World Health Organization

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**WHO Prequalification Team - Inspection services**

**WHO PUBLIC INSPECTION REPORT (WHOPIR)**

**In vitro Diagnostic product**

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| **Inspected site/s** | |
| Name of Organization | Rapigen, Inc. |
| Address/es of inspected manufacturing site/s | 161, Saneop-ro 155 beon-gil, Gwonseon-gu, *Suwon-si,* Gyeonggi-do16648, Republic of Korea |
| **Inspection details** | |
| Start of inspection | 08/01/2025 |
| Inspection duration (in inspector days) | 6 |
| Type of inspection | Initial |
| **Introduction** | |
| Brief description of manufacturing activities conducted at the site/s inspected | Rapigen has two factories in Suwon (Republic of Korea): Suwon Factory 1 for RDT products and Suwon Factory 2 for PCR products. Given the products in scope of this inspection, Suwon Factory 2 was not inspected, except for its warehouse that hosted some finished products. The Anyang R&D Institute was relocated to Suwon in 2024, and at the time of the 2025 site inspection it was located on the 4th floor of the Suwon factory. |
| General information about the organization | Rapigen, Inc. (Rapigen) was established 18 June 2002 by its current CEO Dr Jae Ku PARK. Rapigen major business is IVDs, mainly as RDTs with an ongoing diversification into molecular diagnostics since 2023. It obtained ISO 13485 certification in 2011, KGMP certification in 2015, and MDSAP certification in 2024. The three malaria products in scope were ERPD-certified in 2019 and Rapigen applied for prequalification in 2020 and again in 2024. The present inspection was performed as part of this new application and is, therefore, the initial inspection under this application. |
| **Brief report of inspection activities undertaken – Scope and limitations** | |
| Areas inspected | As detailed below, the areas inspected were sampled from the areas of activities performed on site that were relevant to the products in scope. The sampling was performed using a risk-based approach considering, for example, the impact of the area inspected on the product, as well as past inspection findings. |
| Products in scope | PQDx 13192-160-00 - BIOCREDIT Malaria Ag Pf (pLDH)<br>PQDx 13193-160-00 - BIOCREDIT Malaria Ag Pf (pLDH/HRPII)<br>PQDx 13194-160-00 - BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) |

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| Criteria | • All applicable clauses of ISO 13485:2016<br>• WHO PQ requirements<br>• Organization's own requirements |
| Objective(s) | Verify compliance to the inspection criteria. |
| Limitations | Due to the language barrier and the associated delays, not all the inspection plan could be covered. |
| Out of scope | Any processes or activities not related to the products in scope were considered out of scope of this inspection. |
| **Abbreviations** | **Meaning** |
| CAPA | Corrective and Preventive Action |
| CoA | Certificate of analysis |
| IQ | Installation qualification |
| IVD | In vitro device |
| MR | Management review |
| MRM | Management review meeting |
| MSDS | Material safety data sheet |
| NC | Non-conformity |
| PPE | Personal protective equipment |
| OOS | Out-of-specifications test result |
| OQ | Operational qualification |
| PM | Preventive maintenance |
| PMS | Post Market Surveillance |
| PQ | Performance qualification |
| PW | Purified water |
| QA | Quality assurance |
| QC | Quality control |
| QMS | Quality management system |
| QRM | Quality risk management |
| RA | Risk assessment |
| RCA | Root cause analysis |
| SOP | Standard operating procedure |

**Summary of the findings and comments**

## 4 Quality management system

### 4.2 Documentation requirements

#### *4.2.2 Quality manual*

The organization did document a quality manual that included:

a) the scope of the QMS, including details of and justification for any exclusion or non-application;

b) the documented procedures for the QMS, or reference to them;

c) a description of the interaction between the processes of the QMS.

The quality manual did outline the structure of the documentation used in the QMS.

#### *4.2.4 Control of documents*

Documents required by the quality management system were controlled. Records were a special type of document and were controlled according to the requirements given in Clause 4.2.5.
A documented procedure did define the controls needed to:

a) review and approve documents for adequacy prior to issue;
b) review, update as necessary and re-approve documents;
c) ensure that the current revision status of and changes to documents were identified;
d) ensure that relevant versions of applicable documents were available at points of use;
e) ensure that documents remain legible and readily identifiable;
f) prevent deterioration or loss of documents;
g) prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization did ensure that changes to documents were reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.
The organization did define the period for which at least one copy of obsolete documents were retained. This period did ensure that documents to which medical devices had been manufactured and tested were available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record, or as specified by applicable regulatory requirements.

#### *4.2.5 Control of records*

Records were maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.
The organization did document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.
Records did remain legible, readily identifiable and retrievable. Changes to a record did remain identifiable.
The organization did retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.
The nonconformities identified were successfully addressed through a CAPA process.

## 5 Management responsibility

### 5.1 Management commitment

Top management did provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;
b) establishing the quality policy;
c) ensuring that quality objectives were established;
d) conducting management reviews;
e) ensuring the availability of resources.

### 5.4 Planning

#### *5.4.1 Quality objectives*

Top management did ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, were established at relevant functions and levels within the organization.

### 5.5 Responsibility, authority and communication

#### *5.5.1 Responsibility and authority*

Top management did ensure that responsibilities and authorities were defined, documented and communicated within the organization.
Top management did document the interrelation of all personnel who manage, perform and verify work affecting quality and did ensure the independence and authority necessary to perform these tasks.

#### *5.5.2 Management representative*

Top management did appoint a member of management who, irrespective of other responsibilities, had responsibility and authority that included:

a) ensuring that processes needed for the quality management system were documented;
b) reporting to top management on the effectiveness of the quality management system and any need for improvement;
c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

## 6 Resource management

### 6.2 Human resources

Personnel performing work affecting product quality were competent on the basis of appropriate education, training, skills and experience.
The organization did document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.
The nonconformities identified were successfully addressed through a CAPA process.

### 6.3 Infrastructure

The organization did document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure included, as appropriate:

a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).

The organization did document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, could affect product quality.
Records of such maintenance were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

### 6.4 Work environment and contamination control

#### *6.4.1 Work environment*

The organization did document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment could have an adverse effect on product quality, the organization did document the requirements for the work environment and the procedures to monitor and control the work environment. The nonconformities identified were successfully addressed through a CAPA process.

#### *6.4.2 Contamination control*

As appropriate, the organization did plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. The nonconformities identified were successfully addressed through a CAPA process.

## 7 Product realization

### 7.1 Planning of product realization

The organization did plan and develop the processes needed for product realization. Planning of product realization were consistent with the requirements of the other processes of the quality management system. The organization did document one or more processes for risk management in product realization. Records of risk management activities were maintained.

### 7.4 Purchasing

#### *7.4.1 Purchasing process*

The organization did document procedures to ensure that purchased product conforms to specified purchasing information.
The organization did establish criteria for the evaluation and selection of suppliers.
The organization did plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product were monitored.
Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities were maintained.

#### *7.4.2 Purchasing information*

Purchasing information did describe or reference the product to be purchased, including as appropriate:

a) product specifications;
b) requirements for product acceptance, procedures, processes and equipment;

To the extent required for traceability given in Clause 7.5.9, the organization did maintain relevant purchasing information in the form of documents and records.

#### *7.4.3 Verification of purchased product*

The organization did establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities were proportionate to the risks associated with the purchased product.
Records of the verification were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

### 7.5 Production and service provision

#### *7.5.1 Control of production and service provision*

Production and service provision were planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls did include:
a) documentation of procedures and methods for the control of production;
b) qualification of infrastructure;
c) implementation of monitoring and measurement of product characteristics;
d) availability and use of monitoring and measuring equipment;
e) implementation of product release, delivery and post-delivery activities.
The nonconformities identified were successfully addressed through a CAPA process.

#### *7.5.6 Validation of processes for production and service provision*

The organization did document procedures for validation of processes, including:

a) defined criteria for review and approval of the processes;
b) equipment qualification and qualification of personnel;
c) use of specific methods, procedures and acceptance criteria;
d) as appropriate, statistical techniques with rationale for sample sizes;
e) requirements for records;
f) revalidation, including criteria for revalidation;
g) approval of changes to the processes.

Records of the results and conclusion of validation and necessary actions from the validation were maintained. The nonconformities identified were successfully addressed through a CAPA process.

#### *7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems*

The organization did document procedures for the validation of processes for sterilization and sterile barrier systems. Processes for sterilization were validated prior to implementation and following product or process changes, as appropriate. Records of the results and, conclusion of validation and necessary actions from the validation were maintained. The nonconformities identified were successfully addressed through a CAPA process.

#### *7.5.8 Identification*

The organization did document procedures for product identification and identify product by suitable means throughout product realization.
The organization did identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status were maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession was dispatched, used or installed.

#### *7.5.9 Traceability*

7.5.9.1 General

The organization did document procedures for traceability. These procedures did define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.
The nonconformities identified were successfully addressed through a CAPA process.

#### *7.5.11 Preservation of product*

The organization did document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation did apply to the constituent parts of a medical device.
The nonconformities identified were successfully addressed through a CAPA process.

### 7.6 Control of monitoring and measuring equipment

The organization did determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.
The organization did document procedures to ensure that monitoring and measurement could be carried out and were carried out in a manner that was consistent with the monitoring and measurement requirements.
As necessary to ensure valid results, measuring equipment:

a) was calibrated or verified, or both, at specified intervals, or prior to use;
b) was adjusted or re-adjusted as necessary: such adjustments or re-adjustments were recorded;
c) had identification in order to determine its calibration status;
d) was safeguarded from adjustments that would invalidate the measurement result;
e) was protected from damage and deterioration during handling, maintenance and storage.

The organization did perform calibration or verification in accordance with documented procedures.
Records of the results of calibration and verification were maintained. The nonconformities identified were successfully addressed through a CAPA process.

## 8 Measurement, analysis and improvement

### 8.2 Monitoring and measurement

#### *8.2.1 Feedback*

As one of the measurements of the effectiveness of the quality management system, the organization did gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information were documented. The organization did document procedures for the feedback process. This feedback process included provisions to gather data from post-production activities. The information gathered in the feedback process did serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

#### *8.2.2 Complaint handling*

The organization did document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures did include requirements and responsibilities for:

a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;

e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions.

Any correction or corrective action resulting from the complaint handling process were documented. Complaint handling records were maintained.

#### *8.2.6 Monitoring and measurement of product*

The organization did monitor and measure the characteristics of the product to verify that product requirements had been met. This were carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.

Evidence of conformity to the acceptance criteria were maintained. The identity of the person authorizing release of product were recorded. As appropriate, records did identify the test equipment used to perform measurement activities. Product release and service delivery did not proceed until the planned and documented arrangements had been satisfactorily completed. The nonconformities identified were successfully addressed through a CAPA process.

### 8.3 Control of nonconforming product

#### *8.3.1 General*

The organization did ensure that product which did not conform to product requirements was identified and controlled to prevent its unintended use or delivery. The organization did document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions were maintained.

#### *8.3.2 Actions in response to nonconforming product detected before delivery*

The organization did deal with nonconforming product by one or more of the following ways:

a) taking action to eliminate the detected nonconformity;
b) taking action to preclude its original intended use or application;
c) authorizing its use, release or acceptance under concession.

The nonconformities identified were successfully addressed through a CAPA process.

#### *8.3.3 Actions in response to nonconforming product detected after delivery*

When nonconforming product was detected after delivery or use has started, the organization did take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken were maintained. The organization did document procedures for issuing advisory notices in accordance with applicable regulatory requirements. Records of actions relating to the issuance of advisory notices were maintained.

#### *8.3.4 Rework*

The organization did perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures did undergo the same review and approval as the original procedure. After the completion of rework, product were verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework were maintained.

### 8.4 Analysis of data

The organization did document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system.
The analysis of data did include data generated as a result of monitoring and measurement and from other relevant sources and included input from:

a) feedback;
b) conformity to product requirements;

Records of the results of analyses were maintained. The nonconformities identified were successfully addressed through a CAPA process.

### 8.5 Improvement

#### *8.5.2 Corrective action*

The organization did take action to eliminate the cause of nonconformities in order to prevent recurrence. The organization did document a procedure to define requirements for:

a) reviewing nonconformities (including complaints);
b) determining the causes of nonconformities;
c) evaluating the need for action to ensure that nonconformities did not recur;
d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
e) verifying that the corrective action did not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
f) reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken were maintained.

#### *8.5.3 Preventive action*

The organization did determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.The organization did document a procedure to describe requirements for:

a) determining potential nonconformities and their causes;
b) evaluating the need for action to prevent occurrence of nonconformities;
c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
d) verifying that the action did not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken were maintained.

### Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report the company, ***Rapigen, Inc.*** located at ***161, Saneop-ro 155 beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do 16648, Republic of Korea*** was considered to be operating at an acceptable level of compliance with ISO 13485:2016 and WHO *Information for Manufacturers on Pre-qualification Inspection Procedures for the Sites of Manufacture of Diagnostics* (PQDx_014).

All the non-compliances observed during the inspection that were listed in the full report were addressed by the organization to a satisfactory level prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided the outcome of any WHO pre-qualification inspection or other audit from regulatory authorities that WHO relies on conducted during this period provides evidence of current compliance with the audit criteria.

**List of WHO Guidelines referenced in the inspection report**

1. WHO Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics (PQDx_014). (https://www.who.int/diagnostics_laboratory/evaluations/en/)
2. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
3. WHO Post-market surveillance of in vitro diagnostics 2020 (ISBN 978 92 4 001532 6)
4. Medical devices - Application of risk management to medical devices - ISO14971:2019
5. GHTF/SG3/N19:2012 “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange”
6. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
7. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy
8. GHTF/SG4(pd1)/N33R16:2007 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports ISO 13485:2016, Commitments to WHO PQ.