Investigation Report

Global Fund-financed procurements

Fraudulent practices in the sale of rapid diagnostic tests

GF-OIG-26-006
9 June 2026
Geneva, Switzerland

THE GLOBAL FUND
Office of the Inspector General

What is the Office of the Inspector General?

The Office of the Inspector General safeguards the Global Fund's assets, investments, reputation and sustainability by ensuring that it takes the right action to end the epidemics of AIDS, tuberculosis and malaria. Through audits, investigations and advisory work, it promotes good practice, enhances risk management and reports fully and transparently on abuse.

If you suspect irregularities or wrongdoing in programs financed by the Global Fund, you should report them to us.

Online Form: Available in English, French, Russian, Spanish

Email: hotline@theglobalfund.org

Learn about fraud, abuse and human rights violations at the OIG's e-learning site, **www.ispeakoutnow.org**

Contents

1. Executive Summary

1.1 Investigation at a glance

The Office of the Inspector General (OIG) found that the sale of some health products by a supplier to Global Fund implementers (the Supplier) (either directly or through a Procurement Service Agent (PSA))[1], was compromised by fraudulent practices.[2] Findings are established by a preponderance of evidence. More information about the OIG's methodology is available in Annex B of this Report.

Global Fund implementers procured HIV and malaria Rapid Diagnostic Tests (RDTs), either directly or through the PSA, which were presented by the Supplier as prequalified products under the World Health Organization's (WHO) prequalification scheme for in vitro diagnostics (IVDs).[3] Such prequalification would have ensured compliance with the contractual obligations and/or the Global Fund's *Guide to Global Fund Policies on Procurement and Supply Management of Health Products* and *the Global Fund Quality Assurance Policy for Diagnostics Products* (the "Quality Assurance Policies").[4]

Evidence obtained by the OIG demonstrates that the Supplier stopped procuring uncut sheets, used as components of the RDTs, containing antigens and antibodies, from the manufacturer mentioned in the WHO prequalification documentation.

The Supplier was required, under WHO's applicable policies, to notify WHO of reportable changes to the prequalified RDTs, particularly about changes related to the manufacturing process, including the change of a supplier of antigens and antibodies.[5]

The OIG found no indications that the Supplier notified WHO, the relevant implementers, or the PSA that it did not intend to source the uncut sheets from the manufacturer mentioned in the WHO prequalification documentation.

The OIG found that this omission or misrepresentation was more likely than not done knowingly or recklessly and that it misled the PSA and/or the Global Fund implementers into believing that the RDTs were compliant with the Supplier's contractual obligations, when, in fact, they were not. The OIG found that it is more likely than not that the omission or misrepresentation by the Supplier was aimed at obtaining a financial benefit or avoiding an obligation.

---

[1] The Global Fund adopted a Pooled Procurement Mechanism that aggregates order volumes on behalf of participating implementers to negotiate prices and delivery conditions with manufacturers. The order and fulfilment of procurements is delegated to a PSA. The Global Fund selected PSAs to act as agents on behalf of implementers in the procurement of health products.

[2] This Investigation Report contains findings of fraudulent practices, as defined in the Global Fund Code of Conduct for Suppliers dated 15 December 2009, with respect to the following sales (the "Relevant Sales"): 1) PSA RFQ PE50174 dated November 2016, the Supplier's offer to the RFQ (Sub: PE50174), dated November 2016; 2) Contract for the supply of goods between the Supplier and the PSA, dated 30 October 2018, purchase order PO-539570 dated 15 April 2019; 3) The Global Fund Implementer 1, Competitive Bidding documents, dated May 2017; 4) Contract between the Supplier and the Global Fund Implementer 2 dated 9 October 2017, Annex #5-2, dated 14 March 2018.

[3] WHO prequalification is one of the ways such health products can meet the applicable Global Fund procurement and quality assurance standards. WHO prequalification aims to ensure that key health products meet global standards of quality, safety, and efficacy in order to optimize use of health resources and improve health outcomes. The prequalification process consists of a scientifically sound assessment, which may include dossier review, product testing, performance evaluation, and inspection of manufacturing sites / contract research organizations, see "What We Do", https://extranet.who.int/prequal/about/what-we-do, accessed on 22 March 2024.

[4] Guide to Global Fund Policies on Procurement and Supply Management of Health Products, dated June 2012, July 2016, July 2017, and October 2018; Global Fund Quality Assurance Policy for Diagnostic Products, dated 14 December 2010 (amended on 5 February 2014 and 4 May 2017).

[5] Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device, WHO Prequalification Team: Diagnostics, dated 27 June 2014 and December 2016.

The OIG also found that the Supplier did not comply with the OIG's reasonable requests for information related to the performance of Global Fund-financed contracts and to allow access to relevant staff of the Supplier.

The OIG makes no findings regarding the efficacy of the RDTs supplied by the Supplier at any point, or regarding any other products currently[6] or previously manufactured by the Supplier. No evidence is made available to the OIG regarding any adverse outcomes linked to the use of the RDTs.

1.2 Genesis and scope

The Global Fund received an allegation that the Supplier supplied Global Fund implementers with RDTs that were not manufactured in compliance with the WHO prequalification specifications, which is one of the Global Fund's quality assurance standards applicable to IVDs. Allegedly, the Supplier's RDTs at issue contained testing strips from a manufacturer other than the one referenced in the relevant WHO prequalification documentation.

The investigation covered two health products and WHO prequalification periods:

- HIV RDTs with the manufacturer product code I05, for the period between 14 July 2016 and 7 February 2020.
- Malaria RDTs with the manufacturer product code I13, for the period between 25 February 2015 and 12 June 2019.

RDTs include a testing strip sourced from an uncut sheet, which is then cut into individual testing strips for assembly. As part of the WHO IVDs prequalification process, suppliers are required to disclose the details and origin of individual components that make up the RDTs. This includes instances where components are sourced from third-party manufacturers.

RDTs were procured directly from the Supplier by Global Fund implementers and indirectly, via the Global Fund Pooled Procurement Mechanism, by the PSA.

The OIG conducted a review of selected procurement and contractual documents between the Supplier, the PSA and implementers, which represent approximately 16% of the total RDTs provided by the Supplier to Global Fund implementers.[7] Through the review of the selected records, the OIG verified that the Global Fund Code of Conduct for Suppliers and the Quality Assurance Policies were applicable to these contracts and associated sales (the "Relevant Sales"), either directly by reference or indirectly by being integrated in substance into the contractual documents.

Under the Requests for Quotations and subsequent contractual documents with the PSA and the implementers, the Supplier was required to supply HIV I05 and malaria I13 RDTs that fulfilled the WHO prequalification requirement and/or the Quality Assurance Policies.[8] For the HIV I05 and malaria I13 RDTs directly procured by Global Fund implementers from the Supplier, contractual documents were concluded between the two parties. For the Relevant Sales, the contracts included references to the WHO prequalification requirement.

[6] The Supplier's HIV PI05 RDT became WHO prequalified on 16 September 2019, and the Supplier's malaria PI13 RDT became WHO prequalified on 4 December 2018.
[7] The total number of RDTs supplied by the Supplier to Global Fund implementers is derived from data reported through the Pooled Procurement Mechanism, the Global Fund's Price and Quality Reporting (PQR) tool—which is based on self-reported implementer data—and documentation obtained during the investigation.
[8] Guide to Global Fund Policies on Procurement and Supply Management of Health Products, dated June 2012, July 2016, July 2017, and October 2018; Global Fund Quality Assurance Policy for Diagnostic Products, dated 14 December 2010 (amended on 5 February 2014 and 4 May 2017).

While the OIG's findings of fraudulent practices, see Section 2.1, are directly in relation to the Relevant Sales, OIG's analysis found that during the WHO prequalified period of the HIV I05 RDTs and malaria I13 RDTs, Global Fund implementers in 28 countries reported procuring 34.4 million RDTs from the Supplier with an approximate total value of US$12.3 million.[9]

Due to the timing of the OIG's investigation and the limited availability and shelf life of RDTs, the OIG was unable to draw any conclusion about their quality and performance. During the referenced WHO prequalification periods, the Global Fund did not receive any reports related to the quality or performance of the RDTs from the Supplier. Consequently, the OIG makes no inference as to the efficacy or any potential health risks related to the use of these RDTs.

1.3 Findings

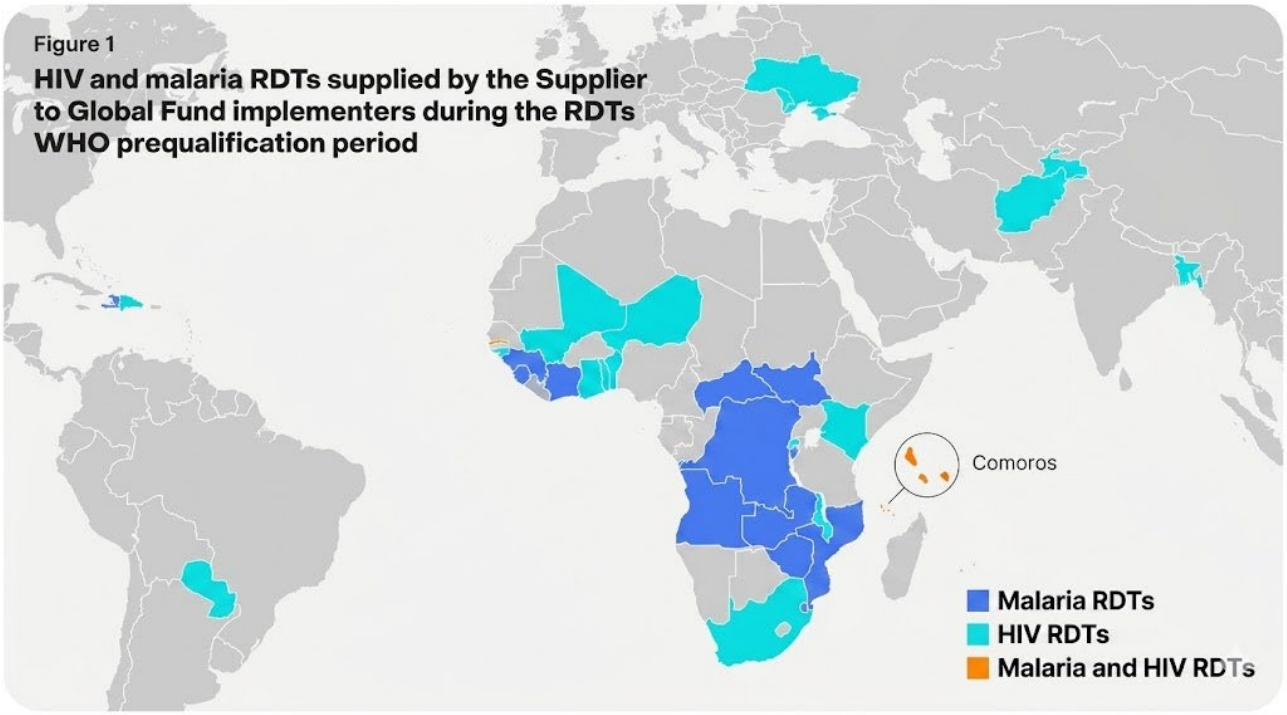
- The sale of HIV and malaria RDTs with Global Fund funds was, more likely than not, compromised by fraudulent practices.
- The OIG finds that it is more likely than not that the Supplier did not comply with reasonable requests for information related to the performance of Global Fund-financed contracts and to allow access to relevant staff.

1.4 Impact of the investigation

The Global Fund plays a leading role in the global market for medicines and technologies that prevent, diagnose, and treat HIV and malaria. Every year, the Global Fund invests around US$2 billion for grant implementers to procure medicines and health products, including through the Pooled Procurement Mechanism.[10] The procurement and supply management of health products is fundamental to the Global Fund partnership. When ensuring the quality assurance of health products, the Global Fund relies in part on the mechanisms provided by third-party technical agencies, such as WHO and its IVDs prequalification scheme.[11]

The OIG found that, between 2015 and 2020, the Supplier supplied Global Fund implementers in 28 countries (Figure 1), either directly or through the PSA, with over 34.4 million RDTs.

[9] The Supplier's HIV RDTs were WHO prequalified between 14 July 2016 and 7 February 2020. The Supplier's malaria RDTs were WHO prequalified between 25 February 2015 and 12 June 2019. The Supplier's HIV RDTs were procured by implementers in Afghanistan, Bangladesh, Benin, Comoros, Dominican Republic, Gambia, Ghana, Guinea-Bissau, Kenya, Mali, Moldova, Niger, Paraguay, South Africa, Tajikistan, Togo, and Ukraine. The Supplier's malaria RDTs were procured by implementers in Angola, Burundi, Central African Republic, Comoros, Côte d'Ivoire, Eswatini, Gambia, Haiti, Malawi, Sierra Leone, South Sudan, Zambia, and Zimbabwe.
[10] Sourcing & Management of Health Products, www.theglobalfund.org/en/sourcing-management/, accessed on 19 June 2024.
[11] Prequalified In Vitro Diagnostics, https://extranet.who.int/prequal/vitro-diagnostics/prequalified-vitro-diagnostics, accessed on 21 May 2025.



As reflected in Section 2 of this report, the OIG calculated that approximately 89% (30.8 million) of RDTs supplied by the Supplier during this period to Global Fund implementers, either directly or through the PSA, could not have contained testing strips sourced from the manufacturer mentioned in the WHO prequalification.

During the WHO prequalification period, approximately 1 billion malaria and HIV RDTs were procured with Global Fund funds. The 34.4 million RDTs supplied by the Supplier represent about 3.4% of the total procured volume.

The investigation uncovered a prohibited practice in the sale of health products. As a result of this case, the Secretariat implemented an Agreed Management Action through the application of the Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers.

2. Findings

2.1 Finding 1 – The sale of HIV and malaria RDTs with Global Fund funds was, more likely than not, compromised by fraudulent practices.

The Global Fund Code of Conduct for Suppliers defines fraudulent practice as any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a person or entity to obtain a financial or other benefit or to avoid an obligation.[12]

i. The Supplier supplied Global Fund implementers with RDTs that did not comply with WHO prequalification specifications.

In its engagement with the PSA, the Supplier warranted, implicitly or explicitly, that the RDTs supplied complied with WHO IVDs prequalification. For example, in 2016, the PSA accepted the Supplier's offer in response to a Request for Quotations, which specifically stipulated that the HIV RDTs complied with WHO prequalification requirements.[13] In another example, a Purchase Order specified that, "Products supplied must be according to Global Fund Quality Assurance Policy meaning that the products should WHO prequalified and/or (T) FDA approved." The framework contract between the Supplier and the PSA, dated 2018 and covering this transaction, requires that the offered products be in compliance with the Quality Assurance Policy and "The products are produced and processed in compliance with the World Health Organization (WHO) or Stringent Drug Regulatory Authority (SDRA) good manufacturing practices requirements (as the case may be) and accreditation and applicable requirements for that accreditation".[14]

Similarly, when supplying directly to the implementers, the Supplier accepted the bidding documents' requirement that the malaria RDTs should be prequalified by WHO.[15] In an example contract signed with another implementer in 2018, the Supplier warranted that "all Goods […] are recommended by WHO for use in HIV/AIDS programs on a technical review of quality and performance indicators; and are included in the WHO list of prequalified in vitro diagnostics".[16]

To meet the WHO prequalification specifications, the RDTs, among other requirements, had to contain testing strips sourced from uncut sheets supplied by the manufacturer represented in its WHO prequalification documentation.

As early as 2012, Company A acted as an intermediary for the Supplier. It was responsible for supplying uncut sheets for the HIV and malaria RDTs from the third-party manufacturer referenced in the WHO prequalification documentation. According to the Supplier, Company A managed the logistics, transportation and distribution of these uncut sheets for the Supplier. Company A was operated by one individual, who served as its sole owner and employee. This individual also held a senior position within the Supplier.

As shown in Table 1 and 2, the Supplier stopped using the uncut sheets from the manufacturer mentioned in the WHO prequalification documentation as early as 2016 for the HIV RDTs and 2015

[12] The Global Fund Code of Conduct for Suppliers dated 15 December 2009.
[13] PSA RFQ PE50174 dated November 2016, Supplier's offer to the RFQ (Sub: PE50174), dated November 2016.
[14] Contract for the supply of goods between the Supplier and the PSA, dated 30 October 2018, purchase order PO-539570 dated 15 April 2019.
[15] The Global Fund Implementer 1, Competitive Bidding documents, dated May 2017.
[16] Contract between the Supplier and the Global Fund implementer 2 dated 9 October 2017, Annex #5-2 dated 14 Mach 2018.

for the malaria RDTs. In part, this finding is based on the shelf life of the uncut sheets purchased by the Supplier[17], along with the assumption that the Supplier did not use expired uncut sheets. Interviews and records reviewed by the OIG indicate that the Supplier and Company A stopped purchasing uncut sheets from the manufacturer referenced in the WHO prequalification documentation in mid-2014, resuming only for two transactions involving HIV uncut sheets in 2018 and 2019.

In accordance with WHO's applicable guidance, the use of testing strips from a different manufacturer constitutes a "reportable change" under a plain reading of the applicable WHO prequalification policies. WHO states that failure to report changes in accordance with WHO prequalification requirements may result in the delisting of the product from the prequalified IVDs list.[18]

While the Supplier also supplied RDTs to other national and international customers – who may have received products made with the uncut sheets in question - the OIG adopted a conservative approach by assuming that all uncut sheets procured by the Supplier from the manufacturer referenced in the WHO prequalification documentation were used in Global Fund-financed RDTs.

As shown in Table 1 and 2, during the WHO prequalified period, the OIG estimates that 7.1 million HIV RDTs and 23.7 million malaria RDTs provided by the Supplier to Global Fund implementers could not have contained testing strips from the manufacturer mentioned in the WHO prequalification documentation.

Supplier's HIV I05 RDTs					
Year	HIV uncut sheets sold by the manufacturer to the Supplier / Company A	Amount of HIV RDTs that can be produced from these uncut sheets[19]	Amount of HIV I05 RDTs supplied by the Supplier to Global Fund implementers	Estimate of I05 RDTs supplied by the Supplier to implementers that could not contain testing strips from the manufacturer[20]	Estimate of US$ value of I05 RDTs supplied by the Supplier to implementers that could not contain testing strips from the manufacturer[21]
2014	49,464	4,154,976	This time frame is out of scope of the investigation.[22]		
2015	-	-			
2016 (Jan–Jun)	-	-			
2016 (Jul–Dec)	-	-	2,755,030	2,755,030	$2,436,985
2017[23]	-	-	2,408,480	2,408,480	$2,245,138
2018	5,000	420,000	2,022,920	1,602,920	$1,101,430
2019	9,000	756,000	342,810	341,820	$259,897
2020 (Jan–Feb)	-	-	3,930	-	-
Total	**14,000**	**1,176,000**	**7,533,170**	**7,108,250**	**$6,043,450**

Table 1: Analysis of HIV uncut sheets supplied by the manufacturer to the Supplier/Company A and HIV RDTs supplied by the Supplier to Global Fund implementers.

[17] HIV testing strips have a shelf life of 24 months, malaria testing strips have a shelf life of 24 or 30 months.
[18] Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device, WHO Prequalification Team: Diagnostics dated 27 June 2014 and December 2016.
[19] To estimate these amounts the OIG considered the information that 84 RDT strips can be produced from one uncut sheet, not accounting for any potential errors.
[20] This analysis takes into consideration the shelf life of 24 months and the expiration date of the HIV uncut sheets mentioned in the documentation. Some transactions have been excluded because the underlying documentation provided ambiguous information about the product code.
[21] These amounts do not include the shipment and storage costs.
[22] The scope of this investigation for I05 HIV RDTs is limited to the WHO prequalified period (14 July 2016 to 7 February 2020); therefore, any events or actions not related to this time frame fall beyond its scope.
[23] From 1 May 2017, the Quality Assurance Policies include the WHO prequalification standard for HIV RDTs.

Supplier's malaria I13 RDTs					
Year	Malaria uncut sheets sold by the manufacturer to the Supplier / Company A	Amount of malaria RDTs that can be produced from these uncut sheets[24]	Amount of malaria I13 RDTs supplied by the Supplier to Global Fund implementers	Estimate of I13 RDTs supplied by the Supplier to implementers that could not contain testing strips from the manufacturer[25]	Estimate of US$ value of I13 RDTs supplied by the Supplier to the implementers that could not contain testing strips from the manufacturer[26]
2014	258,129	21,682,836	This time frame is out of scope of the investigation.[27]		
2015 (Jan)	-	-			
2015 (Feb–Dec)	-	-	6,219,650	6,196,800	$1,116,310
2016	-	-	379,925	379,925	$136,839
2017	-	-	8,002,475	8,002,475	$1,751,021
2018[28]	-	-	11,543,800	9,093,025	$1,949,350
2019 (Jan–Jun)	-	-	766,475	-	-
Total	**-**	**-**	**26,912,325**	**23,672,225**	**$4,953,520**

Table 2: Analysis of malaria uncut sheets supplied by the manufacturer to the Supplier/Company A and malaria RDTs supplied by the Supplier to Global Fund implementers.

During the investigation, the Supplier did not provide the OIG with records of the uncut sheets purchases and in-house manufacturing for the entire period; see Finding 2. The Supplier stated that these records were routinely destroyed after their retention period ended, claiming that this practice aligns with Indian regulations and International Organization for Standardization (ISO) 13485 requirements. When the OIG requested records of this destruction, the Supplier did not provide them. Given the challenges faced with accessing all relevant records, the figures above were reconstructed by the OIG based on other reliable records and statements obtained, as well as reasonable inferences.

Based on the above, the OIG finds that it is more likely than not that the Supplier could not have supplied Global Fund implementers with an estimated 7.1 million HIV RDTs and 23.7 million malaria RDTs containing testing strips sourced from the manufacturer identified in WHO prequalification documentation. The total value of these RDTs is approximately US$11 million. While the OIG is not making findings of prohibited practices beyond the Relevant Sales, this analysis is presented to illustrate the scale of RDTs potentially non-compliant with the contractual obligations and/or Quality Assurance Policies.

ii. The Supplier did not inform WHO of a reportable change to WHO prequalified RDTs, nor did it inform the PSA and implementers that it did not intend to supply WHO prequalified RDTs, constituting an omission or misrepresentation.

As demonstrated above, the OIG concluded that the Supplier more likely than not supplied Global Fund implementers with HIV I05 and malaria I13 RDTs containing testing strips not sourced from the manufacturer identified in the WHO prequalification documentation. The OIG found no evidence

[24] To estimate these amounts the OIG considered the information that 84 RDT strips can be produced from one uncut sheet, not accounting for any potential errors.
[25] This analysis takes into consideration the shelf life and the expiration date of the malaria uncut sheets mentioned in the underlying documentation. The malaria uncut sheets have a shelf life of 24 or 30 months. For this analysis, the maximum shelf life of 30 months has been used. Some transactions have been excluded because the underlying documentation provided ambiguous information about the product code.
[26] This amount does not include the shipment and storage costs.
[27] The scope of this investigation for the I13 malaria RDTs is limited to the WHO prequalified period (25 February 2015 and 12 June 2019); therefore, any events or actions not related to this time frame fall beyond its scope.
[28] From 1 January 2018, the Quality Assurance Policies include the WHO prequalification standard for malaria RDTs.

that the Supplier notified WHO of the change in the testing strip manufacturer from the third-party manufacturer specified in the WHO prequalification documentation to another source.

The OIG found no evidence that the Supplier notified the PSA or any implementers of the fact that it ceased purchasing testing strips from the relevant manufacturer. As stated above, the Supplier stopped using the uncut sheets from the manufacturer mentioned in the WHO prequalification documentation as of 2016 for the HIV RDTs and 2015 for the malaria RDTs. Previously cited examples in Section 2.1(i) demonstrate that after these dates, the Supplier warranted that the supplied RDTs complied with WHO IVDs prequalification.

Similarly, when supplying directly to an implementer, the Supplier warranted that "all Goods […] are recommended by WHO for use in HIV/AIDS programs on a technical review of quality and performance indicators; and are included in the WHO list of prequalified in vitro diagnostics".[29]

The conduct described above constitutes an omission or misrepresentation.

iii. The Supplier's omission or misrepresentation knowingly or recklessly misled the implementers and PSA and enabled the Supplier to obtain benefits or avoid obligations.

For the Relevant Sales, the Supplier was contractually obligated to supply HIV and malaria RDTs that met the specifications set out in the contractual documents, including compliance with WHO prequalification requirements. Based on the shelf life of the uncut sheets[30] and assuming the Supplier did not use expired uncut sheets, the RDTs could not have contained testing strips sourced from the manufacturer identified in the WHO prequalification documentation.

The OIG cannot speculate on the actions that would have followed had the Supplier notified WHO of a reportable product change in the prequalified RDTs. However, the costs of any WHO-related activities for the change assessment would have had to be borne by the Supplier. This could have caused a delay in access to the market, or a delisting of the Supplier's RDTs. Such outcomes might have resulted in the cancelation of contracts or the Supplier's disqualification from future procurement processes funded by the Global Fund. To retain eligibility for these procurement opportunities, the Supplier would have needed to undergo requalification by WHO or demonstrate compliance with other relevant criteria outlined in the Quality Assurance Policies.

Importantly, WHO clearly states that "failure to report changes in accordance with WHO prequalification requirements may result in the delisting of the product from the WHO List of Prequalified IVDs".[31]

In the absence of the notification of a planned change before its implementation, the RDTs could no longer be considered prequalified by the Global Fund, its implementers and the PSA.

The OIG finds that it is more likely than not that the Supplier knew, or should have known, that some I05 and I13 RDTs could not be described as prequalified at the time of the Relevant Sales for the reasons described in this Investigation Report.

The Supplier had contractual obligations to provide products complying with the WHO prequalification for the Relevant Sales. There is no evidence that the Supplier provided the required

[29] Contract between the Supplier and the Global Fund implementer, 2 dated 9 October 2017, Annex #5-2 dated 14 March 2018.
[30] HIV testing strips have a shelf life of 24 months, malaria testing strips have a shelf life of 24 or 30 months.
[31] Changes to Prequalified IVDs, https://extranet.who.int/prequal/vitro-diagnostics/changes-prequalified-ivds, accessed on 3 June 2024.

notification of the change to WHO for the prequalified IVDs and misled the PSA and implementers regarding their compliance with WHO prequalification processes.

The OIG finds that it is more likely than not that the Supplier's omissions or misrepresentations regarding the compliance with WHO prequalification requirements with respect to the Relevant Sales of I05 and I13 RDTs described in this Investigation Report were made knowingly or recklessly, with the intent to mislead the PSA and implementers into purchasing these products. As a result, the Supplier denied the PSA and the implementers of the opportunity to take appropriate actions to address the RDTs' non-compliance with the contractual obligations and/or applicable Quality Assurance Policies. The Supplier's actions allowed for it to both obtain financial benefits derived from the contracts and avoid its obligations to provide RDTs in compliance with the contractual obligations and/or Quality Assurance Policies. Therefore, the OIG finds it more likely than not that these acts constitute fraudulent practices.

2.2 Finding 2 – The OIG finds that it is more likely than not that the Supplier did not comply with reasonable requests for information related to the performance of Global Fund-financed contracts and to allow access to relevant staff.

i. The Supplier did not provide the records requested by the OIG.

The OIG finds that it is more likely than not that the Supplier failed to comply with the OIG's reasonable request to provide records related to the performance of Global Fund-financed contracts, which were material to this investigation. Paragraph 12 of the Global Fund Code of Conduct for Suppliers stipulates that "Suppliers and Suppliers Representatives are expected to cooperate with the Global Fund and comply with any reasonable request, in the opinion of the Global Fund, of its OIG […] to allow access to relevant staff and to inspect any relevant accounts and records and other documents relating to bidding for and performing Global Fund-financed contracts."[32] The Global Fund Code of Conduct for Suppliers is, either directly by reference or indirectly by being integrated by substance, part of the Supplier's contractual obligations with the PSA and the implementers.

While the Supplier provided access to certain records and personnel, the Supplier did not fulfill OIG's reasonable request to provide access to the financial, procurement, manufacturing, and sales records related to the HIV and malaria RDTs supplied to the implementers. The Supplier stated that they destroyed the requested procurement and manufacturing records.

According to the Supplier, they destroyed the procurement and manufacturing records in line with their internal document retention period for discontinued products of one-year after the 24-month shelf life, which the Supplier claimed is in line with Indian and the ISO standard retention period requirements. The Supplier stated that they were unaware of the Global Fund Code of Conduct for Suppliers and therefore, had no awareness that the requirement stated in this document[33] was not in line with their practices.

The OIG found the statements to lack credibility and do not constitute a plausible explanation for non-compliance with its contractual obligations. Global Fund Code of Conduct for Suppliers is

[32] The Global Fund Code of Conduct for Suppliers, dated 15 December 2009.
[33] Requirement is to maintain accurate and complete records in appropriate books of account for all financial and business transactions under Global Fund-financed contracts for a minimum period of five years after the date of last payment made under the Global Fund-financed contract.

referenced in several documents available and contractually applicable to the Supplier. In addition, the PSA's Code of Conduct for Vendors & Suppliers also requires a five-year retention period of records. This document is referenced in the PSA's purchase orders and PSA's terms and conditions. Furthermore, the OIG notes that the minimum retention periods specified in the Indian and ISO standards do not prevent the Supplier from retaining records for a longer duration. This allows the Supplier to comply with the Global Fund's retention period requirements.

The Supplier confirmed that they had the financial records related to the goods purchased for RDTs manufacturing, and the sales data related to the transactions in question available. However, they declined to share them with the OIG following a request, citing concerns that the Supplier could not differentiate between the financial records related to components used in Global Fund-financed RDTs and those used for RDTs supplied to other customers. The OIG determined that the choice to commingle records was the Supplier's own and that the justification provided for not allowing the OIG to inspect records was, therefore, insufficient.

ii. The Supplier did not ensure the cooperation of a key employee with the OIG investigation.

An employee of the Supplier, who was also the owner of Company A, did not comply with the OIG's request to cooperate in the investigation and make themselves available for an interview. The employee signed the current Framework Agreement between the Supplier and the Global Fund[34] on behalf of the Supplier, which is one of the sources of the requirement to cooperate with the investigation.

Despite multiple requests, the employee failed to make themselves available for an interview citing a busy schedule and personal matters. Other senior managers of the Supplier echoed the justifications and took no reasonable steps to ensure adequate cooperation.

The Supplier's failure to allow access to relevant staff materially impeded the investigation, given that the individual was a material witness and, in a position, to clarify matters related to the number and the value of uncut sheets purchased from third parties and the RDTs manufactured by the Supplier.

The OIG finds that it is more likely than not that the Supplier failed to comply with the reasonable request to allow access to relevant staff during an OIG investigation.

2.3 Additional observations

As outlined in Section 1.1 and 1.2, the OIG did not assess the efficacy of the supplied RDTs due to the timing of the investigation and, therefore, makes no findings in this regard. However, the OIG notes that to ensure implementers remain vigilant about the quality of health products once they are on the market, it is essential that implementers monitor the quality of diagnostic products procured with grant funds.

As stipulated in the Global Fund Quality Assurance Policies, the primary responsibility for monitoring of the quality of IVDs lies with implementers. They are required to adhere to relevant WHO guidelines on product quality monitoring of IVDs, which advocate a risk-based approach to optimize resource

[34] The Framework Agreement between the Supplier and the Global Fund, signed on 10 February 2020, was established following the Global Fund's selection process for HIV and malaria RDTs. It outlines the terms and conditions under which the Supplier would serve as a panel supplier, including via the Pooled Procurement Mechanism.

allocation and prioritize high-risk areas where adverse outcomes are more likely. Additionally, the Global Fund allows implementers to allocate grant funds for these activities.

During the Global Fund Grant Cycle 6 (2021 – 2023), the Global Fund allocated nearly US$1 billion for RDTs globally. Despite the explicit Post Market Surveillance (PMS) requirements in the Quality Assurance Policies, the OIG found a material gap in the implementation of these policies. Between 2021 and 2024, the Secretariat received only one report on RDT PMS activities from countries impacted by this investigation, and no quality control testing results for RDTs were submitted to the Global Fund during this period. While such reviews would not likely have detected the change of the testing strip manufacturer, it may have detected specific variations in quality, if any. Technical support and capacity-building to implementers where needed could strengthen their ability to conduct and report PMS effectively.

3. Global Fund Response

Action to be taken	Due date	Owner
1. Based on the findings of this report, the Secretariat will address the Supplier misconduct in accordance with the Secretariat's policy on supplier misconduct and the Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers.	Implemented	Head, Supply Operations

Based on the OIG's findings, the Secretariat implemented the Agreed Management Action through the application of the Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers. The OIG observed this process, in accordance with applicable policy.

Annex A: Summary of subject responses

On 28 March 2024, the OIG provided the Supplier with a copy of the Letter of Preliminary Findings, which represented the full record of relevant facts and preliminary findings related to the OIG investigation. The Supplier was requested to review the preliminary findings and provide its comments and supporting documents on the OIG preliminary findings and conclusions. The Supplier provided its response on 22 April and 26 May 2024. On 26 July 2024, the OIG provided the Supplier with the Notice of Findings for its review. The Supplier responded on 9 and 13 August, 8 September 2024 and 9 December 2024. The OIG responded to these communications on 26 August 2024, 18 October 2024, and 2 December 2024.

Below is a summary of the Supplier's response. All points made by the Supplier were duly considered by the OIG and appropriate revisions were made to the findings as part of the final report.

The Supplier stated that there were no reported adverse events, such as major quality failures or recalls, associated with the supplied RDTs during the OIG's investigation period. The quality of the products at issue was never called into question through multiple feedback channels, including internal Quality Control and Quality Assurance processes, WHO-nominated laboratory testing, and PMS sampling and testing, among others.

As noted in Section 1.1, 1.2 and 2.3, the OIG's investigation did not assess the quality or performance of the supplied RDTs. Instead, it focused on whether the RDTs complied with the contractual specifications, including adherence to WHO prequalification requirements.

The Supplier stated that for the HIV I05 and malaria I13 RDTs the retention of records focused on adherence to Indian record retention laws, which require retention of records for one year following the expiration date of the last batch manufactured of a discontinued product. Given that focus, the Supplier did not fully recognize the discrepancy between its recordkeeping practice and the requirements under the Global Fund's Code of Conduct for Suppliers. Due to the decision to dispose of records, the Supplier did not have necessary documents to respond to the OIG's findings. As such, it requested that the OIG provide records related to the Supplier's purchases and sales.

This point was duly considered and is addressed in Section 2.2. In addition, the OIG directed the Supplier, as contract counterparty to all relevant transactions, as to where it could obtain such records given that said records were either still partially in the Supplier's possession or reasonably obtainable by the Supplier by virtue of its role as a party to the contracts.

The Supplier noted that, because the OIG is relying upon evidence provided by the third-party manufacturer, this information should be viewed skeptically due to flagged concerns about control of production and service provision. Additionally, the OIG should consider the potential biases that the third-party manufacturer may have, given that the relationship between the Supplier and the manufacturer transitioned from supplier-competitor to direct competitors.

The OIG assessed this claim and critically considered the available evidence mindful of possible bias. Overall, the OIG assessed the credibility of the available evidence in order to finalize the conclusions reached.

Regarding the OIG's findings related to the Supplier's lack of cooperation, the Supplier stated that it permitted the OIG to be on-site at the Supplier's facility as part of its investigation. It stated that the OIG Investigators received full and unfettered access to the Supplier's employees, including key staff and management. In addition, the OIG was granted complete access to three computers and email communications and was able to freely copy data and emails. The Supplier's senior management were also made available for interviews.

While the Supplier provided access to certain records and personnel, the Supplier did not fulfill OIG's reasonable requests for access to all records and personnel deemed relevant to the investigation, as specified in Section 2.2.

The Supplier stated that as a result of the investigation, they have taken significant steps to strengthen its document retention policies and updated the retention of records for a term of 10 years to be in line with the Global Fund's Code of Conduct for Suppliers.

While this information is encouraging, the OIG has not separately assessed the revised document retention practices but has made this information available to the Secretariat for consideration in their response to the findings.

Annex B: Methodology

Why we investigate:

Wrongdoing, in all its forms, is a threat to the Global Fund's mission to end the AIDS, tuberculosis and malaria epidemics. It corrodes public health systems and facilitates human rights abuses, ultimately stunting the quality and quantity of interventions needed to save lives. It diverts funds, medicines and other resources away from countries and communities in need. It limits the Global Fund's impact and reduces the trust that is essential to the Global Fund's multi-stakeholder partnership model.[35]

What we investigate:

The OIG is mandated[36] to investigate any use of Global Fund funds, whether by the Global Fund Secretariat or grantees, Principal Recipients and their sub-recipients, Country Coordinating Mechanisms, Local Fund Agents, or suppliers who work to support Global Fund-funded programs, and report its findings in a transparent and accountable manner.[37] The Global Fund Secretariat ensures this oversight is included in related agreements.

Investigations aim to identify instances of wrongdoing, such as fraudulent and corrupt practices, but also failure to uphold the applicable human rights standards and instances of sexual exploitation and abuse. Investigations are predicated by whistle-blower allegations[38], routine escalation of business information, risk analysis or referrals from other entities.

The OIG bases its investigations on the contractual commitments undertaken by grant recipients and suppliers. Requirements with respect to the management of funds and performance of activities are notably defined in the Global Fund's Code of Conduct for Suppliers and Code of Conduct for Recipients.[39]

OIG investigations aim to:

- identify the nature and extent of wrongdoing affecting Global Fund grants and the entities accountable and, if applicable, determine the amount of grant funds that may have been compromised by wrongdoing; and
- place the Global Fund in a position to understand the root causes for the wrongdoing, to recover funds, and to take remedial action and preventative measures by identifying where and how the misused funds have been spent.

Who we investigate:

The OIG investigates wrongdoing by the entities accountable for performance and execution of activities funded by the Global Fund. These are grantees, Principal Recipients and their sub-recipients, Country Coordinating Mechanisms or Board Constituencies who receive financial support from the Global Fund, Local Fund Agents, recipients of Catalytic Funding, and other suppliers to the

[35] Global Fund Policy to Combat Fraud and Corruption, §1.1.
[36] Charter of the Office of the Inspector General, as amended from time to time.
[37] Policy for the Disclosure of Reports Issued by the Office of the Inspector General, as amended from time to time.
[38] Whistle-blowing Policy and Procedures for the Global Fund to Fight AIDS, Tuberculosis and Malaria, as amended from time to time.
[39] Global Fund Code of Conduct for Suppliers, and the Code of Conduct for Recipients of Global Fund Resources, as amended from time to time. Grants are typically subject to the Grant Regulations (2014), which incorporate the Code of Conduct for Recipients and mandate communication of the Code of Conduct for Suppliers. Terms may vary however in certain agreements.

Global Fund or to recipients. Secretariat activities linked to the use of funds are also within the scope of the OIG's work.

Principal Recipients are accountable to the Global Fund for their compliance with all applicable contracts, Codes and policies in the use of all grant funds, including those disbursed to sub-recipients and paid to suppliers.[40] They ensure the appropriate requirements are made applicable to those entities.

How we investigate:

The OIG conducts administrative, not criminal, investigations. It is not a law enforcement or judicial authority. It is the recipients' and suppliers' responsibility to demonstrate that their actions and those of their agents and employees comply with applicable agreements. OIG findings are based on facts and related analysis, which may include drawing reasonable inferences. Findings are established by a preponderance of evidence. All available information, inculpatory or exculpatory, is considered by the OIG.[41]

Investigations into allegations of sexual exploitation and abuse are conducted with a victim-centered, trauma-informed methodology, following a case-specific risk assessment, and are guided by the Global Fund's Operational Framework on the Protection from Sexual Exploitation and Abuse, Sexual Harassment, and Related Abuse of Power.[42]

The investigation will attempt to quantify the extent of any non-compliant expenditures, including an amount proposed to the Secretariat as recoverable.

The OIG may also discharge its mandate by overseeing the activities of recipients or other parties having the appropriate capacity and mandate to perform investigative tasks. It may also share allegations and evidence with third parties, pursuant to its confidentiality obligations, where it is relevant to their work.

What happens after an investigation?

The OIG ensures the relevant entities have the opportunity to review and provide evidence or comments on the findings and on the draft report.[43]

The OIG has a fact-finding role and does not determine what remedial and preventative measures the Global Fund may take as a result of its findings. The OIG is required to make final investigation reports available publicly in full.[44]

Following an investigation, the OIG and the Secretariat agree on management actions that will mitigate the risks that wrongdoing poses to the Global Fund and its recipients' or suppliers' activities. These may include specific managerial decisions, financial recoveries, instructions applicable to implementers and suppliers, internal process changes, or other contractually available remedies. With respect to suppliers, this can include recommending a referral to the Sanctions Panel.[45] The scope of such actions is subject to the mandate and capacity of the Global Fund and does not directly amend, or otherwise deviate from, the existing terms of agreements and contracts.

[40] Compliant expenditures are defined in the Global Fund Guidelines for Grant Budgeting, as amended from time to time.
[41] These principles comply with the Uniform Guidelines for Investigations, 2nd edition, Conference of International Investigators.
[42] See The Global Fund's Operational Framework on the Protection from Sexual Exploitation and Abuse, Sexual Harassment, and Related Abuse of Power, in particular sections IV. *2. Investigations* and IV. *3. Support to survivors & victims*, as amended from time to time.
[43] See the OIG Investigations Stakeholder Engagement Model, as amended from time to time.
[44] See the Policy for the Disclosure of Reports Issued by the Office of the Inspector General, as amended from time to time.
[45] See the Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers, as amended from time to time.

OIG may make referrals to other organizations which have an interest in the investigation outcome, or to national authorities for criminal prosecutions or other regulatory and administrative actions, and support such processes as appropriate. The Global Fund, in its sole discretion, may share also information related to its findings, including regarding individuals identified in this report, with third parties, as deemed appropriate.