

INSTRUÇÃO DE TRABALHO

SISTEMA DE GESTÃO DA QUALIDADE

Cód.: IT-EXP-003

Nº Rev.: 9

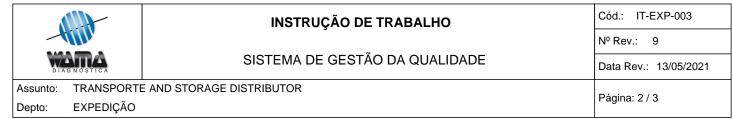
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Assunto: TRANSPORTE AND STORAGE DISTRIBUTOR

Depto: EXPEDIÇÃO

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ELABORAÇÃO: R	ICARDO RIO			
VERSÃO	DESC	RIÇÃO	DATA	
8	08 26/02/2018 IMPLANTAÇÃO DO QUALIS. 07 04/05/2012 UPDATE THE PROCEDURE T ELETRODES. 06 18/02/2011 UPDATE THE PROCEDURE TO INC ADD INFORMATION ON THE COAGULATION LIN 05 24/11/2009 CHANGE THE DOCUMENT FORMA 04 06/04/09 CHANGE THE PERIOD THAT A PROE	ELUDE EQUIPMENTS AND E. T.	26/02/2018	
9 FULL DOCUMENT REVIEW, 13/05/2021				
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CONTROLADA NÃO SERÁ SUBSTITUÍDA EM CASO DE REVISÃO				
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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 distributors and conduct the checks on facilities, storage and procedures performed by distributors, when necessary.
- It is the responsibility of the Commercial Manager/ Director to disqualify a Distributor in its absence when non-compliance with the guidelines indicated by WAMA Diagnostica.

3. Description

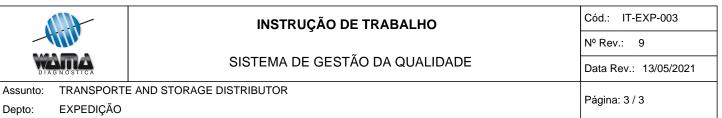
To characterize that the distributor has the minimum adequate conditions to distribute the organization's products, the company must present a License of Health Surveillance from Company country. The Distributor will have to observe the way the company's products are kept and prioritize their deliveries as well as take care not to turn/drop boxes according to Wama Diagnostica instructions.

If there is a problem in the receipt of WAMA Diagnostic 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 or Commercial sector.

The Distributor shall establish a way to track the products sold together to its customers to complete the traceability cycle created by WAMA Diagnostica and cargo handling established by WAMA Diagnostics. 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 should be followed to obtain proper packaging for the products:
- Kits that require refrigeration at controlled temperature (e.g. kits with storage temperature between 2 and 8°C) shall be stored in a cold chamber or a properly cleaned refrigerator.
- Kits with storage temperature of 15 and 30°C shall be kept in stocks with room-controlled temperature.
- The storage of diagnostic kits should be at room-controlled temperature, in a dry and clean place.
- In the need to stack boxes, take care to put them in a maximum of 04 boxes.
- The shelves will have to be at minimum distance from the wall where it can allow cooling and facilitate the site cleaning.
- **3.1.2. For equipment and accessories:** The following precautions should be followed to obtain proper packaging for the products:
- Storage of equipment must be at room-controlled temperature, in a dry and clean place.
- Stacking must be a maximum of 04 boxes, thus avoiding hazards of falls and damage to the equipment.



• The shelves will have to be at minimum distance from the wall where it can allow cooling and facilitate the site cleaning.

3.2. Conservation methods by product line:

The products must be packaged as described in item 3.1 and stored at room according to the following table:

PRODUCT LINE	CONDITIONING AND STORAGE TEMPERATURE	
COAGULAÇÃO	2 to 8°C	
DIVERSOS	2 to 8°C	
 Urine Strip Uri-Color Check 	15 to 30ºC, and cannot be exposed to moisture	
IMUNO-COM	2 to 8°C	
IMUNO-ELISA	2 to 8°C	
IMUNO-HAI	2 to 8°C	
IMUNO-LATEX	2 to 8°C	
IMUNO-RÁPIDO QUANTI	2 to 30°C	
IMUNO-RÁPIDO	2 to 30°C	
○ IMUNO-RÁPIDO HCG	15 to 30°C, and cannot be exposed to moisture	
ELETRÓLITOS	2 to 30⁰C	
 Electrolyte deproteinizer (Registry at 	≥ to 8°C	
the Ministry of Health 10310030114)		
 Electrolyte Deproteinizer (Registry at the Ministry of Health 10310030173) 	10 to 30⁰C	

3.3. Transport

Distributors are committed to transporting WAMA Diagnostica Kits to their end customers with the quality provided to them, i.e. in a thermal box with recyclable ice, when applicable, and within the stipulated period of validity, according to AIT-EXP-016- TRANSPORT AND STORAGE POLICY.

Equipment must be transported in its original transport boxes. It is mandatory to include in the invoice the batch of the product/ serial number sold to enable the traceability of the same SUBSTITUÍDA EM CASO DE REVISÃO

4. Attachments

AIT-EXP-016-TRANSPORT AND STORAGE POLICY

5. RELATED DOCUMENTS

Not applicable.