São Paulo, 19 de março de 2018.

Assunto: Notificação urgente de recolhimento
Referência:CARTA AOS CLIENTES 01PTSCHOLGLU A707
Processo: 2018.03.003703

Prezado Cliente Mex Global,

Esta carta destina-se a todos os clientes que utilizam **PTS PANELS CHOL+GLU Test Panel Test** Strips e que receberam o **Lote A707**.Você está recebendo essa notificação pois nosso sistema indica que a sua empresa recebeu esse produto e o respectivo lote.

Objetivo:

Conforme solicitação do Fabricante, Polymer Technology Systems, Inc., a Mex Global Produtos para Diagnósticos LTDA iniciou um processo de Recolhimento Voluntário do Produto referido acima, o qual deverá ser devolvido à sede da Mex Global.

Problema relacionado:

Baseados nos resultados de testes internos conduzidos pelo Fabricante, Polymer Technology Systems, Inc. existe uma potencial perda de atividade para o analito glicose e, por isso, obtenção de resultados relacionados a glicose mais baixos. Não existem eventos adversos reportados e relacionados a esse produto. Entretanto, optou-se por recolher o produto do mercado por precaução.

O PTS PANELS CHOL+GLU Test Panel Test Strips, Lote A707, validade 28-08-2018, está sendo objeto de um recolhimento ou "recall" voluntário. Essa correção está sendo conduzida devido ao potencial perda de atividade do analito glicose antes do término do prazo de validade (Agosto/2018).

Produto:

Produto	Registro Número	Lote	Validade
PTS PANELS CHOL+GLU Test Panel Test Strips	**80812770002**	**A707**	**28-08-2018**

Risco:

Obtenção de resultados mais baixos para o analito glicose.

Orientação e Ações necessárias:

1. Não utilize o produto PTS PANELS CHOL+GLU Test Panel Test Strips, Lote A707 - Validade 28-08-2018 remanescentes em seu estoque.

2. Por favor, compartilhe essa notificação com as pessoas adequadas da sua empresa e repasse esta informação a todos os setores que utilizam o produto, incluindo aos quais você pode ter encaminhado.

3. Por favor, segregue o estoque remanescente do produto PTS PANELS CHOL+GLU Test Panel Test Strips, Lote A707 - Validade 28-08-2018.

4. Preencha o formulário anexo RELATÓRIO DE RECOLHIMENTO, encaminhando-o para o e-mail info@mexglobal.com.br e a orientação sobre o recolhimento do (s) produto (s) será fornecida pela Mex Global.

5. Os produtos recebidos pela Mex Global serão substituídos por outro e sob este processo não incidirá nenhum custo aos nossos clientes.

6. Por gentileza, é imprescindível que sua instituição preencha o Formulário anexo – RELATÓRIO DE RECOLHIMENTO e envie ao e-mail info@mexglobal.com.br.

**Em anexo, segue na íntegra carta do Fabricante.

Muito obrigada pela atenção e nos desculpamos por qualquer inconveniente. Embora a probabilidade de sérias consequências a saúde sejam improváveis, Mex Global está iniciando essa ação voluntária tendo em vista a nossa preocupação com a segurança do paciente e a qualidade do produto.

Se você tiver qualquer dúvida, por gentileza, contate a empresa Mex Global diretamente pelo telefone 0800 798 8888 ou e-mail: info@mexglobal.com.br.

Atenciosamente,

_____

Atendimento ao Cliente
MEX GLOBAL

mexglobal | Group

"Soluções completas para o Diagnóstico Clínico"

RELATÓRIO DE RECOLHIMENTO

Razão Social Cliente:

Nome Fantasia Cliente:

CNJP/CPF Cliente:

Endereço: **Telefone:** **E-mail:**

Produto para recolhimento: PTS PANELS CHOL+GLU Test Panel Test Strips - Lote A707.

Modelo: Não se aplica

Número de lote/série: Lote A707

Quantidade em estoque:

Número de caixas: ☐

Número de tiras em caixa aberta: ☐

Não possuo produtos relacionados a esse lote: ☐

Número da nota fiscal:	**Data de emissão da nota fiscal:**
(Preenchimento da mex Global)	(Preenchimento da mex Global)

Descrição/observação:

Forma de Entrega:

☐ Eu li e compreendi as instruções de recall/recolhimento fornecidas no documento:
- CARTA AOS CLIENTES 01PTSCHOLGLU A707 - Processo: 2018.03.003703 de 19/03/2018.

Responsável pela devolução e informação (colaborador do cliente):

Nome Legível:_____ Assinatura:_____

Data:_____/_____/_____

URGENT MEDICAL DEVICE RECALL

From: Heidi Hancock Strunk
Senior Director, Quality and Regulatory Affairs

Date: March 13, 2018

Our records indicate that you have received lot numbers A705 and/or A707 of the PTS Panels® CHOL+GLU test strips. These lot numbers are currently subject to a voluntary product recall. This correction is being conducted due to the potential for loss of activity of the glucose analyte prior to the full stated shelf life (August 2018).

Based on the results of internal testing, there is potential for under-recovery of the glucose analyte, and therefore, potential for lower glucose test results. There have been no adverse events reported in conjunction with this product, to the best of our knowledge. However, PTS Diagnostics has decided, in an abundance of caution, to remove remaining product from the market.

Product Affected

Reference number: 1765
Lot number: A705 and A707
Unique Device Identification Code: Lot A705: (01)00381931765016(17)180813(10)A705
Lot A707: (01)00381931765016(17)180828(10)A707
Size: 25 count
Label information is attached for ease of identification.

These lot numbers were shipped during the timeframe of April 19 to June 2, 2017. Please immediately check your inventories and, if you have further distributed this product, please identify the users and notify them at once of this product recall.

Any materials from lot numbers A705 and A707 that are at your facility and/or your users' facilities should be immediately segregated and destroyed in such a manner as to prevent further use.

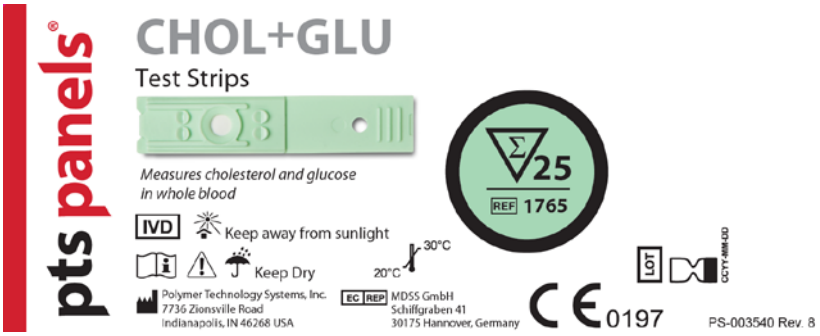
It is very important that you complete and return the enclosed response forms to indicate what actions have been taken at your facility. The response forms may be emailed to hstrunk@ptsdiagnostics.com or mailed separately to the address provided. After receiving your response form, PTS Diagnostics will issue replacement product or a credit to your account for the quantities of items that you have destroyed.

Thank you for your assistance and prompt action, and we apologize for any inconvenience this issue may have caused you and your facility. Although the probability of serious health consequences is unlikely, PTS is initiating this voluntary action in support of our continued focus on patient safety and product quality.

If you have any questions, please contact Heidi Hancock Strunk directly at 317-870-5610.

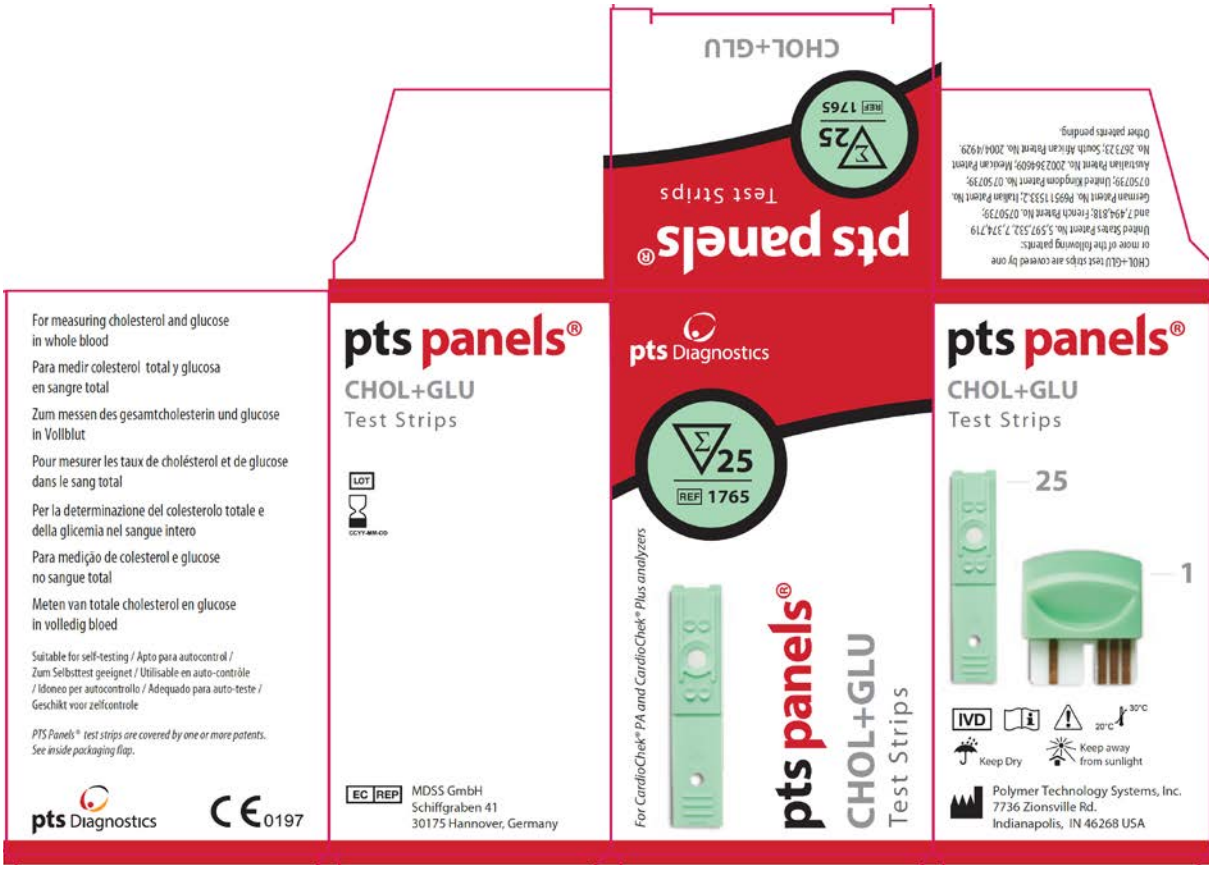
PTS Diagnostics 7736 Zionsville Road / Indianapolis, IN 46268 / USA / ptsdiagnostics.com / +1 (317) 870-5610

Example of Vial Label (blank):



Lot-Specific Labeling:

Example of Box (blank):



RECALL RESPONSE FORM – Lot A705

PTS Panels CHOL+GLU Test Strips
Reference number: 1765
Lot number: A705
Unique Device Identification Code: (01)00381931765016(17)180813(10)A705

Step 1: (Please check **ALL** appropriate boxes.)

- ☐ I have read and understand the recall instructions provided in the letter of March 13, 2018.
- ☐ I have checked my stock and have quarantined inventory consisting of ___ unopened vials, and ___ partial vials.
- ☐ I have checked my stock and have no remaining inventory of this lot.

Step 2: Indicate disposition of recalled product:
(Please check **ALL** appropriate boxes.)

- ☐ No stock remaining at time of inventory check
- ☐ Destroyed **(specify quantity of strips, date, and method)** _____
  Signature of person performing destruction: _____

Step 3: (Please check **only** one box.)

- ☐ I have identified and notified users that may have received this product.

or

- ☐ Attached is a list of my users who may have received this product.

or

- ☐ This step does not apply to my facility.

Step 4: (Please check appropriate box.)

Were there any adverse events associated with the recalled product? ☐ Yes ☐ No
If yes, please explain in full: _____

Step 5: (Please check appropriate box.)
If you had inventory remaining of these lots, do you prefer a credit to your account or replacement product?

☐ Credit to account ☐ Replacement product shipped ☐ N/A - No inventory remaining

Step 6: (Please check **ALL** appropriate boxes to describe your business.)

- ☐ Hospital
- ☐ Medical facility other than hospitals, e.g. physician's office
- ☐ Health screening company
- ☐ Distributor
- ☐ Pharmacy
- ☐ Other: _____

Step 6:
Your Name: _____
Title: _____
Facility Name: _____
Telephone Number: _____
Business Name: _____
Address: _____
City/State/Zip/Country: _____

Please return completed response form:
Via email to: hstrunk@ptsdiagnostics.com
Or via mail to:
PTS Diagnostics
Attention: Heidi Strunk
7736 Zionsville Road
Indianapolis, IN 46268, USA

RECALL RESPONSE FORM – Lot A707

PTS Panels CHOL+GLU Test Strips
Reference number: 1765
Lot number: A707
Unique Device Identification Code: (01)00381931765016(17)180828(10)A707

Step 1: (Please check **ALL** appropriate boxes.)

- ☐ I have read and understand the recall instructions provided in the letter of March 13, 2018.
- ☐ I have checked my stock and have quarantined inventory consisting of ___ unopened vials, and ___ partial vials.
- ☐ I have checked my stock and have no remaining inventory of this lot.

Step 2: Indicate disposition of recalled product:
(Please check **ALL** appropriate boxes.)

- ☐ No stock remaining at time of inventory check
- ☐ Destroyed **(specify quantity of strips, date, and method)** _____
  Signature of person performing destruction: _____

Step 3: (Please check **only** one box.)

- ☐ I have identified and notified users that may have received this product.

or

- ☐ Attached is a list of my users who may have received this product.

or

- ☐ This step does not apply to my facility.

Step 4: (Please check appropriate box.)

Were there any adverse events associated with the recalled product? ☐ Yes ☐ No
If yes, please explain in full: _____

Step 5: (Please check appropriate box.)
If you had inventory remaining of these lots, do you prefer a credit to your account or replacement product?

☐ Credit to account ☐ Replacement product shipped ☐ N/A - No inventory remaining

Step 6: (Please check **ALL** appropriate boxes to describe your business.)

- ☐ Hospital
- ☐ Medical facility other than hospitals, e.g. physician's office
- ☐ Health screening company
- ☐ Distributor
- ☐ Pharmacy
- ☐ Other: _____

Step 6:
Your Name: _____
Title: _____
Facility Name: _____
Telephone Number: _____
Business Name: _____
Address: _____
City/State/Zip/Country: _____

Please return completed response form:
Via email to: hstrunk@ptsdiagnostics.com
Or via mail to:

PTS Diagnostics
Attention: Heidi Strunk
7736 Zionsville Road
Indianapolis, IN 46268, USA