

Roche Diabetes Care Supplier Shipping Requirements

1.0 Overview

Purpose The purpose of this document is to establish supplier shipping requirements and guidelines to achieve optimum quality deliveries that are free of damage, have proper material identification and labeling, and can be efficiently handled within the Roche Diabetes Care Supply Chain system.

Scope All internal and external supplier shipments received by Roche Diabetes Care warehouses located in Indianapolis, Indiana and Ponce, Puerto Rico in accordance with local Diabetes Care Standard DCS 039.01 (Supply Chain Controls) and regulation 21 CFR 820.80 Receiving and 21 CFR 820.140 Handling. Supplier shipments received directly by Roche third party logistics providers are also included within the scope of this document.

Note: Changes to this procedure should be coordinated with representatives from RDO to determine impact to equivalent RDO requirements in RDCP-081.

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1.0 Overview, Continued

References The following documents are referenced in this procedure.

| Document | Description |
|------------|--|
| DCS 039.01 | Diabetes Care Standard for Supply Chain Controls |
| RDCP-081 | Supplier Shipping Requirements (RDO) |

2.0 Roles and Responsibilities

| Role | Responsibility |
|------|--|
| RDCI | <p>It is the responsibility of Roche Diabetes Care (RDCI) to ensure that updated product specifications, for proper identification of the product, are made available to RDCI suppliers. RDCI Procurement Department shall be responsible for maintaining a current revision of this document on the RDCI supplier web-portal on the Roche Diagnostics-Indianapolis Internet site listed on all Purchase Orders. Procurement or Receiving may also provide a hard copy of the supplier Shipping guidelines if requested from a supplier.</p> <p>Only RDCI Procurement and Forwarding/Logistics can authorize:</p> <ol style="list-style-type: none">1) Use of a freight carrier not listed in this procedure.2) A change in standard supplier freight terms. Standard freight term is: FOB (Free On Board) Ship Point-Freight Collect, 3rd Party billing for Domestic shipments. <p>Roche Diagnostics is a member in good standing with the US Customs-Trade Partnership Against Terrorism (C-TPAT) program. Membership requires that Roche perform annual recertification efforts up to and including supply chain security assessment of our foreign suppliers. Business partners must comply with the Security Assessments provided in order to continue supporting this membership.</p> |

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2.0 Roles and Responsibilities, Continued

| Role | Responsibility |
|----------|---|
| Supplier | <p>It is the responsibility of the Vendor/Supplier to do the following:</p> <ul style="list-style-type: none">▪ To comply with requirements in this procedure (Supplier Shipping Requirements).▪ To make certain that all appropriate departments within the Supplier's organization are made aware of all requirements in this document.▪ To ensure product temperature is within the storage temperature requirements as stated in the product specification before loading.▪ To ensure that the set point and actual temperature of the trailer meet requirement specifications before loading. <p>(Note: Set points for temperature controlled units are as follows: +2°C to +8°C shipments is +5°C, & +15 °C to +25 °C is + 20 °C.</p> <ul style="list-style-type: none">▪ To load freight in such a manner as to not restrict airflow.▪ To ensure actual trailer temperature is at +5°C for refrigerated, +20 °C for ambient material before releasing driver.▪ To ensure the load is braced and blocked properly to prevent damage.▪ To pack product in a manner that prevents damage during transit.▪ To seal all trucks.▪ To note on the Bill of Lading (BOL) the set point, seal number, and the time that the seal was placed on the trailer.▪ To notify Roche Forwarding at 317-521-2664 or 317-521-4676 if the truck does not meet the required specifications.▪ To require second-tier suppliers that ship on first-tier supplier's behalf to follow RDCI Supplier Shipping Requirements. <p>All packaging/pallet components must comply with The International Standard for Phytosanitary Measures, publication number 15 (ISPM 15) latest edition.</p> |

3.0 Shipment Documentation

**Documents
required for
receiving**

Each shipment(s) must have the following documentation:

| Document | Requirement |
|--|---|
| Invoice (International shipments only) | <ul style="list-style-type: none">▪ Written in English▪ Shipper name/address▪ Bill to name/address▪ Consignee name/address▪ Purchase Order number▪ Invoice number▪ Date▪ Incoterms▪ Part number▪ Detailed description of items▪ Quantity▪ Unit of measure▪ Unit value and currency▪ Total value and currency▪ Country of origin |
| Packing List | <ul style="list-style-type: none">▪ Supplier's Name▪ Purchase Order Number▪ Roche Diagnostic's Part Number (According to Product Specification)▪ Batch Number▪ Shipment Quantities by Batch Number (where applicable)▪ Number of Cartons▪ Quantity Per Carton (i.e., 5 @ 1500)▪ Expiration Date (where applicable)▪ Storage or Temperature Conditions |

Continued on next page

3.0 Shipment Documentation, Continued

Documents required for receiving, continued

| Document | Requirement |
|----------------|---|
| Bill of Lading | <ul style="list-style-type: none"> ▪ Ship From – Complete name of shipper and address (origin/shipping location, city, state, zip code) ▪ Ship To – Complete name, address and telephone number of Recipient ▪ Date when material was shipped ▪ Ship to arrive date – as stated on the PO number ▪ Seal number (if applicable) ▪ PO information – Applies to each PO and the entire shipment. If a Roche credit card was used, put the Roche employee's first initial and last name on the BOL. ▪ Packages: Quantity & type (e.g., cartons) ▪ Handling unit: Quantity & type (e.g., pallet, etc.) ▪ Weight ▪ Temperature condition (e.g., +2°C to +8°C, etc.) ▪ Carrier name ▪ Freight payment terms ▪ Special delivery instructions – indicate any delivery instructions received including the name of the authorizing individual ▪ Air freight instructions – <u>Must have written approval by Roche Forwarding.</u> ▪ Exclusive use/Rush/Expedited service – When an “exclusive use”, “expedited service”, or “rush” shipment is requested, the supplier must obtain and record the Roche individual name that approved/requested expedite, department and the purchase order number. ▪ Multiple POs shipped at the same time must be tendered to the carrier as one shipment. If your system or your supplier's system prints separate bills of lading, it is advisable to link all bills of lading under one master BOL. ▪ Describe the product under the appropriate National Motor Freight Classification (NMFC) description, indicating the item number, class and weight. ▪ Density bump if your NMFC items permit it, this will result in lower transportation charges. ▪ On all truckload shipments or less than truckload (LTL shipments) of five (5) pallets or more, it should be noted on the BOL to contact the Roche for an appointment at (317) 521-2664 or (317) 521-2706. |

Continued on next page

3.0 Shipment Documentation, Continued

Documents required for receiving, continued

| Document | Requirement |
|--|---|
| Certificate of Conformance (C of C) or Certificate of Analysis (C of A) | <p>Each shipment(s) must have a certificate, unless otherwise noted on the specification, that provides the following information:</p> <ul style="list-style-type: none">▪ Identification of the type of document (for example, C of C or C of A)▪ Vendor Name and/or Logo▪ Roche material number▪ Suitable means of traceability (i.e., batch number, serial number, manufacturing date, ship date)▪ Affirmation that the product meets the specifications of the materials referenced in the purchase order▪ Signature and date of appropriate company representative <p>Notes:</p> <ul style="list-style-type: none">▪ A Certificate of Analysis should be used when the supplier tests the product on a lot by lot basis and the results are verified to be within a predetermined specification. The document may be titled other than Certificate of Analysis but must include analytical results.▪ A Certificate of Compliance should be used when the supplier confirms the Product complies with specified requirements established by the supplier.▪ All documents must be centrally located for easy access for each shipment.▪ Vendor part number may be used, if mentioned in the specification. <p><u>Packing list and C of C or C of A should be located together on the top of a container or pallets for easy access.</u></p> <p>Electronic copies of C of C and C of A must be emailed to:</p> <p>Indianapolis.Incoming_Inspection@Roche.com.</p> <ul style="list-style-type: none">▪ Please name the file by: vendor_material number_batch number. |

4.0 Temperature Sensitive Shipments of Products

Overview

All temperature sensitive products, including refrigerated (+2°C to +8°C) products must be transported in supplier qualified packaging or in transportation that is temperature controlled and monitored, unless otherwise is specified in the Raw Material Specification. Other products should be monitored as stated in the material specification. Seasonal freeze protection should be used if required.

Expedited shipments must adhere to the same requirements.

All temperature sensitive materials must be clearly identified on all four sides of the pallet with a minimum 4"x 4" in size, separate label, stating the required temperature condition of the material. (e.g., +2°C to +8°C).

Any material which requires frozen shipping conditions (-15 to -25°C) must be shipped with dry ice. Each shipping container must be clearly marked with a Dry Ice label.

Temperature controlled transportation

When using temperature controlled transportation (such as refrigerated trailers), it is required that temperature monitoring devices are included with the shipment. Refrigerated trailer temperature readings for the shipment must be available for review upon request if needed. The devices must record both the temperature and duration of the shipment. Intervals between data points must not exceed once every 10 minutes. The device should be situated in the tail of the trailer and the middle of shipping container contents. Record the quantity of temperature devices, the device serial number(s), and the date and time at which the door of the trailer is closed on the packing list.

Temperature monitoring devices

The Sensitech TempTale 4 is the standard approved temperature monitoring device. The devices can be sourced from:

support@SENSITECH.COM
Phone 978-927-7033

Roche negotiated pricing can be obtained from Sensitech upon request.

Contact Roche Procurement to coordinate software installation and training.

Continued on next page

4.0 Temperature Sensitive Shipments of Products, Continued

Temperature monitoring devices, continued

The following DC TempTale 4-USB device is used for monitoring of all RDCI shipments handled by 3PL provider, including shipments from Ponce.



DC TempTale 4 USB
Model Number TT4 16K LCD

The following devices are used by RDO and are acceptable for use for Diabetes Care shipments with specific temperature requirements when applicable.

Roche/Sensitech Material #'s



Transportation temperature:
0 to 30 °C (Shipping Cat A)
Roche Mat# 07652143-001

Transportation temperature:
0 to 15 °C (Shipping Cat B)
Roche Mat# 07652151-001

Transportation temperature:
0 to 45 °C (Shipping Cat D)
Roche Mat# 07652160-001



Sensitech ID-No:
TUM00-10-141



Sensitech ID-No:
TUM00-11-141



Sensitech ID-No:
TUM00-12-141

The supplier is responsible for supplying and activating the devices. Upon arrival, Roche will recover the device and review the recorded temperature results. If the results are within transportation temperature specification, the shipment can proceed in the release process. If the results are not within transportation temperature specification, the shipment will be quarantined for further review by Roche Quality.

5.0 Hazardous Material

Hazardous material

Refer to Code of Federal Regulation 49 (CFR 49) and International Air Transportation Administration (IATA) for all material classification and handling instruction.

Any material and/or product intended for Roche Diabetes Care use and/or redistribution, classified as hazardous, must fully comply with CFR49 and IATA.

Documentation supporting the compliance with these regulations must be provided to Roche Diabetes Care upon request for all products classified as semi-finished and finished goods, including but not limited to packaging test reports.

Documentation supporting the compliance with these regulations must be made available to Roche Diabetes Care for all incoming material not identified as semi-finished or finished goods.

Any subsequent re-certification of the packaging must also be provided.

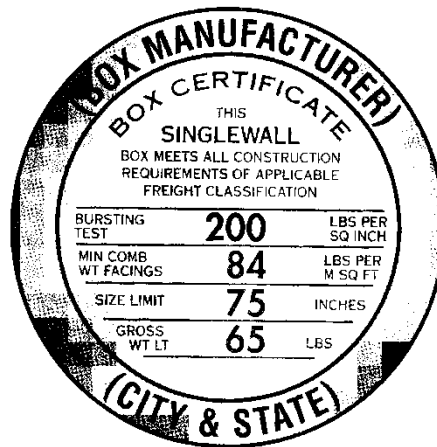
Hazardous materials packaged in plastic bottles must have 95Kpa pressure test certificates and be available upon request.

6.0 Corrugated Containers

Corrugated containers

- Generally, the selection of a corrugated container will depend on the specific component, method of transportation, and the method of handling by both the supplier and receiver.
- Roche prefers and highly encourages the use of recycled materials.
- Other factors to consider are:
 - Handling Labor
 - Handling equipment
 - Transportation cost
 - Packaging
 - Direct Labor
- When volumes warrant, palletizing is required.
- Individual containers should not weigh greater than 60 pounds.
 - This does not include bulk raw chemicals.
 - Deviation requires approval in writing.
- All containers must have a manufacturer's certificate with bursting, puncture or ECT (edge crush test) limits visible on the underside (bottom) of the assembled container. (Fig. 1)
- Rice Paper or yellow corrugated is not allowed.

The following diagram illustrates a typical Manufacturer's Certificate.



(Fig. 1)

7.0 Containment

Containment

- The only acceptable methods of sealing manually handled cartons are strippable reinforced, asphaltic, or plastic tapes, and spot gluing. Staples are only acceptable with prior approval from the Roche Supply Chain Packaging.
 - All cartons must be secured to a pallet.
 - The preferred method of securing material(s) to pallets is plastic, heat sealed polyester strapping, shrink/stretch film, (PVC films are unacceptable) and unitizing adhesives for cartons.
 - To protect product from banding damage, cardboard edge protectors are required. Plastic edge protectors are not permitted.
 - If stretch wrap film is used, the edge protectors are to be attached to the product cartons with the stretch wrap film applied on top of the edge protectors.
 - When shrink /stretch films are used, labels used and adhered to the film are encouraged to be of the same material as the film for ease of recycling.
 - Metal banding is only acceptable when prior approval is obtained.
 - All products smaller than 10" x 10" x 6" must be supplied in corrugated trays unless otherwise authorized by Roche Supply Chain Packaging. Depending upon the product configuration, weight, etc., the trays may be stacked directly onto a pallet or placed inside an over pack carton.
-

8.0 Packing Materials

Overview

The preferred void fill material for partial container(s) is Bubble Pack/Air Pillows. Paper can also be used for void fill material.

The use of Styrofoam packing peanuts **is not an acceptable** packing material for Roche Shipments.

The use of vermiculite **is not an acceptable** absorbent material for Roche hazardous material shipments.

Supplier qualified packaging

Cold Chain Packaging must contain the appropriate materials (insulation materials, phase change materials) to meet product specifications during transit. Supplier is responsible to maintain records of the packaging shipping stability data/qualification. All shipments sent in qualified packaging must be 100% monitored.

9.0 Material Labeling

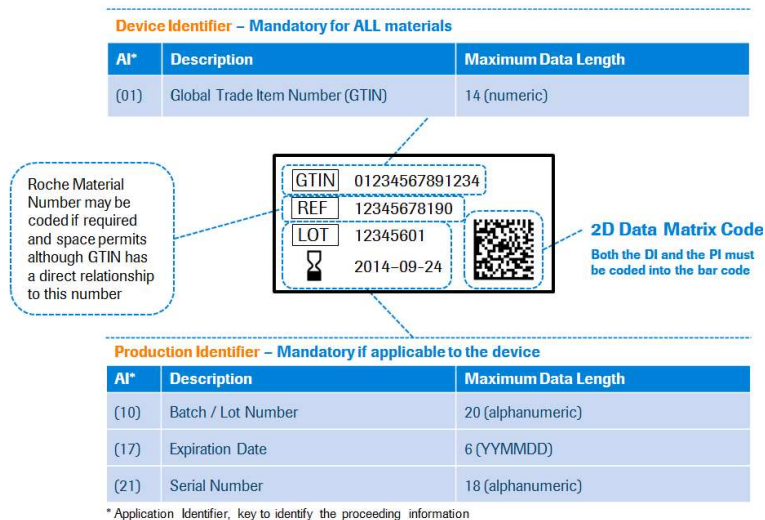
| | |
|-----------------|---|
| Overview | <p>Material(s) in a container/pallet or box, unless otherwise stated in the Material Specification, <u>must</u> be identified individually with:</p> <ul style="list-style-type: none">• Roche Diagnostics material number (according to product specification)• Batch number, if applicable, (10 digit maximum)• Quantity• Temperature storage conditions (other than room temperature)• Unit of measure• Expiration date when applicable. <p>The format of this information may vary by product. Items with serial number(s) should be identified on the container or box where applicable.</p> |
|-----------------|---|

| | |
|-----------------------|---|
| UDI regulation | <p>To comply with the new Unique Device Identifier (UDI) Regulation published by the FDA in September 2013, Medical Device/IVD manufacturers are required to adapt the product labelling to meet the new labelling requirement. This means all medical devices/IVD's distributed in the United States must carry a Unique Device Identifier (UDI). This regulation does not apply to raw materials. The UDI consists of 2 parts:</p> <ol style="list-style-type: none">1. The UDI Device Identifier (UDI-DI) is mandatory and is the unique numeric or alphanumeric code that uniquely identifies the device, for Roche, this is the 14 digit Global Trade Item Number (GTIN). This number is assigned and provided by Roche.2. The UDI Production identifier (UDI-PI) this identifies the unit of production of the device (e.g., Batch/lot number, serial number, expiry date); this part is mandatory only where the device is controlled in this manner. |
|-----------------------|---|

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9.0 Material Labeling, Continued

This UDI must be placed on the label of the medical device within a GS1 2D DataMatrix barcode and in human readable text (or in symbols) as shown in the below example (**Fig. 3**).



(Fig. 3)

The compliance date on which the changes must be implemented is based on the regulatory risk class of the product as follows:

- Medium risk classification devices (Class 2) - must comply by September 2016
- Lowest risk classification devices (Class 1) - must comply by September 2018

Raw material label GS1 overview

GS1 DataMatrix is primarily intended for implementation in an open system (e.g., a system in which the supplier can mark items in the expectation that all trading partners will be able to read and correctly interpret the data encoded). In this context, a standard implementation is essential to avoid each partner having to re-label products for different customers and / or at different points of the supply chain.

GS1 Details may be found here:

https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf

https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

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9.0 Material Labeling, Continued

Containerized
raw material:
measured by
length, such as
rolls

| Field Name | AI | Description |
|-----------------------------|-------|---|
| Description | N/A | Description of the material (not in 2D code) |
| Exp Date | (17) | Expiration date |
| Part Number | (241) | Roche Material Number |
| Length | (311) | Length of material |
| Batch | (10) | Vendors Batch |
| Vendor ID | (90) | Unique ID assigned by Roche to each vendor |
| Item ID | (240) | Dependent on product, typically master roll, slit |
| Source Entity (optional) | (251) | Refers to the original item from which the trade item was derived, typically parent roll batch |

Product Description




PN: 05949033001
QTY: 1012.34
VENDOR: 123456
BATCH: ABC123
ItemID: 22A
Exp Date: 12/12/12

Containerized
raw material:
measured by
count, such as
vials

| Field Name | AI | Description |
|-------------|-------|---|
| Description | N/A | Description of the material (not in 2D code) |
| Exp Date | (17) | Expiration date |
| Part Number | (241) | Roche Material Number |
| Quantity | (30) | Quantity |
| Batch | (10) | Vendors Batch |
| Vendor ID | (90) | Unique ID assigned by Roche to each vendor |
| Item ID | (240) | Dependent on product, typically master roll, slit |

Product Description



PN: 05949033001
QTY: 1000
VENDOR: 123456
BATCH: ABC123
ItemID: 22A
Exp Date: 12/12/12

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9.0 Material Labeling, Continued

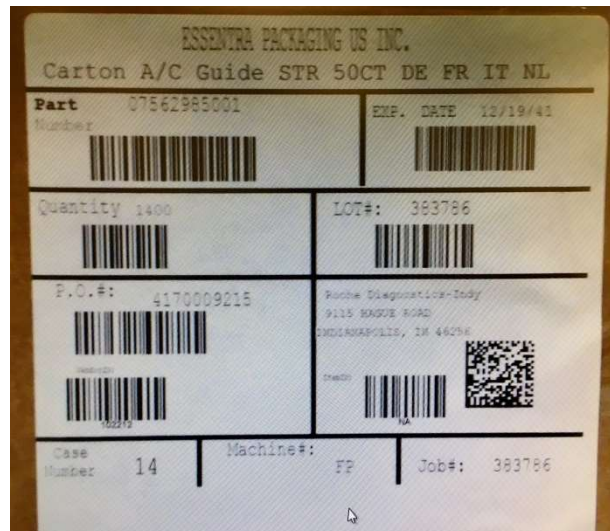
Container labels

- Label(s) shall be a minimum of 4" x 6" (102 x 152mm) and applied to one end of package (**Fig. 4**). If carton is too small to support this label size, make appropriate to the size of the carton.
- All information (except for vendor name, description and temperature condition) must be both human readable and bar-coded.
- Labels must be white in color with bold black printing.
- Adhesive type can be pressure sensitive or dry gummed as long as adherence to the package is assured and application is wrinkle free.
- Character sizes of the label are as follows:

| | |
|--|--------------------------------------|
| ➤ Supplier name: (Minimum 1/4") | ➤ Roche Address: (Minimum 1/8") |
| ➤ Part Number: (Minimum 1/2") (According to Specification) | ➤ P.O. Number (Minimum 1/4") |
| ➤ Batch Number (Minimum 1/2") | ➤ Quantity: (Minimum 1/2") |
| ➤ Description (Minimum 1/2") | ➤ Expiration Date (where applicable) |
| ➤ Storage Temperature Condition (In Celsius unless instructed by the material specification) (Minimum 1/2") | |

- The barcode must be Interleaved 2 of 5, EAN13, 3 of 9 or code 128.
- Barcode height shall be 1/2".
- Labels must be adhered to one (1) side of the container.

Note: The orientation of the cartons on a pallet should be where carton labels are visible.



(Fig. 4)

Continued on next page

9.0 Material Labeling, Continued

Container labels, continued

The following illustration (**Fig. 5**) is an example of a container label. The container label must provide all the required information as stated above.

| | | |
|--|------------------------------|--------------|
| Supplier Name: | | |
| Company Name | | |
| Description: | | |
| Product Description | | |
| PN: 12345678901 12345678901 | PO: 1234567890 1234567890 | |
| Batch 1234567890 No. (10 digit maximum) 1234567890 | Quantity: 123456 123546 | |
| Expiration MM/DD/YYYY Date: MM/ΔΔ/ΨΨΨΨ | | |
| Temperature Storage Condition | Refrigerated | 2C-8C |

(Fig. 5)

Continued on next page

9.0 Material Labeling, Continued

Pallet load labels

- One lot for each material per shipment is preferred.
- Labels shall be a minimum of 4" x 6" (102mm x 152mm).
- Labels shall be white in color with bold black printing.
- All information (except for vendor name, description and temperature condition) must be both human readable and bar-coded.
- Adhesive type can be pressure sensitive or dry gummed as long as adherence to the package substrate is assured and application is wrinkle free.
- The character sizes of the label are as follows:

| | |
|---|--|
| ➤ Supplier name: (Minimum 3/32") | ➤ Roche Address: (Minimum 1/8") |
| ➤ Part Number: Minimum 1/2" (According to Product Specification) | ➤ P.O. Number: (Minimum 1/4") |
| ➤ Batch Number: (Minimum 1/2") | ➤ Quantity: (Minimum 1/2") |
| ➤ Description: (Minimum 1/2") | |
| ➤ Expiration Date (where applicable) (Minimum 1/4") | ➤ Storage Temperature Condition (In Celsius unless otherwise instructed by the material specification) (Minimum 1/2") |

- The barcode shall be Interleaved 2 of 5, EAN13, 3 of 9 or code 128.
- Barcode height shall be 1/2"
- Pallet load labels must be applied to front and back side of the load
- Storage conditions
- All temperature sensitive material must be clearly identified.

Refer to example of Pallet Label on next Page (Fig. 6)

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9.0 Material Labeling, Continued

| | | | |
|--|--|--------------|--|
| From: | Company Name Company Address City, State, Country 12345-1234 | To: | Roche Diabetes Care 9115 Hague Rd Indianapolis IN. 46250 |
| Pallet Load Label | | | |
| Description: Product Description | | | |
| MN: | 12345678901 12345678901 | PO: | 1234567890 1234567890 |
| Batch No. | 1234567890 (10 digit maximum) 1234567890 | Quantity: | 123456 123546 |
| Expiration : | | MM/DD/YYYY | |
| Date: | | MM/ΔΔ/ΨΨΨΨ | |
| Temperature Storage Condition | Refrigerated | 2C-8C | |

(Fig. 6)

Continued on next page

9.0 Material Labeling, Continued

Labeling mixed pallet loads

Mixed pallet load labels for multiple part number and or batch number items:

- One lot per shipment is preferred. Pallets of mixed lots should only be used if one lot is not sufficient to fill a pallet.
- Mixed pallets are to be labeled “Mixed Pallet” and noticeably segregated on pallet for efficient handling by buyer.
- Labels shall be a minimum of 4" x 6" (102 mm x 152 mm).
- Labels shall be **yellow** in color with bold black printing.
- Adhesive type can be pressure sensitive or dry gummed as long as adherence to the package substrate is assured and application is wrinkle free.
- Pallet load labels must be applied to front and the back side of the load
- **Materials with more than one temperature condition are not to be mixed on a single pallet.**

The following example (**Fig. 7**) illustrates an example of the Mixed Pallet label. The format of this label is for the required information.



(Fig. 7)

10.0 Pallet Guidelines

Overview

1. Expendable pallets are designed specifically for one-trip only.
2. Four-way entry pallets are designed to permit entry of fork or pallet jacks from all sides (**Fig. 8**).
3. Notched stringer is designed to permit four way entry for forklift and two-entry for pallet jacks.
4. Deck boards make up the faces of a pallet and either carry or rest upon the goods packed.
5. Stringers are the wooden runners to which the deck boards are fastened and serve as a spacer between top and bottom decks to permit the entry of mechanical handling devices.
6. Flush stringer pallets- outside stringers are flush with the ends of deck boards.
7. The A1 grade pallet has a like new clean appearance with no stringer repairs. Typically this is a GMA repaired close to its original condition. Broken stringers may have been replaced and not repaired with metal plates. All damaged deck boards are replaced and is structurally sound. A1 grade pallets have 7 top deck boards & 5 bottom deck boards.

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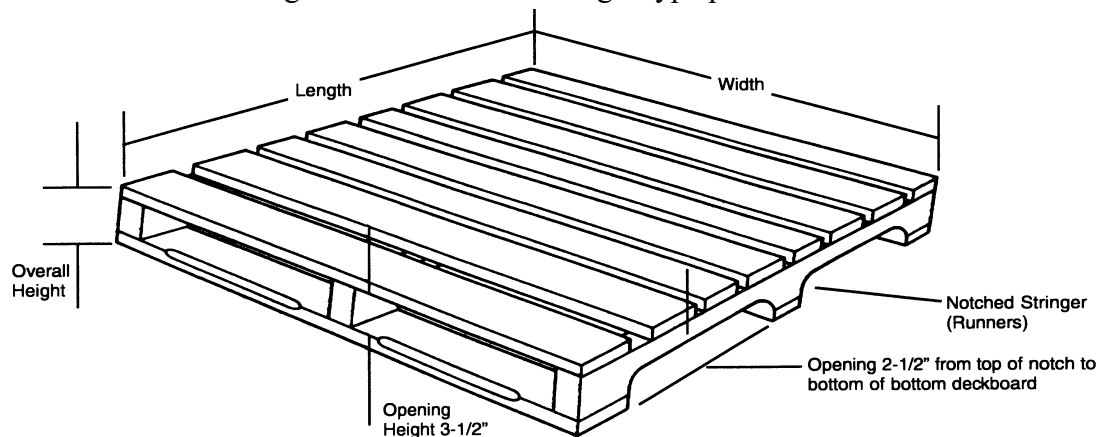
10.0 Pallet Guidelines, Continued

Roche standard U.S. pallets

| | |
|--|---|
| Type | All wooden pallets must be Grade A1 double face, non-reversible wood construction and be of flush stringer design (Fig. 7). All pallets are to be four-way entry. Roche must approve any intended deviations. Standard pallet 48"(L) x 40"(W). Deliveries with non-grade A1 pallets may be refused or rejected at point of delivery. |
| Top & bottom Deck Boards (Edges) | The edge deck boards of the top and bottom decks shall be not less than a nominal 6" board and no less than 5/8" thick. |
| Top & bottom Deck Boards (interior) | The interior or remainder of boards may be a random – width stock 4" – 6" and must be 42" in length and no less than 5/8" thick. Deck board spacing shall not exceed 3". |
| Stringers | All pallets will have no less than three (3) stringers |
| Attachment | Minimum of two double screw nails on each side of the stringers parallel to the 3.5" entry opening. Stapling of pallet boards is not permitted. |
| Chamfers | Only the outside edge of the bottom edge deck boards shall be chamfered. Chamfers shall be at least 12" long and shall be cut on a 35° angle to the face so as to leave an edge adjacent to the chamfer not less than 1/4" from the outer edge of the deck boards. |
| Recycled pallets | Grade A1 used pallets meeting Roche Diagnostic's specifications can be used provided they are inspected for durability prior to shipment. |
| Load | Including pallet, must not exceed 48" (ground to top of load), unless otherwise authorized by Roche Diabetes Care. Carton overhang is not permissible. |

Diagram

The following is a flush notched stringer type pallet



(Fig. 8)

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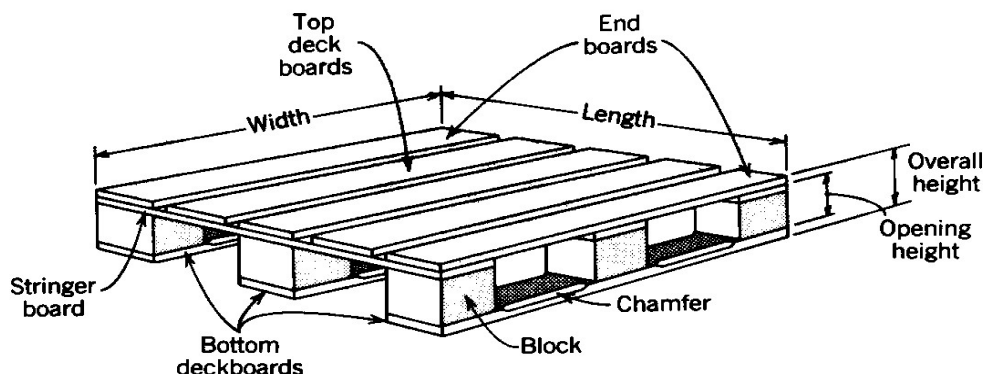
10.0 Pallet Guidelines, Continued

Roche standard Euro pallets

All wooden pallets must be double-face, non-reversible wood construction and be of Block design (**Fig. 9**) Per DIN 15146 120cm (L) X 80cm (W) ($47\frac{1}{4}$ X $31\frac{1}{2}$).

Roche Diabetes Care must approve any intended deviations as the pallets will be used in an automated warehouse environment that has strict tolerance requirements.

Note: Certain materials must be supplied on Euro EPAL pallets. Roche will advise when euro pallets must be used.



(Fig. 9)

Other pallets

Plastic pallets are permitted only with prior approval from Roche Supply Chain Packaging & Procurement, and must meet the following criteria:

- They must meet the dimensions for Standard US pallet 48(L) x 40(W) or Euro pallets 120cm (L) X 80cm (W) ($47\frac{1}{4}$ X $31\frac{1}{2}$)
 - They must be sturdy enough for basic transportation requirements.
 - They must be sturdy for material movements after delivery.
 - Metal or chipboard pallets are not permitted under any circumstances.
-

11.0 Transportation / Carrier / Routing

Carrier/ transportation and security information

For International shipments, you must call Import/Export Compliance at 317-521-2975 or 317-521-7395 for shipping instructions.

Roche requires:

- Trailer seals for all truck load and refrigerated or frozen truck shipments.
- Trailer must be sealed with a high security seal which meets or exceeds the current ISO/PAS 17712 standard for a security seal.
- Suppliers are responsible for purchasing and stocking the seals at their site.
- Suppliers must apply the trailer seals after the loading process has been completed, and **MUST NOTE** the seal number on the shipment bill of lading. LTL shipments must be secured and seal numbers noted on the shipment bill of lading by the freight agent.

Contact the Forwarding Department if there are any questions at 317-521-2664 or 317-521-4676 or email at rdo.routing@roche.com.

Routing

The routing instructions apply to all Collect or 3rd party shipments when Roche is responsible or could be billed for the freight charges, including:

- All shipments to our Distribution Center in Indianapolis, Indiana.
- Shipments between suppliers made on Roche's behalf.
- Drop shipments made to Roche customers.

Contact the Roche Forwarding Department at rdo.routing@roche.com or call (317) 521-2664 or (317) 521-4676 for instructions on routing the following types of shipments:

- Volume shipments of 5,000+ lbs. or > 10 pallets
- Shipments to or from Alaska or Hawaii
- Shipments requiring expedited service
- All temperature sensitive shipments

When calling for routing, have the following information:

- Origin City, State and Zip
 - Purchase Order Number
 - Number of Cartons
 - Total Weight by Freight Class
 - NMFC Item Numbers
 - Cube (if possible) or Linear Feet
-

Continued on next page

11.0 Transportation / Carrier / Routing, Continued

Routing, continued

The use of overnight/expedited AM delivery service for any shipment to the Roche Indianapolis location is not authorized for parcel deliveries. All parcel deliveries take place before 10 a.m. regardless of delivery service selected.

All Bills of Lading should be marked “Freight Collect – 3rd Party Billing.”

The Third Party Billing Address is:

Roche Diagnostics

c/o Software Solutions Unlimited Inc.

9595 SW Gemini Drive, Beaverton, OR

97008-7120

Phone number: (971) 249-5400.

Fax: (971) 249-5401.

Website: www.ssui.com

The local phone numbers for FedEx can be found on their website at

www.fedex.com.

The local phone numbers for XPO Logistics can be found on their website at

www.xpologistics.com.

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11.0 Transportation / Carrier / Routing, Continued

Routing instructions for domestic shipments

| Mode | Shipment Wt. or Cube | States | Carrier Assignment |
|-------------------------------------|---------------------------|--------|---|
| Ground | 1 – 300 lbs. | All | FedEx Ground Collect |
| | 301 – 4999 lbs. | All | See LTL Carrier Matrix |
| | > 5000 lbs. or 10 Pallets | All | Call or email Roche Forwarding Department at 317-521-2664 or rdo.routing@roche.com |
| Air | | | |
| Next Day | All | All | Call or email Roche Forwarding Department at 317-521-2664 or rdo.routing@roche.com |
| Second Day | All | All | Call or email Roche Forwarding Department at 317-521-2664 or rdo.routing@roche.com |
| All Temperature Sensitive Shipments | All | All | Call or email Roche Forwarding Department at 317-521-2664 or rdo.routing@roche.com |

LTL carrier routing matrix

| Ship From | Ship To | Carrier |
|--|----------------------------|---|
| AK or HI | All States | Call or email Roche Forwarding Department at 317-521-2664, 317-521-4676 or rdo.routing@roche.com |
| All states | AK or HI | Call or email Roche Forwarding Department at 317-521-2664, 317-521-4676 or rdo.routing@roche.com |
| OH, IN, MI, WI, IL, KY, TN, MO, WV | All states except AK or HI | FedEx Freight |
| All other states EXCEPT AK, HI, OH, IN, MI, WI, IL, KY, TN, MO, WV | All states EXCEPT AK or HI | XPO Logistics |

Continued on next page

11.0 Transportation / Carrier / Routing, Continued

Parcel shipments

- Use FedEx Ground® for all small package domestic shipments (<300 lbs.).
- Select COLLECT as the billing option. Suppliers do not need a Roche shipping account number to ship via FedEx Ground Collect. Process the shipment under supplier's account number and FedEx will capture the account and shipment information for billing purposes at the time of delivery.
- Supplier will be responsible for any fees which are the responsibility of the shipper, including weekly pick up fees where applicable.

12.0 Miscellaneous Information

| | |
|--|--|
| Receiving Hours | Monday through Friday: 6:00 am - 2:00 pm. After hours receipts must be authorized in advance by Roche Diagnostics Logistics Operations Management. |
| Dock Appointment | An appointment is required for shipments with 5 pallet loads or more. Contact Roche Diagnostics at 317-521-2664 or 317-521-4676 for an appointment. |
| Material Reworks | Reworked material(s) returned to Roche Diagnostics must have all previous labeling removed and replaced with new labels. The packing list must identify the load and/or items that are "reworks." |
| Shipments not meeting Supplier Shipping requirements | Failure to comply may result in return of goods, fees associated with re-labeling, rework, overtime and other charges incurred due to damaged goods. |
| Advanced Shipment Notification (Recommended not required) | <p>When possible, provide an ASN (Advance Shipping Notice). This can be provided by faxed, hard copy mailed or electronically through email. Notification should include the following information:</p> <p>PO number, part number, batch number, and quantities per pallet(s).</p> <p>Mail to: Indianapolis.rdo_deliveryappointment@Roche.com</p> <p>Fax Number: 317-521-4237</p> <p>ASN labels should follow the format below in Fig. 10. Please note that Fig. 11 is a sample label. The Uniform Code Council (UCC) has approved a standardized format for the UCC-128 Shipping Container Label. For more information, call the UCC at 800-543-8137 or on the Internet:</p> <p>http://www.uc-council.org</p> |

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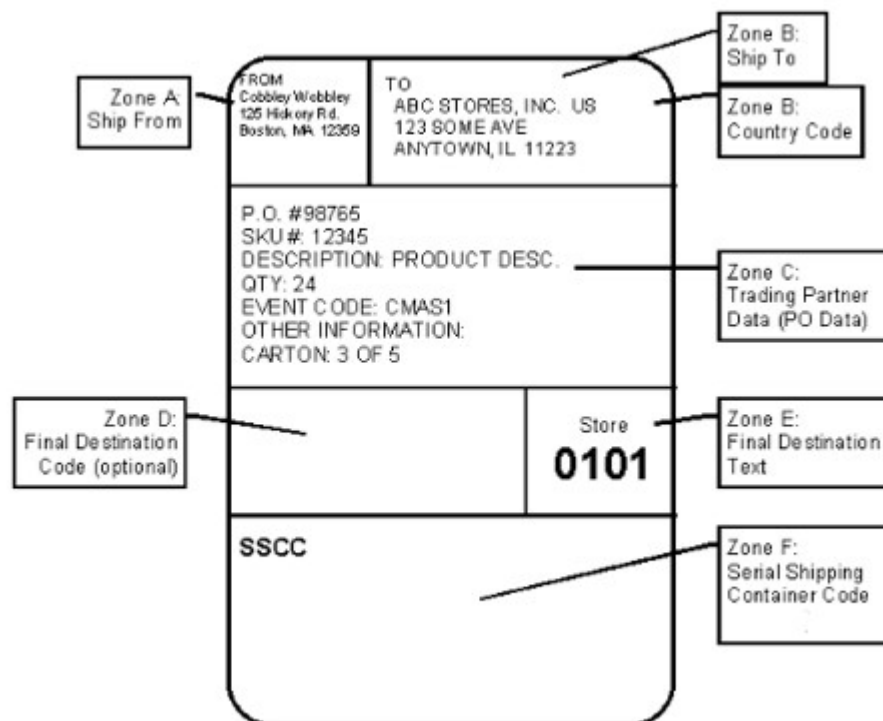
12.0 Miscellaneous Information, Continued

Figure 10 lists the format for the ASN label.

| Block | Block Name | Requirement | Contents | Height | Width | Text Point |
|--------------------------------------|--------------------------------|-------------|--|--------|-------|------------|
| A | Ship From | Required | Complete Name and Address of Vendor | 1" | 1.25" | 8 to 10 |
| B | Ship To | Required | Complete Name and Address of DC | 1" | 2.75" | 12 to 14 |
| C | Trading Partner Data | Required | P.O. #, Event Code, SKU, Description, Inner Pack Quantity, Casepack Quantity, Carton Count for the P.O.#, Sequential numbering of cartons required for Parcel shipments only | 2" | 4" | 8 to 12 |
| D | Final Destination Code | Optional | Bar Code for DC # | 1" | 1.5" | n/a |
| E | Final Destination Text | Required | DC# | 1" | 1.5" | 36 to 72 |
| F | Serial Shipping Container Code | Optional | Serial Shipping Container Code | 2" | 4" | n/a |
| General Characteristics of the Label | | | | | | |
| Recommended Dimensions | | 4" x 8" | | | | |

(Fig. 10)

Figure 11 is an example of the ASN label using the format in Figure 10.



(Fig. 11)

13.0 Definitions

| Term | Definition |
|--------|---|
| 3PL | Third Party Logistics |
| ASN | Advanced Shipment Notification |
| BOL | Bill of Lading |
| C-TPAT | US Customs-Trade Partnership Against Terrorism |
| GTIM | Global Trade Item Number |
| IATA | International Air Transportation Administration |
| RDCI | Roche Diabetes Care Inc. |
| RDO | Roche Diagnostics Operations |
| UDI | Unique Device Identifier |

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