Customer Script

Subject: Alinity s System List Number 06P16-01

Customer Information

Alinity s Serial Number(s):
Customer Name:
Address:

Greeting

Ask to meet / speak directly with Lab Manager or Supervisor responsible for Alinity s testing.

Record: *Full name of person:* _____

Title: _____

Purpose

"Hello, MR/MS XXXXXX, I wanted to discuss an issue regarding Alinity s System List Number 06P16-01.

Our records indicate that you have received one or more of the above systems. During Abbott internal testing, it was identified that the rotation of the Optics Turret within the Alinity s System may result in very small electrostatic discharge events that are detected by the system's optics.

If a discharge event occurs during a sample read, the results for that sample may be falsely elevated. This could cause a false reactive result. This can occur for any assay on the Alinity s System.

There is no safety risk to the user from the small electrostatic discharges.

Your Abbott representative will be scheduling a mandatory upgrade of your Alinity s System to lubricate the optics turret, as well as weekly re-lubrication. Abbott has performed in-house testing that demonstrates the lubrication addresses the electrostatic discharge events. Abbott is developing additional improvements to the Alinity s to remove the weekly re-lubrication requirement.

We sincerely regret any inconvenience this may cause your laboratory."

Action

Ask the customer if they have any questions regarding the above information. Open an inquiry ticket to document any additional questions with Reply Requested = Yes, Experience Code 3040.

If the customer conveys any information related to impacted patient results, document the information in a complaint ticket with the Alinity s System List Number 06P16-01 as the causative agent per standard call documentation procedures.

Thank the customer for their time and apologize for any inconvenience.

Effectiveness Check:

Sign and date:

Initiator's Name: _____ _____
(Print) *Signature*

Date: _____

Please return the completed form to your Affiliate QA/RA representative