

**INSTRUÇÃO DE TRABALHO****SISTEMA DE GESTÃO DA QUALIDADE**

Cód.: IT-EXP-003

Nº Rev.: 10

Data Rev.: 13/09/2023

Assunto: DISTRIBUTOR TRANSPORT AND STORAGE

Depto: EXPEDIÇÃO


Página: 1 / 3

ELABORAÇÃO: RICARDO RIO

VERSÃO	DESCRIÇÃO	DATA
8	08 26/02/2018 IMPLANTAÇÃO DO QUALIS. 07 04/05/2012 UPDATE THE PROCEDURE TO INCLUDE NEW PRODUCTS: CLIA AND ELETRODES. 06 18/02/2011 UPDATE THE PROCEDURE TO INCLUDE EQUIPMENTS AND ADD INFORMATION ON THE COAGULATION LINE. 05 24/11/2009 CHANGE THE DOCUMENT FORMAT. 04 06/04/09 CHANGE THE PERIOD THAT A PRODUCT CAN BE LEFT OUT OF REFRIGERATION.	26/02/2018
9	FULL DOCUMENT REVIEW,	13/05/2021
10	ADJUSTMENTS IN TERMINOLOGIES AND TEMPERATURE RANGES.	13/09/2023

CÓPIA**NÃO****CONTROLADA****NÃO SERÁ SUBSTITUÍDA EM CASO DE REVISÃO**

Nome	Cargo
RICARDO ALEXANDRE BAVARO RIO	RESPONSÁVEL EXPEDIÇÃO
JOAO CARLOS MONTAGNINI JUNIOR	GERENTE COMERCIAL
LEISE DAIANA MARTINS	RESPONSÁVEL CONTROLE DE QUALIDADE
MARCOS VINICIUS DE SOUSA	GERENTE INDUSTRIAL
RENATA MILANI	CONSULTOR ASSUNTOS REGULATÓRIOS
TULIO ULHOA	COORDENADOR DE QUALIDADE

	INSTRUÇÃO DE TRABALHO	Cód.: IT-EXP-003
	SISTEMA DE GESTÃO DA QUALIDADE	Nº Rev.: 10
		Data Rev.: 13/09/2023
Assunto: DISTRIBUTOR TRANSPORT AND STORAGE		Página: 2 / 3
Depto: EXPEDIÇÃO		

1. OBJECTIVE

This Work Instruction is intended to guide distributors and customers on how to handle, preserve, store and transport WAMA Diagnostica products at their facilities.

2. RESPONSIBILITIES

- It is the responsibility of the Commercial Manager / Seller / Scientific Advisor to inform customers about the information presented in this Work Instruction.
- It is the responsibility of the Commercial Manager / Seller / Scientific Advisor to carry out the visits to the distributors and to conduct the checks regarding the facilities, storage and the procedures performed by the distributors, when necessary.
- It is the responsibility of the Commercial Manager / Director to disqualify a Distributor in his absence when non-compliance with the guidelines indicated by WAMA Diagnostica.

3. DESCRIPTION

To characterize that the distributor has the minimum adequate conditions to carry out the distribution of the organization's products, he company must present a License of Health Surveillance from Company country, as described in PROC-VN-001- SISTEMÁTICA DE ANÁLISE CRÍTICA DE VENDAS. The Distributor will have to observe the form of conservation of the company's products and prioritize their deliveries as well as take care not to turn / drop boxes according to the instructions of WAMA Diagnostica.

If there is any problem in the receipt of WAMA Diagnostica products at the Distributor, such as a malfunction that causes damage to the product such as breakage, leakage and loss of the material, immediately communicate to WAMA Diagnostica, through contact with the Scientific Advisory sector.

The Distributor must establish a way to track the products sold together to its customers to complete the traceability cycle created by WAMA Diagnostica and take the same care established by WAMA Diagnostica. The Distributor must commit to guide its customers (i. e. end customer) regarding the handling of the products purchased.


3.1. Packaging

3.1.1. For Diagnostic Kits: The following precautions must be followed to obtain a proper packaging for the products:

- Pack in a cold chamber or properly cleaned refrigerator, the kits that require refrigeration at controlled temperature (e.g. kits with storage temperature between 2 and 8°C)
- For Kits with storage temperature of 15 and 30°C keep in stocks with controlled room temperature.
- The storage of diagnostic kits should be at controlled room temperature, in a dry and clean place.
- In the need to stack transport **boxes**, take care to place them in a maximum of 04 **transport boxes**.
- The shelves will have to be with minimum distance from the wall where it can allow cooling/refrigeration and facilitate the site cleaning.

3.1.2. For equipment and accessories: The following precautions must be followed to obtain proper packaging for the products:

- The storage of the equipment must be at controlled room temperature, in a dry and clean place.

	INSTRUÇÃO DE TRABALHO	Cód.: IT-EXP-003
	SISTEMA DE GESTÃO DA QUALIDADE	Nº Rev.: 10
		Data Rev.: 13/09/2023
Assunto: DISTRIBUTOR TRANSPORT AND STORAGE		Página: 3 / 3
Depto: EXPEDIÇÃO		

- The stacking should be a maximum of 04 **transport boxes**, thus avoiding dangers of falls and damage to the equipment.
- The shelves will have to be with minimum distance from the wall where it can allow refrigeration and facilitate the cleaning of the place.

3.2. Preservation methods by product line:

The products must be packed as described in item 3.1 and kept at temperature according to the following table:

PRODUCT LINE	TEMPERATURE OF PACKAGING AND CONSERVATION
• COAGULAÇÃO	2 to 8°C
• DIVERSOS	2 to 8°C
○ Uri-Color Check Urine Strip	15 to 30°C, and cannot be exposed to moisture
• IMUNO-CON	2 to 8°C
• IMUNO-HAI	2 to 8°C
• IMUNO-LATEX	2 to 8°C
• IMUNO-RÁPIDO QUANTI	2 to 30°C or 4 to 30°C
• IMUNO-RÁPIDO	2 to 30°C
○ IMUNO-RÁPIDO HCG	2 to 30°C
• ELETRÓLITOS	2 to 30°C
○ Electrolyte deproteinizer (Ministry of Health Registration, 10310030114)	5 to 35°C
○ Electrolyte deproteinizer (Ministry of Health Registration, 10310030173)	10 to 30°C

3.3. Transport

Distributors are committed to transporting the WAMA Diagnostica Kits to their final customers with the quality that is provided to them, that is, in a thermal box with recyclable ice, when applicable, and within the stipulated period of validity, according to AIT-EXP-008- TRANSPORT AND STORAGE POLICY.

The equipment must be transported in its original transport boxes. It is mandatory to include on the invoice the lot of the product / serial number sold to enable its traceability.

4. ATTACHMENTS

AIT-EXP-008- TRANSPORT AND STORAGE POLICY

5. RELATED DOCUMENTS

PROC-VN-001- SISTEMÁTICA DE ANÁLISE CRÍTICA DE VENDAS