of commerce (Chauveau 2009; Busby, Kent, and Farrell 2014; Waldby and Mitchell 2006; Sunder Rajan 2006).

In the last section of the article, I discuss how molecular test development in Brazil creates a centralised and 'closed' system in order to assert sovereignty in the face of pressure to adopt other platforms available on the market instead—a path that would not only jeopardise public investment in the national product but also leave the country vulnerable to the market decisions of global, *in vitro* diagnostic (IVD) companies. Here, I highlight how national blood experts question the country's model of blood screening, the quality of its technology, and the ways in which the

initiative is embedded in the construction of a national imaginary around the right to universal access to health. In Brazil, a country marked by deep socioeconomic inequality and avid consumerism, that right, many have argued, has fallen well short of its realisation—torqued to include cosmetic surgery within its remit on the one hand (Edmonds 2010), and delimited by the profound racial complexity of Brazilian national identity on the other (Kent, Santos, and Wade 2014). The case of the Brazilian NAT offers fresh empirical ground from which to consider the national provenance of the right to health, showing how the molecularisation of blood, through the construction of a unified healthcare system driven by the constitutional right to health, can be deployed to construct imagined communities on the scale of a nation.

Blood safety and universal access to healthcare

Many factors lay behind the introduction of molecular tests for blood screening in Brazil. They include historical and political factors to do with the particular status of blood in the country as well as the importance that health and the right to health gained in the country's transition to democracy. In the mid-1980s, a major outcome of the debates that marked Brazil's new constitutional order and the country's return to democracy was the definition of healthcare as a constitutional right. That right to health, very broad in scope, also entailed a duty and a responsibility on the part of the Brazilian state. This was realised by the creation of a unified and universal healthcare system, the Sistema Único de Saúde (SUS), which replaced a system in which healthcare was the preserve of the employed. The significance of creating a universal healthcare system in a country bedevilled by stark inequalities cannot be underestimated. However, the creation of the SUS did not suppress the private sector's participation in healthcare; rather, it was intended that the latter would supplement the former's public health activities.

The creation of the SUS was also a defining moment for the regulation of blood products. Although the establishment of a national blood system had already been a project in the making for several decades, it only came to fruition in the 1980s. It was based on a network of haematology and blood therapy services (*hemocentros*) that was put in charge of implementing the national blood policy introduced by the federal authorities in their respective regions. This system, funded in the main by federal resources, not only expanded blood collection but also tipped the balance in favour of the public sector and away from the previously dominant private sector: in 2015, out of a total 3,720,867 blood collection procedures performed nationwide, 3,436,375 (in other words, 92.4%) were performed by blood services connected to the SUS (Ministério da Saúde 2018). By comparison, in the late 1980s the private sector was estimated to account for 70% of all blood collected (Santos, Moraes, and Coelho 1992).

With this new configuration of the blood sector, in which the state both regulated and executed policy on blood access, safety and quality became a state affair. Moreover, the constitution considerably reduced the private sector's participation when it outlawed any form of blood commercialisation. This legal mandate was introduced, in the context of debates on the constitutional order, to tackle the apparent connection between cases of blood contamination in the country and remuneration for donating blood, which was permitted until 1988 (Santos, Moraes, and Coelho 1992).

The national blood system would not be fully operational until the following decade, but blood quality immediately became a major concern for the Brazilian federal government. First, it was the state's responsibility to fulfil the population's need for blood products: as with medical provisions, ensuring that blood banks were well stocked became the responsibility of the state when the SUS was created. Second, because blood is a vector for infectious diseases, there was also the matter of regulating blood safety. The HIV epidemic, which emerged in the 1980s, together with the spectre of contaminated blood supplies, created the conditions for politicisation and pressure for important reforms in blood services. Action to ensure blood quality was advocated by the newly emergent HIV/AIDS civil society, as well as by the Ministry's AIDS department. As a result, in 1988 blood screening with serological tests for AIDS and a number of other transfusion-transmitted diseases (e.g., hepatitis B, syphilis, Chagas, and malaria) became compulsory.

From the 1980s onwards, the development of nucleic acid amplification techniques, particularly the polymerase chain reaction (PCR)², opened up new avenues for preventing blood-borne diseases around the world (Rabinow 1996; Jordan and Lynch 1998). In 1997, for instance, a number of German blood services started testing transfusion blood with a PCR-based system in order to identify AIDS and the hepatitis C and B viruses (Roth, Weber, and Seifried 1999). The purpose of these tests was to complement serological tests for blood-borne viral diseases that might be present in donors. The nucleic acid-based tests, or NATs, were intended to reduce the 'window period' between contamination and the development of the antibodies identifiable by serological tests. Thus, these molecular tests were designed not to replace serological tests but rather to *complement* them.

The tests were gradually introduced in most industrialised countries for blood screening in transfusion services during the 1990s and 2000s (Roth et al. 2012). In some countries, such as France, scientists opposed their introduction because

2 As opposed to serological tests, which detect antibodies that act against pathogens, PCR tests directly test for the presence of a pathogen's genetic material.

of the economic impact—introducing such technology would ultimately cost more than would treating someone who became contaminated (Kameda and Kessel 2021). As the French scientists argued, no diagnostic is perfect and there will always be some degree of risk in blood screening. Nevertheless, industrialised countries progressively introduced NATs for HIV and hepatitis, reaffirming a highly cautious approach in the control of blood safety that prevailed following the contaminated-blood scandals that swept across these nations in the 1980s and 1990s (Feldman and Bayer 1999; Busch and Dodd 2000; Farrugia 2002).

In Brazil, the Ministry of Health issued a resolution in 2002 making the use of molecular tests compulsory for screening transfusion blood for HIV and hepatitis viruses in all public and private blood services in the country. While some private services had already started using molecular tests, the government's decision to make NATs a requirement would have major implications for the SUS.

I discussed this particular point in time with Brazilian scientists and representatives of the Ministry's Blood Coordination Office early in my fieldwork in 2015. Their responses revealed a paradoxical relationship with the NAT that gave greater depth to my understanding of why and how the government introduced the technology. The Brazilian blood system, which was modelled on the system in France, paid particular attention to the role of blood-contamination scandals in the reorganisation of blood regulation in that country. According to one molecular biologist who would later play a key role in introducing the NAT in the SUS, 'the pressure to improve blood quality that came after HIV alerted public health managers to the fact that it was important to be prepared' (Interview, Director of Technological Development, IBMP, Curitiba, July 2015). The introduction of technologies such as the NAT into the national blood system to make them 'universal'—that is, used throughout the country and available through the public healthcare system—thus became paramount and was a further factor informing Brazilian blood policy at the SUS. As another representative of the Blood Coordination Office proudly claimed, blood policy in Brazil had now acquired the same status as that conferred on blood policy in France and the US.

The relationship between blood and HIV policies is important, not only because of the latter's impact on blood safety but also because of the politicisation of the AIDS epidemic around access to essential medicines. In 1996, the arrival on the international market of new HIV treatments under patent protection quickly ran counter to the Brazil's public health and trade interests. At the time, the country had just begun to recognise pharmaceutical patents again, this being a prerequisite for entering the global market as laid out by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). Nevertheless, this did not prevent the Ministry of Health, under the

leadership of José Serra, from experimenting with new forms of market regulation for life-saving medicines—and in particular, from working with civil society and the national pharmaceutical industries to circumvent monopolies. This they did through legal, technological, and political strategies ranging from the public manufacturing of antiretroviral therapies to advocating for the flexibilization of patent rights in international forums (Biehl 2007; Cassier and Corrêa 2018).

The introduction of molecular tests was not just a way for the Brazilian state to assert a public health value regime. Although the introduction of viral load tests, one type of NAT, did become a priority, primarily to support pharmaceutical policies around HIV, molecular technologies have more broadly paved the way for other uses that are crucial to the country. As a representative of the Blood Coordination Office told me during an interview, the use of NATs in blood screening would allow them to compile a 'Brazilian profile' of remaining risks associated with the transmission of blood-borne diseases.

It is worth briefly resituating blood safety within the debate on the movement for global health. Concern over the transmission of infectious diseases through blood represents a departure from what Lakoff (2010) has described as the two regimes of global health: 'humanitarian biomedicine' and 'biosecurity'. As some of the major blood transfusion-transmitted diseases include viral infections, such as HIV and hepatitis, that disproportionately affect the poorest populations, but also because the supply of blood itself is insufficient in some developing countries, strengthening blood systems would appear to qualify as a priority area for global health intervention. Yet, as data has shown, blood safety projects received less than 0.9% of all global health funding between 2000 and 2015 (Ifland, Bloch, and Pitman 2018). Moreover, national blood transfusion systems also seem to be informed by the global health security regime in terms of the role that such systems might play in monitoring emerging and resurging diseases. The high investment that wealthy nations make to ensure that new disease outbreaks can be incorporated into their blood surveillance systems, contrasts with the situation of poorer nations and the challenges they face in implementing quality-assured blood systems (Busch, Bloch, and Kleinman 2019).

Technological autonomy

When José Serra, of the Brazilian Social Democracy Party, left the Ministry of Health to run for President in the 2002 elections, it became clear that the ministerial decree issued six months earlier to introduce nucleic acid tests (NATs) throughout the country could not be implemented. The deadline set by the decree, now the responsibility of the Luiz Inácio Lula da Silva's Workers' Party, was postponed twice. Accessing testing kits became a major problem: at that time only two

commercial NAT technologies existed, which had just been registered by the United States' Food and Drug Administration (FDA), and they were expensive.

In March 2003, blood policymakers from the Ministry of Health approached the Institute for Immunological Technology (Bio-Manguinhos) regarding the possibility of setting up a project to develop its own molecular biological blood-screening tests. This proposal arose from discussions held within the government's technical group in charge of analysing the introduction of NAT tests in Brazil. As described in an official letter from the Ministry of Health to Bio-Manguinhos, the technical group suggested that the government 'find alternatives to reduce the cost of its implementation'. These alternatives included developing the production of tests in the country and investing in a development project or establishing joint-venture agreements to allow for the test to be performed on donated blood samples at a substantially lower price.³

Here, I take a little historical step back to explain how Bio-Manguinhos became an important industrial player on the Brazilian scene and one capable of responding to the government's demand for a national technological alternative.

Bio-Manguinhos was set up in 1976 as a unit of the Oswaldo Cruz Foundation (Fiocruz), itself part of the Ministry of Health. Its core mission was to produce vaccines to supply the national immunisation programme launched in 1973 to control major infectious diseases epidemics in the country. With the need to quickly acquire industrial capacity for vaccine production, Bio-Manguinhos turned to international institutes and multinational companies, with whom it negotiated technology transfer agreements.⁴ With these partnerships, the company was able to begin vaccine production.

In the 1990s, a set of administrative and organisational reforms⁵ enabled Bio-Manguinhos to expand and ultimately to become a major supplier of biotechnologies to the Brazilian Ministry of Health. In particular, the laboratory

3 Official letter sent by the Brazilian Health Regulatory Agency (ANVISA), the equivalent of the FDA in the US, to Bio-Manguinhos, on June 9, 2003 (Ofício 519/2003/GGSTO). ANVISA is an independent regulatory health agency under the remit the Ministry of Health. At the time the letter was signed, ANVISA was in charge of coordinating the national blood system, including the country's blood use policy. Said policy was later entrusted to another body in the Ministry of Health, the General Coordination of Blood and Blood Products, created in 2004, where it has remained.

4 Moreover, at that time the position of Bio-Manguinhos, as that of the other research and production units of Fiocruz, was precarious. Fiocruz was itself created in 1970 by bringing together already existing institutions belonging to the Ministry of Health—from basic research institutes to a public health school, a hospital and both biotechnology and pharmaceutical industrial sites, including what would become Bio-Manguinhos. Fiocruz also incorporated the Oswaldo Cruz Institute, created in 1900, which had gained international and national recognition in the first half of the 20th century for its work on tackling tropical diseases. By creating Fiocruz the government intended to find support in national science and technology for its health programmes, as the country had done in the earlier part of the 20th century. However, Fiocruz's research and production facilities suffered from the lack of public investment of previous decades (Stepan 1976).

5 This included reforms conferring autonomy from, and flexibility in relation to, Fiocruz, as well as a major re-evaluation of its technological portfolio.

adopted a new policy of investing in ‘high value-added’ products that it would seek to manufacture through the negotiation of technology transfer agreements. This meant concentrating on more expensive technologies, initially mainly vaccines, that the Brazilian state intended to purchase. The incentive for other companies to enter into such agreements would be access to the public market during the period of technology transfer. Moreover, Bio-Manguinhos focused on acquiring technological ‘platforms’ that could be applied to a large number of diseases (Keating and Cambrosio 2003).

All this brought Bio-Manguinhos closer to the world of biotechnology venture capital. With its new products, alongside exports of its yellow fever vaccine, the company increased its revenues by 6,300%—from BR\$ 4 million (Brazilian reais) to BR\$ 280 million (Ponte 2007). The reorganisation of the unit also included advancing its diagnostics portfolio, from 2000 onward. Diagnostics had gained particular importance with the development, in the 1990s, of testing platforms to support the country’s HIV policies, which were becoming increasingly pharmaceutical-based. Bio-Manguinhos intended to supply the Ministry’s AIDS programme with rapid tests as part of efforts to improve diagnostics, alongside the viral-load technologies that were necessary to monitor HIV patients.

These diagnostics development projects were meant to provide the government with alternative and cheaper products. At the time, the molecular diagnostics sector was dominated by a few multinational companies that would eventually come to propose closed, automated platforms that required expensive kits and maintenance services. Commenting on the reasons for setting up molecular diagnostics manufacturing at Fiocruz, the head of the diagnostics development department cited the government’s concern over the country’s ‘very high dependence’ on the sector. The two multinational companies marketing NATs on the international market were ‘greedy’, they pointed out, charging the government high amounts and seeking to establish its ‘eternal dependency’ on imports of their technologies (Interview, head of the IVD development department, Bio-Manguinhos, Rio de Janeiro, 2014).

Fiocruz’s decision to enter the molecular diagnostics field nevertheless had to contend with a national context in which no molecular biology products were being manufactured in either the private or the public sector. By contrast, the national pharmaceutical industry had played a decisive role in the government’s HIV policies since the 1990s. Indeed, this ‘ability to produce’ generic drugs by mobilising existing industrial capacity infrastructure was identified as a factor in the ‘pharmaceutical sovereignty’ of Latin American countries (Hayden 2007).

Fiocruz’s efforts to innovate in the diagnostic arena was challenged by the fact that although the market in nucleic acid tests for blood safety was growing, it had

already consolidated around two large pharmaceutical companies. Roche and the Gen-Probe/Chiron joint venture had successfully ‘conquered’ the NAT market in developed countries across Europe, North America, and Japan—particularly after they had introduced automated platforms that gradually replaced the in-house systems developed by some national blood centres.⁶ In an interview on a news website, the executive of one of the two main NAT producers stressed how this ‘high-support business [involving] training the operators, installing machines, and making sure they run smoothly’ had enabled its double-digit growth. By comparison, immunological products constituted a high-volume, low-price market, making it a ‘pretty flat’ one. The growth of NATs was also driven by what the executive called ‘geographic expansion’ into emerging countries like China and India (Genomeweb 2012).

These considerations raise several questions about how new blood screening technologies transcend their value for reducing the risks of infectious disease transmission. This perceived value can put significant pressure on regulatory authorities to introduce new technologies in spite of the impact on public budgets. The configuration of the technological systems themselves, as closed platforms attached to required services, not only adds further value to the tests—for instance, automation of the tests makes them faster, easier to use, and, by reducing human intervention, less susceptible to contamination—but also consolidates the market around a few multinational players that rely on intellectual property rights to assert their power.⁷

Building a national diagnostic

Assembling technologies and creating markets through partnerships

Following the Ministry’s call to develop a molecular blood-screening system, Bio-Manguinhos set up a technological consortium comprising researchers from both the Federal University of Rio de Janeiro (UFRJ) and the Institute of Molecular Biology of Paraná (IBMP). These researchers had already worked together to develop a viral load test for the national AIDS programme.

Bio-Manguinhos subsequently established a partnership with the US biotech company Life Technologies, which had expertise in polymerase chain reaction (PCR) tests, to develop the viral load project. However, after one year the company suddenly reneged on the agreement under pressure from its partner, Abbott, which

6 These were the first two commercial NATs for blood screening to obtain FDA market authorisation, in 2002. By 2008, between them the producers of these two platforms shared the global market: 22 countries used Chiron/Gen-Probe tests, 18 used Roche kits, and seven used both (Röth et al. 2012).

7 In this regard, the global NAT companies, as much as other multinational *in vitro* diagnostic (IVD) companies, rely on their patent portfolios linked to PCR techniques and the HCV and HIV viruses, as well as on their merger and acquisition practices in the sector (Storz, Flasche, and Driehaus 2012).

had plans for both the HIV diagnostic and drug markets in Brazil.⁸ In one of my interviews, Brazilian scientists affirmed how this episode gave them a sense of the stakes of entering the market when all the industrial capacities they needed the country lacked. Nevertheless, it somehow drove the consortium on to do more to acquire those capacities.

Insight into how Bio-Manguinhos went on to develop a highly complex assembly strategy to produce the ‘NAT Brasileiro’ was provided by a researcher at the Institute. This researcher described how they had looked into the ‘black box’ of the closed systems marketed by the *in vitro* diagnostics (IVD) companies to find strategies to capture the various technologies in order to be able to repackage and offer the test to the government. The process involved the scientists and industrial actors breaking down the molecular diagnostic into its main technological components—diagnostic kits, machines, the various software programmes—and in turn, organising them into sub-components. The molecular biology kit was in fact an articulation of three technological modules essential to the PCR technique: a nucleic acid extraction module, an amplification module, and a control module. This specific organisation into modules, not uncommon in vaccine development (Bureth et al. 2007), helped the consortium to identify the technologies that would go into the Bio-Manguinhos NAT kit.

The ‘amplification module’, with primers, probes, a buffer, and, most importantly here, the enzyme *Taq* DNA polymerase, captures this assemblage well. Described as the linchpin that made comprehending the PCR as an amplification technique possible (Swanson 2007), this enzyme was the main technological item—together with the buffer—chosen by the Brazilian consortium for a know-how transfer agreement.⁹ That eventual agreement was the fruit of a collaboration that researchers from the UFRJ and Bio-Manguinhos had proposed to the German diagnostics company Qiagen. In an interview, a Qiagen representative talked about how they had perceived the proposal as an opportunity to go beyond the business aspect and collaborate in supporting a national, public health programme. It was deemed, in their own words, ‘a good opportunity, and a good thing. Not only a good commercial opportunity, but also one for the country’ (Interview, Qiagen’s representative, 2017).

Still, the agreement, signed between April and May 2009, did also provide the company with opportunities to explore the potential blood screening market in Latin America’s largest economy. In an article in Qiagen’s magazine QIAGENer, the

8 It was announced that the company was giving up on the technology transfer because of its commercial ties with Abbott, which was interested in the Brazilian market for HIV monitoring tests. At the time, Abbott was also litigating against the Brazilian government regarding its HIV drug, Kaletra (Chaves, Vieira, and Reis, 2008).

9 This was a know-how agreement, as the specific enzyme was no longer under patent protection.

company publicised the partnership and provided further information on the content of the agreement:

QIAGEN's researchers provided valuable support to Bio-Manguinhos during the development process, while also securing a five-year delivery contract for ourselves, covering reagents and instruments. QIAGEN will also support Bio-Manguinhos in the creation of an enzyme mixture that is part of the product. The Brazilian workers involved in the project spent several weeks in Hilden training up for their mission. In turn, QIAGEN employees will fly to Brazil for several weeks to train their colleagues on site there. (QIAGENer, Issue 3/2009)

In this excerpt, Qiagen outlines some of the characteristics of the partnership. It involved two agreements: one, for know-how on the enzyme and the buffer; the other, for the supply of the reagent and instruments involved in the extraction module. The know-how transfer contract was similar to other technology transfer contracts that Bio-Manguinhos enjoyed for vaccines and diagnostics, establishing the temporary payment of royalties from the commercialisation of the resulting product.

To house production of the enzyme, the government, through its Blood Coordination Office and the public blood company Hemobrás, funded the construction of an industrial plant on the premises of one of the NAT consortium members, the IBMP. As explained above, the second agreement concerned supply of the extraction module's components. These included not only the reagents for nucleic acid extraction but also equipment for handling the components. This time, Bio-Manguinhos opted to outsource the module to Qiagen. For that purpose, the company brought in its Original Equipment Manufacturer (OEM) department. The OEM represents an entirely different market, one that instead of supplying an entire product provides only part of the workflow. Qiagen duly provided the extraction module, which was then given Bio-Manguinhos labelling. In this way, the German company gained access to at least one country's market in the oligopolistic, blood screening NAT business.

The agreement cleverly tied together two completely different components and, as a result, two completely different markets. The transfer of the amplification module components (the *Taq* polymerase and the buffer) were tied to the extraction module. In fact, the agreement granted Bio-Manguinhos the right to use the transferred know-how on amplification components in a way that could only be exploited in that configuration, i.e., with Qiagen as the supplier of the extraction module's equipment and reagent (as well as the associated technical assistance).

The Brazilian actors' acceptance of the company's negotiation strategy, which limited knowledge transfer in order to ensure the former's continued need for the latter's products, reflects the power asymmetries between the two 'partners'. This arrangement was accepted on the understanding that Brazil would acquire the technological capabilities it needed to overcome its complete technological dependence in the production of molecular kits. In the context of a system that required a range of technologies and capabilities, the Brazilian consortium developed a 'pragmatic' form of resistance. This was guided by the imperative to gradually 'nationalise' the supply of technological components considered strategic for supporting its public health programmes, while recognising that achieving technological independence for other components was beyond the country's ability. To manufacture those other components, i.e., the extraction equipment, the country would require capabilities in robotics engineering, fluidics, and optics, all 'major gaps in the technological development of biotechnology in Brazil' (Interview, researcher at the UFRJ, Rio de Janeiro, 2015).

Observing molecular sovereignty in action

In this subsection, I briefly describe a visit to a blood screening centre in Rio de Janeiro to show how the various components of the test work together in practice. In 2016, I visited the Blood Centre of Rio de Janeiro (Hemorio), the public blood service that coordinates blood collection and treatment for the state of Rio de Janeiro. I spent several hours at the site where blood was screened using nucleic acid testing (NAT). Hemorio is one of the 14 blood centres that came to offer blood screening with the NAT. This country-wide network of 'NAT sites' was established gradually, from May 2011, a few months after the Bio-Manguinhos NAT kit obtained regulatory authorisation to enter the Brazilian market. In fact, some of these centres had helped to support the kit's authorisation by producing blood test data as part of the national project. The entire network started to fully screen blood for the public health system in 2012, initially for HIV and hepatitis C, and two years later for hepatitis B as well. It was only once this network of public 'NAT sites' had been created that screening blood using NATs became compulsory for blood services nationwide, whether or not they were connected to the Sistema Único de Saúde (SUS).

Two Hemorio technicians, wearing white jackets with an SUS logo—a blue cross—prepare the blood samples that will enter what appear to be four main stages of the test, which uses the nucleic acid amplification technique of real-time polymerase chain reaction (PCR). In a rather small room, two large machines perform the initial steps of the test. First, an enormous machine from the US equipment giant, Perkin Elmer, prepares the pools of six blood samples, with their respective controls, allowing for up to 92 blood bags to be tested at the same time. They will subsequently undergo nucleic acid extraction in an equally large red and

white machine from the German company Qiagen. Technicians will then collect the tubes with the extracted genetic material and take them to another room, where a Thermo machine will finally perform amplification with real-time screening for the genetic material of viruses. This will help to screen the blood and indicate whether the blood is contaminated. In contrast with these three large machines, all the molecular biology components are stored in a small blue box branded with the Bio-Manguinhos logo, left open by the aluminium sink alongside pipettes and tubes.

This observation points to the highly complex assemblages that characterise the Brazilian molecular testing system. The presence of some of the main global *in vitro* diagnostics players in the same lab is worthy of note, brought together through the range of equipment, expertise, and political authority that formed the Brazilian platform and ultimately integrated into the Bio-Manguinhos molecular biology kit.

The ‘NAT Brasileiro’ model

In 2015, in Brasilia, during a conversation with representatives of the Ministry of Health’s Blood Coordination Office, I ask about the significance of them having developed their own molecular blood screening system. ‘This is really a product to be proud of,’ one of them says. The molecular test, this person claims, was not only constantly under development but is currently being tweaked to identify a fourth disease. The product, registered as a Bio-Manguinhos technology but sometimes referred to as the ‘NAT Brasileiro’, obtained market authorisation from the Brazilian Health Regulatory Agency (ANVISA) in 2010. Two more years were necessary to introduce the test at the 14 testing sites around the country, which include Hemorio. Bio-Manguinhos produces and supplies the kits, in accordance with a centralised approach. It also provides training for technicians and has created a technical assistance service to coordinate the support provided by the company supplying the machines.

There are economic reasons for this centralised model. For one thing, it guarantees the purchaser, the Brazilian state, control over all the steps involved in the test. Although transporting the blood samples entails considerable logistics, those I interviewed felt that the model helped to defend Brazilian values of universal access and the right to health against the incursions of the multinational pharmaceutical industry. Based on what the consortium members described as a ‘one-source solution’ organised around Bio-Manguinhos, this centralised system is ironically similar to the ‘closed platform’ model adopted by most multinational *in vitro* diagnostic (IVD) companies. In fact, by protecting this national initiative, the state has effectively reserved ‘public’ blood for the Bio-Manguinhos system. The state also requires that all testing sites use the Brazilian NAT, incentivising its use,

albeit indirectly, by providing it free of charge to the centres and paying the indirect costs associated with testing.¹⁰

One, perhaps unexpected, outcome of this centralised model has been the creation of a nationwide testing system in a country characterised by a vast geographic scale and socioeconomic, healthcare, and scientific inequalities between its various regions. The development of a national healthcare system that is universal and free is a challenge in itself for the Brazilian state, and in recent decades its considerable public market has been used to support industrial and economic development policies. However, this universal model ultimately reinforces the division between the SUS and the private healthcare system, which uses commercial NAT systems. It also makes comparison with other technologies possible, and it was on this basis that the Brazilian NAT came under intense pressure from the country's own blood experts.

The Brazilian Association of Haematology and Haemotherapy (ABHH) was the strongest voice in this field. An organisation representing the professional haematology, blood-therapy, and cell-therapy community working in both the private and public sectors, the ABHH advocated the immediate and routine adoption of NATs by all blood services. This position was stated in the Association's official journal, in 2008. As the Brazilian testing system was still under development at that time, this would mean adopting 'commercial tests' instead of waiting for national technology to become available. On the government side, NAT project members decried the constant pressure from the ABHH and other private entities to introduce commercial kits. Consequently, in November 2013, the ABHH launched the campaign '*Transfusão, só com NAT*' ('Transfusion only with NAT') at its symposium, *Hemo*, to pile further pressure on the government to craft a mandate obliging all blood services to adopt molecular testing. A month later the Ministry of Health did indeed issue a decree, making blood screening for HIV and hepatitis C using the NAT compulsory throughout the country (see Figure 1). The decision did not affect the government's plan to adopt its own diagnostic system, however, because by this point the Brazilian test had been taken up by the public sector.

This decree by the government did not end the controversy around NATs in the public sector, though. Pushing back against the Brazilian NAT model, the ABHH questioned the quality of the public test compared with that of the commercial technologies available on the market. On February 27, 2018, it filed a lawsuit (*ação direta de inconstitucionalidade*, or ADI) challenging the constitutionality of the ministerial decree that reserved the public market for Bio-Manguinhos technology.

10 Indirect costs relate to electrical energy, human resources, the transportation of samples, and other inputs necessary for NAT testing.

While the action challenged the obligation to use the national kit, the main argument revolved around its quality. The petition asserted that the performance of the Bio-Manguinhos test was inferior to that of the technology offered by multinational companies, and made allegations about the kit's performance, problems with the equipment, and the fact that the Brazilian test was not fully automated and required human intervention.

Dismissing the suit for technical reasons, the Supreme Court ended up not analysing the content of the Association's claims.¹¹ Nevertheless, we can reflect on how this case sheds light on the differing points of view of the state and of the private actors when it comes to providing diagnostics. On the one hand, the government reconciled its commitment to adopting new blood safety technologies with considerations on the country's economy and autonomy, by supporting the creation and improvement of a 'not-for-profit' test. On the other, by highlighting the advantages of multinational companies' tests compared with the Brazilian NAT (for instance, fully automated versus semi-automated systems), the Association sought to defend a different values regime in the introduction of diagnostics. In doing so, the latter reproduced to some extent the legal and scientific narratives that have characterised the strategies of global pharmaceutical companies to undermine the role of states and industries in the South (Banerjee 2017).

11 The technical reasons outlined were that the Association was not in a legitimate position to propose the action since it only represented a fraction of the medical field, and that it was seeking a constitutional remedy to challenge a secondary-level standard (not directly based on the Constitution).

2002	On February 5, 2002, the Ministry of Health publishes a ministerial decree (Portaria MS/GM No. 262) requiring all Brazilian blood banks to perform NAT to screen for the Aids and hepatitis C viruses as part of their blood screening routine, within both the SUS and exclusively private services, within six months. Other decrees extend this deadline.
2003	Under the government of the Workers' Party, the Ministry of Health decides to gradually introduce the NAT test. In 2003, Bio-Manguinhos is approached to develop a national NAT test.
2004	A 2004 ministerial decree (Portaria MS/GM No 112) opts for implementing NAT in steps and does not set a deadline for incorporation.
2006	Decision to build a plant at IBMP, in Curitiba, for molecular test components.
2009	Signing of a knowhow transfer agreement with Qiagen for the Taq DNA Polymerase enzyme. Inauguration of the industrial plant.
2010	NAT Bio-Manguinhos test registered by Anvisa in 2010.
2012	The test is gradually introduced in 14 blood banks by 2012.
2013	NAT testing is made mandatory (for all services, in the SUS and in the exclusively private sector).
2014	The Brazilian NAT covers the hepatitis B virus.
2016	President Dilma Rousseff announces the development of NAT for zika screening in transfusion blood, but this does not materialize.
2018	ABHH files a constitutional lawsuit challenging the NAT model and the obligation for the SUS to use the national test.
2020	Inclusion of malaria as a target of the Brazilian NAT.

1. Timeline of the NAT's introduction into the unified healthcare system (SUS).

Conclusion: Molecular sovereignty—build and imagine the Brazilian nation

This research article has critically examined the molecularisation of transfusion diagnostics in Brazil as a stimulus for reflecting on the complex and often contradictory value regimes applied in defining national testing priorities. The exercise of molecular sovereignty through a state-driven enterprise, as outlined here, required investments in industrial, technological, and organisational capacities; furthermore, it led to a technopolitical solution in which 'national' translated into the creation of a system to screen blood *for* the national healthcare system, while excluding the private services that did not serve it.

Initiatives like the Brazilian nucleic acid test (NAT) are, in their own way, dependent on the increasingly widespread strategy of public–private partnerships for product development. This dependency reflects the gradual shift of states from a discourse opposing intellectual property standards to a strategy of 'latching onto' the owners of technologies—from well-established Big Pharma companies to emerging

technological corporations. In negotiating transfer agreements, an approach to acquiring capacity and mastering platforms that can yield other benefits in the form of new uses and homegrown research and development, Brazil's public-industrial actors anticipated the prospect of gradual technological independence. Such initiatives became instruments of Brazil's national industrial policy from the late 2000s and into the 2010s, and were often criticised at the international level by the US Trade Department for their potential threat to US corporations' interests (Cassier and Corrêa 2018). However, their ambitious goals failed to resolve the long-standing challenge of consolidating Brazilian innovation. Moreover, the political and economic crises of the last five years have frozen investment in an already underfunded public healthcare system, revealing the fragilities of NAT-like projects that require long-term investment and government support that is hard to imagine nowadays.

With the emergence of COVID-19, polymerase chain reaction (PCR) tests have become central to the World Health Organization's (WHO) epidemiological response, with international experts calling on countries to increase testing (Street and Kelly 2020). The obstacles to scaling up testing have raised questions about dependence in the production of health technologies and the need to reinvest in 'industrial and technological sovereignty', even in wealthy nations. However, the pandemic has also spurred all kinds of technological nationalism, with wealthier nations reserving diagnostic kits and vaccines at the expense of poorer ones (Gaudillière 2020; Velasquez 2020).

In Brazil, the federal government has lost its grip on national biomedical innovations. Nonetheless, the nationwide mobilisation to enhance PCR testing capacity points to the continuity of a certain way of molecularising the public healthcare system. It extends the Brazilian NAT approach to controlling technologies and to providing a testing infrastructure in a broader sense, from the logistics of transporting samples to providing trained personnel to perform crucial laboratory work.

The expansion of the state's diagnostic capacity has not translated into a robust, national, public health response to COVID-19. Nevertheless, the degree to which diagnostic innovation has been possible reveals the resilience of Brazilian public health actors and the ability of a national institution like Fiocruz to assert a public health regime. The presence of new partners and new funding capital to support testing efforts requires further investigation, in order to understand their influence on how molecular sovereignty is defined. More broadly, by extending the notion of 'molecular sovereignty', this article calls on anthropologists, social scientists, and critical scholars of global health and biomedicine to consider molecularisation

efforts in developing countries as intersecting with efforts to build and imagine the nation.

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References

- Banerjee, Dwaipayan. 2017. 'Markets and Molecules: A Pharmaceutical Primer from the South'. *Medical Anthropology: Cross Cultural Studies in Health and Illness* 36 (4): 363–80. <https://doi.org/10.1080/01459740.2016.1209499>.
- Benchimol, Jaime. 2017. 'Yellow Fever Vaccine in Brazil: Fighting a Tropical Scourge, Modernising the Nation'. In *The Politics of Vaccination: A Global History*, edited by Christine Holmberg, Stuart Blume, and Paul Greenough, 174–208. Manchester, UK: Manchester University Press.
- Biehl, João Guilherme. 2007. *Will to Live: AIDS Therapies and the Politics of Survival*. Princeton, NJ: Princeton University Press.

- Bureth, Antoine, Moritz Müller, Julien Pénin, and Sandrine Wolf. 2007. 'Brevet, Innovation Modulaire et Collaboration'. *Revue D'Économie Industrielle* 120: 135–54. <https://doi.org/10.4000/rei.3123>.
- Busby, Helen, Julie Kent, and Anne-Maree Farrell. 2014. 'Revaluing Donor and Recipient Bodies in the Globalised Blood Economy: Transitions in Public Policy on Blood Safety in the United Kingdom'. *Health* 18 (181): 79–94. <https://doi.org/10.1177/1363459313476966>.
- Busch, Michael P., Evan M. Bloch, and Steven Kleinman. 2019. 'Prevention of Transfusion-Transmitted Infections'. *Blood. American Society of Hematology* 133 (17): 1854–64. <https://doi.org/10.1182/blood-2018-11-833996>.
- Busch, Michael P., and Roger Y. Dodd. 2000. 'Nucleic Acid Amplification Testing and Blood Safety: What Is the Paradigm?' *Transfusion* 40 (10): 1157–60. <https://doi.org/10.1046/j.1537-2995.2000.40101157.x>.
- Cassier, Maurice, and Marilena Corrêa. 2018. *Health Innovation and Social Justice in Brazil*. Cham, Switzerland: Palgrave Macmillan. <https://doi.org/10.1007/978-3-319-76834-2>.
- Chauveau, Sophie. 2009. 'From Human Blood to Blood Products. Blood Collection and Blood Derived Products in France after 1950: A Third Way of Standardising Therapeutic Agents?' In *Harmonizing Drugs. Standards in 20th-Century Pharmaceutical History*, edited by Christian Bonah, Christophe Masutti, Anne Rasmussen, and Jonathan Simon, 181–201. Paris, France: Éditions Glyphe.
- Chaves, Gabriela C., Marcela F. Vieira, and Renata Reis. 2008. 'Acesso a medicamentos e propriedade intelectual no Brasil: Reflexões e estratégias da sociedade civil'. *SUR – Revista Internacional de Direitos Humanos* 5 (8): 170–98. <https://doi.org/10.1590/S1806-64452008000100009>.
- Clarke, Adele E., Laura Mamo, Jennifer R. Fishman, Janet K. Shim, and Jennifer Ruth Fosket. 2003. 'Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine'. *American Sociological Review* 68 (2): 161. <https://doi.org/10.2307/1519765>.
- Dumit, Joseph. 2012. *Drugs for Life: How Pharmaceutical Companies Define Our Health*. Durham, NC and London, UK: Duke University Press. <https://doi.org/10.2307/j.ctv125jgdj>.
- Dussauge, I., C. F. Helgesson, and F. Lee. 2015. *Value Practices in the Life Sciences and Medicine*. Oxford, UK: Oxford University Press.
- Edmonds, Alexander. 2010. *Pretty Modern: Beauty, Sex, and Plastic Surgery in Brazil*. Durham, NC and London, UK: Duke University Press. <https://doi.org/10.2307/j.ctv11312gv>.
- Farrugia, Albert. 2002. 'The Regulatory Pendulum in Transfusion Medicine'. *Transfusion Medicine Reviews* 16 (4): 273–82. <https://doi.org/10.1053/tmrv.2002.35213>.
- Feldman, Eric A., and Ronald Bayer. 1999. *Blood Feuds: AIDS, Blood, and the Politics of Medical Disaster*. New York, NY and Oxford, UK: Oxford University Press.

- Flynn, Matthew. 2015. *Pharmaceutical Autonomy and Public Health in Latin America: State, Society, and Industry in Brazil's AIDS Program*. New York, NY: Routledge.
- Gadelha, Carlos, Laís Costa, José Maldonado, Pedro Barbosa, and Marco Vargas. 2013. 'The Health Care Economic–Industrial Complex: Concepts and General Characteristics'. *Health* 5 (10): 1607–21. <https://doi.org/10.4236/health.2013.510217>.
- Gaudillière, Jean-Paul. 2020. 'Covid-19 et Santé Globale: La Fin Du Grand Partage? Tourmant Gestionnaire et Gravité de La Pandémie'. AOC, 3–7. <https://aoc.media/analyse/2020/04/02/covid-19-et-sante-globale-la-fin-du-grand-partage/>
- Genomeweb. 2012. 'New Novartis Dx President Discusses Nucleic Acid Testing, Blood Screening Business'. GenomeWeb, March 16, 2012. <https://www.genomeweb.com/pcrsample-prep/qa-new-novartis-dx-president-discusses-nucleic-acid-testing-blood-screening-busi>.
- Hayden, Cori. 2007. 'A Generic Solution? Pharmaceuticals and the Politics of the Similar in Mexico'. *Current Anthropology* 48 (4): 475–95. <https://doi.org/10.1086/518301>.
- Hogarth, Stuart, Michael M. Hopkins, and Victor Rodriguez. 2012. 'A Molecular Monopoly? HPV Testing, the Pap Smear and the Molecularisation of Cervical Cancer Screening in the USA'. *Sociology of Health and Illness* 34 (2): 234–50. <https://doi.org/10.1111/j.1467-9566.2011.01411.x>.
- Ifland, Luke, Evan M. Bloch, and John P. Pitman. 2018. 'Funding Blood Safety in the 21st Century'. *Transfusion* 58 (1): 105–12. <https://doi.org/10.1111/trf.14374>.
- Jordan, Kathleen, and Michael Lynch. 1998. 'The Dissemination, Standardization and Routinization of a Molecular Biological Technique'. *Social Studies of Science* 28 (5): 773–800. <https://doi.org/0803973233>.
- Kameda, Koichi, Ann H. Kelly, Javier Lezaun, and Ilana Löwy. 2021. 'Imperfect Diagnosis: The Truncated Legacies of Zika Testing'. *Social Studies of Science* 51 (5) 683–706. <https://doi.org/10.1177/03063127211035492>.
- Kameda, Koichi, and Nils Kessel. 2021. 'Quel Consensus ? La Sécurité Transfusionnelle En Allemagne et Au Brésil'. *Cahiers Droit, Sciences & Technologies* (12) : 97–115. <https://doi.org/10.4000/cdst.3483>.
- Keating, Peter, and Alberto Cambrosio. 2003. *Biomedical Platforms: Realigning the Normal and the Pathological in Late-Twentieth-Century Medicine (Inside Technology)*. Cambridge, MA: MIT Press.
- Kent, Michael, Ricardo Ventura Santos, and Peter Wade. 2014. 'Negotiating Imagined Genetic Communities: Unity and Diversity in Brazilian Science and Society'. *American Anthropologist* 116 (4): 736–48. <https://doi.org/10.1111/aman.12142>.
- Lakoff, Andrew. 2010. 'The Two Regimes of Global Health'. *Humanity* 1 (1): 59–79. <http://humanityjournal.org/wp-content/uploads/2014/06/1.1.lakoff.pdf>.
- Latour, Bruno. 2011. *Ciência Em Ação*. São Paulo, Brazil: Editora Unesp.

- Löwy, Ilana. 2006. *Vírus, Mosquitos e Modernidade: A Febre Amarela No Brasil Entre Ciência e Política*. Coleção História e Saúde. Rio de Janeiro, Brazil: Editora Fiocruz.
- Loyola, M. A. 2008. 'Medicamentos e Saúde Pública Em Tempos de AIDS: Metamorfoses de Uma Política Dependente'. *Cien Saude Colet* 13 (Suppl): 763–78. <http://www.scielo.br/pdf/csc/v13s0/a27v13s0.pdf>.
- Ministério da Saúde, Secretaria de Atenção à Saúde, Departamento de Atenção Especializada e Temática. 2018. *Caderno de Informação: sangue e hemoderivados: dados de 2016*. Brasília, Brazil: Ministério da Saúde.
- Nading, Alex M. 2015. 'Chimeric Globalism: Global Health in the Shadow of the Dengue Vaccine'. *American Ethnologist* 42 (2): 356–70. <https://doi.org/10.1111/amet.12135>.
- Nguyen, Vinh-Kim. 2010. *The Republic of Therapy: Triage and Sovereignty in West Africa's Time of AIDS*. Durham, NC: Duke University Press Books.
- Petryna, Adriana, Andrew Lakoff, and Arthur Kleinman. 2006. *Global Pharmaceuticals: Ethics, Markets, Practices*. Durham, NC: Duke University Press.
- Pollock, Anne. 2019. *Synthesizing Hope: Matter, Knowledge, and Place in South African Drug Discovery*. Chicago, IL: University of Chicago Press.
- Ponte, Carlos Fidelis. 2007. 'Bio-Manguinhos: Um Ponto de Confluência Entre a Saúde Pública, a Ciência e a Tecnologia.' In *Inovação Em Saúde: Dilemas e Desafios de Uma Instituição Pública*, edited by Nara Azevedo, Carlos Augusto Grabois Gadelha, Carlos Fidelis Ponte, Cláudia Trindade, and Wanda Susana Hamilton, 35–138. Rio de Janeiro, Brazil: Editora Fiocruz.
- Rabinow, Paul. 1996. *Making PCR: A Story of Biotechnology*. Chicago, IL: University of Chicago Press.
- Roth, W. K., M. P. Busch, A. Schuller, S. Ismay, A. Cheng, C. R. Seed, C. Jungbauer, et al. 2012. 'International Survey on NAT Testing of Blood Donations: Expanding Implementation and Yield from 1999 to 2009'. *Vox Sanguinis* 102 (1): 82–90. <https://doi.org/10.1111/J.1423-0410.2011.01506.X>.
- Roth, Willi Kurt, Marijke Weber, and Erhard Seifried. 1999. 'Feasibility and Efficacy of Routine PCR Screening of Blood Donations for Hepatitis C Virus, Hepatitis B Virus, and HIV-1 in a Blood-Bank Setting'. *Lancet* 353 (9150): 359–63. [https://doi.org/10.1016/S0140-6736\(98\)06318-1](https://doi.org/10.1016/S0140-6736(98)06318-1).
- Santos, Luiz A. de Castro, Cláudia Moraes, and Vera Schattan P. Coelho. 1992. 'Os Anos 80: A Politização Do Sangue'. *PHYSIS* 2 (1): 107–49. <https://doi.org/10.1590/S0103-73311992000100005>.
- Stepan, Nancy. 1976. *Beginnings of Brazilian Science: Oswaldo Cruz, Medical Research and Policy, 1890–1920*. New York, NY: Science History Publications.
- Storz, Ulrich, Wolfgang Flasche, and Johanna Driehaus. 2012. *Intellectual Property Issues*. Springer Briefs in Biotech Patents. Berlin, Heidelberg: Springer Berlin Heidelberg.

- Street, Alice, and Ann Kelly. 2020. 'Counting Coronavirus: Delivering Diagnostic Certainty in a Global Emergency'. *Somatosphere*, March 6, 2020. <http://somatosphere.net/forumpost/counting-coronavirus-diagnostic-certainty-global-emergency/>.
- Sunder Rajan, Kaushik. 2006. *Biocapital: The Constitution of Postgenomic Life*. Durham and London, UK: Duke University Press. <https://doi.org/10.1215/9780822388005>.
- Swanson, Kara. 2007. 'Biotech in Court: A Legal Lesson on the Unity of Science'. *Social Studies of Science* 37 (3): 357–84. <https://doi.org/10.1177/0306312706071793>.
- Velasquez, German. 2020. *Re-Thinking Global and Local Manufacturing of Medical Products After COVID-19*. Research Paper 118. Geneva, Switzerland: The South Centre. <https://www.southcentre.int/wp-content/uploads/2020/09/RP-118-REV.pdf>.
- Waldby, Catherine. 2000. *The Visible Human Project: Informatic Bodies and Posthuman Medicine*. London: Routledge.
- Waldby, Catherine, and Robert Mitchell. 2006. *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism (Science and Cultural Theory)*. Durham, NC: Duke University Press Books.